POSITION
STATEMENT

PSYCHOTROPIC
DRUGS AND
EXPANDED USES:
an Ethical
Perspective
PSYCHOTROPIC DRUGS AND EXPANDED USES: an Ethical Perspective
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Printing
Impression Gauvin & Harbour inc. (Summary and recommendations)

Position statement adopted at the 40th meeting of the Commission de l'éthique de la science et de la technologie, April 29, 2009.

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Legal deposit: 3rd quarter 2009
Bibliothèque nationale du Québec
National Library of Canada

ISBN: 978-2-550-56849-0 (Printed)
ISBN: 978-2-550-56850-6 (PDF)

To facilitate the reading of the text, the masculine is used without any discriminatory intent.
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Monsieur le Ministre,

C'est avec plaisir que je vous transmets par la présente la version finale de l'avis *Médicaments psychotropes et usages élargis : un regard éthique*.

Espérant le tout à votre entière satisfaction, je vous prie d'accepter, Monsieur le Ministre, l'expression de ma haute considération.

La présidente de la Commission

[Signature]

Édith Deleury

c.c. Michel Jébrak, président du Conseil
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LIST OF ACRONYMS

ADHD
Attention-Deficit Hyperactivity Disorder

AHFS
American Hospital Formulary System
Pharmacological/Therapeutic Classification

APA
American Psychiatric Association

ATC
Anatomical Therapeutic Chemical (classification)

CHSLD
Residential and Long-term Care Centre

CNS
Central Nervous System

CMDP
Conseils des médecins, dentistes et pharmaciens
(Councils of Quebec Physicians, Dentists and Pharmacists)

CSST
Commission de la santé et de la sécurité du travail (Quebec Commission for Occupational Health and Safety)

DSM
Diagnostic and Statistical Manual of Mental Disorders

DTCA
Direct-to-Consumer Advertising of Prescription Drugs

FDA
Food and Drug Administration

fMRI
Functional Magnetic Resonance Imaging

GABA
Gamma-aminobutyric acid

GAF
Global Assessment of Functioning Scale
**HPFB**
Health Products and Food Branch – Health Canada

**ICD**
International Classification of Diseases

**MSSS**
Ministère de la Santé et des Services sociaux
(Quebec Ministry of Health and Social Services)

**OCD**
Obsessive-Compulsive Disorder

**R&D**
Research and Development

**RAMQ**
Régie de l'assurance maladie du Québec
(Quebec Health Insurance Board)

**RGAM**
Régime général d'assurance médicaments
(Quebec Drug Insurance Plan)

**SAAQ**
Société de l’assurance automobile du Québec
(Quebec Automobile Insurance Plan)

**SSRIs**
Selective Serotonin Reuptake Inhibitors

**WHO**
World Health Organization
SUMMARY AND RECOMMENDATIONS
Medications play an important role in therapeutic treatments. They have led to improvements in the quality of care, and to significant gains in the area of mental illness: indeed, before psychotropic drugs were discovered, mental health interventions were often restricted to the use of straight jackets and lobotomies. The return to or maintenance of health also has a social connotation, beyond the strictly medical dimension. This is an age in which the values of performance, efficiency, improvement and self-realization are ever-present. Good physical and mental health is therefore considered a major asset in society. These values can be defined in various ways, such as the development of different relationships to suffering, pain and happiness. Nonetheless, these values are well-established and common to many cultures.

Knowledge about the brain remains limited, but new generations of psychotropic drugs have raised enormous hopes, particularly for maintaining memory and cognitive function in people with dementia, for improved concentration in children with attention disorders and for emotional stability in people suffering from depression.

Several factors motivate the Commission’s interest in psychotropic medications: the growing popularity of drugs that stimulate or, conversely, decrease cognitive function; widespread public enthusiasm for products that seek to produce the same effects (“smart drinks”, caffeine, vitamins, omega-3, etc.); the growth of this segment in the pharmaceutical industry; and finally the incomplete nature of information on long-term side effects on the nervous system.
Neuropharmacology is the discipline studying those medications that affect the central nervous system (CNS), such as psychotropic drugs (affecting mood, behaviour and cognition), anesthetics, sedatives, anticonvulsants and narcotics. For some people, psychotropics include any substance that affects the CNS; according to this definition, caffeine, nicotine, cocaine and alcohol would also qualify as psychotropics.

In this position statement, the Commission focuses on the expanded uses of psychotropic drugs. In so doing, the Commission defines "psychotropic" as a prescription medication affecting the central nervous system and psyche. In addition, the terms psychotropic drug, psychotropic medication and the plural psychotropics are used interchangeably, as are the terms illness and disease. Finally, the position statement focuses primarily on prescribed psychotropics, without neglecting non-drug products, given the significant differences from one regulatory environment to the next.

Neuropharmacology is a booming discipline. Scientific advances in neuropharmacology have been accompanied by an increase in diagnoses of some mental disorders such as depressive disorder and attention deficit disorder with or without hyperactivity (ADHD), as well as an increase in prescriptions of psychotropic medications in recent years, both internationally and in Quebec.

Underlying these increases are numerous factors which are not mutually exclusive: a decrease in taboos surrounding mental health; a growing awareness of mental illness among general practitioners, leading to more prescriptions for psychotropic medications; better diagnostic tools; increased accessibility to medications due to implementation of the public drug insurance plan; an idealized notion of performance and normality; "lifestyle drugs" which are used in non-therapeutic settings to improve a person’s cognitive functions in the absence of mental problems.
In these two latter cases, the problem lies less in the abuse of medication than in its use, which may involve expanded use, extended use, off label use, inappropriate use or cosmetic use of psychotropic drugs. The Commission is concerned about the causes and consequences of these new uses of psychotropic drugs, and in the present position statement, seeks to deepen its understanding of the issues at stake.

At the outset, the Commission wishes to emphasize that it is well aware its position statement may raise several issues in the general population. It wishes to underline the fact that psychotropic drugs have demonstrated their effectiveness and efficiency in the treatment of mental and neurological diseases. People wondering about their health status and medication should consult their physician.

THE CONTEXT OF MEDICATION

In identifying ethical issues related to expanded use of psychotropic medications, it is important first of all to lay out the social, socio-political and legal context in which the “medication” product assumes its place.

Medication in the Health System

Throughout its history, Quebec has maintained a health and social services system offering a wide range of services to the population. The values underlying this system are accessibility, equity and solidarity. In this modern health system, medication is the most widely used and most accessible treatment.

The Quebec government has acknowledged the importance of drugs in the therapeutic arsenal. In 1997, it adopted the Act respecting Prescription drug insurance (RSQ, chapter A-29.01), which provides for the establishment of a public drug insurance plan. As a result, since 1997, all Quebec citizens enjoy universal coverage of prescription drug insurance. When drugs are administered in hospitals or long-term care facilities (CHSLDs), the hospital insurance plan covers the costs. In other situations, the public drug insurance plan or private group insurance plans intervene.

However, over the years, the increased use of medications and the growing costs of new medications have become causes for concern. In 2007, the growing financial burden of drug insurance plans led the government of Quebec to adopt the Drug Policy.

Medication: a Diversity of Prices and uses

The cost of medications is related to their price and the volume of their uses.

Several factors influence drug prices, such as diverse production costs, inflation and market entry of generic medications. Volumes of the use of medications vary, based on different factors.

- **Therapeutic Uses** – The quantity of medications used depends on several situations or factors. First, demographic factors such as age, gender, human health and increased life expectancy lead to fluctuations in drug consumption. New guidelines or new medical indications also have an impact on the use of specific drugs. Third, the promotional activities of pharmaceutical companies influence drug consumption. Finally, it is safer to prescribe new molecules which offer fewer adverse drug reactions as compared to molecules currently used. Such new molecules therefore tend to be used more frequently. As a result, the volume of use of these medications tends to increase.
- **Prevention** – The emphasis on prevention and lifestyle-related risk factors also explains the growing use of medications. The promotion of healthy lifestyles is a big part of public health discourse. The media stress the importance of reducing risk factors. However, lifestyle improvements are not always sufficient to address certain risks. As a result, better prevention requires a combination of pharmacological and non-pharmacological measures. It is therefore important to ensure that the medications effective in controlling certain lifestyle-related risk factors are not seen as a valid alternative to behavioural changes, which are often more difficult to bring about. Consequently, there also exists a real potential for medicalization and medicamentation of the concept of prevention itself.

- **The expanded use of drugs** – There is nothing new about the desire to improve perception, attention, memory, reasoning or mood. What is more recent is that in the quest of enhancement, healthy people are resorting to medications used in the treatment of pathological mental conditions. The use of drugs for enhancing what is already functional, such as the quest of increased performance or job efficiency, means pursuing a non-therapeutic goal.

**Essential Concepts**

Without being exhaustive, the Commission has chosen four elements that play a role in drug utilization: definitions of health and illness, resource scarcity in the public health and social services network, the rise in self-care and the medicalization of non-pathological traits and behaviour.

**Health and Disease**

Health and disease are intimately related, but defining what it means to be “ill” or “healthy” is not straightforward. These definitions are dynamic: they evolve over time and across societies. The boundary between health and disease is unclear and may therefore be particularly difficult to delineate in the case of mental or neurological disorders. It is therefore appropriate to conceptualize the notions of “health” and “disease” on a continuum where one pole is a proven pathology and the other is the quest for perfect health (or well-being). Between these two poles exists a vast grey zone within which lie intermediate situations as well as the concept of prevention, and the notions of enhancement and performance.
Resource Scarcity in the Public Health and Social Services Network

A number of factors point to a sustained use, in years to come, of health and social services resources. However, for several years now, the health-care system has faced a shortage of human resources. As a result, the workforce in the health and social services network is undergoing a heavy workload and is running out of steam. In this setting, drug-related errors are more likely to occur. Medical consultations are usually short, which may hinder the exchange of information between patient and doctor, the diagnosis, the determination of the appropriate treatment and the transmission of information on medications being proposed.

Rise in Self-care

With increases in the educational level of the population and of access to new information sources (including Internet), users of health and social services are affirming their intellectual and decision-making autonomy, to the point of questioning the expertise of health professionals. Respect for the value of “autonomy” encourages the public discourse of individual responsibility, self-care and self-medication in the absence of medical advice. This practice mostly concerns over-the-counter drugs, but also includes drugs left over from a previous prescription or those obtained from third party sources.

Medicalization of Non-pathological Traits and Behaviour

The difficulties in identifying and defining the concepts of “health” and “disease” as well as in delineating their respective boundaries is leading to constant arbitration between the various stakeholders. As a result, according to some authors, Western societies are experiencing the medicalization of events, emotions and things that are not necessarily part of the biomedical field. In medicalizing life events, this phenomenon promotes the expanded non-“traditional” use of medications. Taken to the extreme, medicalization ignores the importance of the social, cultural and environmental context as well as the social constructs that define what constitutes normality, health and performance. It also tends to minimize the fact that the vast majority of the population is healthy and that disease usually only affects a minority of individuals.

Stakeholders

Several stakeholders reflecting different and possibly contradictory interests are central to the way medications are characterized in society:

- Governments: notably through their legislative and regulatory power;
- Health professionals: particularly nurses, pharmacists and physicians;
- The Individual: both citizen and user of health and social services network;
- The pharmaceutical industry: an important economic sector, whose activities are central to medical innovation and manufacturing methods;
- Foundations, associations and community organizations: through their roles in providing information and support, and in applying pressure;
- The media: in addition to publications targeting scientists and the general public, Internet is playing an increasingly important role – with its strengths and weaknesses in terms of scientific validity.
The Normative Framework for Medication

Laws, regulations, codes of ethics and guidelines have been implemented at the international, national and provincial levels, to map out the domain of medications, to limit their inherent dangers and to provide adequate monitoring of multiple stakeholders. The regulatory process for drugs in Canada includes the licensing process, manufacturing, marketing, distribution, prescription, and professional practices.

In Canada, federal and provincial governments legislate all matters relating to medications. Health Canada is the department responsible for drug registration at the federal level, while the Ministry of Health and Social Services of Quebec (MSSS) is responsible for the registry of drugs approved for reimbursement in Quebec.

The most important laws and regulations are the *Food and Drugs Act* (R.S., 1985, Chapter F-27), the *Food and Drug Regulations* (C.R.C., chapter 870), the *Act respecting health services and social services* (R.S.Q., chapter S-4.2) and the *Act respecting prescription drug insurance* (R.S.Q., chapter A-29.01). Professional laws such as the *Medical Act* (R.S.Q., chapter M-9) and the *Pharmacy Act* (R.S.Q., chapter P-10) set standards for the medical and pharmacy professions and define activities in which they are authorized to engage. Professional orders are also subject to the *Professional Code* (R.S.Q., c. C-26), which requires codes of ethics for their members.

In addition to laws and regulations, a wide range of guides, guidelines, lines of conduct and administrative norms set additional standards for medications. At the international level, the World Health Organization, the World Medical Association (Declaration of Helsinki), the National Institute for Health and Clinical Excellence (NICE) (United Kingdom) and the American Psychiatric Association (United States) are prime examples. In Canada and Quebec, governments and professional associations are also active in terms of monitoring activity.

Theoretical frameworks cover many aspects of medication, but practical applications raise several concerns. One has only to think of: the new challenges posed by the rise of Internet and of cyber-pharmacies, that circumvent national and international regulatory frameworks and raise questions about the scientific validity of information and the safety of buying medications under unknown conditions from anonymous individuals; the approval of drugs where there is little independent verification of data provided by the pharmaceutical promoters of the drugs; direct-to-consumer advertising (DTCA) of prescription drugs that provides the drug’s name, identifies health problems the drug seeks to address and insists on its effectiveness. Only the United States and New Zealand allow this form of advertising. However, even though this type of advertising is banned in Canada, there are ways to get around the ban, such as consulting the Web, watching American television, reading American newspapers and periodicals intended for international audiences and distributed in Canada.
PSYCHOTROPIC DRUGS

The second chapter provides specific details on psychotropic medications. These drugs are used in the treatment of neurological and mental diseases, and aim to control symptoms, relieve pain or lead to recovery. These diseases particularly affect the mood, cognitive function, behaviour and quality of life of people suffering from them; examples include depression, Parkinson’s disease, schizophrenia, personality disorders and bipolar disorders. These are disabling and stigmatizing pathologies that strike regardless of age, gender, wealth or intelligence.

In recent years, an increase of mental and neurological disorders has been observed – particularly depression – accompanied by an increase in prescriptions for psychotropic medications, both internationally and in Quebec. However, although the use of psychotropic drugs is not restricted to particular categories of persons, it is nonetheless the case that groups or individuals with specific socio-economic characteristics seem to stand out in their use of psychotropics, including minors, women, seniors and the underprivileged. In addition, two significant phenomena related to drug treatments have been observed: determination of the duration of treatment – whether too short or too long – and the use of polymedication as a way of addressing different symptoms of disease.

The Functioning of the Central Nervous System

In all cases, mental and neurological illnesses involve dysfunctions of the central nervous system (CNS). Yet, the CNS is essential to maintaining the health and life of the organism. The CNS has information-collecting and transmitting functions, as well as tools to process this information and act accordingly. By changing the neurochemistry and electrical communications within the brain, psychotropic drugs seek to correct the brain’s dysfunctions, focusing specifically on neurons and neurotransmitters.

Indeed, the brain is one the most important parts of the CNS. It is the organ receiving and processing information from the body, and determining subsequent actions, decisions, thoughts and emotions. To carry out its functions, the brain has an extraordinary malleability – or plasticity. Its networks of cells are constantly reorganizing themselves, depending on outside influences and personal experiences, which makes the brain the most highly adaptable organ of the human body.

Of CNS tissues (and therefore of brain tissues), 90% consist of glial cells. The remaining 10% is made up of neurons, cells specially suited for the transmission of information. The neuron is the basic operational unit of the CNS. This unit collects, processes and retransmits information to other neurons and to the various body parts. It is able to perform its functions because of its components – the cell body, the axon and dendrites. The cell body of the neuron transmits data in the form of an electrical impulse (or action potential) to its axonal terminals, while the dendrites of other neurons capture the information. Neurons communicate with each other without entering into physical contact. Neurotransmitters – chemical molecules synthesized and released by neurons to transmit information – are responsible for conveying the flow of information to other neurons from the specialized contact area, the synapses.
Each contact is likely to trigger a cascade of complex biochemical reactions, many of which may be simultaneous, with a feedback loop instantly setting off a new chain reaction.

Given the nature and complexity of the information relayed in the brain or triggering a physical reaction, an extremely precise communication process exists, which involves neurotransmitters. As a result, an imbalance in the production of neurotransmitters or a damage to postsynaptic receptors alters the functioning of the nervous system and can lead to neurological problems or mental disorders. In order to correct this situation, psychotropic medications alter the concentration of neurotransmitters or the availability of axonal and dendritic receptors.

A clarification is needed at this point. Research on neurotransmitters has led to a better understanding of mental and neurological disorders, which in turn has opened the way to development of more effective pharmacological treatments. Even so, several unknowns remain, such as the role of neurotransmitters in mental disorders. Consequently, the relationship between “mental disorder” and “neurotransmitter” has not been clearly established. Similarly, several psychotropic drugs are used – and have a positive effect – although their modes of action are not fully understood. Also, the medium- and long-term effects of psychotropic drugs on the central nervous system are not well known or are unknown. Finally, science cannot currently tell us whether the effects on “healthy” people will be the same as those having a neurobiochemical imbalance at the time of medication.

The “Risk/Benefit” Ratio: Assessing the Use of Psychotropic Drugs

Psychotropic drugs, like any other medications, offer demonstrated benefits for each disease and each medication; at the same time, they are not free of risks and side effects. The benefits of taking psychotropic drugs, as well as risks and side effects, will not necessarily all occur during drug therapy, either with the same intensity or at the same time.

The “risk/benefit” ratio is established by analysing possible risks and expected benefits associated with taking a specific drug in a given situation. The assessment of this ratio is based on evidence, good practice guidelines and clinical experience (or professional judgment). In addition to a given situation, i.e. indications for which a specific drug is approved, one should factor in the specific context of a medical consultation and the clinician’s position on psychotropic drugs. Thus, for the same suspected health problem, the “risk/benefit” ratio varies according to the attending physician, the individual being examined, as well as that individual’s overall health status, current medication and medical history.
Evidence is essential for assessing the scientific validity of a treatment. In the biomedical sphere, such evidence is mainly derived from pharmaceutical clinical trials. Such trials are important for the drug licensing and other therapies, but they also come with a significant limitation: the conditions under which clinical trials are conducted have little relation to the everyday reality of the clinical setting. Therefore, the results of clinical trials are hard to transpose onto a large population. Acknowledging this does not mean that drugs tested and available to the public are ineffective. Instead, it means that data obtained from clinical trials demonstrate above all the theoretical effectiveness of medications.

Evidence is also derived from meta-analyses. These meta-analyses are subject to two limitations, namely (1) selection bias of publications arising from the lack of any obligation to publish the results of clinical trial, including negative test results, and (2) levels of scientific evidence used in meta-analyses, ranging from anecdotal evidence to rigorous methodology.

The first important consequence of an uncertain “risk/benefit” ratio concerns medication adjustments. If expected benefits are slow to occur or if side effects persist, the explanation may lie in various factors, including slow action of the drug, interactions with other drugs or drug products (e.g. antioxidants and vitamin supplements), poor compliance or an inappropriate drug for that individual. Once the appropriate drug and optimal dose are determined, one should estimate the duration of treatment and therefore the time when treatment will be completed. However, practice guidelines on prescribing psychotropics are not specific in this regard.

As a result, “risk/benefit” ratio associated with psychotropic drugs open the way to uses not foreseen by Health Canada; any use which does not fully respect approved medical indications is, by definition, an off label use.

THE EXPANDED USES OF PSYCHOTROPIC DRUGS

Determining whether use of psychotropic medications is called for or not presents a real difficulty. Given varying factors such as health status, age, culture and social environment, each situation needs to be scrutinized on a case-by-case basis. However, some people seek to use a psychotropic drug less because of known medical reasons than as a means to enhance performance in class, work or sports, or to help manage difficult personal situations. In these latter cases, one can speak of “expanded use”.

Expanded Uses: Refining the Concept

As a means of designating uses not recognized by the regulatory authorities or which lie in the grey zone of the “health-disease” continuum, several expressions are currently used, although they do not refer to the same reality: the use of medication that has not been specifically sanctioned (off label), non-optimal use, expanded use, misuse. In this position statement, the Commission prefers the term "expanded use", in the sense of use outside of established practices and combining both medical and social dimensions.

Strictly speaking, expanded use goes beyond the scope of medical indications that are established by Health Canada during the drug licensing process. However, in the clinical setting, it is quite common that uses do not comply fully with approved indications. In fact, once a drug is approved, its use on a larger scale and by people with multiple health profiles can produce effects that were not previously detected during clinical trials. Ultimately, Health Canada may establish new medical indications, and as a result these uses will no longer be considered “expanded”. This is how the range of recommended uses for a specific medication expands.
Moreover, the increase in diagnoses of mental illness and in psychotropic prescriptions raises questions. These increases may actually be biomedical in origin. For example, they may be due to more precise or faster diagnosis, or to newly approved medical indications. An additional explaining factor may be that medication is an easily accessible solution that seems relatively inexpensive, requires little effort and can be taken quickly.

Other cultural and social trends are also involved. For example, resorting to medical care as a result of certain life events or personality traits influences diagnosis or the decision to prescribe. The increase in prescriptions may also be the consequence of the low tolerance of individuals or people around them to psychological suffering or so-called disturbing behaviours, such as sadness, anger or agitation. Finally, this increase may be associated with performance-related uses: memory, attention, in order to avoid feeling tired, etc.

Two Categories of Expanded Uses of Psychotropic Drugs

Two major categories of expanded uses emerge from medical sources and social sources. These categories are not independent of each other. Several stakeholders and contextual elements are common to both categories. In addition, scientific research and applications are guided by standards which are culturally determined. The medical context exists within a social context, and in turn modifies this social context. Separating the two would have the effect of diminishing the currency and strength of interrelations. However, the two categories are distinguished one from the other for the purposes of demonstration and discussion.

Expanded Uses of the “Medical” Type

Expanded uses of the “Medical” type occur in a context of professional practices that contributes to the expanding uses of psychotropics. For example, scientific uncertainty due to lack of knowledge about the brain, the roles and interactions of neurotransmitters and the modes of action of psychotropic drugs in turn provides conditions for use outside of approved indications. Similarly, Quebec’s non-optimal health-care network means it is difficult to do medical and non-medical follow-up with people who have mental health needs. Finally, the emphasis on the concept of prevention plays a role.

The Difficulty of Mental Health Diagnosis

Physicians need to make a diagnosis, for medicine to be prescribed. However, it is very hard to establish a mental illness diagnosis. Indeed, it is harder for physicians to note the presence of mental disorders through objective observation than that of physical disorders. In making a diagnosis, physicians and psychologists refer to the presence of symptoms that are graded on a scale of intensity. They then establish their diagnosis using one of the two main reference works in mental health, the Diagnostic and Statistical Manual of Mental Disorders IV-TR (DSM-IV-TR) of the American Psychiatric Association (APA) – a manual used in Canada and Quebec – and the International Classification of Diseases 10th Revision (ICD-10) of the World Health Organization, whose diagnostic criteria may differ.
Since *DSM-III* was published, mental and neurological illness has been conceptualized in a way that tends to focus on specific symptoms. This emphasis on symptoms poses practical difficulties. First, the recognition and description of symptoms will vary from person to person. Second, a symptom may occur in more than one mental or neurological disorder. Third, a disease may have a multi-factorial etiology, i.e. it may be caused by the presence of several biological, social and environmental factors. The decision of treatment or non-treatment should therefore take the whole context into account.

**Therapy or Enhancement?**

When a physician is faced with diagnostic doubt, it may be more appropriate to prescribe a new generation psychotropic drug – resulting in less severe adverse drug reactions – than not to prescribe at all, given the suffering and hardship experienced by people with a mental or neurological disorder. Accordingly, lower diagnostic thresholds of these diseases could also help transform a condition previously considered “normal” into a condition which has become “medical”.

Psychotropic medications with lesser side effects are opening up new possibilities, and this in turn highlights the need to distinguish between therapy and enhancement. *Therapy* aims to prevent or heal a known or anticipated health deficit in a person, i.e. a recognized medical condition or physiological dysfunction. *Enhancement* seeks to boost a function beyond a person’s usual capacity, without any dysfunction being identified.

The difference between “therapy” and “enhancement” usually lies in the grey zone of the “health/well-being-disease” continuum, but how is one to draw a distinction between an enhancement and a treatment? A narrow definition of the term “enhancement” is of little use, partly because the concepts of disease and health are linked on the continuum and are part of a cultural and historical context, which is based on compromise and social values. However, on the practical level, a *modus operandi* lies in determining an optimal state, which varies according to time and place, and then intervening based on normal functions. The question of what is normal is therefore central to the concept of enhancement: the attempt to enhance a function is related to personal or social criteria. Noting this fact, however, does not answer the question: enhanced compared to what? Or in relation to whom?

The concept of enhancement can also be confused with that of prevention. By enhancing a cognitive function that is functional or a behaviour deviating from certain norms, one may avoid what are considered more harmful consequences, such as difficulties at school, negative evaluations in a professional setting or stigmatization by one’s peers.

Finally, taking WHO’s definition of health literally blurs the line between enhancement and therapy (according to this definition, “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”). Indeed, the notions of “well-being” and “completeness” are hazy, so it is relatively easy not to feel in the best of health. Thus, an intervention aimed at enhancing a function could be presented as therapeutic if it served to promote well-being.
Some Factors Involved in Prescribing Practices

The Commission has taken a special interest in four factors likely to influence the prescribing practices of physicians. First, the current limits of knowledge about psychotropic medications and mental and neurological illness. Second, the influence of the pharmaceutical industry through its investments in promotion and marketing, as well as the impact of promotional activities on the availability of therapies. Third, the organization of the health and social services system, given staff shortages and the silo functioning of various components of the health and social services system, which complicate patient monitoring – it should be noted that this situation is changing, thanks to the development of multidisciplinary teams and the growth of networks of facilities in Quebec. Finally, patient demand, given that individuals may have up made their mind in advance and may have specific requests.

The Consequences of Expanded Uses of the “Medical” Type

The main anticipated benefit is represented by the progress of knowledge, i.e. the discovery of therapeutic uses for a particular drug that were not foreseen at the time of Health Canada’s approval of that drug. It should be remembered that clinical trials, guidelines and good practice guides do not take into account all conditions of life and health in the existing population. Positive effects may emerge from clinical use, which were not foreseen initially. Subsequently, clinical studies and additional analysis may support these empirical advances with an evidence base.

The Commission has identified four potentially adverse consequences:

- The accessibility and quality of care may decrease, since the expanded uses of psychotropic medications may create a vicious circle: a medical consultation is a precondition for a person (potentially) to get a prescription. In a context where the health and social services network is hardly able to meet demand, health professionals could promote a drug therapy “by default” so as not to leave people without care. As a result, human resources allocated to consultations and follow-up would have an even harder time meeting demand, and so forth. And, paradoxically, the increase in consultations could result in less screening and inadequate follow-up for users already diagnosed with mental and neurological illnesses. In addition, expanded uses also result in an increase in the prescription of psychotropic medications, which in turn affects the financial viability of the network.

- Individual safety is at stake because, as the use of psychotropic medications increases, the prevalence of adverse reactions and drug interactions also risk increasing. In the case of benzodiazepines, given current knowledge, two types of risks are particularly worth noting. In terms of work safety, the rising use of medications may affect the health of workers and possibly also of their colleagues; in terms of traffic safety, it risks causing an increase in road accidents – automobiles, trucks, bicycles, four-wheel scooters, etc. – placing at risk the health of the driver, as well as of passengers and bystanders. In short, the risks to individual safety stemming from the use of psychotropics are likely to affect individuals and
also lead to consequences at the collective level through compensation paid by the Commission de la santé et de la sécurité du travail (Quebec Commission for Occupational Health and Safety), and hospitalization benefits paid by the Société de l’assurance automobile du Québec (Quebec Automobile Insurance Plan).

- In a context of diagnostic uncertainty, and given the daily disruptions experienced by people with mental health problems, the possibility of “overdiagnosis” is ever-present. In addition, prescriptions may increase since these diagnoses are often associated with the prescription of psychotropics. As a result, there exists a risk of medicalizing life events that are unpleasant, stressful or painful, but inevitable in the course of life, whereas these events do not necessarily belong to the field of medicine. However, the fact a medical diagnosis has been made may change an individual’s perception of the gravity of his situation. When an expert establishes that a mental health state is problematic, the implication is that illness is involved. When the expert proposes that a patient take medicine, this has the effect of legitimizing treatment. The prescription of psychotropic drugs justifies their use, which in turns diminishes the importance of the role played by the individual in his own life, for example in using personal resources to cope with life events and to develop critical thinking.

- When a person’s cognitive or mental capacities are functional or correspond to non-pathological physical conditions, then one may speak of prescription of psychotropics as expanded use for the purposes of enhancement. In these situations, prescribing psychotropic medications means the physician is expanding the boundaries of the traditional therapeutic relationship. Several reasons may explain why physicians assume this role, from the lack of time for consultations and follow-up to the method of billing fees for service (favouring a greater number of services), and of maintaining contact with their patients. Also, at the individual level, physicians operate in a social context where they are required to perform. They may in fact identify with this value personally. However, in prescribing psychotropic drugs for non-therapeutic purposes, physicians are contributing to the current trend of meliorism and performance as well as to the trivialization of drug use.

Expanded Uses of the “Lifestyle” Type

Often called “lifestyle” drugs, some psychotropic medications have effects favouring their use in meeting social expectations – performance, productivity, health, “youth”, rapid change. However, using drugs in order to match a lifestyle and fulfill its underlying values is completely different from using drugs in order to heal people diagnosed with mental or neurological illness. There is little ambiguity about “Lifestyle” type uses: they are related to meliorism, conformism or recreation.

Towards a Redefinition of Social “Normality”

Normality can be understood as the statistical concept of “normal distribution”. According to this concept, the characteristics of a given population can be mathematically distributed, and illustrated by a symmetrical bell-shaped curve where the mean is found in the centre. The mean is a precise figure serving as a reference point: a person will be closer to or farther from the statistical mean.
Normality may also reflect a social or subjective decision. Behaviours deviating from social expectations are evaluated positively or negatively. As a result, "normal functioning" is a social question and subject to constant redefinition. Similarly, defining a disease and determining its importance in society depends not just on biological characteristics, but also on norms and values associated with it. Several groups of stakeholders take part in defining what constitutes a "disease": health professionals, associations and professional special interest groups and charities, citizens, the media, pharmaceutical companies and different levels of government. Given that these stakeholders influence each other, it is hard to consider the particular contribution of each in isolation.

From Normality to Normativity

"Normality" and "norm" are intimately linked: social or axiological normality ("axiological" means "value-based") may lead to a norm, i.e. to a statement describing what to do or to refrain from doing. Normative statements generally refer to a type of action, specifying what agents should or should not do and under what circumstances.

In general, social expectations lead to norms that in turn translate into expected behaviours. If this "social normativity" has great resonance in society, then it may result in people being ostracized when they deviate from behaviour deemed inappropriate or, more generally, when they are judged to be less "efficient". And medications in Western societies are becoming instruments of socialization, or of compliance.

The Impact of Psychotropic Medications on the Concept of Normality

The concept of enhancement highlights the complex interactions between the society and the individual, where the use of psychotropics is concerned. The space currently accorded to values such as performance and individualism tends to make individuals deviating from these values less acceptable. Although the values of performance, efficiency and improvement have been positive ones throughout history and in different societies, the fact they are perceived in idealized terms raises questions. What ought to be "a means to an end" has become an end in itself.

This normalization of conduct, mood, and the effects of aging may lead to social homogeneity. The definition of normality changes, when people use psychotropic medications in pursuit of certain standards or an ideal: if it is "normal" to use drugs for non-therapeutic purposes, then normality becomes a medicated normality. The resulting normalization increases social pressure to conform and makes the consumption of psychotropic medications seem more legitimate.
Some Psychotropic Applications Related to Lifestyle

There is nothing new about the idea of resorting to drugs or biomedical technologies in pursuit of an ideal, whether in terms of physical appearance or performance. Sports doping is prohibited, but so-called “cosmetic” applications are legally available in Quebec. R&D departments are increasingly focusing on the development of psychotropics with a view to enhancing certain cognitive and vegetative functions among healthy people, such as maintaining and stimulating memory and cognitive function, enhancing attention capacity and controlling fatigue, stabilizing and controlling moods, as well as decreasing anxiety.

Some Factors in Life Choices

Without drawing up an exhaustive list, the Commission has identified three factors that influence expanded lifestyle-related uses. The first factor is the influence of the pharmaceutical industry through its promotional activities, which affect the availability of therapies as well as the price of medications. The second is the message conveyed by the media and the Internet – these major sources of information generally present medications in a positive and uncritical light, and their programmes and advertisements promote an active lifestyle or the importance of health and youth, reinforcing the same compelling picture of life. The growth of Internet has more recently been accompanied by the emergence of cyberpharmacies. The Commission is concerned that people may decide to buy drugs or non-drug products without being informed, while being even minimally aware of the real risks associated with their lack of knowledge about the product they have purchased: expiry date, counterfeiting, the presence of toxic ingredients, etc. The consequences for their health could be serious. The third factor is the differences between psychotropics and other CNS stimulants/depressants. This difference does not seem obvious to everyone, since the idea of profiting from the brain’s plasticity in order to enhance mental performance is an old one. People make frequent use, and on an everyday basis, of medicinal substances (such as herbal infusions, vitamin and mineral supplements, caffeine, glucose and nicotine) or techniques. Given this context, in terms of risk, some people liken taking psychotropic medications to taking products such as coffee and alcohol, which are nonetheless recognized to be harmful when consumed in large quantities: the consumption of these products is legal in Canada; they are safely manufactured; they may produce effects on everyone; the negative effects of excessive or prolonged consumption of coffee and alcohol are widely known – and yet they remain both accessible and popular – whereas for psychotropic medications, the long-term effects are poorly documented.

The Consequences of Expanded Uses of “Lifestyle Drugs”

It should be noted that scientific evidence and public perceptions both play a role in shaping the character of benefits expected from a particular drug. To date, only a handful of scientific studies has focused on psychotropics used strictly for enhancement purposes. As a result, it is risky to transpose an evidence base on healthy people using psychotropics.
In its analysis, the Commission has identified three expected benefits related to expanded “Lifestyle” use:

- The enhancement of certain cognitive capacities is one of the objectives being pursued. People stand to gain both personally and socially when they enhance mental abilities that enable learning, information processing and memory, improved concentration or resistance to fatigue. In this perspective, enhanced cognitive functions also contribute to meeting the demands of the labour market, which represents a gain for the labour market (i.e. both for employers and employees). For example, certain neurostimulants may prove useful in occupations where the safety of others is crucial – pilots, air traffic controllers, truck drivers, etc. – and which therefore require constant attention. In these professions, the expanded use of psychotropic stimulants could lead to gains in terms of public safety, at least apparently and in the short term. Moreover, in their personal lives, people are often subject to a frenetic pace of life. For example, conciliating work and family life is often accompanied by cultural outings, sports activities, volunteering, and so on. In short, for some people, psychotropic stimulants meet the needs or expectations of everyday life.

- Another important category of benefits includes the regulation of mood, the improvement of behaviours, personality traits and self-image. Psychotropic drugs can quickly make people feel better, while promoting better integration; at least that is what many users hope. People take these drugs to obtain results on the personal and professional levels: harmonious personal relationships, a more attractive personality, increased sociability, better cooperation, initiatives, improved productivity, fewer absences, and so on. On the one hand, feelings of grief and sadness decrease, while on the other, self-esteem and a sense of performance and of efficiency are expected to increase. As a result, people expect to achieve a state of well-being or better well-being.

- There is a positive correlation between cognitive functions and the standard of living: a slight increase in cognitive functions leads to a rise in incomes and an improved quality of life. Several factors increase cognition: healthy eating, physical exercise, intellectual stimulation, satisfactory social relations, etc. However, some people have limited cognitive abilities and are unlikely to improve them; these people stand most to gain from a pharmacological enhancement of their cognitive functions.

In short, the benefits of expanded uses of almost all classes of psychotropic drugs seem to point to improved self-esteem, social validation of their achievements leading to promotion in the workplace, an improved social life, a favourable reputation, etc. The sum of these individual gains may increase education levels and the productivity of society, which would in turn mean that everyone would stand to benefit from this situation. But other consequences should also be noted, such as increased competitiveness to the detriment of other social values, or impacts on the health of individuals that could lead to an increased workload or fewer hours of sleep.
As a result, expanded “Lifestyle” uses of psychotropic medications do not just involve benefits. Risks are potentially associated with this type of use, including risks for human safety, external pressures, psychological dependence and the trivialization of psychotropic drugs.

- In the short term, negative side effects may be associated with non-compliance with the indicated dosage. In addition, the use of psychotropic drugs provided by friends or bought illegally on the Internet exposes consumers to two types of risks: those associated with the use of psychotropic medications and those relating to the unknown quality of medications ingested. In several situations, the safety of others is also at stake. In addition, certain “Lifestyle” uses may impair the physical and mental health of users. For example, taking a psychotropic drug that promotes resistance to fatigue reduces the hours of sleep, but sleep deprivation can in turn make it hard to function during the day and is also a risk factor for physical illnesses such as hypertension and type 2 diabetes.

In the long term, science cannot tell what the effects of psychotropic medications are on the brains of healthy people. It is possible that other mental states including moods and emotions, may be affected, either positively or negatively, by the fact of changing or enhancing a given cognitive function. At the present time, with the exception of tranquilizers and benzodiazepines (anxiolytics), the evidence base regarding the impact and scale of these effects on the central nervous system is extremely limited.

- It should be noted that social pressures, even to the point of coercion, have an impact on the process of individual decision-making. People resort to expanded “Lifestyle” uses in pursuit of a certain ideal, self-image and group, both in their professional and personal life. As a result, direct and indirect pressures to comply with this ideal may be brought to bear from different directions: the social network, hierarchical superiors, work colleagues, organizational culture, the family, parents, schools, the media, etc.

- For people using and benefitting from psychotropic medications, the fear of losing such benefits is a powerful motivation for continuing to take the medications, even when medical conditions no longer indicate such use. In consequence, some people may use psychotropic drugs as a strategy for confronting unpleasant or painful life events; they may come to the conclusion that the difficulties of life could be resolved by taking medication. Faced with these situations, a chronic use of psychotropics will end up addressing symptoms instead of mobilizing the personal resources needed to cope with life. This may also lead to a devaluation of other forms of therapy.

- The trivialization of psychotropic drugs was discussed above, in the section on the expanded uses of the “Medical” type. However, trivialization is even more a concern where expanded uses of the “Lifestyle” type are concerned, since in this latter case the use of psychotropic medications is designed to help fulfill idealized norms, images or values that have become ends in themselves. Also, the fact that consumers overstate the desired benefits and under-estimate the risks increases the trivialization of “Lifestyle” related uses.

A Synthesis

The Commission has decided to distinguish between two categories of expanded uses of psychotropic drugs, namely expanded “Medical” and “Lifestyle” uses. Several common points of interest emerge from the expanded uses of psychotropics.

First, although the term “expanded use” is applied to both categories, the first category consists for the most part of an extension of therapeutic uses of psychotropics, while the second illustrates above all expanded uses in the absence of this therapeutic goal. Second, although some factors are specific to each class, the same stakeholders are often involved. Third, it is not always easy to distinguish between therapy and enhancement, and as a result it is relatively easy for anyone to justify resorting to psychotropics. Fourth, it seems obvious that widely available and transparent scientific information of a high quality is
important; however this precondition is not always met, whether by the general population or by health and social services professionals. Fifth, the lack of knowledge of the effects of psychotropic medications on healthy individuals means that the expected benefits are held out as promises, while risks are often neglected or ignored. Finally, regardless of the categories used here, the increased use of psychotropic medications raises the broader question of the identity of the person and the normality of socially expected behaviours.

**AN ETHICAL QUESTIONING ABOUT EXPANDED USES OF PSYCHOTROPIC DRUGS**

Underlying these benefits and risks are several values, including the protection of persons, freedom, autonomy, responsibility, equity, accessibility, justice, the availability of information and the quality of this information. The concepts of identity, normality and the concept of human being are also at stake.

In considering these issues, the Commission has identified four key values: the protection of individual health and safety, autonomy and the affirmation of individual freedom, equity and representations of the human being.

**Protection of Individual Health and Safety**

Psychotropic medications are powerful. Even under medical supervision, benefits may be accompanied by significant side effects. For this reason, psychotropic medications cannot be dispensed outside of the logic of drug safety, which aims to protect persons, and is one of the fundamental values underlying the health and social services system.

Psychotropics pose special challenges because they induce biochemical changes in brain functions. But brain functions are still largely unknown; as a result, potential mid-term and long-term effects induced by psychotropics are also unknown. Consequently, persons are to be protected against the unknown risks of psychotropic medications, and a greater knowledge base is needed in this field.

**Improving Knowledge: an Essential Precondition**

In the short term, both the risks and modes of action of psychotropics are still largely unknown. Knowledge about the optimal duration of pharmacological treatments also poses a problem, because it varies from one author to the next, and guidelines do not always clearly state when and how to stop treatment. Nonetheless, the duration of treatment is an important factor in a person’s well-being and health.
The long-term effects of taking psychotropic drugs raise several fundamental questions: Will cognitive functions be affected – and, if so, by which psychotropic drug, how, and for how long? Will their effects be reversible or permanent? Are gender or age at the time of use important? The long-term risks faced by young users of psychotropic drugs raise particular concerns. Indeed, young people could experience negative impacts on their physical or mental health at an early age, and then be forced to deal with these impacts for the rest of their lives.

To date, there is very little scientific data from longitudinal studies capable of answering these questions. The anticipated increase in the use of psychotropic medications makes the need for knowledge about these drugs even more compelling. Meanwhile, it is important to draw a profile of the use of psychotropic drugs, and to monitor their development. In order to be able to quantify and qualify the short, medium and long term effects of psychotropics in Quebec, the Commission recommends:

**Recommendation No. 1**

That the main stakeholders deepen the knowledge of psychotropic medications, namely:

a) that the Minister of Health and Social Services give the Conseil du médicament (the Medication Council) the mandate of establishing a profile of current uses of psychotropic medications in the Quebec population and of monitoring their evolution over time;

b) that Quebec granting agencies incorporate into their programming the funding of qualitative and quantitative studies on the uses of psychotropic medications and on the different types of impacts induced by them;

c) that the relevant associations and professional orders document the practices of their members where the use of psychotropic medications is concerned.

Improving Various Modes of Information

During a medical consultation, the physician takes into account the consequences of the use of psychotropic drugs and correlates them with the benefits which may accrue to the patient. In the case of self-medication or expanded “Lifestyle” uses, adverse drug reactions and possible risks of expanded uses of psychotropic medications are often ignored or underestimated by those people using them without expert guidance.

In all cases, people obtain information through various channels, notably through the Web and other media.

*Influences of the Internet*

The Internet influences the dissemination of knowledge through scientific information sites for specialists, but also through sites offering popularized scientific information, discussion forums and blogs. The popularity and accessibility of the Internet offer many benefits, such as the diversity of sources and the kind of information accessed, which can be useful and educational for people consulting it.
However, the quality of this information is uneven and its validity is hard to verify. Consequently, Internet-based information may be incomplete, biased, and may even constitute misinformation. Where information on drugs is concerned, the consequences can be serious, because websites can reach those individuals likely to use psychotropics or those more vulnerable persons who are concerned about their health or who already suffer from a disease. Similarly, the rise of cyber-pharmacies and online shopping – without any after-sales service – raises the question of the validity of the information provided and the safety of drugs sold.

Given the difficulty of scrutinizing the quality of information found on the Internet and to ensure that people safely consume psychotropic medications, the Commission recommends:

**Recommendation No. 2**

That main stakeholders ensure the reliability of information transmitted to the population on the Internet, namely:

a) that the Minister of Health and Social Services, together with the Conseil du médicament and the relevant associations and professional orders, direct the general public to sources and Internet sites containing reliable popularized information;

b) that the Ordre des pharmaciens du Québec (Quebec College of Pharmacists) raise awareness in the general public of the risks of relying solely on information found on the Internet, and of the importance of validating this information by consulting health professionals.

**Influence of Other Media**

The mass media and the scientific literature tend to present, in an very favourable light, the idea of using psychotropic medications as a way of inducing cognitive enhancements and behaviour and mood regulation.

In the *scientific literature*, the most widespread trend acknowledges expanded uses of psychotropic medications, but considers it unrealistic to try to ban these expanded uses: this is the argument of inevitability; according to this argument, it is better to accept psychotropic drugs and to regulate them. For their part, the mass media, whether print or electronic, reach a high proportion of homes in Quebec. But in the mass media, the space and treatment accorded to scientific advances, including medications, is very unsatisfactory. Given their wide-reaching influence, stakeholders in the field of information – from journalists, researchers, senior staff to owners of media organizations – have a responsibility to provide accurate information to their audiences.
As a result, in presenting risks, benefits and questions with multiple layers of detail and meaning, the mass media and distributors of scientific information are participating actively and objectively in societal debates around psychotropic medications and their expanded uses. To this end, the Commission recommends:

**Recommendation No. 3**

That stakeholders in the field of information ensure the dissemination of critical, balanced and complete information on knowledge and uncertainties relating to mental health disorders, the use of psychotropic medications and the non-pharmacological treatments used in the treatment of mental and neurological disorders.

The Commission invites the stakeholders in the field of information to evaluate their roles and practices in providing health information. In order to do this, they may call on Quebec research groups studying psychotropic medications, mental health disorders or the influence of media on society.

**Other Stakeholders in a Global Perspective**

The Commission is of the view that the expanded use of psychotropic medication has an impact not only on protection of the individual, but also on protection of the population. Three sources of risks and social costs resulting from expanded use of psychotropics have been identified in this position statement, namely: pressures on the health and social services network, the current model of medical practice and the high proportion of certain user profiles.

In terms of the protection of “individual health and safety”, professionals in the health and social services network, the pharmaceutical industry and the State are the key stakeholders.

**Professionals in the Health and Social Services Network**

Physicians, pharmacists, nurses, psychologists and social workers are the health and social services professionals most directly involved in the use of medications. They practice their professions in demanding conditions.

For physicians – the ones prescribing psychotropics – two new questions arise. The first relates to the uncertainty around psychotropic drugs which can make clinicians uncomfortable in their decision-making role, and even lead to a moral dilemma, especially for general practitioners. Indeed, general practitioners provide care for the majority of patients suffering from mental or neurological disorders; but even they find that existing information is highly complex, often scattered or difficult to access. They would benefit from improved access to more centralized and better organized scientific information. Therefore, the Commission recommends:
Recommendation No. 4

That the Minister of Health and Social Services, together with the Conseil du médicament, and the relevant associations and professional orders:

a) establish an accessible mechanism to disseminate information on psychotropic medications and on the state of knowledge relating to non-pharmacological treatments;

b) develop best clinical practice guidelines for mental health;

c) develop decision support tools.

The second question refers physicians to the social dimension of their role. It is important that they think about their role, or the one they recognize, in the phenomena of medicalization and medicamentation of life situations and events such as bereavement, professional failure or extreme shyness. Similarly, another aspect of their social role is the place they give to non-pharmacological therapies during medical consultations related to these events. Their role in expanding the therapeutic area and their share of responsibility for the consequences arising therefrom are elements of debate. To this end, the Commission recommends:

Recommendation No. 5

a) That the relevant associations and professional orders sensitize their members about the phenomena of medicalization and medicamentation, as well as the reality and potential consequences of expanded uses of psychotropic medications.

b) That the universities, associations and professional orders concerned provide integrated mental health programmes in the core curriculum and in continuing education programmes.

c) That the universities, associations and professional orders involved include non-pharmacological treatments in the core curriculum and in continuing education programs.

Finally, the Commission invites associations, federations and professional associations in the health and social services network, as well as their members, to think broadly about two dimensions of their professional responsibility. The first is to take account of the asymmetric nature of the relationship between the professional and the layman, which highlights in turn the importance of their professional responsibility: this responsibility is related to the knowledge they possess, and their power over the people consulting them is directly proportional to their knowledge. Second, certain professional practices are raising new questions: Is the emphasis on prevention increasing the scale of expanded “Medical” and
“Lifestyle” uses? How are health professionals dealing with the scale of expanded uses? What position should they take in terms of professional responsibility when they have to deal with patient demands to be “better than well”?

Pharmaceutical Companies

In Canada, innovative pharmaceutical companies are major sponsors of clinical trials that form the basis of drug licensing; they also play a leading role in pharmacovigilance once drugs are marketed. As a result, pharmaceutical companies are key stakeholders where information on human safety is concerned. They must therefore reconcile the imperatives of product efficiency and safety with the aim of profitability and social responsibility. However, according to several authors, pharmaceutical companies are actively involved in the phenomena of medicalization and medicamentation.

The importance pharmaceutical companies give to research activities, training, promotion and marketing of drugs is well-known. In this respect, the Commission identifies four levels of responsibility. In terms of research, a responsibility to ensure that R&D also focus on the medium- and long-term effects of psychotropic medications reaching the market. This form of vigilance would increase the knowledge base relating to the medium- and long-term safety and effectiveness of medication – a knowledge base which this position statement deems is insufficient. In terms of dissemination of results, a responsibility to ensure that all results are disseminated and are made available without restriction. In terms of marketing, a responsibility to ensure that information on psychotropics is presented in an understandable, balanced and exhaustive manner so that professionals and individuals can make informed decisions. In terms of education and training, a responsibility to ensure that training offered by pharmaceutical companies includes knowledge presented objectively and exhaustively.

The State

The public has high expectations about the safety and effectiveness of medications they take. The fact that drugs are approved by Health Canada and are prescribed by physicians tends to reinforce these expectations and the perception of safety. Thus, transparency and accuracy of information about the risks and benefits of medications are central to the trust people place in monitoring authorities, pharmaceutical companies and prescribers.

With respect to protection of the individual and the population, the Commission has focused attention on two factors relating to the regulatory framework, namely direct-to-consumer advertising (DTCA) of prescription drugs and the drug licensing process.

The current Canadian regulatory framework is not well adapted to deregulation in the United States, which allows direct-to-consumer advertising (DTCA) of prescription drugs, without major restrictions. This form of advertising is banned in Canada and is subject to several regulations, but the ban is easily circumvented through Canadian access to American television, newspapers and magazines. Given that information easily crosses the border, there are pressures to allow DTCA in Canada. One of the arguments used in support of deregulation is that DTCA makes it possible to reach people directly and to better inform them as a consequence. In this regard, the Commission distances itself from the pro-DTCA argument and, in endorsing the position taken by the Conseil du médicament du Québec, recommends:
Recommendation No. 6

That the Minister of Health and Social Services intervene with the Minister responsible for Health Canada, in order

a) to keep in effect the ban on direct-to-consumer advertising (DTCA) of prescription drugs in Canada as long as the pharmaceutical industry or the advertisers have not demonstrated its benefits for the health of the population and for the health system;

b) that regulations continue to preserve the unique character of the Canadian health care system, which is based on solidarity;

c) that existing regulations concerning the prohibition of the third kind of DTCA (which mentions the medication by name, the pathologies which it addresses and the benefits associated with its use) are applied to advertisements coming from the United States.

In addition, the Commission has focused attention on two weaknesses in the drug licensing process, namely the lack of independent audits of the results produced by pharmaceutical companies, and the theoretical and clinical limits on which drugs licensing are based.

If this process is not updated with tools and independent evaluation of the pharmaceutical industry, it may not meet the high and legitimate expectations of citizens relating to the safety of drugs they consume. In this respect, the new progressive licensing process proposed by Health Canada would constitute an improvement since it takes into account several criticisms of the process currently in place.

Also, the World Health Organization and the World Medical Association, two international regulatory bodies, have called on pharmaceutical companies to disclose all research results in a registry. In Canada, Health Canada also encourages that clinical trials be recorded and disclosed in a public register. For its part, the Inter-agency Advisory Panel on Research Ethics has called for the reporting of clinical trials in a recognized public registry which is easily accessible by Internet, in its draft revision of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

2 Ibid.
3 Ibid.
To date, these initiatives call for the voluntary participation of researchers and pharmaceutical companies. In the interest of maintaining the bond of trust, ensuring a better flow of knowledge and allowing for greater transparency, the Commission recommends:

**Recommendation No. 7**

That the Minister of Health and Social Services intervene with the Minister responsible for Health Canada, so that Health Canada makes disclosure of clinical trials and of all results compulsory, in an accessible registry, and that this registry is regularly updated.

The concern for drug safety with regard to psychotropic medications reflects a kind of prudence, and multiple stakeholders shoulder responsibility for this attitude of prudence in various ways. Nevertheless, solving the difficulties associated with risk management and improving scientific knowledge would not necessarily make expanded uses of psychotropic drugs acceptable in social and ethical terms. Other ethical concerns are raised by the expanded use of psychotropic medications. One of these concerns involves autonomy and the affirmation of individual freedom.

**Autonomy and the Affirmation of Individual Freedom**

In a context in which autonomy, freedom and a sense of responsibility are valued, the relationship between individual choices and the limits that may be imposed on them is paramount. This question – which is central to contemporary debates – arises in a particularly delicate way in the context of this position statement.

**The Moral Subject: a Thinking Being**

The moral subject is endowed with reason and capable of thinking, and is autonomous and free. As a result, he is able to think out his actions and to answer for, and take responsibility for, their consequences. This responsibility of the moral subject implies a causal link, the ability to reason, awareness of one's actions and their consequences and the freedom to act (or not to act). It is based on a premise: that the person has the ability to make choices and take decisions.

The Commission considers that emphasizing the autonomy, freedom and responsibility of the subject enables him to be an actor in terms of caring for his own health. In this context, can limits be imposed, and how can they be posed, on the use of psychotropic medications which the individual deems personally appropriate? By what criteria can the moment be determined when individual needs have priority over those of the community? What should the person be told who wants a prescription for psychotropics in order to maintain or enhance personal performance?

The idea of limiting subjects in their decisions and actions conflicts with the “strong” concept of autonomy, according to which individuals are free, have the right to live their lives as they wish, and are limited only by the right of others to do the same. Yet the question of the balance between individual interests and collective interests has not been addressed.

**External Pressures**

The person identifies with groups and shares social values. A person may be autonomous and free to choose, while nevertheless being subject to strong pressures from all directions, to comply with various group models, professional expectations, ideals of behaviour or appearance, etc. The expression “everybody else is doing it, so just do it yourself” provides
a compelling illustration of the pressures to conform which are exerted on the individual. It is used in many fields of activity: at school, work, in artistic leisure activities, and in sports. The expression encourages the quest for performance, and trivializes the use of psychotropic medications as a means of leading this quest.

This vision of performance and enhancement confronting society may challenge the autonomy of the individual, but it may have much the same effect on other groups “at risk” of expanded use of psychotropics, who are often vulnerable and find themselves in a power relationship which is rarely advantageous for them. One may think for example of minors, individuals with little schooling or who live in poverty, the elderly who are losing autonomy or living in isolation, and workers unable to refuse a “request” from their employer.

By placing too much emphasis on autonomy and individual responsibility, one risks forgetting the other factors that influence an individual’s health, such as the physical environment, the social milieu, dominant values, as well as the responsibilities of other stakeholders: government, business, the media, pressure groups, etc. In addition, some expanded uses of psychotropic medications meet the expectations of society while camouflaging their social causes of these expectations; as a result, the medicalization of social problems through expanded “Medical” or “Lifestyle” uses is not addressing the root causes of these problems.

**Commission Cautionary Note on External Pressures**

The Commission is concerned that the pressures exerted in many social spheres and activities that aim to homogenize behaviours will lead to the regular use of psychotropic drugs.

**Equity**

Equity can be understood as a quality consistent with the ideal of justice, considered independently of laws currently in effect. In the context of this position statement, equity means that people receive care and services which they require because of their physical and mental health needs. However, the development of expanded uses of psychotropic medications in turn raises questions about equity.

On the one hand, the use of psychotropic drugs is expanding, and statistics as well as current forecasts regarding the uses of psychotropics suggest that this use will continue to increase. Moreover, it is clear from the scientific literature consulted that new psychotropic drugs are more expensive than drugs previous used. Consequently, even if the use of psychotropics does not increase, the overall cost expenditure related to psychotropic drugs would increase.
Commission Cautionary Note on the Accessibility of Medications

Given the likely increase in the use of psychotropic drugs caused by expanded “Medical” and “Lifestyle” uses, the Commission is concerned about the impact of this increase on access to medications. It is concerned about the impact this increase may have on the list of medications eligible for reimbursement, the affordability of drug insurance plans and the possibility that persons suffering from pathologies could be faced with unmanageable financial obligations.

On the other hand, disruptions in the continuity of care and services would contribute to expand “Medical” and “Lifestyle” uses. Walk-in clinics, for instance, are the appropriate venue for brief consultations and emergencies, but are not designed to address complex mental health problems or to ensure regular monitoring of chronic or recurrent health problems. Psychotropics can become a means of camouflaging the problem, rather than of treating it. In this situation, patients are not receiving appropriate care.

A vicious circle is being created, which in turn highlights a tension regarding access to the health and social services system: the shortage of health professionals and the organization of the network would seem to facilitate the expanded use of psychotropic medications; since expanded use requires a prescription written by a physician, the number of medical consultations is increasing, which in turn reduces the availability of these professionals; it becomes impossible to escape this vicious circle. As a result, disruption in the continuity of care sets up conditions leading both to more frequent expanded uses and to less accessibility to the health network.

Given the challenge of coordinating care and sharing information, the Commission recommends:

Recommendation No. 8

That the Minister of Health and Social Services continue to implement integrated mental health practices to ensure better continuity of care and services and to help reduce expanded uses.

With regard to relevant non-drug therapies, such as consultations with psychologists, social workers or speech therapists, the costs of consultations are not covered by the public system when they take place in private clinics; however, this situation frequently arises, given the shortage of these professionals in the public network. Some private insurance plans reimburse a portion of these costs, but not all Quebeckers have access to these plans. This situation leads to unequal access to care and services for non-medical services.

This inequity in access to care is particularly disturbing, given that in the case of several mental and neurological diseases, the combination of “drug therapy/psychotherapy” provides better short-term results for suffering individuals. In the long term, non-drug therapies – including psychotherapy, a healthy diet and exercise – would seem to lead to lasting positive results for several mental or neurological disorders such as depression, anxiety and diseases linked to the reduction of cognitive functions.
To ensure the equity and accessibility of the health-care network and of the different drug insurance plans, which are fundamental values at the heart of the Quebec health care system, the Commission recommends:

**Recommendation No. 9**
That the Minister of Health and Social Services:

a) establish the conditions for improving service delivery within the public system of services offered by professionals for non-pharmacological therapies used in the treatment of mental and neurological disorders;

b) study the conditions for reimbursement by the Régime d’assurance maladie du Québec of professional services provided for private non-pharmacological therapies used in the treatment of mental and neurological disorders.

The positive impacts on the network of increased access to non-drug therapies have yet to be demonstrated, both in terms of the health-care network and of individual health and well-being. Indeed, it is possible that the overall effort expected of health and social services professionals will not diminish, or that the budgetary appropriation for the Ministry of Health and Social Services will not be adjusted downward. However, the Commission considers it would be interesting to explore this avenue in order to see whether efficiencies can be identified in terms of the network’s human and financial resources. In addition, more systematic and accessible recourse to non-pharmacological therapies could demedicalize and demedicate certain life events that are not necessarily within the medical sphere. In order to characterize the possible effects on the public network of access to non-pharmacological treatments, the Commission recommends:

**Recommendation No. 10**
That the Quebec granting agencies include in their programming the funding of qualitative and quantitative studies on the impacts of increased use of non-pharmacological therapies on the public health and social service system.
Representations of the Human Being

Psychotropics influence the functioning of the brain, which is the organ representing the higher faculties, the seat of the spirit, of the soul, and of personal identity. Consequently, psychotropic drugs have different effects than other classes of drugs on the symbolic relationship with the "self", the identity and the concept of the human being. Given the many advances of neurosciences, psychotropic medications are provoking philosophical debates about human nature: Are we truly "ourselves" when we act under the influence of drugs that alter our thinking, our behaviours, our mood and our cognitive functions? To what extent do these drugs change the identity of the person and transform that person’s relationship to the world? Should we use different criteria to judge the morality of acts committed in a context of expanded use of psychotropic medications?

These issues are not solely related to expanded uses of psychotropics. They also arise, but with less intensity, in cases where drugs are used for therapeutic purposes, which aim to restore or maintain health, which is not the case of all the expanded uses of psychotropic drugs.

Human Nature and Meliorism

The desire for improvement is part of the human condition, which includes the enhancement of cognitive functions. As a result, the question of enhancement by means of psychotropic medications leads to debates on the nature of the human being, on what it means to live a successful life and on self-realization.

Indeed, Western societies situate the brain at the centre of what it means to be a person and to have an identity. The brain is the organ of thought, of consciousness, of acting or not acting, of memories, of individuality. Losing one’s cognitive abilities – including memory – can alter what defines us as individuals. However, psychotropic medications affect the chemical and biological foundations of the brain, and therefore involve what or who we are at the deepest level possible, at the human essence. The development of genetics has already launched the debate about human nature, but psychotropics are actually easier to use than genetic engineering and have a more direct relationship with our “self”.

In modern societies, three representations of humans can be distinguished – the religious, the naturalist, and the dualist, each of these three representations is in turn subject to subtle differences in meaning. All of these three representations are being rocked by advances in neuroscientific knowledge. As a result, it is important to pay close attention to drug uses that are designed to enhance or regularize function, whether of the “Medical” or “Lifestyle” type, since they influence the foundation of concepts of the human being and of life in society, including normality, suffering, performance and effort.

Normality

What does it means to be “normal”? Responses vary over time, and depend on individuals, groups and societies. In statistical or social terms, being “normal” means meeting a standard. However, human diversity is such that it is difficult to imagine a standard benchmark for cognitive function. Any definition of normality is bound to be complex, subjective and evolutionary in nature.

If the use of psychotropic medications to enhance performance and present regulated behaviours and moods is becoming trivialized, this medicated normality risks favouring the homogenization of diversity and the social ostracization of “deviants”. The effects of this homogenizing trend have yet to be demonstrated in detail, but it does not seem possible to mitigate personal and cultural differences without incurring consequences: a loss of cultural and social diversity, a lack of openness to differences that could lead to intolerance, coercion – whether mild or otherwise – and thus an assault on the autonomy of moral subjects, and moralization with respect to individual behaviour.
Suffering

The use of psychotropic medications as a means of maintaining or achieving a level of performance, efficiency and stability of mood may lead to helplessness, and even to physical and mental suffering, whether these objectives are met or not.

On the one hand, the perception of pain varies from person to person. The perception of pain follows a path between two extremes: the value assigned to it by certain people, religions, spiritual traditions and societies, and the intolerance of pain: why suffer when you can avoid it? Between these two extremes are a range of subtle gradations.

On the other hand, the cause of this suffering is often overlooked: a hectic rhythm of work and life can cause physical health problems, and harm interpersonal and family relationships. This would seem to militate in favour of psychotropic medications as a means of correcting a mental health problem caused by this rhythm. However, the consequences for individuals and their environment cannot be ignored: such people are suffering and, hopefully, they are receiving appropriate assistance. Should they be left without care because the cause of their suffering is related in part to a social level and not to a proven pathology? The Commission does not believe so, but considers that this form of suffering should lead us to question an emerging social trend.

Performance

The values of performance and self-realization can be found at various levels and are expressed in various ways across the ages and in different societies. Personal satisfaction and public recognition provide a sense of achievement and strengthen the positive perception of performance, which are powerful and creative forces driving personal and collective well-being.

The potential role of psychotropics in fulfilling these values should not leave one indifferent. In industrialized societies, performance, efficiency and going beyond one’s personal limits are all important, and contribute to self-realization. However, these values may be diverted from their objective once they become ends in themselves. This concept of self-realization depends on the trivialization of psychotropic drugs and leaves little room for different interpretations of what it means to “realize oneself” and of the various ways to bring about this self-realization. As a result, taking psychotropics in order to attain this objective of self-realization ends up normalizing expanded uses of psychotropic drugs for the purposes of enhancement. In cases like this, the end justifies the means, regardless of one’s health or critical reflection on the values at stake.
Effort

The issues of effort and cheating are relevant to concepts of performance, enhancement and self-realization. Indeed, the result of an action will often be considered in a favourable light if it is the result of effort, of personal investment. In addition, many societies and spiritual traditions value the use of personal resources, effort and discipline.

In the scientific literature, many authors draw a parallel between cheating, effort and the use of psychotropic medications to enhance cognitive and emotional performance, usually accompanying this parallel with a comparison to sports doping. An observation can be made at this point: sports doping is universally discredited, whereas cognitive “doping” is better accepted or is interpreted with more layers of detail.

It is beyond the scope of this position statement to reflect on the importance of “effort” in Quebec society. However, research suggests that it would be appropriate to reflect on the place and interpretations of “effort” in different dimensions of our social and personal life.

In sum, diverse conceptions of the human being and of the cultural, religious and traditional aspects associated with the human being coexist in modern societies. This very plurality militates in favour of broadening the debate on the role of psychotropics and on the place of expanded uses in Quebec.

Public Forums

When it comes to defining what is meant by health, disease, therapeutic use and cognitive enhancement, there is a lot of debate but not much consensus. For this reason, several questions arise: Who can draw the line between the medical and social dimensions of health? Is self-transformation a moral duty, in the interests of self-enhancement (cognitive functions, stable behaviours and mood)? Is it desirable to use psychotropics without any restriction for escaping physical and cognitive boundaries? What criteria should be used for decision-making?

Given the democratic and pluralistic nature of contemporary societies, it is difficult to invoke a single overarching vision of the common good. Political authorities are well-suited to arbitrate between different visions. Indeed, elected officials bear the responsibility of defining the common good and of ensuring that the community values are not subordinated to the interests of the few.

A better assessment of the “technical” risks and benefits of psychotropics and their expanded uses requires the expertise of health professionals – including physicians, pharmacists, nurses, psychologists and social workers. However, expanded uses go far beyond these frameworks of expertise and are part of a dynamic involving citizens. The decision-making process that defines the choice of issues, should go beyond the “expert-political class” relationship. Several other stakeholders are concerned, starting with the citizen-as-user, and should participate in social and ethical debates on expanded uses of psychotropics. In this regard, people who are not necessarily familiar with technical language and expert knowledge should also participate in discussions about expanded uses. Excluding them would undermine the legitimacy and effectiveness of decisions taken by others.
Integrating a diversity of views will promote conditions for the greater social acceptability of issues and decisions, while reducing the risk of paternalism, whether on the State’s part or on that of groups of health and social services experts. To this end, the Commission recommends:

**Recommendation No. 11**

a) That the Minister of Health and Social Services and the Minister of Education, Recreation and Sport promote the participation of civil society in discussions and decisions related to the place of medications, and particularly to the expanded use of psychotropic medications.

b) That the Commissaire à la santé et au bien-être (the Commissioner of Health and Welfare) lead a public debate on the expanded uses of psychotropic medications.

**CONCLUSION**

People suffering from mental and neurological health problems and those closest to them are obtaining real relief thanks to the progress in therapeutic treatments brought about by psychotropic drugs. However, increases in diagnoses of certain mental and neurological disorders as well as in prescriptions of psychotropics do not rest solely on medical grounds. Several factors are involved in these increases, but the Commission is focusing on the expanded uses of drugs.

It has rapidly become clear that the phenomenon of expanded uses is complex and goes beyond the medical setting alone. The lack of a consensus definition of “expanded use” of psychotropic drugs does not call into question the reality of expanded use. However, it highlights different perceptions of the same reality as well as major differences in terms of language, the assessment of risks as well as ethical issues raised by the expanded uses of psychotropics. Indeed, the place of psychotropics and of their uses in society is shaped by the presence of numerous social actors, with diverse interests, by the complexity of their interrelationships and by the social and economic influences they exert.

Consensus about the expanded uses of psychotropic medications is emerging in several areas. First, psychotropic medications are absolutely essential in the treatment of people diagnosed mental or neurological illness. Second, expanded “Medical” and “Lifestyle” uses are currently a reality in Quebec and constitute a well-established trend. Third, knowledge of the functioning of the brain is still limited, and the medium- and long-term effects of use of psychotropics remain largely unknown. Fourth, the claims made about the benefits and risks of expanded use of psychotropic medications are supported by very little scientific data and are instead of a rather speculative nature. Fifth, the idea of altering the brain, the seat of thought and a symbol of the “self”, rarely leaves people indifferent. Finally, the expanded uses of psychotropics affect both individual values, such as autonomy, well-being, self-confidence, performance and safety, and collective values, such as solidarity and accessibility.
The Commission is focusing on three potential kinds of drift related to expanded uses of psychotropic drugs. The first kind of drift is made up of external pressures bearing on the individual as well as incomplete and even partial information on psychotropic medications and their benefits. The Commission sees in this drift a risk both of homogenizing moods and behaviours and of intolerance towards people who depart from “normality” which has become a medicated normality. The second kind of drift is related to trivialization of expanded “Lifestyle” uses, and to a lesser extent of expanded “Medical” uses. Some uses are considered as means to achieve personal and professional goals, or to cope with painful but inevitable life events; as such, they mark a shift towards the maximization of quick results and the minimization of personal resources. Finally, the third kind of drift challenges the notion of personal identity and the representation of human beings. Self-realization includes success and performance, but are all means to achieve these goals desirable? Is the human brain an object liable to be turned into an instrument, or is it a feature distinguishing a human being not only from other animals, but also from every other human being?

The Commission is making its recommendations in fulfilment of its mission. Some of these recommendations as well as the Commission’s cautionary notes revolve around the need for information. By the same token, the Commission proposes on the one hand that spaces for public debate be rapidly developed, in order to keep up with the evolution of expanded uses, especially in terms of the objective of regulation, and on the other hand, because it sees public debate as an excellent opportunity for concerted reflection and multi-stakeholder decision-making.
INTRODUCTION
The primary objective of medication\textsuperscript{*1} is to improve the well-being and health of a suffering individual. For this reason, medications (also referred to in this position statement as "drugs") have an important place in therapeutic treatments: they have led to and continue to lead to improvements in the quality of care and to significant gains in the area of mental illness\textsuperscript{*}. Indeed, before psychotropic drugs were discovered, mental health interventions were often restricted to the use of straight jackets and lobotomies. The return to or maintenance of health also has a social connotation, beyond the strictly medical dimension. This is an age in which the values\textsuperscript{*} of performance, efficiency, improvement and self-realization are ever-present. Good physical and mental health\textsuperscript{*} is therefore considered a major asset in society.

These values can be defined in various ways, such as the development of different relationships to suffering, pain and happiness. Nonetheless, these values are well-established and common to many cultures. Amidst this historical continuity, a recent innovation has changed the means of realizing these values: psychotropic drugs\textsuperscript{*}. They mark the passage from more symbolic means to technological means: in former times, sustained and repeated personal efforts were called for; drugs now exist that may – possibly – fulfill the same purpose.

Thus, although knowledge about the brain remains limited, new generations of psychotropic drugs have raised enormous hopes, particularly for maintaining memory and cognitive function\textsuperscript{*} in people with dementia, for improved concentration in children with attention disorders and for emotional stability in people suffering from depression.
The Commission de l’éthique de la science et de la technologie has a long-standing interest in neuroscientific disciplines. In a position statement published in 2005, the Conseil de la science et de la technologie provided an overview of neurosciences with a particular focus on the situation in Quebec\(^1\), at the same time calling on the Commission to analyse certain ethical issues\(^2\). In 2006, the Commission published a position statement on nanotechnologies, in which it noted the possibility that these latter technologies could be used for enhancement of cognitive functions. Following these two documents, the Commission decided at its 28-29 November 2006 meeting to study the ethical issues arising from neuropharmacology\(^3\), a neuroscientific discipline, and to develop a position statement on this subject.

Several factors explain the Commission’s interest in psychotropic medications: the growing popularity of drugs that stimulate or, conversely, decrease cognitive function; widespread public enthusiasm for products that seek to produce the same effects (“smart drinks”, caffeine, vitamins, omega-3, etc.); the growth of this segment in the pharmaceutical industry; and finally the incomplete nature of information on long-term side effects on the nervous system.

This position statement focuses on the use of psychotropic drugs (the clinical dimension) and does not address in detail their development (the research dimension). Moreover, it focuses primarily on prescribed psychotropic medications, but does not ignore non-drug products; this decision is motivated by the fact that there are significant differences between regulatory settings. Indeed, there is stricter regulation of drugs than of non-drug products, in terms of manufacturing processes, quality controls, the licensing process, advertising, distribution and sale.

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1 Terms followed by an asterisk are defined in the glossary at the end of this position statement.
In this position statement, the Commission is addressing a complex subject about which the current state of knowledge leaves room for a significant level of uncertainty; several questions are raised to which no clear answers have been found. Given the breadth of the topic, the Commission chose not to conduct an exhaustive study, but to develop the most complete overview possible, while raising what appeared to be the most relevant issues. This position statement has been developed with a view to provide decision-makers and civil society with a “pedagogical” tool, in order to sensitive them about the set of problems related to the expanded uses of psychotropic drugs.

Neuropharmacology is the discipline studying those medications that affect the central nervous system* (CNS), such as psychotropic drugs (affecting mood, behaviour and cognition), anesthetics, sedatives, anticonvulsants and narcotics. These medications are used in the treatment of neurological* and mental diseases and are grouped together under the term psychotropic drugs.

There is no universal definition of psychotropics. According to the Office québécois de la langue française, a psychotropic drug is “a substance, whether natural or artificial, able to modify mental activity and acting mainly on the central nervous system and psyche.” This definition also provides the synonymous terms “psychotropic substance” and “psychotropic medication”. Accordingly, psychotropic drugs are not limited to prescription drugs but include any substance that affects the CNS; according to this definition, caffeine, nicotine, cocaine and alcohol would also qualify as psychotropics.

In this position statement, the Commission focuses on the expanded uses of psychotropic drugs. In so doing, the Commission defines “psychotropic” as a prescription medication affecting the central nervous system and psyche. (In addition, in the English version of this position statement, the terms psychotropic drug, psychotropic medication and the plural psychotropics are used interchangeably, as are the terms illness and disease.)

Neuropharmacology is a booming discipline. Scientific advances in neuropharmacology have been accompanied by an increase in diagnoses of some mental disorders* such as depressive disorder and attention deficit disorder with or without hyperactivity (ADHD), as well as an increase in prescriptions of psychotropic medications in recent years. Underlying these increases are numerous factors which are not mutually exclusive: a decrease in taboos surrounding mental health; a growing awareness of mental illness among general practitioners, leading to more prescriptions for psychotropic medications; better diagnostic tools; increased accessibility to medications due to implementation of the drug insurance plan; an idealized notion of performance and normality; “lifestyle drugs” which are used in non-therapeutic settings to improve a person’s cognitive functions in the absence of mental problems.

In these two latter cases, the problem lies less in the abuse of medication than in its use, which may involve expanded use, extended use, off label use, inappropriate use or cosmetic use of psychotropic drugs. The Commission is concerned about the causes and consequences of these new uses of psychotropic drugs, and in the present position statement, seeks to deepen its understanding of the issues at stake.
The first chapter discusses the various roles of medication and the social trends shaping these roles, by describing the social, socio-political and legal context in which the “drug” product assumes its place. The Commission begins by examining the concepts surrounding medication, such as definitions of “health” and “disease”, the organization of the health and social services network, the concept of medicalization* and self-care*. Different stakeholders, with different and sometimes divergent interests are then presented, all of whom are involved in the characterization of the role and uses of drugs. Finally, given that drugs are highly regulated products in Canada and Quebec, the Commission addresses the regulatory framework surrounding all aspects of medicine – research, licensing, manufacturing, distribution, marketing and prescription. Several laws, regulations, codes of ethics, guidelines and good practice guides are briefly summarized, as well as the major limitations placed on their practical applications.

In the second chapter, the Commission focuses on those questions specifically related to psychotropic drugs raised in Chapter 1. The first part of the chapter is devoted to psychotropic drugs as medications, presenting statistics on their use, existing classifications, applications and some medication use profiles. Since psychotropics affect the central nervous system, the anatomy and functioning of the CNS are briefly described. In the last part of the chapter, the Commission focuses on the clinical evaluation of the use of psychotropic drugs, namely the “risk/benefit” ratio. It identifies some of the benefits and risks of psychotropic drugs, which are mainly derived from clinical trials conducted by innovative pharmaceutical companies*. These clinical trials are the main source of evidence since the research findings provide the basis for drug approvals and recognized uses of medications. The chapter then discusses certain clinical and theoretical difficulties associated with clinical trials and the relatively limited state of current knowledge of brain functions. The information provided illustrates the difficulty of establishing the “risk/benefit” ratio for the treatment of mental or neurological* disorders, which in turns is opening the way to expanded uses, i.e. uses of psychotropics not recognized for indications licensed by Health Canada.

In chapter 3, the Commission offers an analysis of some expanded uses of psychotropic drugs. It identifies two major categories of such use, namely expanded “Medical” uses (derived from certain medical practices) and expanded “Lifestyle” use (related to the fulfillment of personal and social values). Although these sources of influence are closely linked, they are presented separately for demonstration purposes. The factors that shape these uses are described, as are the possible consequences, both positive and negative, related to expanded uses of psychotropic drugs.

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4 OFFICE QUÉBÉCOIS DE LA LANGUE FRANÇAISE (our translation).

5 The original French version of this position statement uses the term “neuromédicament” which has been proposed to and accepted by the OFFICE QUÉBÉCOIS DE LA LANGUE FRANÇAISE. In the English version of this position statement, “psychotropic drug” is the term most commonly used.
The consequences identified in chapter 3 are at the heart of the ethical questioning in Chapter 4. In this latter chapter, the Commission questions certain impacts on individuals and society of expanded uses of psychotropic drugs, whether of the “Medical” or the “Lifestyle” type, and the values at stake in each case. In considering these issues, the Commission has identified four key values: protection of individual health and safety, autonomy and the affirmation of individual freedom, equity and representations of the human being.

In presenting this position statement, the Commission is making eleven recommendations to policy makers and other stakeholders. It aims to contribute to advancing ethical reflection on the set of problems arising from expanded uses of psychotropic drugs, but also to provide the main stakeholders with guidance that takes into consideration the ethical issues and fundamental values at the heart of our society. In some cases, where it seemed impossible to make a recommendation on an issue that is nonetheless clearly important, the Commission provides a cautionary note in order to focus on the issue at stake, in the broader perspective of opening debates to Quebec society as a whole and to the citizens. Indeed, expanded uses of psychotropics go beyond the medical setting alone, and make clear that the drug exists in a given context where citizens act and interact.

Before going further, two further points need to be made. First, some trade names of drugs are included in this position statement. This was a deliberate choice, for the benefit of readers to whom the generic names are not familiar. This should not be construed as a form of advertising. In the text, the trade name is usually accompanied by the generic name. Tables 1 and 2 cite a few of these names, while a more exhaustive list of generic names of psychotropic drugs sold in Canada is to be found in the appendix.

The Commission wishes to emphasize that it is well aware its position statement may raise several issues in the general population. It wishes to underline the fact that psychotropic drugs have demonstrated their effectiveness and efficiency in the treatment of mental and neurological diseases. The questioning in this position statement should not lead people with current prescriptions for psychotropics to unilaterally stop taking their medication. People wondering about their health status and medication should consult their physician.
Given its increasing power as a value, “health” has become a new normative field which covers many aspects of our lives, and also a political and social issue. In this respect, medication plays a significant role in disease therapy and prevention, and more and more in the potential enhancement of people’s physical and mental capacities. Before moving on to identify ethical issues associated with expanded uses of psychotropic drugs, the Commission considers it important first of all to examine the place of medications in Quebec society. This chapter addresses concepts that affect the place of medications, as well as the stakeholders involved, the normative framework surrounding the development and marketing of drugs, and some issues raised by their use.

**MEDICATION IN THE HEALTH SYSTEM**

**A Predominant Presence**

**History**

Throughout its history, Quebec has maintained a health and social services system offering a wide range of services to the population. The values underlying this system are accessibility, equity and solidarity. In this modern health system, medication is the most widely used and most accessible treatment.

The Quebec government has acknowledged the importance of drugs in the therapeutic arsenal. In 1997, it adopted the Act respecting Prescription drug insurance (R.S.Q., chapter A-29.01), which provides for the establishment of a public drug insurance plan. The spirit of this public plan “is not based on the right of each person to have access to drugs that the individual deems necessary but on the mutuality of the insurance plan, and on solidarity, since it is a public plan [œuvre publique].” The drug insurance plan is in continuity with the Health Insurance Act of 1970 and is based on the same philosophical principles. In this respect, Article 2 of the Act respecting prescription drug insurance is explicit: “The purpose of the basic plan is to ensure that all persons in Québec have reasonable and fair access to the medication required by their state of health.”
As a result, since 1997, all Quebec citizens enjoy universal coverage of prescription drug insurance. When drugs are administered in hospitals or long-term care facilities (CHSLDs), the hospital insurance plan covers the costs. In other situations, the public drug insurance plan or private group insurance plans intervene.

However, over the years, the increased use of medications and the growing costs of new medications have become causes for concern. In 2007, the growing financial burden of drug insurance plans led the government of Quebec to adopt the Drug Policy, which articulated several values, including fairness, freedom and planning. The Policy proposes an integrated strategy to guide decisions and actions relating to drugs, taking into account all stakeholders, the interests at stake and the financial capacity of the State. It sets out 29 department orientations grouped in four areas: the accessibility of drugs, establishment of fair and reasonable prices, optimal use, and maintaining a dynamic biopharmaceutical industry. Of these four areas, the one concerning optimal use involves stakeholders from many settings – the “patient, prescriber and pharmacist” trio, other health professionals, universities, the Ministry of Health and Social Services (MSSS), insurers, drug manufacturers, the media, pharmaceutical companies, etc. – and affects both therapeutic use and the financial interests of individuals and of the community. Therefore, practical applications in this area are complex.

While the Drug Policy was being formulated, a draft policy was the subject of several briefs and public consultations. Researchers examined the documents submitted and noted a trend. In their words, “we find that neither the policy being proposed by the government nor the briefs [devoted to it] undertake a critical analysis of the socio-cultural norms underlying the consumption of drugs and the central place drugs occupy in health concerns.” The Commission wishes to contribute as much as it can to this reflection.

Medication: a Diversity of Prices and Uses

The “central place” of medication in Quebec and Canada is borne out by the facts. In 1992, the Ministry of Health and Social Services (MSSS) noted in its Health and Welfare policy that “drug consumption is constantly rising in the population.” And since 1997, in Canada as a whole, drugs accounted for the second-largest share in health expenditure, after hospitals. In 2005, the cost of prescription drugs in Canada amounted to $19.4 billion, or more than the $18.5 billion paid in physician services.
In noting that drugs play an important part in health expenditures, it is important to draw a distinction between phenomena related to changing costs and those related to changes in their volume of use.

**Drug Pricing**

Several factors influence drug prices. First, prices vary depending on research and development (R&D) costs, production costs, promotional costs, profit margins sought by companies, competitive pressures, etc. In addition, inflation contributes “naturally” to higher prices. Finally, modifications to existing regulations result in additional costs if the required adjustments result in additional administrative measures for pharmaceutical companies (staff training, purchase and adaptation of software, written reports, etc.).

It is also worth noting that the market entry of generic drugs* generally decreases the costs associated with drug consumption, contrary to the licensing of new drugs, whose costs are generally higher than those of existing drugs for treatment of the same health problems, which increases the overall cost of medication.

**Volume of use of medicines**

**Therapeutic Uses**

Several situations or factors influence the quantity of drugs used. First of all, demographic factors such as age, ethnicity, gender, human health, increased life expectancy, population size lead to fluctuations of drug consumption. In addition to demographic factors, other elements affect the volume of drug use. For example, new guidelines encourage an increase or decrease in the use of certain drugs. New medical indications recognized by Health Canada extend the list of approved use of specific drugs. For example, Revatio® was initially prescribed to treat pulmonary hypertension, and under the name Viagra® was subsequently used in cases of erectile dysfunction. Also, the outbreak of a disease can increase the use of certain drugs, whereas when the outbreak subsides, drug use also decreases. Finally, the promotional activities of pharmaceutical companies, such as training courses offered to health professionals, samples, brochures available in health institutions, websites and advertising, also influence drug consumption.

The use of drugs can also reduce the use of more invasive techniques such as surgery, and the number or duration of visits to health facilities. This is a direct result of new technologies and new drugs reaching the market and it leads to increased drug use. Given that this phenomenon of "surgery-drug substitution" is relatively recent, some of its consequences have not yet been taken into account overall. For example, there are potential effects on the daily lives of patients outside of health facilities and on those closest to them offering care in these settings; there may also be financial consequences for individuals who must now buy drugs formerly provided by hospitals during hospital stays. Similarly, financial and human costs and the overall impact on the health of the population resulting from these substitutions have yet to be calculated – with all the challenges associated with such calculations. Despite these reservations, the Commission recognizes that in some cases, individuals may benefit from greater drug use given that such use may help prevent invasive treatments.
Prevention

The emphasis on prevention and lifestyle-related risk factors also explains growing drug use. Indeed, where possible, the health system acts upstream, i.e. not only by treating and curing diseases, but also in preventing them.

There are typically three levels of prevention:25

- **Primary prevention** occurs in the absence of any symptoms and is directed towards preventing the initial onset of an illness. It includes acts known to decrease the likelihood of specific problems, such as vaccination or taking vitamins and minerals. It also promotes a lifestyle recognized as healthy because of its multiple positive effects on health; this lifestyle is characterized by regular physical activity, moments for relaxation and healthy eating. In several cases, the preferred strategies for promoting these practices consist in educational and information activities directed at the population.

- **Secondary prevention** focuses on the detection of early symptoms or high risk factors associated with health problems that are considered important. The goal is to intervene early on, before the onset or at the very beginning of a health problem, when it is still possible to prevent the onset of clinical disease or to reduce its development and consequences. Drug treatments are commonly used in secondary prevention.

- **Tertiary prevention** aims to reduce the consequences of disease (disability and handicap) and to avoid relapses. It includes a focus on rehabilitation and social and professional reintegration.

18 CIHI (2008), op. cit., pp. 37-41, provides a list of factors influencing the amounts allocated to medication, for pricing among others.


20 Patents grant exclusive rights to an innovative company for a defined duration, and also constitute of factor contributing to high drug prices. Since 1 October 1989, the term limited for the duration of patents (including pharmaceutical patents) in Canada is twenty years (Patent Act, R. S., 1985, chapter P-4, art. 44; GOVERNMENT OF CANADA, DEPOSITORY SERVICE PROGRAMME. Patent Term Extensions for Pharmaceutical Products, document MR-144E, 20 February 1997, updated 2 October 2002, http://dpd-psd.pwgsc.gc.ca/Collection-R/LoPBdP/MR/mr144-e.htm [consulted 2 March 2009]). In addition, the Quebec government created the “15-year rule” in 1994, according to which innovative medications are reimbursed if they have been registered for less than 15 years on the RGAM’s list of medications or the list of health facilities, even if a generic equivalent is also registered on the list at a lower price; it should be noted that this rule does not construe a monopoly the way patent protection does (MSSS [2007], op. cit., pp. 64-65).

21 CIHI (2008), op. cit., pp. 37-41 provides a list of factors influencing the amounts allocated to medication, notably for variations in use.


23 CIHI (2008), op. cit., p. 38; COMMISSION ON THE FUTURE OF HEALTH CARE IN CANADA (ROMANOW COMMISSION), op. cit., p. 193.


25 WORLD HEALTH ORGANIZATION (WHO), Health Promotion Glossary, Geneva, WHO, 1984, p. 20; LAROUSSE MEDICAL, Prévention, Paris, Éditions Larousse, 2003, p. 831. Another level of prevention exists – pre-primary prevention – although it is not used in practice in Quebec, where it is considered part of primary prevention. This level of prevention is applied to different pathologies such as cirrhosis or hypertension when health indicators are at threshold limits known to be problematic (it should be noted that the results of these studies and literature reviews do not suggest that pre-primary prevention is in itself a treatment to follow). Consequently a new vocabulary has been developed by some authors: some refer to pre-hypertension or by extension to pre-problem. (*) : Carolina TIANI et al., "Portal Hypertension: Pre-Primary and Primary Prophylaxis of Variceal Bleeding", *Digestive and Liver Disease*, vol. 40, no. 5, 2008, pp. 318-327; Melissa A. MINOR and Norman D. GRACE, "Pharmacologic Therapy of Portal Hypertension", *Clinics in Liver Disease*, vol. 10, no. 3, 2006, pp. 568-569. (*) : Kurt J. GREENLUND et al., "Prevalence of Heart Disease and Stroke Risk Factors in Persons With Prehypertension in the United States, 1999-2000", *Archives of Internal Medicine*, vol. 164, no. 19, 2004, pp. 2113-2118. (*) GREENLUND et al. op. cit. (*) Johanne COLLIN, "Relations de sens et relations de fonction: risque et médicament", *Sociologie et sociétés*, vol. 39, no. 1, 2007, p. 105.
All levels of prevention are concerned about disease risk factors, such as smoking, hypertension and hypercholesterolemia, which are characterized by the fact that lower exposure to the risk factor results in a better health outcome. As a result, over the last few decades, more aggressive smoking cessation campaigns (with medication reimbursed) have been seen, along with a tendency to lower diagnostic thresholds justifying drug use for cholesterol and blood pressure values. Thus, concerns about prevention may make it acceptable and legitimate to medicalize a large part of the population. The evolution of these thresholds reflects the fact that a (non static) consensus has been established between a set of considerations, leading to important consequences for drug use.

The promotion of healthy lifestyles is a big part of public health discourse. The media stress the importance of reducing risk factors, and such reduction is promoted and even instrumentalized. However, lifestyle improvements are not always sufficient to address certain risks. As a result, better prevention requires a combination of pharmacological and non-pharmacological measures. It is therefore important to ensure that medications effective in controlling certain lifestyle-related risk factors are not seen as a valid alternative to behavioural changes, which are often more difficult to bring about. Consequently, there also exists a real potential for the medicalization and medicamentation of the concept of prevention itself.

Expanded uses of drugs

The place of drugs is expanding, and this phenomenon is linked particularly to the discovery of new molecules, especially those having fewer adverse drug reactions than molecules currently used for the same purpose. Since these new drugs are safer, it seems acceptable to prescribe them for less severe physical or mental conditions than before. As a consequence, the volume of use of these drugs tends to increase. One thing leads to another, and these treatment adjustments can be integrated into updated indications issued by Health Canada as well as publication of new guidelines by associations and professional orders.

There are also drugs which seem to be able to produce effects in “healthy” individuals similar to those in individuals suffering from disease. These include some antidepressants promoting cooperation, and reducing negative perceptions and reactions (such as fear and hostility), without altering positive emotional states (e.g. happiness). In addition, the psychostimulants methylphenidate (sold primarily under the brand names Ritalin® and Concerta®) and modafinil (a drug used for narcolepsy [a sleep disorder characterized by difficulty staying awake] marketed in Canada under the brand name Alertec®) have shown an increase in the speed of decision-making and greater alertness at various levels and in certain cases. Finally, a well-known study showed that a drug used to treat Alzheimer’s disease, donepezil (sold under the brand name Aricept®), had increased cognitive functions in pilots during flight simulations.
There is nothing new about the desire to improve perception, attention, memory, reasoning or mood. What is more recent is that in the quest of enhancement, healthy people are resorting to medications used in the treatment of pathological mental conditions.²⁹ The use of drugs for enhancing what is already functional, such as the quest of increased performance or job efficiency, means pursuing a non-therapeutic goal. Such uses also contribute to increasing the overall volume of drug use.

In short, drug-related expenditures are growing because of an increase in costs and expanded uses. The Commission is particularly interested in the causes and consequences of this expansion of uses, as well as in the key stakeholders involved.


29 This aspect is regularly discussed and often amplified. See Steven E. HYMAN, "Improving our Brains?", BioSocieties, vol. 1, 2006, p. 106 and FARAH (2002), op. cit., p. 1124 who discuss several studies.


**Essential Concepts**

Without being exhaustive, the Commission has chosen four elements that play a role in drug utilization: the difficulty of defining “health” and “illness”, resource scarcity in the public health and social services network, the rise in self-care (with the natural practical consequences of autonomy and individual responsibility) and the medicalization of non-pathological traits and behaviour that do not necessarily belong to the medical field.

**Health and Disease**

Health and disease are intimately related, but defining what it means to be “ill” or “healthy” is not straightforward. These definitions are dynamic: they evolve over time and across societies.

On the conceptual level, two definitional models of the word “disease” are used in the literature. The first definition, currently used by a minority, does not clearly refer to health, but rather to a statistical standard – without defining the standard. For example: “Any deviation from or interruption of the normal function of any part, organ, or system, or combination thereof, of the body that is manifested by a characteristic set of symptoms or signs, and whose etiology, pathology, and prognostic may be known or unknown.”

The second more widely used model is as follows: “Changes in health status, manifested as a [general] rule by symptoms and signs.”

The Office québécois de la langue française uses much the same formulation while adding a characteristic: “Changes in health status attributed to internal or external causes, resulting in symptoms and signs, and manifested by functional disruptions or by lesion.”

In general, therefore, disease is defined in terms of health, which it makes it all the more important to clarify what is meant by health.

Several definitions of health have been articulated, particularly in the context of guideline development, and uphold a certain ideal of perfection. For example, the World Health Organization (WHO) enshrined in its 1946 constitution the following widely influential definition: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”

Several levels of government in Canada have drawn inspiration from the WHO’s definition of health. For example, the Canada Health Act stipulates that “the primary objective of Canadian health care policy is to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers.”

In Quebec, the Act respecting health services and social services states that “The health services and social services plan established by this Act aims to maintain and improve the physical, mental and social capacity of persons to act in their community and to carry out the roles they intend to assume in a manner which is acceptable to themselves and to the groups to which they belong.”
These definitions project a positive image of health. Besides taking into account physical health and disease, they involve other determinants, such as individual and social well-being related to access to education and employment, income level, the rich dimensions of interpersonal relations and of the social milieu, housing safety, etc. In proposing a model of integration into the social and physical environment, these definitions transcend purely medical aspects of health\textsuperscript{39} moving towards social normality, i.e. adapting to rules and norms in society.

They also pose a particular challenge in terms of evaluating the level or acceptability of the health of an individual or population. Indeed, health includes variables which can be quantified or measured, but it also involves psychoaffective and relational dimensions in which subjectivity is the predominant characteristic: people and the communities to which they belong are the sole judges of the quality of their existence. Moreover, individual perceptions change, depending on individual health states, age, life experience, transformations in their environment, etc.\textsuperscript{40} It follows that all definitions include a strong cultural and subjective component, in terms of the “patient", of groups to which the patient belongs and of healthcare professionals.

While it is important to define what is meant by “health”, the Commission recognizes that in the absence of any operational consensus, there are several different definitions of this term. Indeed, the concept of health expresses “a bundle of values which constitute the ethos of our society, although the concept’s definition is fluid and hard to quantify.”\textsuperscript{41}

The boundary between health and disease is unclear and may therefore be particularly difficult to delineate in the case of mental or neurological disorders. It is therefore appropriate to conceptualize the notions of “health” and “disease” on a continuum where one pole is a proven pathology and the other is the quest for perfect health (or well-being).\textsuperscript{42} Between these two poles exists a vast grey zone within which lie intermediate situations as well as the concept of prevention, and the notions of enhancement and performance. However, as stated above, the concept of disease is defined in relation to health, and the notion of health is relative and not absolute; as a consequence, the poles of the concepts of “health” and “disease” are themselves variable in time and space, and the grey area between these two extremes is even more liable to fluctuate.
Mental Health and Mental Illness

These two regularly used expressions describe closely related realities which are nonetheless distinct.

- **Mental health** is “the capacity of the individual, the group and the environment to interact with one another in ways that promote subjective well-being, the optimal development and use of mental abilities (cognitive, affective and relational), the achievement of individual and collective goals consistent with justice and the attainment and preservation of conditions of fundamental equality.” Thus, a **mental health problem** is “a disruption in the interactions between the individual, the group and the environment”; this disruption may result from numerous social and physical factors, and be temporary.

- **A mental disorder (or mental illness)** is defined as “a recognized, medically diagnosable illness that results in the significant impairment of an individual’s cognitive, affective or relational abilities. Mental disorders result from biological, developmental and/or psychological factors.”

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Two paths may be noted:

- The first path is associated with disease, and includes the ability to prevent and treat disease and lessen its consequences, while considering the process of recovery or deterioration, relapse, chronification, etc.

- The second is more closely associated with mental health or well-being, and includes an individual’s ability to fulfill himself and to grow in the presence or absence of illness, difficult situations, etc. The presence of disease may hinder well-being, but it also may not affect well-being if the individual strikes a new life balance in life and experiences this balance in a fulfilling manner.

As a result, an individual not demonstrably suffering from a disease, not living painful life events (separation, bereavement, unemployment, etc.) may have fragile mental health or a mental health problem. Similarly, an individual experiencing mental illness which is under control and accepted both by the individual himself and by those closest to him may enjoy good mental health.
Resource Scarcity in the Public Health and Social Services Network

A number of factors point to a sustained use, in years to come, of health and social services resources. There are several reasons for this, among them the increase in the number of elderly people expressing more frequent needs than previously, and development of more effective diagnostic tools for early detection and treatment of health problems.

Yet for several years now, the health care system has had to deal with a shortage of human resources, which restricts access to primary care (general care) and second-line care (medical specialists). Many job classes are particularly affected, including nurses (technicians and bachelors of nursing), pharmacists (including those working in public health facilities), social workers, psychologists, psychoeducators and physicians. Whether the latter physicians are general practitioners or specialists, in Quebec and elsewhere in Canada, they are practicing in a context where they struggle to meet demand.

Several consequences flow from this situation. The organization of work in the health system remains a significant challenge in a context where successive reforms have to be integrated in order to better meet the needs of the population and of the people working work in the network. In addition, the workforce in the health and social services network is undergoing a heavy workload and is running out of steam, leading to burnout or career change decisions, which in turn is intensifying the shortage of skilled workers. This context of scarcity and workload encourages risk of medication errors, which constitutes the second cause of incidents in some public health institutions studied. A recent Canadian study on


hospital nurses also concludes that there are links between the organization of their work and the risk of drug errors. Finally, the lack of qualified personnel for home care, social workers and psychologists for non-drug therapies and family physicians is detrimental to the continuity of care and services and makes it more difficult to adequately respond to needs. It should be noted that these shortages particularly affect certain members of society, including native people and those people living in remote or rural regions.

The shortage of physicians also has consequences for the “patient-doctor” relationship. Medical consultations are usually short, which may hinder the exchange of information between patient and doctor, diagnosis, determination of the appropriate treatment as well as transmission of information on medications being proposed; this also applies at the time of evaluation for the purposes of prescription renewal. Several factors explain the brevity of consultations, including patients’ prior knowledge about the disease and the medications involved, the experience of physicians, time constraints and low patient participation, the method of billing fees for service, and familiarity with a medical file resulting from mid- and long-term follow-up. Organizational factors come into play, both negatively and positively. Thus, the emphasis on accessibility to the network has brought about a significant increase in “walk-in” consultations. However, this situation means there is a greater number of physicians who often do not know their patients, which in turn makes it harder to integrate patient information and therefore to offer follow-up and continuity of care. In addition, new practice models are being established, according to which other health professionals take over in areas where their expertise complements that of the physician. These new practices aim to reduce the amount of time physicians devote to consultation without reducing the quality of care received by patients.

However, one constant remains: perceptions vary considerably concerning drug information as it is provided by the physician, on the one hand, and drug information as it is received by patients, on the other. In a literature review on the subject, researchers report that physicians overestimate the time allocated to information transmission, including information concerning drugs. According to the researchers, “we can only conclude there is a convergence of research data on the lack of patient knowledge about medications they use and the difficulty that patients experience in integrating and managing this information.” In addition to this observation made by researchers, note should be taken of the individual’s literacy level: in Canada, half of the population struggles to read information they come across, in the course of their daily activities. Difficulty in reading instructions on drug labels or information sheets may lead to misuse of drugs and impacts on the health of people concerned. This constitutes a major challenge, given the need to ensure safe drug use, and both physicians and patients should share knowledge in a mutually satisfactory way.

Finally, the Commission wishes to emphasize that the lack of resources in the health and social services network imposes an ethical obligation on physicians, given their role of providing relief to patients. In this context, prescription drugs can be seen as tools providing temporary relief, although this in turn creates a situation which is conducive to overprescribing, a complex phenomenon in itself involving several different factors and stakeholders. Without ignoring the role of physicians, it is worth asking whether “in this context, stakeholders, not to mention the health system itself, may confer on medication a substitutive role [...] Doesn’t what we refer to as ‘misuse’ actually express another order of problems?”
Rise in Self-care

With increases in the educational level of the population and of access to new information sources (including Internet), a new phenomenon is emerging: citizens are now able to build up personal knowledge on health by drawing on various sources of information. Indeed, the traditional “patient-doctor” relationship has been subject to change, becoming more complex as a result. Medical professions are imbued with authority and they continue to enforce it, but this authority is now accompanied by a critical attitude, depending on the people and situations involved.

Given the sociopolitical context both of demands for individual rights and of critical expression by individuals and community groups, users of health and social services facilities are arguing in favour of autonomy of thought and decision-making even to the point of challenging the expertise of health professionals.  

For example, in this perspective, being denied a drug by a doctor may only constitute a minor setback: the individual can “shop around” and quite possibly find another clinician willing to prescribe the drug. Similarly, the individual is free to take or not to take the drug prescribed by a physician or to observe the pharmacist’s indications.

This relationship is changing in a context of scarce human and material resources in the health and social services network. This imbalance as well as respect for the value of citizen’s “autonomy” favour a public discourse of individual responsibility and self-care. According to Consumer Health Products Canada (formerly NDMAC):

Self-care, the decisions people take to promote health, prevent and treat some diseases, is a vital and underestimated part of health care. Nevertheless, increasing evidence supports the view that self-care leads to improved health and quality of life.

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47 “relationships between risks to patient care and certain aspects of hospital nurses’ work organization and the workplace environment. Usually working overtime, feeling overloaded, an environment where working relations physicians and nurses are poor or where staffing and resources are inadequate, and lack of help from co-workers were all related to medication error.” (Kathryn WILKINS and Margot SHIELDS, Correlates of medication error in hospitals, 82-003-XW, Ottawa, Statistics Canada, 2008, p. 17).

48 Michael J.L. KIRBY (chair) and the STANDING SENATE COMMITTEE ON SOCIAL AFFAIRS, SCIENCE AND TECHNOLOGY. Out of the Shadows: Transforming Mental Health, Mental Illness and Addiction Services in Canada, Ottawa, Senate of Canada, 2006, p. 149; COMMISSION ON THE FUTURE OF HEALTH CARE IN CANADA (ROMANOW COMMISSION), op. cit., p. 56. The MSSS also recognizes this state of affairs; the list of regions lacking health care professionals mostly comprises rural and isolated regions far from urban centres; (http://msssa4.msss.gouv.qc.ca/fr/sujets/medregion.nsf/2c86ceaa3329dbc85256d03006d3d34/79433045157548d0f85256dd600571cdc?OpenDocument), these regions are subdivided into different groups and sectors depending on the severity of the shortage prevailing in each – for example, for physicians, see: http://msssa4.msss.gouv.qc.ca/fr/sujets/medregion.nsf/0ae537bb5abe17885256de004858d86ac4107db0b058385256dd60058d8fd1?OpenDocument).


53 Ibid., p. 355.(our translation).

54 Reported by Chantal OUELLET et al., “Alphabétisme, santé et médicaments : des liens importants à connaître et à comprendre”, in LEVY and GARNIER, op. cit., p. 319.

55 OUELLET et al., op. cit., discuss and analyse this question in their study.

56 DOUCET, op. cit., pp. 116-117 (our translation).

57 LECLERC et al., op. cit., p. 22.

58 Brief tabled at public audiences of the Quebec Social Affairs Committee, summarized by SAIVES et al., op. cit., p. 123 (our translation).
A concept related to self-care is self-medication, i.e. the use of medication without medical advice. This practice mostly involves over-the-counter drugs, but also includes drugs left over from a previous prescription or those obtained from third parties. For some, self-medication leads to greater autonomy since it helps an individual control his own health. In other cases, it may result from an unsatisfactory doctor-patient relationship or from loss of confidence in the health system. It can also be seen as a time saver, since it occurs in response to a context of reduced accessibility to the health and social services network. It should be noted that time savings and self-care also correspond to a certain concept of performance and efficiency.

The phenomena of self-care and self-medication are part of a broader logic involving the "client", autonomy and performance, according to which "the individual takes responsibility in affirming his freedom of choice and decision-making autonomy with regard to a range of services." Self-care and self-medication do not just reflect an individual's quest for information and decision-making as a means of monitoring his own health and well-being; in addition, they often involve the purchase of products or therapeutic services. This concept of taking responsibility and exercising self-control is defended by some authors in the pharmaceutical industry. Moreover, the way in which individuals take charge of their health may conflict with the professional responsibilities of physicians and other health and social services professionals, creating tensions between lay knowledge and expert knowledge, and between autonomy and authority.

**Medicalization of Non-pathological Traits and Behaviour**

The difficulties in identifying and defining the concepts of "health" and "disease" as well as in delineating their respective boundaries is leading to constant arbitration between the various stakeholders. The social sciences are actively involved in this debate and are enriching it with their perspectives. They demonstrate in particular the significance of socioeconomic and environmental factors in the understanding of concepts, which are usually defined from the biomedical angle, given the "power of medical language" in society.

As a result, according to some authors, Western societies are witnessing the medicalization of events, emotions and things that are not necessarily part of the biomedical field. The phenomenon of medicalization can be defined as a "process by which nonmedical problems become defined and treated as medical problems, usually in terms of illnesses and disorders, decontextualizing human problems and turning attention from the social environment to the individual". The phenomenon has been studied since the 1950s, and is thus not a new concept, nor one about to disappear.

Several factors are involved in the process of medicalization, such as the promotional activities of the pharmaceutical industry, public health discourse focusing on prevention and risks, or the representation of health as an objective and a norm. Even the market for non-drug products has become increasingly involved in this quest for health, through the promotion of products such as omega-3, antioxidants, homeopathic products, vitamin supplements, etc.
Taking drugs does not imply that one is treating a disease. For example, memory loss, which is naturally associated with the aging process of the body, and extreme shyness are increasingly presented as problems that deserve to be corrected. As a result, extremely shy people can now receive prescriptions for beta-blockers that reduce physiological responses related to stress. Similarly, elderly people in the United States diagnosed with mild cognitive impairment (MCI) are receiving acetylcholinesterase inhibitors, medications originally developed for treatment of Alzheimer’s disease; according to some authors, mild cognitive impairment does constitute a pathology, yet controversial diagnostic criteria promote medicalization and medicamentation of the normal process of aging.

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59 See the literature review on self-medication in Christine THOER-FA BRE et al., "Le médicament dans les sciences sociales: une analyse documentaire d'un champ en construction", in LÉVY and GARNIER, op. cit., pp. 39-40.


66 FLOWER, op. cit., p. 183.


This medicalization of non-pathological personality traits and behaviours is part of a trend towards biological, genetic and medical reductionism or a deterministic vision of experience. In medicalizing life events, this phenomenon promotes the expanded non-“traditional” use of medications. Taken to the extreme, medicalization ignores the importance of the social, cultural and environmental context as well as the social constructs that define what constitutes normality, health and performance. It also tends to minimize the fact that the vast majority of the population is healthy and that disease usually only affects a minority of individuals. Opening up new diagnostic and therapeutic opportunities has the effect of adding to the number of people under medication, and paradoxically increases the impression that disease is strongly present, whereas in fact the population as a whole has better health overall than it did before.

In sum, the phenomenon of medicalization is complex and cannot be reduced to a “conspiracy” orchestrated by parties likely to benefit from it. However, it is clear that drugs, particularly with the advent of new molecules, play a role in medicalizing everyday life, since “[medication] bears the promise of helping attain a state of well-being, comfort, performance, efficiency and balance, without effort and at a lower cost.” It is also important to remember that a departure from normality does not imply the presence of a disease or the need for a biomedical intervention.

STAKEHOLDERS

Several stakeholders reflecting different and possibly contradictory interests are central to the way medications are characterized in society. Governments, health professionals, individual citizens, the pharmaceutical industry, associations and pressure groups as well as the media exert great influence.

Governments: Regulation and Public Welfare

Modern societies have given their governments a mandate to ensure safety and the common good, among other things. This has long been the case, but it became more marked with the establishment of the welfare state in the 19th century and the advent of broad-based social programmes (such as protection of the unemployed, people suffering from illness and workers) and economic programmes of an interventionist nature.

Given that physical and mental health is crucial to personal and collective development, the government maintains careful vigilance of different dimensions of health and welfare, including drugs. The different levels of government deploy different means to ensure the effectiveness, safety and appropriate use of medications: laws, policies, advisory and monitoring bodies, public awareness campaigns, community-based funding programmes, public health and R&D. Indeed, drugs are more accessible than many other therapies for the relief and cure of diseases, but that does not make them harmless. Medications can relieve and heal, but they can also have adverse drug reactions or be fatal, even when manufactured and tested in compliance with standards (safety).
Governments must also take into account the economic benefits and new knowledge generated by the activities of the pharmaceutical industry. Indeed, economic growth and a high level of knowledge are crucial for the development of modern society and, by extension, for public welfare. In fact, the jobs and tax revenues generated by the pharmaceutical industry are significant.

Thus, governments regulate drugs and ensure the provision of care and services to the population. Ultimately, once the interests of different stakeholders have been accommodated, governments give priority to the values of health and safety, and decide in favour of the common good.

Health Professionals: Care and Professional Practices

Drug therapies start off with a drug prescription, which is followed by distribution of the drug, consumption (or drug administration) and professional follow-up. Several professions are involved in drug therapies, three of them standing out in particular: nurses, pharmacists and physicians. The act of prescribing is restricted to physicians, but there are also legally specified circumstances whereby pharmacists, dentists, optometrists, midwives and certain nurses can prescribe medications.\(^78\) It is also worth noting that the Act to amend the Professional Code and other legislative provisions as regards the health sector (2002, c. 33)\(^79\) provides for the sharing of acts formerly restricted to certain professions. This new dynamic has led to some movement in the health community, including the fact that arbitrations concerning the delegation of these acts are on-going.

Nurses provide many types of care to beneficiaries of the health system – they administer and adjust prescribed medications or other substances subject to prescription, and they undertake clinical follow-up alongside physicians. As they acquire new academic qualifications, the clinical nurse (bachelor) and the registered nurse or nurse practitioner (graduate programs) also acquire new responsibilities.

In Quebec, pharmacists are experts on pharmacotherapeutics and drug interactions. When preparing drugs and delivering them to individuals submitting a prescription, pharmacists are in a position to give much advice on drug therapy: how best to take the medication, potential adverse drug reactions, possible interactions with other drugs or non-drug products (such as natural products and vitamin supplements), things to watch out for in terms of physical activity, or foods to recommend or avoid. Pharmacists receive remuneration based primarily on fees collected for each order made, which vary according to the drug plan of each client. In Quebec, this professional fee is included in the cost appearing on the invoice and given to the client, which makes it seem the drug itself costs more than it actually does.

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74 OTERO, op. cit., p. 72, Nick BOSTROM and Rebecca ROACHE say much the same thing but from a different perspective. These two authors are in favour of enhancing cognitive functions and thus of “demedicalizing” what does not belong to the field of pathology. ("Ethical Issues in Human Enhancement", in Jesper RYBERG et al. (eds), New Waves in Applied Ethics, New York, Palgrave MacMillan, 2007, p. 141.)
75 COLLIN (2007), op. cit., p. 100.
79 Frequently (but erroneously) referred to as “Bill 90”.
Physicians, meanwhile, are trained to diagnose, determine the medical treatment and prescribe drugs as they deem appropriate for each individual.

The role of doctors is often implicated in increased drug use. Indeed, they alone have the right to prescribe, which gives them decisive influence over the place of medication in Quebec, all the more since medication plays a central role in the exercise of the medical profession.80 Doctors may also consider, for clinical reasons, that the use of the best drugs and therapies available should take precedence over their cost,81 without always taking into account whether this reflects a real gain in terms of cost-effectiveness, or the fact that ultimately costs must be absorbed, either by users or by the community.

The phenomena of prescription and over-prescription82 are very complex however and cannot be summarized in simplistic terms. Accordingly, the action of prescribing, “from the physician’s point of view, may well be defended by a rationale departing from scientific and so-called objective standards.”83 For example, drug use may be integrated into clinical practice – often before changes in indications are authorized by Health Canada – providing a level of scientific evidence outside of clinical trials; or again, as noted previously, the lack of resources in the health system may lead to increased use of medication to provide individuals with relief. Other factors are also involved in the decision whether to prescribe a drug, especially for general practitioners. These factors include the demands – even the pressures – from patients for fast relief; a physician’s discomfort about refusing to prescribe, the desire to maintain the relationship with patients; the personal values of physicians; their perception of illness and treatment; free samples provided by pharmaceutical companies; diagnostic uncertainty, including confusion arising from the presence of symptoms associated with several diseases or to side effects of other drugs; lack of appropriate knowledge; waiting times for access to specialists such as psychiatrists and neurologists; clinical experience and habits of practice.84

The Individual: Citizen and Patient
Quebeckers have a dual relationship with medication: both as citizens and as users (potentially or actually) of the health and social services system.

As citizens, many Quebeckers are becoming better informed, given their access to multiple information sources.85 More recently, some have become critical of government and professional authorities, and affirm their autonomy in making decisions regarding their health status. In addition, citizens shape the values of the society in which they live, such as health and solidarity. Finally, as taxpayers, citizens are funding the health and social services system through consumption taxes (on goods and services) as well as income taxes.86

When people consult health professionals in order to benefit from their expertise, they become users with high expectations. They want high-quality services, and quickly. However, in recent years, access to the health and social services network has been more difficult than before, with the result that certain types of care have longer waiting times. In addition, patient expectations include a high demand for easily accessible drugs known to act quickly and effectively. Patient expectations also indicate a preference for the most recent drug, even if it more expensive, because it is perceived as better than those already offered for the same diagnosis,87 a perception which is not necessarily based on scientific evidence.
The “user” and “citizen” aspects of this relationship sometimes conflict with one another. The cost of the health and social services system is increasing under the pressure of higher drug use and the availability of more expensive new drugs. Citizens/taxpayers therefore have to pay more to maintain the same access to the network. However, when they need care, they face delays and costs in accessing their drugs (deductibles and insurance premiums) as well as some health care interventions. As a result, the “user”, the recipient of health care, wants more, whereas the “citizen”, the taxpayer, generally favours rationalized costs, even when he is aware of the issue of accessibility – at least in terms of his own situation or of those closest to him.

When this fact is combined with higher education and information levels, one notes that users/citizens are now able to exert pressure on physicians and other health professionals for care and services. They therefore hold part of the responsibility for their own health, but also for the provision of care and services to the population and, by extension, for the sustainability of the health and social services system. As a result, Quebeckers must strike a balance between individual needs and collective solidarity.

The Pharmaceutical Industry: R&D and Financial Interests

Pharmaceutical companies engage in activities that are central to innovations in medicine and in manufacturing methods. Pharmaceutical research is framed by a set of laws and regulations, and leads to the discovery of chemical molecules which provide relief to suffering individuals.

In Quebec, the pharmaceutical industry is important. Several companies maintain operations in Quebec and are mainly located in the Montreal and Quebec regions, including Merck Frosst, GSK (GlaxoSmithKline), Pfizer, Novartis and Bristol-Myers Squibb. Their economic contribution is significant. Some companies invest in research, development and the manufacture of patented drugs – innovative pharmaceutical companies – while others produce generic drugs. These companies offer high-quality jobs to highly skilled people, and they generate tax revenues – taxes on businesses and individuals – as well as taxes on the drugs they produce.

82 “Excessive prescription of drugs or therapeutic products received by a person whose needs are well below what he believes or what he is being advised to do. The phenomenon of over-prescription represents a health hazard, and is not necessarily solely attributable to a physician. It sometimes happens that the physician is not aware the patient is already consuming medication prescribed by another health professional. In this latter case, one can also speak of over-prescribing.” (OFFICE QUÉBÉCOIS DE LA LANGUE FRANÇAISE) (our translation).
83 COLLIN (2005), op. cit., p. 120 (our translation).
84 See the analysis and literature reviews in THOËR-FABRE et al., op. cit., pp. 39-40; COLLIN (2005), op. cit., pp. 119-121; ÉQUIPE DE RECHERCHE SUR LE MÉDICAMENT COMME OBJET SOCIAL (MÉOS), Le médicament comme objet social et culturel: recension des écrits et propositions sur les perspectives de travail à prioriser, Research report submitted to the Conseil de la santé et du bien-être, Québec, Conseil de la santé et du bien-être, 2005, pp. 12-13.
85 The issue of literacy, discussed above, has a central place in terms of the ability to be informed and to develop skills to read, process and develop a critical perspective about available information. Subgroups of the population of Quebec are unfortunately poorly equipped in this regard.
86 It should be emphasized that companies also fund the health and social services system.
87 MSSS (2007), op. cit., p. 15.
In addition to their R&D activities, pharmaceutical companies have also developed dynamic promotion and marketing services. This is not surprising, considering that pharmaceutical companies are profit-making ventures, i.e., companies seeking profits for their shareholders, and maximizing the value of their investments. The development of a new drug takes several years: a drug must provide a beneficial effect greater than that offered by competing drugs, or limited negative side effects and interactions with other drugs. For a drug investment to be profitable, different practices include the selling price of drugs, control of production costs, development of new uses for existing medications as well as active marketing. In this respect, the Ministry of Health and Social Services lists a few examples in the Drug Policy:

In Canada, the business practices of drug manufacturers take different forms such as advertising targeting the general public, promotion targeting health professionals, continuing medical education and distribution of samples [...].

Other activities such as holding post-market “Phase IV clinical studies” or studies aiming to analyse drug use for the purpose of improving market position are often disguised marketing strategies, since they aim to support long-term growth in demand for the product. Additional practices common to several industries include offers of volume discounts, gifts or participation in social activities. These practices are also used by drug wholesalers.92

As a result, according to data from the pharmaceutical industry, the sums invested in 2004 in sales and marketing services were almost equivalent to those invested in R&D, namely U.S.$27.7 billion90 and U.S.$29.6 billion.91 Quebec and American researchers have analysed publicly available data, comparing them to those obtained from another public source (CAM Marketing, a marketing research firm), and have come up with a different interpretation of the situation. Taking into account the cost of advertising, samples and gifts to health professionals, sponsored activities and activities of pharmaceutical representatives, these researchers reached a very different conclusion: in 2004, the promotional activities of pharmaceutical companies amounted to US$57.5 billion, almost double the amount allocated to the R&D.92

While it is true that the pharmaceutical industry is at the cutting edge of technology, is dynamic in terms of innovation, and provides tangible benefits through drugs, the industry’s role in medicalizing certain life events or behaviours is frequently noted. Given the dollar value for these companies, in terms of R&D costs for new molecules and of the lucrative market for drugs, the industry’s influence on society is worth emphasizing.

Foundations, Associations and Community Organizations: Support and Information

Professional orders, federations and groups play a well-established role in public debates. To these groups can now be added patient associations, foundations, support groups and community organizations.
These groups all play roles in the provision of information, support – sometimes care – and pressure. They aim to affirm their respective views and to sensitize policy makers and the general public. To this end, they often emphasize the educational part of their mission, namely explaining the nature of a given disease, symptoms, causes, risk factors, treatments (whether medical or not), evolution of the disease over time, means of prevention, current research, etc.

The objective of these groups is fundamentally positive: sharing knowledge about life situations and supporting suffering individuals as well as those closest to them. However, some points should be noted. First, as with any group dedicated to a cause, there is a risk that a given group will be subject to information bias and will overstate its case. In addition, taking together the activities of all these orders, associations and groups, one is left with a certain impression of inevitability: it would seem inevitable that the individual will be stricken at some point by one disease or the other. In this sense, the promotion and the amount of information conveyed are part of the medicalization process described above. Finally, the issue of funding is raised from time to time. Funding comes from three main sources: the State, personal donations and the private sector. When these groups are sponsored or supported logistically by interest groups or pharmaceutical companies, then the independence of their public statements and activities may suffer, given the appearance of conflicts of interest or lack of objectivity.

Some concerns can be raised about the information these groups transmit and the influence they exert on other citizens; nonetheless, these groups reflect a form of autonomy, the involvement of citizens in society and the desire of citizens to take responsibility. These groups are transforming social relations and civil society; through their organization and networks, they are communicating their messages and changing the balance of power with governments and, on occasion, with professional groups. Moreover, given the effectiveness of their actions, they are establishing an unavoidable public presence.

The Media: Information and Critical Space

The media are an important vector of information and educational tool. They include scientific publications destined for scientists, knowledgeable readers (those with a scientific background) or the general public, and there are many different distribution channels.

Scientific Journals

Scientific journals are the main source of evidence and information for health professionals. In several cases, the manuscripts that publishers receive are submitted to a reading committee made up of peers who read, reject or accept them, in which case the committee critiques the manuscript and require changes before
publication. The journals adhering to this approach are considered more rigorous and prestigious than those that do not. As a result, they are targeted by both authors who publish and by scientists who seek data. It should be noted that in addition to peer-reviewed articles, some journals have a separate section of non-peer-reviewed content, which is often of a more commercial nature.

Given the large number of scientific studies, including clinical drug trials conducted by researchers wishing to publish their results, scientific journals must make choices. The decision to publish or not to publish scientific studies depends on various factors, including the journal's own objective of profitability and the likelihood that studies with negative outcomes will have less impact on the readership.

Scientific journals are published in a commercial context. When journals represent a group of professionals, as is the case with the *Canadian Medical Association Journal* (CMAJ), the editors also promote their professional interests. Moreover, like any profit-making enterprise, they seek profitability through a large readership, the journal's scientific reputation and advertising revenue. With regard specifically to this last point, it is obvious that advertising is a source of income for all media organizations. However, pharmaceutical advertising is often subject to criticism because these companies are the major sponsors of published studies. As a result, there is keen debate about the influence pharmaceutical companies exert on publishing houses and editorial decisions.

Secondly, studies reporting negative outcomes are less often published than those showing positive outcomes. This publication bias is well known. For example, a recent study by the *New England Journal of Medicine* compared the results of all clinical trials on some antidepressant drugs. The results published in scientific journals were positive in 94% of cases, while analysis of data from the FDA (drawn from all clinical trials, whether published or not) showed a positive rate of 51% for the same types of tests. Consequently, this study showed that one clinical trial in two reflected greater effectiveness for antidepressants studied, whereas published results reported a significantly higher rate of effectiveness. According to another meta-analysis of four SSRI antidepressants, these drugs were statistically just slightly better than the placebo effect, which means that in clinical terms they had little real impact.

The virtual absence of studies showing negative outcomes gives rise to two critical remarks. First, it is conceivable that the judgment of methods used in these studies is more severe when negative outcomes are observed. When studying a medication, the researcher is by default looking for a positive therapeutic effect and minimal side effects; as a result, a double demonstration has to be made, both of effectiveness and harmlessness (safety). However, it is hard to demonstrate beyond all doubt the non-existence of an effect. Second, it is important to recognize that there is a price to pay for not publishing studies in which outcomes have been shown to be negative. Indeed, these studies contain scientific information which is relevant to clinicians and policy makers, and their publication would avoid wasting time and money by allowing other researchers to adjust their research hypotheses or methodology accordingly.
Mass Media

Mass media, whether print or electronic, reach a vast audience and are therefore unique vectors for the transmission of knowledge. However, in general, few mass media organizations assign journalists, with a scientific specialty or not, to cover scientific stories on an ongoing basis.\(^98\)

Electronic media (television and radio) typically use two main formats – news bulletins and current affairs – when broadcasting information on scientific discoveries, new drugs or medical practices. News bulletins usually provide a brief overview of information, with a little background, and often pick up content from wire agencies or company press releases. Current affairs programmes develop topics in more depth and may incorporate substantive interviews with researchers and practitioners.

Print media include newspapers, popular magazines, free newspapers, and to a lesser extent, books. Topics are treated in much the same way as news bulletins: content is picked up from wire agencies, presented without real context, while few substantive interviews are offered to readers. A particular print media segment is made up of "grey publications", i.e., "a wide range of small publications not found in any directory because they come out on such an irregular basis, and have limited resources and a targeted readership."\(^{99}\)

This type of media is above all a vehicle for advertising, which nevertheless transmits information of a scientific nature that may be useful.\(^{100}\)


97 The placebo effect is the improvement of health status – whether measurable, observable or perceived, or subjective – which cannot be attributed to treatment or taking medication. It may be present in clinical trials, following a consultation with a health and social services professional during (biomedical or psychological) treatment, or when substances are taken (placebo, drugs, natural products and homeopathic products).

98 “None of the major dailies has a specialized science journalist covering science news. The same is true for major TV channels and radio stations. [...] We can say that there are virtually no Quebec science journalists covering science news on a daily basis. Or, to represent this in graphic terms, there is no star science journalist reporting science news in the pages of major newspapers, on radio and even on major news websites such as Cyberpresse.” (Personal communication of 29 August 2008 from Jean-Marc FLEURY. Mr. Fleury holds the Bell Globemedia chair in scientific journalism (Université Laval), has served as executive director of the World Federation of Science Journalists since 2004 and has served as editor-in-chief of the magazine *Québec Science*). See also CONSEIL DE LA SCIENCE ET DE LA TECHNOLOGIE (CST), *Rapport de conjoncture 2004 – La culture scientifique et technique : une interface entre les sciences, la technologie et la société*, Québec, CST, 2004, pp. 48-50; CONSEIL DE LA SCIENCE ET DE LA TECHNOLOGIE (CST), *La culture scientifique et technique au Québec : bilan*, Québec, CST, 2002, pp. 115-123.


The influence of the media and advertising on consumers and on their perception of drugs is not a recent phenomenon. The Quebec government has also taken note of this influence: “The influence of the media on patient demand for new drugs should not be ignored, either, given that new drugs are sometimes portrayed as miraculous in the press.” However, information relayed by mass media is not always presented in a critical and analytical way. Indeed, press coverage often emphasizes hoped-for benefits rather than potential risks, while details related to the methodology of clinical trials are often left out. The tone is generally enthusiastic, and uncritical and ethical issues are seldom raised.

In addition to playing an information role, it is important to emphasize that the media are also part of an industry that seeks profitability. In terms of this objective, companies promoting new technologies or new products such as pharmaceutical or biomedical companies provide significant advertising revenues. For example, in the United States, investment in direct-to-consumer advertising (DTCA) of prescription drugs rose eleven-fold over a decade, reaching U.S.$4.2 billion in 2005. The situation in Canada is different, since drug advertising is subject to regulatory limits.

Internet

The Internet is a particular case. The advent of the Internet has brought profound changes in the availability and circulation of information. A spectacular and abundant volume of information is flowing from ever-increasing sources. The development of the Internet entails advantages such as time savings, a decreased need to travel in order to access information, the ability to choose when one wants to read, rapid cross-checking with other information, and increased knowledge. Overall, the Internet has democratized access to information: what was once accessible only in public or school libraries, or held in distant countries, can now be accessed quickly in the home and at work. Moreover, the availability to access information at the time and place of one's choice offers benefits to people with stigmatizing diseases.

However, the Internet also raises certain questions. Is the information found on the Internet valid? Is it valid in all situations? How is one to check? The answer to these questions is that we cannot be sure of the information gathered on the Internet. Blogs and “popular” sites exist where information flows freely without necessarily being true. Similarly, pseudo-scientific sites and electronic journals are alluring; they are written in scientific or layman's language (depending on the public targeted), they provide facts and figures to buttress their claims, and they have the same look and feel as sites whose data are accurate and verifiable. The Internet calls for vigilance, both at the individual and collective levels.
THE NORMATIVE FRAMEWORK FOR MEDICATION

At the national and provincial levels, many normative measures have been implemented to reduce the inherent dangers of drugs and to properly regulate the activities of multiple stakeholders. These norms cover the drug licensing process, drug marketing, manufacturing, distribution, prescription and advertising as well as business practices.

In Canada, the federal and provincial governments legislate and monitor all drug-related matters. Health Canada is the department responsible for drug licensing at the national level, while the Ministry of Health and Social Services (MSSS) determines which drugs will be entered on the list of reimbursable medications in Quebec.

In the following sub-section, the Commission summarizes the laws, ethical codes and guidelines which together makeup the normative portrait of drug manufacture, distribution, prescription and monitoring in Quebec.

Legal Framework

Federal Environment

Federal Law

The Food and Drugs Act (R.S., 1985, chapter F-27) regulates food, drugs, cosmetics and therapeutic devices. In this Act, the word “drug” is used in the sense of “medication” and is defined primarily as including “any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals (b) restoring, correcting or modifying organic functions in human beings or animals.”

This Act guides therapeutic and non-therapeutic drug licensing and monitoring. It also explicitly prohibits any form of advertising to the public of food, drugs, cosmetics or devices for prevention, treatment or cure of diseases, disorders or abnormal physical states.

The Directorate Health Products and Food Branch (HPFB) of Health Canada is the federal authority regulating all pharmaceutical products destined for Canadian citizens.

101 FROSCH et al., op. cit., pp. 6-13 and THOER-FABRE et al, op. cit., pp. 36-38, note several studies on this subject.
102 MSSS (2007), op. cit., p. 44 (our translation).
105 RACINE et al. (2006), op. cit., pp. 131 and 133.
106 Ibid., p. 136.
107 KIRCH et al., op. cit.
108 The regulation of drug advertising is discussed in chapter 1, section The Normative Framework for Medication.
110 "Personal Web site maintained by one or more bloggers to speak freely and with relative frequency, in the form of dated notes or articles, whether of an informative or intimate nature, like a blogbook, signed and filed by anti-chronological order (reverse order), sometimes incorporating hyperlinks, images or sound, and may be the subject of reactions posted by readers" (OFFICE QUÉBÉCOIS DE LA LANGUE FRANÇAISE) (our translation).
111 R.S., 1985, chapter F-27, art. 2.
112 Ibid., part 1, art. 3. Bill C-51, An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts, was tabled in the House of Commons on 8 April 2008. Several amendments to current law are proposed, for example changing the name of the act (Act respecting foods, therapeutic products and cosmetics), the term “therapeutic product” which includes non-prescription products (including natural products) and the prohibition of advertising for therapeutic products. The bill did not become law before Parliament was dissolved on 7 September 2008.
Federal Regulations

The Food and Drug Regulations (C.R.C., chapter 870) establishes the procedures for implementing the Food and Drugs Act. Specifically, part C of the Regulation sets out requirements for the marketing of drugs, including:

- the conditions of approval and assignment of a Drug Identification Number (DIN), whether for a drug already marketed in other countries or for a new drug;¹³³

- detailed reports of the tests made to establish adverse reactions encountered during clinical trials or sales in pharmacies;

- manufacturing conditions;¹³⁴

- drugs destined for clinical trials involving human subjects.¹³⁵

Direct Advertising in More Detail

Under the Food and Drugs Regulations, “where a person advertises to the general public a Schedule F Drug [prescription drug sold in Canada], the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.”¹¹⁶

In terms of drugs and drug-related advertising, three categories of advertising exist (Direct-to-Consumer Advertising – DTCA).¹¹⁷ Two of these categories are legal in Canada.

The first type of advertising consists in outlining a particular health condition and recommending that people consult their doctor, without naming any treatment. This type of advertising is allowed in Canada. For example, a recent television advertisement on erectile dysfunction featured a former star hockey player. The second type of advertising consists in introducing a drug without explaining why it is prescribed or referring to the drug’s effectiveness. With few exceptions, this type of advertising is found in Canada. For example, a Quebec television advertisement celebrated the joy of living, and ended with the image representing medication for erectile dysfunction.

The third type of advertising is authorized in the United States (since 1982, revised in 1997) and in New Zealand. In these countries, this form of advertising is allowed to provide the drug name, the health problems it seeks to address and a statement emphasizing its effectiveness. This category of advertising is the one usually referred to by the term “DTCA”.

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³³⁵
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Provincial Environment

Without drawing up an exhaustive list, the Commission focused in particular on four provincial acts and two government bodies that regulate drug uses, practices and monitoring.

Provincial Laws

- The Act respecting health services and social services (R.S.Q., chapter S-4.2) aims to maintain and improve the physical, mental and social capacity of persons. When medicines are required for this purpose, no health and social services institutions may furnish medicines other than those in respect of which a notice of compliance has been issued by the federal government for approved indications.\textsuperscript{118}

- The Act respecting Prescription drug insurance (R.S.Q., chapter A-29.01), adopted in 1996, provides the entire population of Quebec with reasonable and fair access to the medication required by their state of health. This plan shares costs between the State and citizens through an annual fee and, for participants in the basic prescription drug insurance plan, through a deductible for each purchase of a drug on the list of approved drugs. Any person without private group insurance coverage necessarily receives coverage through this law. As provided by law, a policy respecting medications was enacted in 2007.\textsuperscript{119} The law also provides for the list of medications covered by the basic plan\textsuperscript{120} as well as the Conseil du médicament (created in 2003), a council making recommendations to the Minister of Health and Social Services.\textsuperscript{121}

Quebec Laws Regulating the Professions

- The Medical Act (R.S.Q., chapter M-9) regulates the medical profession which consists in “assessing and diagnosing any deficiency in the health of human beings and in preventing and treating illness to maintain or restore health.”\textsuperscript{122} In addition, it establishes the professional order of physicians and professional activities reserved to physicians, including “prescribing medications and other substances.”\textsuperscript{123}

- The Pharmacy Act (R.S.Q., chapter P-10) governs the “practice of pharmacy [which] consists in determining and ensuring the proper use of medications, particularly to identify and prevent pharmacotherapeutic problems, and in preparing, storing and delivering medications in order to maintain or restore health.”\textsuperscript{124} In addition, the Act establishes the professional order of pharmacists and activities reserved to them, including “prescribing and personally dispensing emergency oral contraception medication, provided a training certificate has been issued to the pharmacist by the Order.”\textsuperscript{125} Finally, as in the case of the Medical Act, the Minister of Justice is responsible for enforcement of the law.

\textsuperscript{113} C.R.C., chapter 870, part C, division 8.
\textsuperscript{114} Ibid., division 2.
\textsuperscript{115} Ibid., division 5.
\textsuperscript{116} Ibid., part C, division 1, C.01.044. This gives the general idea of the article; the act provides other details or exceptions which are not discussed here.
\textsuperscript{118} R.S.Q., chapter S-4.2, art. 79 and 116.
\textsuperscript{119} R.S.Q., chapter A-29.01, chapter IV, division I “Policy respecting medications”.
\textsuperscript{120} Ibid., division III “List of medications”.
\textsuperscript{121} Ibid., art. 53 et seq.
\textsuperscript{122} R.S.Q., chapter M-9, art. 31.
\textsuperscript{123} Ibid.
\textsuperscript{124} R.S.Q., chapter P-10, art. 17.
\textsuperscript{125} Ibid., art. 17.6.
Government Agencies

Two agencies under the Minister of Health and Social Services, i.e. the Conseil du médicament and the Régie de l’assurance maladie, have specific mandates to fulfill with respect to drugs in Quebec.

**Conseil du médicament du Québec**

Established pursuant to Article 53 of the Act respecting Prescription drug insurance, the Conseil du médicament du Québec replaces the Conseil consultatif de pharmacologie, the Comité de revue de l’utilisation des médicaments and the Réseau de revue de l’Utilisation des médicaments. Its mandate is to assist the Minister in updating the list of medications, in promoting optimal use of medications and in making recommendations on the establishment and evolution of prices.

The assessment of drugs for inclusion on the list is based on five criteria. The first is to assess the therapeutic value of a drug, taking the evidence base into account. If a drug’s therapeutic value is recognized, four additional criteria are considered: the fairness of price; the drug’s cost-effectiveness; the consequences of including the drug on the list for the health of the population and other components of the health system; the advisability of entering the drug on the list with respect to the objectives of the basic plan.

The first criterion is fundamental for the assessment process, the following three criteria are related to the economic and financial dimensions of medicines, while the last criterion makes it possible to “assess the reasonableness and fairness of listing the drug, taking into account the societal aspect.”

The mandates and powers conferred upon the Conseil du médicament, therefore, make it central to the licensing and accessibility of drugs in Quebec.

**Régie de l’assurance maladie du Québec**

The Régie de l’assurance maladie du Québec (RAMQ) manages the basic prescription drug insurance plan (RGAM) namely coverage for the elderly, people receiving employment assistance and those without private insurance coverage.

**Codes of Ethics**

The Professional Code (R.S.Q., chapter C-26) requires professionals to have codes of ethics. The primary objective of a code of ethics is to protect the public when it calls on the services of these professionals. To this end, codes of ethics set out the rules of conduct and articulate responsibilities, obligations and duties considered essential for the exercise of a profession. Since they have the force of law, codes provide for sanctions in cases where are breached. They differ, however, from other aspects of the legal framework because instead of addressing the general population, they address registered members of a professional order.

In Quebec, two professions are directly involved in the initiation and monitoring of drug therapies, namely physicians and pharmacists. Code of ethics of physicians (R.S.Q., chapter M-9, r.4.1) govern the professional practice of physicians, whether general practitioners or specialists. Pharmacists are subject to the Code of ethics of pharmacists (R.S.Q., chapter P-10, r.5.1). The statement of duties and obligations of physicians and pharmacists refers first of all to the health and well-being of individuals and to public health.
Psychologists constitute a non-medical profession closely associated with the treatment of mental health problems. The professional activities of psychologists are governed by the Code of ethics for psychologists (R.S.Q., chapter C-26, r.148.1.001). Psychologists are not authorized to prescribe and distribute drugs, but they are experts assessing and providing support to people with mental health problems, whether the latter take drugs or not. Through their practice, psychologists have clinical knowledge of several drugs.

Other Forms of Supervision

In addition to laws and regulations, a wide range of guides, guidelines, lines of conduct and administrative norms set additional standards for drugs.

Governments and national and international organizations promulgate guidelines. These documents usually consist of statements of values and principles. Professional associations, for their part, publish guidelines and policies concerning the professional activities of their members. These forms of supervision are used to guide and inform the many stakeholders involved: researchers, clinicians, ethics committees, research subjects, patients’ associations, etc.

International Organizations

At the international level, the normative framework in place is broad, and covers the dimensions of practice as well as research. For example, the World Health Organization (WHO) publishes and regularly updates guidelines on the use of drugs such as antiretroviral drugs or cultivation of plants used in anti-malaria drugs. In terms of research, the Declaration of Helsinki is a statement of ethical principles for medical research involving human subjects. Adopted in 1972 by the World Medical Association and amended six times, it was revised on 22 October 2008. The 2008 revision amended some of the Declaration’s articles relating to publication of the results of clinical trials, both positive and negative, as well as procedures for clinical trials.131

National Organizations (excluding Canada)

Two organizations stand out in particular in terms of guidelines, and influenced many professional associations. In 2005, the National Institute for Health and Clinical Excellence (NICE),132 in the United Kingdom, published Clinical Guideline 28 – Depression in children and young people: identification and management in primary, community and secondary care, following this up in 2008 with the NICE clinical guideline 72 – Attention deficit hyperactivity disorder. In the United States, the American Psychiatric Association is a leading association, publishing and posting online guidelines on several mental disorders.133
Governments of Canada and Quebec

Nationally, the two levels of government also issue guidelines. Accordingly, the website of Health Canada features over fifteen themes, each with its own guidelines, including drugs and procedures for reporting adverse effects. In Quebec, the Ministry of Health and Social Services enacted its Drug Policy in 2007.

Canadian and Quebec Authorities

Several orders and associations, including the Canadian Medical Association, publish good practice guides and guidelines relating to diseases, medications or professional practices. It should be noted that according to codes of ethics, members of the professional orders concerned may be required to comply with these guidelines; this is the case for psychologists, although for physicians guidelines are not binding, but reflect established rules of the art. For example, in 2001, the Collège des médecins du Québec issued guidelines for ADHD, in collaboration with the Collège des psychologues du Québec, and these guidelines were updated in 2006. In 2006, a conference held in Montreal on the diagnosis and treatment of dementia (Third Consensus Conference on the Diagnosis and Treatment of Dementia) led to recommendations that are still under discussion. A recent study examined recommendations concerning moderate cognitive impairment and cognitive decline without dementia. The study compared those recommendations with evidence on pharmacological and non-pharmacological treatments, which strengthened or moderated the initial recommendations. Three other recent articles contain some recommendations illustrated by case histories, which is a practical form of knowledge transfer.

Finally, each health institution in the province has its own norms and organizational regulations. Each institution must establish a council of physicians, dentists and pharmacists (CMDP) if at least five physicians, dentists and pharmacists practice in that institution. The CMDP is responsible for controlling and assessing the quality and pertinence of medical, dental and pharmaceutical acts performed in the institution, and for making recommendations on the rules governing medical and dental care and the rules governing use of medicines applicable in the institution and developed by the head of each clinical department.

The Challenges of the Normative Framework

This brief presentation of the normative framework shows that the regulatory process surrounding the approval, use and monitoring of drugs, aimed at ensuring drug effectiveness and safety is, in general, precisely defined. The theoretical framework covers the many facets of medication; however, the practical application of laws, regulations and standards raises certain concerns which the Commission wishes to examine more closely.
Safety and the Internet

To ensure drug effectiveness and safety (harmlessness), governments have established a regulatory framework. Thus, according to one researcher:

In several respects and in different contexts, there are limits to the effectiveness of this system [of regulation currently in place], but most of the time the system has provided a framework which is legitimately recognized and supported by industry as well as by the medical profession and the population, in addressing the risks of manipulation, concealment, abuse and exploitation that an unregulated drug market could cause.¹⁴⁰

Yet, the legal framework currently in place does not effectively address new challenges posed by the rise of the Internet and of cyber-pharmacies, which circumvent the national and international regulatory frameworks. The scientific validity of information posted on the Internet is in itself a problem. Buying medications under unknown conditions from anonymous individuals is also a major cause for concern. At present, regulatory and monitoring methods, i.e. laws and national health policies, are unable to respond adequately to the shift brought about by the Internet.¹⁴¹ The difficulty presented by the Internet is even greater, considering that sites can be disabled in one click without trace. The following example illustrates the complexity of this new situation: “In terms of enforcing a law, one has only to think of the problems arising when the retail website operates in Spain, the Internet server is hosted in the United Kingdom, drugs are sent to Mexico, funds transit through Switzerland and the real customer is in Australia.”¹⁴²

Ensuring that drugs and their uses remain safe is a huge challenge, in a context where information about the origin of products, their safety and the responsibility of parties involved are mostly unknown and cannot be traced.
Licensing

The regulatory framework surrounding drug licensing also raises questions.

Scientific analyses undertaken by federal laboratories or independent bodies help cross-check documentation provided by pharmaceutical companies on drug efficacy and safety; moreover, these analyses eliminate the risk of conflict of interest or of apparent conflict of interest. However, given the lack of resources needed for this purpose, Health Canada is unable to reproduce clinical trials. As a result, it uses skill in verifying scientific data provided by pharmaceutical companies but is unable to confirm with complete accuracy the conditions in which clinical trials are undertaken.

The need for independent reviews is even more evident in the case of multicentre international clinical trials. This type of clinical trial recruits large numbers of research subjects with different socioeconomic and genetic profiles. However, it is not easy to check the validity of data from multiple countries, especially for countries where local expertise may be limited, laws very different, or ethical frameworks almost nonexistent.

Direct-to-Consumer Advertising (DTCA) of Prescription Drugs

Three types of direct-to-consumer advertising (DTCA) of prescription drugs were described earlier in this section, the third of which provides the drug’s name, identifies health problems the drug seeks to address and insists on its effectiveness. Only the United States and New Zealand allow this form of advertising. However, even though this type of advertising is banned in Canada, there are ways to get around the ban, such as consulting the Internet, watching American television, reading American newspapers and periodicals intended for international audiences and distributed in Canada.

Many studies have been conducted on the impacts of this type of advertising, which is highly controversial since its content is managed by the marketing departments of pharmaceutical companies. According to these companies, any type of direct advertising makes it possible to reach people directly and to better inform them as a consequence. However, this interpretation respecting enhanced choice and transmission of information is contested.
Thus, according to U.S. researchers, Americans can watch the equivalent of 16 hours of drug advertisements per year. Based on these data, the researchers conducted a study over a four-week period of advertising on the four main U.S. television networks during prime time. Their results show that advertising presented facts and rational arguments, but 95% of them used emotional arguments, 58% of them stressed the loss of control over some aspects of life and 85% the recovery of this control through use of the drug mentioned, while 78% stressed social approval and 56% the ability to engage in recreational and sports activities. Only 26% of advertisements mentioned risk factors or addressed the causes leading to the condition while 25% mentioned its prevalence in the population. The authors concluded that the educational value of these advertisements is limited. Other researchers undertook a literature review on direct-to-consumer advertising and came to the same conclusion, namely that information is not presented in a neutral manner to consumers.

A close reading of scientific literature leads to four observations about DTCA: the information presented is incomplete; the emotional content targets a poorly informed or vulnerable population; the ability to reach people in prime time promotes the use of medication without critical thinking; wide publicity given to medications promotes chronic use and targets a huge market (antihypertensives, erectile dysfunction, antidepressants, etc.), which in turn boosts the sales revenue of pharmaceutical companies.

It should be mentioned that social, financial and safety impacts arising from direct advertising of prescription drugs are addressed in the current legislative framework. However, despite a willingness to act and to protect Canadian citizens, the legislative framework cannot be applied and respected in its entirety.

143 For more details on clinical trials, see Chapter 2 section Evidence: a Tool for Assessing the "Risk/Benefit" Ratio.
146 FROSCH et al., op. cit., pp. 6-13.
Mental illness and neurological disorders involve dysfunctions of the central nervous system (CNS), usually the brain. Depression, anxiety disorders, Parkinson’s disease, schizophrenia and bipolar disorder are examples. For controlling symptoms, relieving pain or healing, physicians use psychotropic drugs.

Contextual Factors

These disorders are disabling and stigmatizing pathologies that strike regardless of age, gender, wealth or intelligence. In 2001, the World Health Organization (WHO) estimated that 450 million people suffered from mental or neurological disorders, including 50 million epileptics and 24 million schizophrenics. National and international health organizations have been focusing on this subject for several decades. They are thus able to trace historical patterns and provide more accurate forecasts. Their analysis has made it possible to distinguish between two mental health disorders at the present time, in terms both of diagnosis and of recourse to medication: depression and, particularly in North America, attention deficit disorder with or without hyperactivity (ADHD).
Interpreting Statistics Relating to Drug Use

Data on drug use should be interpreted with caution. Indeed, there is little information accompanying data, which means that is not always possible to form an accurate overall view of the situation. Here are some examples of sources of confusion.

- Each drug has a generic name (for example, the generic name of Ritalin® is methylphenidate). There is no confusion when these names are used; however, it is common for drugs to be grouped into classes and subclasses. And yet, there are two main classification systems (see below Section Classes and Classifications). Although these systems are quite similar, they are different in some respects, and it quite frequently happens that the classification system used in a publication is not specified. In addition, some authors include drugs in classes of their own invention. Accordingly, the term “psychotropic” may appear in three different publications without referring to the same drugs, so it is risky to compare the data being presented.

- Analysis of prescription-related data is not straightforward. Thus, it is not always clear whether data refer to new prescriptions, or to a combination of new prescriptions and renewals. In addition, it is important to distinguish between the sources of information used: prescriptions made by doctors, claims submitted by pharmacists to drug insurance plans and users themselves. There are more prescriptions than claims, and more claims than drugs actually used. Finally, it is not always clear whether analysis refers to the number of prescriptions prescribed or to the number of individuals who have received a prescription; as a result, the statement “10,000 Quebeckers who take ABC drug during year D” does not mean the same as “10,000 prescriptions for ABC are identified in Quebec during the same year.”

- The presentation of consumption data within a socio-economic or demographic group may also be confusing. For example, one is giving incomplete information by saying that the elderly have doubled their consumption of tranquilizers without providing numbers (from 1% to 2%, or from 10% to 20%) or without mentioning the population dynamics of this group (if the number of elderly people has almost doubled during the study period, increasing real per capita consumption is lower).

- In one study, the estimated consumption of drugs may refer to a typical day or to a longer period. The interpretation will have to take account of the observation period. If a study notes that a given percentage of the population has a prescription of methylphenidate as of 3 June 2007, then that does not mean that the same percentage of the population took methylphenidate throughout 2007.

- Finally, the “silo” structure used in accounting for health care expenditures does not adequately reflect the overall picture. For example, the cost of drugs provided during hospital stays has decreased, particularly through the increased use of day surgery and the implementation of ambulatory care in Quebec in 1997. As a result, the costs associated with hospitals are declining while those related to private and public drug insurance plans are increasing.
Psychotropic Drugs and Expanded Uses: an Ethical Perspective

International Contextual Elements

The recent marked increase in consultations for depression is significant. Based on WHO forecasts, depression seems destined to continue increasing, and is expected to become the second leading cause of morbidity in 2020. Globally, since the late 1980s, the prevalence of depression has increased from 100 people per million to 50,000-100,000 people per million, reaching 300 to 600 million people. This increase coincides with the discovery of new-generation antidepressants, selective serotonin reuptake inhibitors (such as Prozac®), which cause much more limited adverse drug reactions than other antidepressants. Other factors may also explain this increase, at least partially, such as early detection of depressive symptoms, weaker social taboos and the desire or even pressure to reduce hardship associated with certain painful life events.

Diagnoses of depression generally result in a medical prescription for an antidepressant, and approximately 50% of diagnoses of ADHD among minors in the United States result in a prescription for psychostimulants. Without generalizing this result or positing a clear causal link between diagnosis and prescription, it is clear that the segment of sales of psychotropic drugs is important. At the international level, sales of drugs acting on the central nervous system reached U.S.$55.5 billion dollars in 2005 and this market was dominated by the class of antidepressants, which accounted for more than 30% of sales. Worldwide sales of medications to treat attention deficit with hyperactivity disorder reached U.S.$2.4 billion in 2003, over 90% of which was from sales in the United States.

National Contextual Elements

The Canadian situation reflects the global trend. For example, between 1995 and 2003, medical consultations for depression in Canada increased by 60% and the diagnosis of depression has the highest growth of all disorders outside of public facilities. In 2002, Canadians ranked among the highest users of psychotropic drugs in the world. The situation in Quebec is much the same. During 2000, 19.4% of Quebeckers aged over 65 – almost one in five – received at least one prescription for benzodiazepines, an anxiolytic. Among minors, prescriptions for psychostimulants (such as Ritalin®) grew by over 200% between 1993 and 1999 (from 68,000 to 215,000). Moreover, in 2006, a survey of youth centres noted that nearly two out of five young people took at least one psychotropic drug at the time of the survey, regardless of the severity of their disorders.

The use of psychotropic drugs entails costs. As a result, the cost of drugs acting on the central nervous system for the population covered by the public drug insurance plan – about half the population – stood at $620.8 million in 2006, representing 19.6% of the gross cost of drugs borne by the Régie de l’assurance maladie du Québec (RAMQ). Furthermore, as is the case with other classes of drugs, new psychotropic molecules are generally more expensive than previous ones. For example, the monthly cost in Quebec of a generic version of methylphenidate (a stimulant prescribed to treat ADHD) taken three times per day is $16.12, whereas taking Concerta® a methylphenidate capsule taken once per day, costs $71.06.
Organization of the Health Network and Mental Health Disorders

The increase in diagnoses and in medical follow-up related to mental illness is placing increasing demands on medical and social services. And yet, mental health services are also affected by the shortage of human resources in the health system. In 2001, the Conseil médical du Québec published a position statement on the state of mental illness in Quebec.\(^{(166)}\) In this statement, the Conseil stressed the need for front-line and second-line human resources.\(^{(167)}\) At the federal level, the Kirby report on mental health care services was published in 2006. It emphasizes the fact that recommendations issued in the early 2000s did not address this shortage.\(^{(168)}\) The report stresses the need to increase the numbers of human resources, while acknowledging that it will take time to bring about this increase. The report also devotes particular attention to general practitioners who provide the bulk of mental health care services. Indeed, the report encourages forms of collaboration and recommends developing financial incentives for first-line treatment, depending on the services given to the patient and the time devoted to these tasks.

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151 Ibid., p. 30.
153 There is great variability in prevalence between developed and developing countries. According to WHO, approximately 10 % of the world population used primary health care for depressive disorders, prevalence varying from 4.0% (Shanghai, China) to 29.5 % (Santiago, Chile) (2001a, op. cit., pp. 23-24).
157 Ibid.
159 IMS HEALTH (2004), op. cit.
162 COLLÈGE DES MÉDECINS DU QUÉBEC and ORDRE DES PSYCHOLOGUES DU QUÉBEC (2001), op. cit., p. 4.
163 COMITÉ DE TRAVAIL SUR LA SANTÉ MENTALE DES JEUNES SUIVIS PAR LES CENTRES JEUNESSE, *Proposition d’orientations relatives aux services de réadaptation pour les jeunes présentant, autre les problèmes de comportement ou un besoin de protection, des troubles mentaux et qui sont hébergés dans les ressources des centres jeunesse du Québec, 2007*, pp. 16 and 50.
164 RÉGIE DE L’ASSURANCE MALADIE DU QUÉBEC, Tableau AM.07 – Nombre de participants et d’ordonnances, nombre d’ordonnances par participant, coût brut des ordonnances et par participant, coût Régie des ordonnances et par participant selon la classe de médicaments et la catégorie de personnes assurées – 2006, 2007a, Québec.
165 The cost of 20 mg (the daily total) of the generic brand of methylphenidate or of 18 mg of Concerta®, as of 19 March 2008, for a client of the Quebec drug insurance plan. The cost may vary based on the dosage prescribed and pharmacists’ fees, which vary depending on the private drug insurance plan involved.
166 CONSEIL MÉDICAL DU QUÉBEC, *Avis sur les maladies mentales: un éclairage contemporain*, Québec, CMQ, 2001b, pp. 61 et seq.
167 Ibid., pp. 62-63 and 76.
168 KIRBY and STANDING SENATE COMMITTEE ON SOCIAL AFFAIRS, *Science and Technology*, op. cit., pp. 127-130
Medicalization and medication are not the sole means of coping with mental illness; psychotherapy and resources of the social and community network are also valuable tools. However, these alternatives are caught in a double bind: they must contend with a shortage of human and financial resources; also, the related consulting fees are not always covered by Quebec’s public health insurance plan. For those people who do not have private insurance coverage, the fact of having to pay for such services may significantly hinder accessibility.

**Applications of Psychotropic Drugs**

Psychotropic drugs affect the brain’s neurochemistry and electrical communications. They are used to treat pain, for cognitive dysfunctions (affecting, among others, memory, attention, alertness, concentration and problem solving), mood disorders (such as depression and bipolar disorder), anxiety disorders (such as anxiety and phobias), behavioural problems, neurological disorders (including ADHD) and personality disorders (such as borderline personality disorder and obsessive-compulsive disorder). Psychotropics act mainly on the concentration level of neurotransmitters*, modifying their action or duration of action.\(^{169}\)

**Classes and Classifications**

There are two major drug classifications systems: the Anatomical Therapeutic Chemical classification system (ATC, as recommended by WHO)\(^{170}\) and the American Hospital Formulary System Pharmacologic/Therapeutic Classification Scheme (AHFS),\(^{171}\) used by the Quebec Health Insurance Plan. There are significant differences between these classifications systems, which must be taken into account when interpreting statistics and scientific studies based on one or the other system.

In the ATC classification system, drugs are classified at five levels, depending on the site of action (the target organ or system) and their therapeutic and chemical properties.\(^{172}\) Drugs for the central nervous system are found in several sub-classes although the term “psychotropic drug” is not specifically used (see appendix).

The Quebec Health Insurance Plan uses the American AHFS classification scheme, which lists all drugs based on their therapeutic effects. Unlike ATC, AHFS contains a sub-class of drugs for the CNS contains called “psychotropics” (see appendix) but it only includes antidepressants and tranquilizers. However, the Commission has adopted a broader definition, which includes particularly CNS stimulants and antipsychotics. Thus, a quick glance at RAMQ statistics could lead one to underestimate the actual level of psychotropic drug consumption in Quebec.
On the Control of Mood and Behaviour

Mood can be affected by psychiatric disorders* and by neurological disorders, but is also closely linked to the life setting and personality of each person. It is subject to transient variations depending on life events, such as mourning the loss of a loved one and financial difficulties, which are not necessarily characterized by a sustained pathological condition.

Mood disorders are distinguished from normal variations in mood by their intensity and persistence, as well as their tendency to disrupt the individual in his daily life. Pronounced variations in mood may nevertheless affect an individual's ability to function and his quality of life. In this perspective, drugs can be prescribed on a temporary basis.

To help relieve the symptoms associated with mood and behaviour disorders, several types of drugs have been developed, whether to sedate, stimulate or regulate mood.

Anxiolytics are drugs used to reduce anxiety, the best known of which are benzodiazepines. Sedatives are drugs commonly used to regulate sleep disorders. They are related to hypnotic drugs and are divided into two major families, barbiturates and benzodiazepines. Neuroleptics (or antipsychotics) are prescribed in certain cases of acute confusional state (delirium), psychotic decompensation, schizophrenia and, occasionally, in the manic phase of bipolar disorders.

Antidepressants are drugs that treat emotional disorders such as major depression. The advent of a new generation of antidepressants, selective serotonin reuptake inhibitors (SSRIs), has opened up new possibilities for drug treatment. Indeed, these antidepressants have substantially fewer adverse drug reactions than their predecessors (such as tricyclic antidepressants) and their action spectrum is less broad because they specifically target certain neurotransmitters.

Mood stabilizers, such as lithium salts, make it possible to mitigate the manic and depressive phases found in bipolar disorders.

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169 Two classes of regularly prescribed psychotropics are not detailed in this position statement, namely analgesics (for treating pain) and antimigraine drugs (for treating headaches and migraines). Two reasons explain this choice. First, these classes of medications alleviate physical and not mental or neurological disorders. Second, their expanded uses have little or nothing to do with the objectives of this position statement. Analgesics contain opium (for example, in the form of codeine or morphine) and expanded uses reflect a situation of drug addiction stemming from recreational use or from physical dependence following medical treatment. In the case of antimigraine drugs, expanded uses do not seem probable, at least according to the sense of “expanded uses” found in this position statement.

170 See http://www.whocc.no/atcddd/
172 For more details, see Jocelyne MOISAN et al., L’usage de médicaments psychotropes chez les travailleurs : prévalence, déterminants et conséquences, Montréal, Comité permanent de lutte à la toxicomanie, 2000, 78 p.
Table 1 provides examples of psychotropic drugs for stabilizing mood and mental health disorders:

**TABLE 1  EXAMPLES OF PSYCHOTROPICS FOR THE PURPOSES OF CHANGING MOOD AND ANXIETY**

<table>
<thead>
<tr>
<th>Class of drugs</th>
<th>Examples of commercial brands</th>
<th>Pathologies targeted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzodiazepines</td>
<td>Valium®, Ativan®</td>
<td>Generalized anxiety, post-traumatic stress disorder, adaptive disorder</td>
</tr>
<tr>
<td>Tricyclic antidepressants</td>
<td>Trofanil®, Aventil®, Elavil®</td>
<td>Depression, panic, generalized anxiety, obsessive-compulsive disorder, post-traumatic stress</td>
</tr>
<tr>
<td>Antidepressants – selective serotonin reuptake inhibitors of (SSRIs)</td>
<td>Prozac®, Paxil®, Celexa®, Effexor®</td>
<td>Depression, panic, obsessive-compulsive disorder, social phobia, post-traumatic stress</td>
</tr>
<tr>
<td>Atypical antipsychotics</td>
<td>Risperdal®, Zyprexa®, Seroquel®</td>
<td>Schizophrenia, bipolar disorder</td>
</tr>
<tr>
<td>Mood stabilizers</td>
<td>Lithium, Lyrica®</td>
<td>Bipolar disorders, depression</td>
</tr>
</tbody>
</table>

* Effexor® is a selective serotonin-norepinephrine reuptake inhibitor (SSNRI).

Source: MEYER AND QUENZA (2005)

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**On the Enhancement of Cognitive Functions**

Cognition can be defined as all processes used in the acquisition of knowledge, which include perception, intuition and reasoning. This includes particularly the ability to understand contexts, the relationships between ideas, the identification of patterns and parallels, and the speed of integrating information. Cognition therefore brings together memory, reasoning, learning and attention, as well as executive functions, a term which “covers abstract thinking and the ability to plan, initiate, order, control and inhibit complex behaviours.” Interventions for the purposes of enhancing cognitive functions may be associated with one or other of these faculties.

Cognitive functions may be affected by psychiatric and neurological disorders, and thus by the existence “of diseases, disorders and injuries affecting the brain, spinal cord and nervous system: neurological diseases and disorders such as brain tumours, brain and spinal cord injuries, chronic pain, epilepsy and multiple sclerosis; and psychiatric diseases such as anxiety, autism, depression and schizophrenia.” To this list can be added any form of dementia disorder as well as attention deficit with or without hyperactivity (ADHD).
Among the drugs developed to correct memory or attention disorders, two classes of drugs stand out: psychostimulants and anticholinesterases. Despite their name, the former address the symptoms of inattention, hyperactivity and impulsiveness. The latter modulate the degradation of acetylcholine, a major neurotransmitter associated with memory and learning, and are therefore prescribed for people with certain forms of dementia.

Table 2 lists some several psychotropics that stimulate cognition.

### TABLE 2  EXAMPLES OF PSYCHOTROPICS THAT STIMULATE COGNITIVE FUNCTIONS

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Examples of commercial brands</th>
<th>Pathologies targeted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamines</td>
<td>Dexedrine®, Adderall®</td>
<td>ADHD, narcolepsy</td>
</tr>
<tr>
<td>Acetylcholinesterase (or cholinesterase) inhibitors</td>
<td>Donepezil (Aricept®)</td>
<td>Alzheimer’s disease, other dementias</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>Rivastigmine (Exelon®)</td>
<td>ADHD, narcolepsy, apathy-related dementia</td>
</tr>
<tr>
<td>Modafinil</td>
<td>Galantamine (Reminyl®)</td>
<td>Hypersomnolence caused by narcolepsy and sleep apnea, sleep disorders, other clinical conditions associated with fatigue</td>
</tr>
</tbody>
</table>

* Doctors use these drugs, but do not consider them to be psychotropics since dementias are degenerative diseases.

Some User Profiles for Psychotropic Drugs

In 1992, the use and abuse of psychotropic substances in Quebec were considered “major problems”. In the context of its Health and Welfare policy, the MSSS set the target of a 10% reduction in consumption of psychotropic drugs in the elderly and recipients of last-resort assistance. A subsequent evaluation of the policy showed that the target had not been reached, and the situation had actually deteriorated “significantly” over ten years.

People using psychotropic drugs cannot be classified in well-defined categories. In general rather than exhaustive terms, some groups or socio-economic characteristics can nevertheless stand out in terms of the use of psychotropics. These are minors, the elderly, gender and poverty.

Minors

The prevalence of psychotropic drug prescriptions, including the neurostimulant Ritalin, is increasing among American preschool-age children. This level of use of stimulants cannot be explained solely by the increase in medical diagnoses based on clinical evaluation and recognized criteria. Pressure from parents, teachers and principals are factors to take into account. In general, the use of psychotropic drugs in children and adolescents is growing.

The Elderly

The use of certain psychotropics by the elderly is very high: they comprise 12% of Quebec’s population but consume a third of anxiolytic sedatives and hypnotics. Moreover, consumption varies according to gender; women use more psychotropic drugs than men and consumption tends to increase with age. Benzodiazepines (anxiolytic), sleeping pills and antidepressants are the most common psychotropic drugs used by seniors.

Gender

Two major findings emerge: women consume more psychotropic drugs than men, including tranquilizers and antidepressants, and boys are more often diagnosed with ADHD and receive more prescriptions for psychostimulants than young girls.

Poverty

Adverse socioeconomic conditions are a complex phenomenon involving interactions between several different factors. In particular, the relationship between poverty and mental health can work in both directions, each aggravating the other, thus creating a vicious circle: economic stress may affect mental health, which may in turn create obstacles in the search for or maintenance of employment. However, one consistent observation arises from the various studies on the subject: precarious socio-economic conditions expose more people to the consumption of psychotropic drugs. Accordingly, in 2006, the first four sub-classes of medications prescribed for Quebeckers receiving employment insurance benefits were psychotropics, and these accounted for 43.5% of total prescriptions.
In brief, many users show personal and social vulnerability. Some of these people suffer from the effects of social isolation, whereas others have a limited ability to understand the situation and to consent to care. In addition, the taboos and prejudice surrounding mental health problems are still strong in society\textsuperscript{184} and contribute to further isolate suffering individuals.
Two Significant Phenomena

Duration of treatment

The length of time during which people receive drug therapies depends on the disease, the drug and contextual elements. However, it sometimes happens that the duration of treatment is either too short or too long.\textsuperscript{193}

The short duration of treatment resulting from a non-compliance of drug therapy is a relatively widespread and complex phenomenon.\textsuperscript{194} Indeed, several psychotropic drugs must be taken over long periods (e.g. antipsychotics). They may act after the passage of several weeks (as in the case of many antidepressants) or have serious or disruptive side effects in everyday life. Some individuals may, as a result, find it difficult and even daunting to follow the instructions provided by physicians. If they do not feel their health improving, or if they notice very negative side effects or sense that the disease is under control, some people stop taking prescribed medication. Early cessation of drug treatment may mean that these people will return to an imbalanced health state.

Conversely, observations have been made of treatment that lasts too long\textsuperscript{195} in defiance of guidelines and drug monographs, although there are no consensus definitions of "extended use" and "long-term use". For example, in the case of benzodiazepines, duration of treatment varies from 30 days to 180 days after the beginning of treatment.\textsuperscript{196} In addition, there is a tendency to renew prescriptions even if the diagnoses leading to medication are no longer indicated. For example, in the case of long-term treatment of depression, the aim is to prevent possible recurrence, and psychotropic medication plays a prophylactic role in preventing relapse.\textsuperscript{197}

The role of patients should be stressed in connection with the renewal of prescriptions. Indeed, some patients insist on their physician renewing the prescription for psychotropic drugs even if their health no longer justifies medication, either because they felt better under medication, or because they are afraid of relapse if they cease to take it.\textsuperscript{198} In such situations, psychological dependency may develop as a result.\textsuperscript{199}

Polymedication

Psychotropic drugs may be taken concurrently.\textsuperscript{200} Although this has been a well-known situation for many years among the elderly,\textsuperscript{201} all age cohorts are now affected by polymedication. For example, a Quebec study on minors in two metropolitan centres shows that of 48 children taking psychotropic medications, 20 take more than one: 10 take two, 8 take three, one child takes four and one child takes six.\textsuperscript{202} Strangely, although this phenomenon has been noted for a long time, it is not clearly defined and there is consensus about it. As a result, the term “polymedication” is rarely defined; where mention is made of the number of medications taken, some sources refer to two drugs or more,\textsuperscript{203} five or more drugs\textsuperscript{204} or “a greater number of medications than is clinically indicated.”\textsuperscript{205}

It is important to note that polymedication is not harmful in itself. Indeed, there are cases where it is obviously necessary for the welfare of subjects; one may think for example of people with cancer, those suffering from paranoid schizophrenia or in severe cases of comorbidity. However, the risk of adverse drug reactions and drug interactions increases with the number of medications taken.

There are different ways to explain why people take several medications. For example, when a health condition requires more care, as in the case of certain chronic diseases. Again, age may be a factor, since the elderly have increased needs related to the natural effects of aging. The importance of drug prevention also increases the consumption of drugs. In addition, in order to mitigate the risks and negative side effects of a drug, it is common to prescribe another drug. Finally, treating a variety of pathology-related symptoms one by one also reinforces the use of many drugs. For example, depression is
characterized particularly by depressed moods and sleep disorders; pharmacological treatment may include an antidepressant, an anxiolytic and a hypnotic (sleeping pill).  

The number of medications a person takes may strike other people as significant and become a subject of public controversy. Beyond the notion of quantity, three issues are raised by polymedication: Do prescribed drugs correspond to the needs of those people concerned? Are they accompanied by drug interactions? If such interactions are negative, what are the mental and physical consequences for the user, but also for those closest to him? Given these questions, polymedication is of increasing concern for health authorities and caregivers.

The possible consequences of the use of psychotropic drugs and the vulnerability of certain groups of users call for a better understanding of the state of current knowledge on the central nervous system: its structure, mode of action and neurotransmitters and the complex biochemical cascades continuously taking place in there.

193 As applied to the use of psychotropics, the terms “short term” and “long term” are quite imprecise. For example, the effects of some of these drugs turn up after several days or even weeks; others must be used for long period before a person’s state is stabilized. The duration of use of psychotropics varies depending on the drug involved and the individual’s situation, which make the notions of short and long term more vague.

194 MÉOS researchers discuss the set of problems associated with this phenomenon and provide a literature review, op. cit., pp. 17-18.


197 LE MOIGNE, op. cit., p. 95; RAYMOND et al., op. cit., p. 82.

198 LE MOIGNE, op. cit., p. 102-104.

199 COLLIN (2001), op. cit., p. 6-7.

200 MÉOS, op. cit., p. 30 discusses the set of problems associated with this phenomenon and provides a literature review.

201 M. DE MEYERE et al., “Une polymédication inéluctable en EBM?”, Minerva, 2005, vol. 4, no. 8, p. 115; ROULEAU et al., op. cit..


203 Mohamed BEN AMAR, La polyconsommation de psychotropes et les principales interactions pharmacologiques associées, Montréal, Centre québécois de lutte aux dépendances, 2007, p. 13.

204 DE MEYERE et al., op. cit., p. 115; ROULEAU et al., op. cit., p. 153.

205 DE MEYERE et al., op. cit., p. 115 (our translation).

206 LE MOIGNE, op. cit., p. 103. For major depressions, the Mayo Clinic notes on its website: “Other medication strategies: Your doctor may also suggest other medications to treat your depression. These may include stimulants, mood-stabilizing medications, anti-anxiety medications or antipsychotic medications. In some cases, your doctor may recommend combining two or more antidepressants or other medications for better effect, which is sometimes called augmentation.” (MAYO CLINIC, Depression (Major Depression) – Treatment, 2008, http://www.mayoclinic.com/health/depression/DS00175?SECTION=8 (consulted 28 May 2008)).
THE FUNCTIONING OF THE CENTRAL NERVOUS SYSTEM

The central nervous system (CNS) is essential for maintaining the health and life of the organism. Over time, it has refined its functions to meet the new requirements of evolution. An organ, the brain, has become more complex while neurons*, cells of the CNS, have developed specialized functions, straying away from the classical cellular model (for example, they are not able to reproduce).

The nervous system informs the organism about its internal needs and the situations occurring in its external environment. In addition to receiving and transmitting information, it has the tools to process this information and to act accordingly (flee from danger, drink and eat in response to symptoms of thirst or hunger, console a sad person, etc.). It is only in the animal kingdom that a nervous system has developed, and the human has the most developed one of all.

Brain function is not continuous over time. In general, during youth, cognitive capacities, and consequently synapses*, are growing. In aging, brain plasticity decreases, the myelin sheaths that protect nerve fibers are deteriorating, and physical or neurological injuries can cause brain damage. The ingestion of alcohol or drugs can also impair brain function.

If physical activity and lifestyle can improve cognitive functions or delay their deterioration, it is important to emphasize that changes in the central nervous system are part of the natural effects of physical aging.

**Structure of the Central Nervous System**

In anatomical terms, the *central nervous system* (CNS) includes the brain and spinal cord, while the *peripheral nervous system* consists of certain neurons and nerves connecting the spinal cord to organs and limbs.

In functional terms, there are two sub-systems: the *somatic nervous system* and the *autonomic nervous system* (or vegetative), which itself is split into two categories, the *sympathetic nervous system* and the *parasympathetic nervous system*.

By means of various sensory receptors in the body, the *somatic nervous system* is in contact with the external environment. Depending on information received, it allows the body to react and move; as a result, it is responsible for sensory and motor functions. As for the *autonomic nervous system*, it modulates vital and automatic functions such as sleep, appetite, digestion and homeostasis. More specifically, the *sympathetic nervous system* prepares the body for physical and intellectual activity by increasing heart rate, releasing glucose and secreting more adrenaline. The *parasympathetic nervous system* slows body functions in order to conserve energy, with the exception of the digestive function and the sexual appetite, which it activates.
The brain is a major part of the CNS, and is a complex organ consisting of several parts, some of which are very ancient (such as the cerebellum, hippocampus and amygdala) while others have emerged more recently in evolution (such as the cerebral cortex). The brain receives and processes information from the body and determines the result of actions, decisions, thoughts and emotions. By the same token, it oversees and coordinates most movements and behaviours, memory and bodily homeostasis. To carry out its functions, the brain has an extraordinary malleability. Indeed, its networks of cells are permanently reorganizing themselves, based on outside influences and personal experiences, making the brain the most highly adaptable organ of the human body. This plasticity explains the learning capabilities of children and the possibility of person’s recovering lost functions after a cerebrovascular accident.

Cell Types in the Central Nervous System

The nervous tissue of the central nervous system consists of two main types of cells: glial cells and neurons.

Glial Cells

Glial cells make up 90% of cells in the CNS. They play a vital role in ensuring the isolation of brain tissue (they are a component of the blood-brain barrier which filters blood flowing towards the CNS), metabolic functions and physical support for nervous tissue. In addition, recent studies show that some glial cells also play a role in the transmission of nerve impulses. Unlike neurons, glial cells can divide and reproduce throughout their lives. That is why the majority of brain tumours involve glial cells.

Neurons

The brain contains over 100 billion neurons, which belong to one or the other of the 200 types of neurons recorded to date. This wide variety of neurons means they are highly highly specialized cells in terms of their shape, their position in the CNS and the connections they maintain with other neurons.

Their metabolism is exceptionally high and therefore requires a constant and abundant supply of oxygen and glucose. Whereas the brain represents 2% of body weight, it uses 20% of inhaled oxygen and 20% to 25% of glucose ingested (or transformed) daily by adults. A disruption in this supply has serious consequences. Thus, a sustained or repeated lack of glucose can cause neurological disorders, while halting the flow of oxygen to the brain quickly leads to brain death.
The neuron is the basic operational unit of the CNS. It collects, processes and transmits information to other neurons and the various body parts. To this end, the neuron is composed of a cell body* and extensions, namely the axon* and dendrites*.

The cell body continuously receives multiple pieces of information, analyses them, and then relays orders or information to other neurons by means of its axon. The latter is protected by a myelin sheath and conducts electrical impulses* unidirectionally, i.e. from the cell body to the tip of the axon, to branches called terminal arborizations (or axonal terminals). These terminals contain vesicles packaging neurotransmitters which can be released in order to relay information. The dendrites are very numerous and are located near the axons of neighbouring neurons, in order to remain in chemical contact with them. They receive information from neighbouring neurons and transmit them to their cell body.

The cell bodies and dendrites make up the brain’s grey matter (for receiving and processing information), while the myelin sheaths around axons constitute the brain’s white matter (for information transmission).
Nerve Communications and Neurotransmitters

Nerve impulses – or action potential* – are at the origin of thinking. Once thinking starts, the components of neurons each have a role to play in interneuronal communications. The neuron’s cell body transmits data in the form of electrical impulses towards the axonal terminals while the dendrites of other neurons receive the information.

Nerve Communications

Neurons communicate with each other without being in physical contact. Neurotransmitters – chemical molecules synthesized and released by neurons depending on the information to be transmitted – are responsible for conducting the flow of information to other neurons over the specialized junction point: the synapses.

Synapses comprise three parts: the presynaptic element, the postsynaptic element, and between these two, the synaptic cleft. The presynaptic element is located at the axonal terminals that contain neurotransmitters. Once they are released into the synaptic cleft, they are detected by postsynaptic receptors located at the dendrites of neighbouring neurons.

Although each neuron can activate 100,000 synapses at the same time, it regularly uses fewer than that, and establishes contact with thousands other neurons at the same time. Each contact is likely to trigger a cascade of complex biochemical reactions, many of which may be simultaneous, while a feedback loop instantly activates a chain reaction.

This myriad of synapses operates in a neuronal network in a constant state of flux. Indeed, the brain is characterized by learning plasticity, i.e. an ability to reorganize itself depending on experiences and the environment. The interneuronal exchanges alter the processing of information, whether by modifying the number of synapses, by the ability to respond to the same stimulus in different ways, or by creating parallel networks.

As a result, electrical communication is the foundation of all thoughts, emotions and actions, whereas interneuronal communication is chemical.\textsuperscript{215} The translation of electrical information into chemical molecules, and the transcription of this chemical molecule, in neighbouring neurons, into identical electrical information are crucial steps in maintaining the health of the body. Given the nature and complexity of the information relayed in the brain or triggering a physical reaction, an extremely precise communication process which involves neurotransmitters.

\textsuperscript{215} Chemical synapses dominate the great majority of transmissions of nerve impulses. Electrical synapses also exist, although they are very rare in humans and other mammals.
Neurotransmitters

The neurotransmitter is a chemical molecule secreted by neurons to convey information from one neuron to another. Its activity is limited to the time needed to transmit information. Once this is accomplished, the neurotransmitter is destroyed or recaptured by the transmitting neuron in order to be reused.

Over sixty neurotransmitters have been identified to date. Some are well-known, such as dopamine and serotonin. Hormones and peptides may also play the role of neurotransmitters. For example, insulin, glucagon, vasopressin, prolactin and angiotensin II may alter nerve impulses.

Primary neurotransmitters

Acetylcholine

Acetylcholine is an excitatory neurotransmitter with several functions. It is involved in vegetative functions such as sexuality and thirst. Its roles in memory and learning are also important. Indeed, it controls the ability to retain information, storing and retrieving it when necessary. It also plays a role in arousal, attention, anger and aggression.

Adrenaline (or epinephrine)

Adrenaline allows the body to react to a situation of physical or mental stress, in preparing for a reaction either of “flight” or of “confrontation”. To this end, it increases the pulse and blood pressure, improves memory, reduces thinking, increases muscle contraction and breathing capacity and dilates the pupils. Stress reduces adrenaline reserves, while physical exercise increases them.

Dopamine

Dopamine became “famous” once its link to the reward system, and therefore to brain mechanisms of the sensation of well-being and pleasure, was highlighted. This neurotransmitter is not very present in the CNS, given that neurons producing it account for only 0.3% of brain cells. Its functions are nevertheless essential. Physiologically, dopamine is involved in controlling movement and posture, in the growth of tissues and in the functioning of the immune system. It also plays a role in memory and mood regulation.
**GABA (gamma-aminobutyric acid)**

GABA is very common in the brain (GABA and its receptors contribute to almost 40% of synapses in the CNS). It is essentially an inhibitory neurotransmitter: by slowing the transmission of nerve signals, it prevents the system from speeding out of control. By controlling neuronal hyperactivity, it promotes calm and relaxation, reduces muscle tone and slows the heartbeat. It is also involved in certain phases of memorization.

**Glutamate**

Glutamate is the most common neurotransmitter, representing 50% of CNS synapses. It is an excitatory neurotransmitter associated with learning and memory. However, surplus glutamate can be toxic to neurons and excess glutamate can kill them.

**Norepinephrine (or norepinephrine)**

Norepinephrine has a wide variety of functions. For example, it plays a role in attention, emotions, sleep, dreaming, sociability, libido, learning and memory. It is prevalent in the sympathetic nervous system, and is associated with the state of alertness because of its role in increasing heart rate and blood pressure. Finally, it stimulates the release of reserve fat and controls the release of hormones that regulate fertility, libido, appetite and metabolism.

**Serotonin**

Serotonin plays a major role in emotions and judgment, and an important role in sleep and susceptibility to migraines. It also contributes to the regulation of temperature, appetite and pain.

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Functions of Neurotransmitters

Neurotransmitters can play three roles:

- **Exciter/stimulator.** They trigger and propagate new nerve impulses. Dopamine, epinephrine, norepinephrine, glutamate and acetylcholine play this role.

- **Inhibitor.** They are designed to reduce or block neuronal activity by stopping the triggering of nerve impulses. GABA is a neurotransmitter inhibitor.

- **Modulator.** Present in the synaptic cleft, they influence the functioning of neurons by altering synaptic activity related to another messenger. Neuromodulation varies: it can initiate, amplify, reduce or inhibit the action of other neurotransmitters. Depending on the situation, peptides, hormones or neurotransmitters can become neuromodulators.

A neuron may release several neurotransmitters at once, each with distinctive instructions and roles, and the same neurotransmitter (e.g. dopamine) may transmit more than one type of information. As a result, a considerable amount of chemical molecules are found in the synaptic cleft. The data they carry are decoded, given the very strong affinity of neurotransmitters with their postsynaptic receptors. For this reason, there are hundreds of types of receptors, including several subtypes of receptors for the same neurotransmitter. This perfect match exists so that a balance can be brought about in the functions and communications of the central nervous system, although this objective is not always fulfilled.

Dysfunctions of the Central Nervous System

An imbalance in the production of neurotransmitters or a damage to postsynaptic receptors alters the functioning of the nervous system and can cause neurological problems or mental disorders.

A clarification should be made. Research on neurotransmitters has led to a better understanding of mental and neurological disorders, opening the way to development of more effective pharmacological treatments. However, several unknowns remain. While waiting for new scientific advances involving the role of neurotransmitters, the Commission sees the need to share knowledge and current hypotheses related to neurotransmitters and the levels of activity involved. The limits of current knowledge are discussed further in the section *Scientific Uncertainties Related to Psychotropics*.

Mental Illness and the Activities of Neurotransmitters Involved

Psychiatric disorders – or mental illnesses – are characterized “by alterations in thinking, mood or behaviour – or some combination thereof – associated with significant distress and impaired functioning.”

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Certain levels of neurotransmitters may play a role in mental illness.\textsuperscript{218} For example, a lack of dopamine or an excess of serotonin have been noted in the case of autism. An excess of adrenaline and a lack of dopamine and/or norepinephrine and/or serotonin have been observed in the case of depression. In schizophrenics, a lack of GABA and an excess or lack of dopamine, or both at the same time, have been observed, depending on distribution of the neurotransmitter involved in the disease. Bipolar disorder (also known by the names of manic-depressive disorder/disease/psychosis) is divided into two phases: the depressive phase and the manic phase; in the first phase, there is a lack of norepinephrine and/or serotonin, whereas in the manic phase there is an excess of norepinephrine and/or dopamine. Finally, people with obsessive-compulsive disorder (OCD) have too high a concentration of serotonin.

Neurological Disorders and the Activities of Neurotransmitters Involved

Neurology is the branch of medicine that studies the anatomy, physiology and pathology of the nervous system.\textsuperscript{219} Any physical alteration that affects the structure or functioning of the CNS is a neurological disorder. A neurological disorder can also cause changes in behaviour or mood, but in this case, the origin of these changes is primarily physical (such as the destruction of neurons or brain damage).

As in the case of mental illness, inadequate concentrations of neurotransmitters may have an effect. In the case of neurological disorders, the levels of neurotransmitters are generally too low. Thus, for Alzheimer’s disease, there is a lack of acetylcholine and/or norepinephrine, among others.\textsuperscript{217} For other forms of dementia, the concentration of GABA and/or acetylcholine is too low. A lack of GABA can be seen in individuals suffering from epilepsy. Parkinson’s disease may be accompanied by a lack of dopamine and/or GABA. In cases of attention deficit with or without hyperactivity (ADHD), a lack dopamine deficiency is observed.


\textsuperscript{218} The work by Jacques QUEVAUVILLIERS et al. (Dictionnaire médical, 5th ed., Issy-les-Moulineaux, Elsevier Masson, 2007) is the main source on mental and neurological disorders in this part of the position statement.

\textsuperscript{219} OFFICE QUÉBÉCOIS DE LA LANGUE FRANÇAISE.
Psychotropic drugs influence nerve communications in various ways, either by changing the concentration of neurotransmitters in the CNS, or by monopolizing the receptors of dendrites and axons.

Two major kinds of action may be noted. The first is an antagonist action, namely “a molecule that blocks the effect that the neurotransmitter normally has on the post-synaptic neuron.”\textsuperscript{220} The second is an agonist action, which is “a molecule that has the same effect on the postsynaptic neuron as the neurotransmitter itself does.”\textsuperscript{221} Psychotropics have several modes of action in order to get the desired result – whether agonist or antagonist.\textsuperscript{222}

They can bind to specific receptors located on postsynaptic dendrites of neighbouring neurons, resulting in three possible types of consequences:

- Their presence prevents neurotransmitters from using receptors and blocks their effects (action, seeking information, etc.).

- The same unavailability increases the concentration of neuromodulators and expands – or extends – their chemical action;

- By binding to receptors, psychotropic drugs may play the role of neurotransmitters and artificially create an increased concentration of these neurotransmitters and therefore their effects.

Psychotropics also act in other ways. For example, they may affect the synthesis and release of neurotransmitters in the axonal terminals of the neuron emitter. Psychotropic drugs may also alter the release of neurotransmitters from receptor dendrites, once information is transmitted. In addition, they may influence the degradation of neurotransmitters in the synaptic cleft. Finally, psychotropics may promote reuptake of neurotransmitters by the emitter neuron.

Each type of drug has a different mode of action on neurotransmitters. While some drugs only target one neurotransmitter, others act on several at once. Thus, several types of antidepressants act by inhibiting reuptake of serotonin, of norepinephrine, or of both at the same time.\textsuperscript{223} For their part, benzodiazepines are used in the treatment of anxiety and insomnia, and bind on a specific site of a GABA receptor, which reduces brain hyperactivity associated with anxiety.\textsuperscript{224} Anticholinesterases are medications used to treat Alzheimer’s disease: they block the action of cholinesterase, the enzyme that degrades acetylcholine, a defective neurotransmitter in patients suffering from this disease. Amphetamines inhibit dopamine reuptake, but also induce the release of norepinephrine and dopamine. Methylphenidate (Ritalin\textsuperscript{®} and Concerta\textsuperscript{®} are well-known commercial brands) is a psychostimulant widely used to treat ADHD in children and adolescents, has the same pharmacological mechanisms as amphetamines and cocaine\textsuperscript{225} and is considered a drug in Canada.\textsuperscript{226} Methylphenidate also binds to dopamine receptors, and in so doing increases the concentration of the same neurotransmitter, which helps memory, behaviour control and the feeling of pleasure associated with the presence of dopamine.\textsuperscript{227}
Other Drugs Affecting the Nervous System

Several non-psychotropic drugs can influence the functioning of the central nervous system, usually because of their side effects causing vertigo, dizziness, irritability, sleep pattern changes, etc.

For other drugs, effects not identified during the licensing process have led to new uses. For example, beta-blockers are prescribed in the treatment of hypertension and other cardiovascular problems, and may be useful during traumatic events or high stress. In these situations, epinephrine and norepinephrine are synthesized in large quantities. Beta-blockers work by blocking the action of beta-adrenergic receptors, reducing or even eliminating physical symptoms. These drugs can therefore be used to combat all forms of stress, in addition to being prescribed to help extremely shy people overcome their fears in society. They would also seem to have the effect of inhibiting the formation of strongly emotional memories, making them suitable for the treatment of post-traumatic stress.

As a final example, a recent study has shown that a class of anti-hypertensives, the calcium channel blockers, is associated with a reduced risk of developing Parkinson’s disease.

As a result, knowledge exists, but that knowledge is also limited: despite spectacular advances in molecular biology and imaging techniques, as well as the advent of new psychotropics, the molecular cascades of the brain are still not well known. The discovery of unexpected effects of some drugs on the central nervous system illustrates the fact that the functioning of the CNS is still not well known. Since the brain does not operate in a silo fashion, the ability to chemically modify certain molecular reactions without affecting other functions of the nervous system remains to be demonstrated, and the medium- and long-term effects of psychotropics are not well known, or are unknown.
THE “RISK/BENEFIT” RATIO: ASSESSING THE USE OF PSYCHOTROPIC DRUGS

The incomplete state of knowledge does not only involve psychotropics and brain functioning. However, the nature of the brain itself, the plasticity of which enables it to create new neural networks, makes it more difficult to assess the risk/benefit ratio of psychotropics.

Definition

The “risk/benefit” ratio weighs possible risks and expected benefits associated with taking a specific drug in a given situation. It aims to achieve optimal use, which is defined as “use that maximizes the benefits and minimizes risks to the health of the population, taking into account various possible options, costs and available resources, patient values and social values.”

Assessment of this ratio is based on evidence, good practice guides, guidelines and clinical experience (or professional judgment). In a given situation, i.e. indications for which a specific drug is approved, the specific context of medical consultation should be added, as well as the position taken by the clinician on psychotropic drugs. Thus, for the same suspected health disorder, the “risk/benefit” ratio will vary depending on the physician, the individual being examined, as well as the individual’s overall health, current medication and medical history.

Demonstrated Benefits of Psychotropic Drugs

Living with mental illness or a neurological disorder has significant effects on quality of life, security, self-esteem and interpersonal relationships. The suffering individual and those closest to him sustain these impacts. Psychotropic drugs are designed to safely offer treatment and relief in order to promote a better life for the suffering individual and for those closest to him. Several beneficial effects are worth noting, but it is important to bear in mind that the benefits will not accrue to all individuals, with the same intensity or at the same time.

Some of the benefits of psychotropics are as follows:

- **Antidepressants**: decreased depressive symptoms, reduced stress and anxiety, reduction in suicidal ideation, improved sleep, improved academic and professional tasks, increased confidence and self-esteem, increased contacts and behaviour positive social.

- **Stimulants of the central nervous system**: decreased sensation of fatigue and need for sleep, increased concentration and work capacity, increased energy level, loss of sensation of hunger, sense of vigilance and of euphoria.

- **Antipsychotics**: decreased hallucinations and agitation, decreased level of danger for the individual and those closest to him, increased concentration, increased contacts and positive social behaviours.

- **Benzodiazepines (anxiolytics) and hypnotics (sleeping pills)**: decreased anxiety, improved sleep quality, decreased avoidance.

- **Acetylcholinesterase inhibitors**: slowed cognitive and memory loss.

- **Lithium**: stabilized mood, reduced manic and depressive phases, decreased aggression.
Demonstrated Risks and Side Effects of Psychotropic Drugs

It is important to note that there is no drug without risks: all drugs may be associated with side effects representing different types and varying levels of danger. As in the case of the benefits of taking psychotropic drugs, the risks and side effects will not all necessarily occur, either with the same intensity or at the same time of drug therapy.

Some risks and side effects associated with taking psychotropic drugs are presented here:

- **Antidepressants**: changes in heart rate (including tachycardia and arrhythmia, especially in the case of tricyclic antidepressants), increased risk of suicide in young people aged 0-24 years (in the case of SSRIs), breathing difficulties, headache, nausea, digestive problems, sleepiness, insomnia, psychomotor disorders, dizziness, gain and/or weight loss, irritability, sexual dysfunction, dry mouth, restlessness.

- **Antipsychotics**: weight gain, heart problems, drowsiness, stomach problems, fatigue, nausea, dizziness, psychomotor disorders, insomnia, sedation, diabetes, hyperlipidemia, photosensitivity (of the skin).

- **Benzodiazepines (anxiolytics) and hypnotics (sleeping pills)**: drowsiness, weakness, fatigue, falls and fractures, memory disorders, psychomotor disorders, dizziness, dry mouth, gastric problems, sexual dysfunction, physical dependence.

- **Lithium**: weakness, fatigue, drowsiness, nausea, heart problems, vomiting, diarrhea, chronic renal failure, diabetes insipidus, tremors, vertigo, weight gain, hypothyroidism.

- **Stimulants of the central nervous system**: tachycardia, insomnia, headache, loss of appetite, weight loss, nervousness, dizziness, twitching, feelings of depression, hypertension, rash, slow growth (Ritalin®).

It is to be noted that just as benefits associated with psychotropics may affect individuals and indirectly those closest to them, adverse drug reactions may also affect some individuals. For example, if negative side effects occur when the person is driving a vehicle under the influence of psychotropics, then the safety of others may be endangered.

Scientific Uncertainties Related to Psychotropics

Any assessment of the “risk/benefit” ratio is based on an established theoretical and clinical foundation. This ratio is estimated using the best available knowledge and, in the case of uncertainties, the hypotheses used must be made explicit so that other investigators may reach the same outcome – even if the hypotheses are challenged. This underlines the importance of distinguishing between what is known and what is uncertain.


234 Notably for fluvoxamine (Prozac®), paroxetine (Paxil®) and citalopram (Celexa®) (MEDLINE PLUS, op. cit.).
Knowledge about Neurotransmitters

The biochemical bases of the central nervous system, the neurotransmitters, are the subject of increasing studies and documentation. Thus, neurotransmitters in too low or too high a concentration are observed in neurological and mental health disorders.

However, the role of neurotransmitters in mental disorders is the subject of debate. Thus, the relationship between “mental disorder” and “neurotransmitter” is not clearly established: Is a biochemical imbalance at the basis of mental disorders (cause) or is a biochemical imbalance due to the presence of mental disorders (symptom)? Moreover, is a single neurotransmitter involved in a mental or neurological disorder, or are several neurotransmitters involved? The latter hypothesis is increasingly acknowledged. For example, depression used to be described as monoamine disease, i.e. it was caused by a lack of serotonin, but this hypothesis was refuted given that a number of neurotransmitters and genetic and environmental factors are involved. Therefore, optimal use of psychotropics requires knowledge of the number of neurotransmitters, their interactions and relations with genes and the physical environment.

In fact, an imbalance of neurotransmitters is no longer regarded as a causal factor in determining the onset of mental disorders.

To date, several psychotropics are used – and have a positive effect – although their modes of action are not fully understood. For example, we know that Ritalin® is generally effective, but its mechanism of action is still cause for discussion. Similarly, Prozac® allows the increase of serotonin, although the relationship between serotonin and depression is not clearly established, or there is no explanation why the individual begins to feel drug effects after the passage of three to six weeks. Finally, modafinil, originally prescribed in cases of narcolepsy, enables the individual to stay awake, although the process by which the hypothalamus and other brain regions are activated has not been clarified.

Knowledge about the Structure of the CNS

The interrelation of molecular reactions and the high number of simultaneous biochemical cascades make it difficult to study them separately or to identify specific interactions and cognitive functions. Moreover, the plasticity of the CNS, which is so useful for learning and tissue repair, complicates the prediction of brain responses and, therefore, the validation of hypothesis.

The anatomical and functional structures of the CNS are known. Areas in the brain have been mapped; zones relating to functions, such as language and creativity, have been identified. However, noting that an area is activated by a particular stimulant does not go very far. New mental imagery technologies (such as functional magnetic resonance imaging [fMRI], which has led to concrete results in several fields of neurology) have a lot of potential, although this potential still lies in the order of anticipation. These technologies could lead to new applications, such as better clinical diagnosis, a reliable method of screening or neuromarketing, although these applications are still of a speculative nature.

Several questions related to cognitive functions also remain unanswered. These questions focus on possible delayed effects: Will taking psychotropic drugs at a given stage in life affect the individual in later years? Will increasing attention affect mood or memory? In addition, possible differences between extended use and one-time use of psychotropics remain to be demonstrated. Finally, more knowledge is needed about the impact of a biochemical imbalance, because science cannot currently tell us whether the effects on “healthy” people will be the same as those having a neurobiochemical imbalance at the time of medication. These issues arise particularly in the case of minors since their brain has not yet reached its full development. For example, no longitudinal study* has been undertaken on mid-term and long-term cognitive consequences of taking Ritalin® although this drug has been on the market since 1944.
Evidence: A Tool for Assessing the “Risk/Benefit” Ratio

Since the early 1990s, “Evidence-Based Medicine” has been a central concept in biomedical practice. It is defined as “the conscientious and judicious use of current best evidence in making decisions about the care of individual patients” while evidence itself is defined as “the best current evidence”.

Definition

Evidence-based medicine was conceptualized by Archie Cochrane in 1972. It has evolved since then, although the essence of Cochrane’s original formulation has held up over time medical treatments (i.e. professional practices) should be systematically assessed using unbiased methods, and personal knowledge should be continually updated in order to provide the best professional opinion in the circumstances. Evidence-based medicine developed as a set of techniques for reading and evaluating the scientific quality of the medical literature, evidence is now used by researchers, clinicians and decision-making institutions that regularly rely on it to take decisions. Evidence comes from various different sources: clinical observations, longitudinal studies, meta-analysis, literature reviews, cohort studies, etc.

238 NOVARTIS PHARMA CANADA INC., Prescribing Information – Ritalin, Dorval, 2007, p. 2; www.ask.novartispharma.ca/download.htm?res=ritalin_scrp_e.pdf (consulted 29 October 2007). The monograph states: “There is neither specific evidence which clearly establishes the mechanism whereby methylphenidate produces its mental and behavioural effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system”.

240 McGill UNIVERSITY, op. cit.
243 “A branch of marketing using neurosciences imagery technologies to reach a better understanding of the brain’s responses to marketing stimuli in order to bolster promotion campaigns efficiency.” (OFFICE QUÉBÉCOIS DE LA LANGUE FRANÇAISE) (our translation).
244 Joël MONZÉE, “La médicalisation des humeurs des enfants”, Éthique publique, vol. 8, no. 2, 2006, p. 79. Longitudinal studies (over a period from one to ten years) exist, focusing principally on prescription rates, the duration of treatment, short-term effects on the cognitive functions of young users, effects on physical growth, the onset of other disorders (dependence, cancer...) and the persistence of benefits and side effects (between two months and five years). To our knowledge, no studies focuses on long-term monitoring of cognitive functions of young users into adulthood. Furthermore, two Quebec researchers have stressed the practical absence of any study on long term use of methylphenidate (Lily HECHTMAN and Brian GREENFIELD, “Long-Term Use of Stimulants in Children with Attention Deficit Hyperactivity Disorder: Safety, Efficacy, and Long-Term Outcome”, Paediatric Drugs, vol. 5, no. 12, 2003, p. 787). The two authors describe these studies in their article.
Table 3 shows an example of sources of evidence as well as their levels of evidence (scientific validity).

**TABLEAU 3 LEVELS OF EVIDENCE FOR DETERMINATION OF IMPROVED THERAPEUTIC BENEFITS**

<table>
<thead>
<tr>
<th>Level</th>
<th>Therapy/Prevention</th>
<th>Economic and decision analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>SR (with homogeneity*) of RCTs</td>
<td>SR (with homogeneity*) of Level 1 economic studies</td>
</tr>
<tr>
<td>1b</td>
<td>Individual RCT (with narrow confidence interval)</td>
<td>Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>1c</td>
<td>Series of cases of the all or none type§</td>
<td>Absolute better-value or worse-value analyses†</td>
</tr>
<tr>
<td>2a</td>
<td>SR (with homogeneity*) of cohort studies</td>
<td>SR (with homogeneity*) of Level &gt;2 economic studies</td>
</tr>
<tr>
<td>2b</td>
<td>Individual cohort study (including low quality RCT; e.g., &lt;80% follow-up)</td>
<td>Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>2c</td>
<td>&quot;Outcomes&quot; Research; Ecological studies</td>
<td>Audit or outcomes research</td>
</tr>
<tr>
<td>3a</td>
<td>SR (with homogeneity*) of case-control studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
</tr>
<tr>
<td>3b</td>
<td>Individual Case-Control Study</td>
<td>Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.</td>
</tr>
<tr>
<td>4</td>
<td>Case-series (and poor quality cohort and case-control studies§§)</td>
<td>Analysis with no sensitivity analysis</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on economic theory or &quot;first principles&quot;</td>
</tr>
</tbody>
</table>
SR: Systematic Review
RCT: Randomized Controlled Trials
Rx: Therapy

* Homogeneity means a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a “-” at the end of their designated level.

§ Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.

 §§ Poor quality cohort study is defined as a study that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. A poor quality case-control study is defined as a study that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.

† Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and equally or more expensive.

Source: PATENTED MEDICINE PRICES REVIEW BOARD (2008) (which states that “The table above is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001) - produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998).”)
Clinical trials

“An investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.”

**Food and Drug Regulations, CRC, chapter 870, Part C, Title 5, Art. C.05.001.**

Clinical trials are divided into four phases:

**Phase I.** This phase conventionally examines the pharmacological toxicity (safety) of new drugs in humans, to determine the pharmacological effects and pharmacokinetics effects (metabolism, absorption, elimination and preferential route of administration) of the drug and the secondary effects associated with increased dosage. This phase often involves healthy subjects in small numbers.

**Phase II.** This phase primarily studies the short-term safety and efficacy of medications in a small number of patients suffering from specific diseases. It will also determine any side effects or risks associated with the drug. Phase II trials can also be used to test drugs already on sale, but destined for new uses. In most Phase II studies, participants are randomly divided into (two or more) single or double blind groups.

**Phase III.** This phase examines the pharmacological efficacy of new drugs in large cohorts. It aims to collect information on the efficacy and safety of the drug, needed to evaluate the risks and benefits. During this phase, trials are also conducted with special populations of patients in order to improve their chances of survival or their quality of life. Using a large number of participants, most studies in this phase randomly divide them into (two or more) single or double blind groups, spreading them over several years. If this phase is successfully completed, the pharmaceutical company may submit an application to Health Canada for licensing of the drug.

**Phase IV.** In this phase, also known as the post-marketing surveillance phase, trials primarily examine the toxicity and long-term effectiveness of drugs already marketed.

Unlike phases I to III clinical trials, for which a separate application authorizing each phase must be considered by Health Canada, Phase IV clinical trials do not require any application for authorization.
However, evidence is primarily drawn from clinical trials and meta-analysis:

- **Clinical trials** are the main source of evidence. There are several types of clinical trials, one of the most widely accepted scientifically being the double-blind randomized clinical trial, in which research subjects in different groups are distributed randomly, without the investigator and the subjects knowing which treatment is administered. These trials take place through a process rigorously regulated by Health Canada.

In Canada and the United States, pharmaceutical companies fund most biomedical research,\(^\text{248}\) which means they also provide most evidence. The data collected as well as subsequent analyses are submitted to funding agencies and government regulatory agencies, namely the Food and Drug Administration (FDA) in the United States and the Health Products and Food Branch of Health Canada (HPFB) in Canada. These regulatory agencies validate company reports, ask for clarifications and, ultimately, accept or reject the new drug or a proposed new use of a drug. These agencies establish drug indications, i.e medical conditions for which a specific drug should be used, and thus have full power to regulate the dosage, to change the conditions of use and to issue warnings.

The publication of research outcomes in scientific journals means they will turn up in future literature reviews and be integrated into meta-analyses, which will influence guidelines as well as good practice guides.

- **Meta-analysis** consists in combining the results of literature reviews and various studies, including clinical trials, which focus on a given problem. It takes time and complex statistical analysis to compare clinical trials isolated from one another and based on different protocols. The portrait that emerges will provide a summary and give a more accurate indication of the current state of research outcomes as well as, possibly, challenging generally accepted conclusions.


\(^{248}\) STATISTICS CANADA, Science Statistics - Estimates of Total Spending on Research and Development in the Health Field in Canada, 1989 to 2006, 88-001-XIE, Ottawa, 2007, 19 p. The figures on research undertaken in universities included sponsored research, which the Commission considers as private-sector research.
Limitations of Evidence

Evidence from clinical trials

Evidence from clinical trials is established using rigorous methods, and is peer-reviewed, approved by research ethics committees and validated by government agencies. Such evidence meets the scientific criteria of objectivity.

Such evidence, however, is subject to a significant limitation: clinical trials are the main sources of evidence, through their direct results and their use in meta-analysis, yet the conditions in which clinical trials are undertaken bear very little relation to reality, in several different respects.

First, in clinical trials, groups consist of a small number of people, which may affect the accuracy of the results of statistical analysis. Second, those recruited in the studies are not fully representative of the target population. For example, polymedication and comorbidity, as defined in each research protocol, are exclusion criteria, whereas in reality, these situations regularly occur in the general population. Third, few participants in clinical trials are minors (especially young children) and pregnant women. There are obvious reasons for the rarity of participation of these groups, in terms of consent and safety, yet this complicates the clinical decision to prescribe the drug and determine the appropriate dosage for these groups. Fourth, trials take place over a period of time which often depends on the clinical use to be made of the drug. Another element worth considering is that people generally respect the requirements for treatment (greater compliance) in clinical trials more than they would in reality. They also receive more frequent medical follow-up than they would in an actual clinical setting. Fifth, clinical trials produce a multitude of data which are hard to analyse on account of frequent major methodological problems.

As a result, the outcomes of clinical trials cannot easily be transposed onto a large population, which does not itself fulfil the conditions that prevailed during trials. This observation does not mean that drugs tested and made available to the public are ineffective. Instead, it serves to underline the fact that outcomes from clinical trials show above all the theoretical efficacy of medications. If a statistically significant difference exists in relation to an existing drug or a placebo, this higher efficacy is not always observed in the clinical setting.
Evidence from meta-analysis

Evidence from meta-analysis is faced with two limitations: the selection bias of publications and levels of evidence.

Selection bias arises when there is no obligation to publish clinical trial outcomes, particularly negative trial outcomes.\(^{252}\) Indeed, the choice to publish or not is up to the researcher, the pharmaceutical company as well as the publishers of scientific journals. Recently, this selective publication of outcomes was highlighted in the case of certain antidepressants. As a result, clinicians and policy makers do not have access to all scientific information. Of course, government agencies such as the FDA and the HPFB have the information, but for a team of researchers, the tasks of extracting and analysing it are laborious and complex. There is reason to think that the scientific literature available to researchers and clinicians does not necessarily reflect the full picture.

The second limitation is the level of scientific evidence of studies used in meta-analysis, ranging from anecdotal evidence to rigorous methodology. For example, literature reviews, observational studies, clinical trials, cohort studies and case studies do not all reflect the same level of scientific evidence.\(^{253}\) Thus, the relevance of meta-analysis depends partly on the types of studies on which they are based.

Accordingly, evidence provides a useful and verifiable foundation for medical practice and the development of guidelines and policies. But it is important to remember that two different realities are being described: a research context under controlled conditions and the more complex reality of the clinical setting.


\(^{250}\) Ibid., p. 27.


\(^{252}\) Chapter 1, sub-section The Media: Information and Critical Space – Scientific Journals provides more detail about this situation.

Psychotherapeutic Drugs: the Consequences of an Uncertain “Risk/Benefit” Ratio

The first important consequence to note involves medication adjustment. During a medical consultation, a psychotropic drug is prescribed with a dose generally based on the minimum recommended in the drug monograph and practice guidelines. Factors such as age, weight and symptoms are also taken into account in determining the dose.

If the expected benefits are slow to accrue or if adverse drug reactions persist, the explanation may lie in various factors, including slow action of the drug, inadequate dosage (too low or too high), interactions with medications or non-drug products (for example, antioxidants, vitamin supplements), poor compliance or the inappropriateness of the drug for that individual. The result can be a process of “trial and error” involving prescribed molecules or the dosage administered. The difficulty of finding the most appropriate medication and the appropriate dosage increases in the cases of children, pregnant women and those already taking other medication, given the lack of theoretical (evidence) and clinical data.

Once the appropriate drug and optimal dose are determined, it is necessary to estimate the duration of treatment and therefore the time when it will cease. However, practice guides and psychotropic prescribing guidelines are not specific in this regard. Indeed, they indicate the pathologies targeted by psychotropics, but are unclear as to when to cease drug therapy. Professional judgment comes into play, but in a context of great uncertainty, given the absence of studies on the long-term effects of psychotropic drugs.

On the other hand, clinical practice combines the health-care professional's experience and the systematic analysis of clinical observations, in a reproducible and unbiased manner. The appeal for a degree of subjectivity and professional judgment gives a dynamic character to treatment. Guidelines, monographs and clinical trials may not take into account the full complexity of clinical cases, or the uniqueness of the individual seeking medical attention. Indeed, the assessment of risks and benefits is not the same for all individuals and the pathology involved. It is therefore important that the clinician maintain flexibility.
Finally, the “risk/benefit” ratio associated with psychotropics leaves room for manoeuvre, opening the way to uses not foreseen by Health Canada. Approved medical indications for each drug are based on evidence. Thus, any use that does not comply fully with this evidence is, by definition, an off label use; however, such new uses may gradually be justified on the basis of experience and professional judgment. This openness to new medical indications in the clinical setting means that a given drug continues to be used in healing and the relief of illness, but it can also be used to enhance performance or to respond to non-therapeutic requests. These expanded uses are the focus of the next chapter.
Chapter 3

THE EXPANDED USES OF PSYCHOTROPIC DRUGS

It is difficult to determine whether a particular use of psychotropic drugs is called for or not. Indeed, the justification behind use is related to the individual, the context and the drug itself. Given aspects of the individual situation, such as health status, age, culture and social environment, each situation should be analysed case by case. However, sometimes the motivation underlying use is far removed from recognized medical use and aims to enhance performance in educational, work or sports settings, or to manage difficult personal situations. This chapter seeks to define expanded uses of psychotropic drugs, their respective rationales and some of their impacts on Quebec society; these elements in turn will be make it possible to identify the ethical issues arising from expanded uses.

EXPANDED USES: REFINING THE CONCEPT

There are several expressions for designating uses not recognized by the regulatory authorities or which are in the grey zone of the “health-disease” continuum, although these expressions do not all refer to the same reality: off-label medical use, non-optimal use, expanded use, misuse. In this position statement, the Commission prefers the term “expanded use”, understood as that use made outside of established practices and combining medical and social dimensions.

Strictly speaking, expanded use goes beyond the medical indications established by Health Canada when licensing a drug. However, in the clinical setting, it is quite common that uses do not comply fully with approved indications. It is important to remember that indications are determined as a result of clinical trials; however, clinical practice responds to the needs of people who do not necessarily fit the pattern of clinical trials (these latter being conducted in a limited number of people who do not necessarily represent the population targeted for the medication under study). For example, most prescriptions given to children and pregnant women are based on established practice. In concrete situations, the physician’s professional judgment guides the decision to prescribe the drug or not.
It should be noted that clinical practice is consistently ahead of changes to approved indications. Indeed, once a drug is licensed, its use on a larger scale and on people with multiple health profiles can produce effects not detected during clinical trials. These unexpected effects and the new uses arising from them can be very positive, since “off-label prescription or deviating from guidelines has been the basis for important innovations in clinical practice.” Ultimately, new medical indications can be recognized by Health Canada, and these uses will therefore no longer be considered “expanded.” Thus the range of recommended uses for a drug widens. For example, antidepressants are no longer applied solely in cases of major depression. These drugs are now also used for anxiety disorders, neuropathic pain (related to the CNS and the nerves), smoking cessation, premenstrual syndrome, and for unrecognized purposes during sleep disturbances, headaches and fibromyalgia.

Moreover, the increase in diagnoses of mental illness and in psychotropic prescriptions raises questions. These increases may actually be biomedical in origin. For example, they may be due to more precise or faster diagnosis, or to newly approved medical indications. An additional explaining factor may be that medication is an easily accessible solution that seems relatively inexpensive, requires little effort and can be taken quickly.

Other cultural and social trends are also involved. For example, resorting to medical care as a result of certain life events or personality traits influences diagnosis or the decision to prescribe. The increase in prescriptions may also be the consequence of the low tolerance of individuals or people around them to psychological suffering or so-called disturbing behaviours, such as sadness, anger or agitation. Finally, this increase may be associated with performance-related uses: memory, attention, in order to avoid feeling tired, etc.

Given the multiple factors and motives underlying the use of psychotropic drugs, it is unlikely that a consensus definition of expanded use will be reached. The Commission nevertheless makes two observations based on its reflection. First, using psychotropic drugs for clearly non-therapeutic uses (such as performance optimization, recreational use and increased resistance to fatigue) highlights the reality of expanded use. Second, the motivations underlying expanded use have different purposes: improving interpersonal relationships, performance, personal well-being, mental abilities, etc.
Enhancement and Meliorism

The desire to improve the human being is age-old, although the way of bringing about improvement changes with the times. For example, the Greek philosopher Aristotle calls on the human being to improve himself by emphasizing virtue and the attainment of the good life, which are not natural to human beings.²⁵⁸

The contemporary concept of meliorism developed during the late 19th and early 20th centuries, an era characterized by optimism and the positivist doctrine of progress. According to this doctrine, human efforts, when properly thought out and directed, can improve the world. Under the influence of scientific discoveries, meliorism incorporated advances in medicine and biology. Taken to the extreme, it led to the ideology of eugenics, which sought to eliminate genes considered undesirable, and possibly to sterilize or even eliminate individuals carrying these genes, thus constituting a “biological” form of improvement of the human species.

Nowadays, thanks to psychotropics, it seems easier to live “better than well.”²⁵⁹ The availability and accessibility of psychotropic drugs, whose effects can enhance the capacity of healthy individuals, in fact open up new horizons for the development of our natural capabilities and the presence of “character traits that we do not wish to have and against which we are fighting [...] because they darken our relationship with ourselves as well as with others.”²⁶⁰

Some neuropharmacological advances encourage the increasingly “biological” kind of meliorism and, despite the lack of information on the long-term risks to users, there is public demand for enhancement-related drug use.²⁶¹ For example, a current conceptualization of enhancement associates it with the goals of performance and self-realization, and does not exclude using psychotropic drugs as a means of attaining these goals. Transhumanist and posthumanist ideologies have developed along the same line of thought. For their proponents, the human being is constantly evolving and can and should use existing technologies to overcome his biological nature and improve his natural capacities through gene therapy, bio-informatics, psychotropic drugs, nanotechnology, etc.²⁶²
TWO CATEGORIES OF EXPANDED USES OF PSYCHOTROPICS

Two major categories of expanded uses emerge from medical sources and social sources. These categories are not independent of each other. Several stakeholders and contextual elements are common to both categories. In addition, scientific research and applications are guided by standards which are culturally determined. The medical context exists within a social context, and in turn modifies this social context. Separating the two would have the effect of diminishing the currency and strength of interrelations. However, the two categories are distinguished one from the other for the purposes of demonstration and discussion.

Expanded Uses of the “Medical” Type

Expanded uses of the “Medical” type occur in a context of professional practices that contributes to the expanding uses of psychotropics. For example, scientific uncertainty due to lack of knowledge about the brain, the roles and interactions of neurotransmitters and the modes of action of psychotropic drugs in turn provides conditions for use outside of approved indications. Similarly, Quebec’s non-optimal health-care network means it is difficult to do medical and non-medical follow-up with people who have mental health needs. Finally, the emphasis on the concept of prevention plays a role, especially if a development or negative consequences for the individual are anticipated – mental health problems, relationship difficulties, damage to self-esteem, etc.

This section focuses on expanded uses of the “Medical” type, on their context and on some of their consequences. The section will discuss determining a mental health diagnosis, the concepts of “therapy” and “enhancement”, the factors influencing the prescribing practices as well as the consequences, whether positive or negative, of these expanded use types.

The Difficulty of Mental Health Diagnosis

Physicians need to make a diagnosis, for medicine to be prescribed. However, it is very hard to establish a mental illness diagnosis.

Given their various etiologies, it is harder to detect mental disorders on an objective basis than physical disorders, as has been noted in the case of ADHD by the Collège des médecins du Québec and the Ordre de psychologues du Québec: “As is the case with mental health diseases or syndromes, there is no biological marker for the diagnosis of ADHD; diagnosis is based on observing a set of behaviours.” In this way, diminished memory in an elderly person or behavioural problems in a young child do not result necessarily from a pathological condition, but may result in the first case from normal aging and in the other, from environmental conditions (familial, social, economic). Similarly, changes in a normal person’s mood or behaviour could be regarded as psychological symptoms and be treated medically.
In making a diagnosis, physicians and psychologists refer to the presence of symptoms that are graded on a scale of intensity. They then establish their diagnosis using one of the two main reference works in mental health, the *Diagnostic and Statistical Manual of Mental Disorders IV-TR* of the American Psychiatric Association (APA), and the *International Classification of Diseases 10th Revision* ([ICD-10, 1992 and implemented in 2006 in Quebec)] of the World Health Organization. Significantly, ICD-10 and DSM-IV-TR may differ in their diagnostic criteria, which demonstrates both the complexity of mental disorders and the influence of cultural settings, as for example in the case for ADHD or dementia.\(^{265}\) In North America, the DSM-IV-TR classification is the most commonly used.

**The Diagnostic and Statistical Manual of Mental Disorders (DSM)**\(^{267}\)

The DSM is a reference manual used worldwide to diagnose psychiatric and psychological disorders. Published by the American Psychiatric Association (APA) for the first time in 1952 (DSM-I), it has evolved in the light of medical practices and advances in research. The current version, DSM-IV-TR (2000), constitutes a minor revision of the DSM-IV (1994).

DSM is an analytical framework that assesses the presence of mental illness from a bio-psycho-social perspective. To this end, the assessment consists of five main areas (which are divided into categories and subcategories):

- **Axis I** – Clinical disorders or other conditions that may be subject to clinical examination (such as relationship problems, excess food, simulation in a medical-legal context)

- **Axis II** – Personality disorders and mental retardation

- **Axis III** – General medical conditions (physical health)

- **Axis IV** – Psychosocial and environmental disorders

- **Axis V** – The overall assessment of functions.

Axis I lists the symptoms described by the individual or observed by a health and social services professional. The subsequent axes examine dimensions to be considered as the possible causes and aggravating factors of symptoms. Diagnosis combines results from examination and quantitative assessment (e.g., in axis I, it takes at least six symptoms from a list of nine for the professional to consider making a diagnosis of inattention).
The transition from DSM-II to DSM-III led to profound changes in the conceptualization of mental and neurological diseases. A paradigm shift occurred: from the traditional approach which called for a primary diagnosis, and was strongly influenced by psychoanalysis and causes, DSM-III has favoured an approach more focused on specific symptoms; however, these symptoms can found in several diagnostic categories. This approach is supposedly atheoretical, i.e. based on facts (symptoms and quantitative assessment) rather than on a theoretical framework. Thus, with DSM-III and DSM-IV, a psychiatrist and a psychologist behaviourist can reach the same diagnosis. However, according to some researchers, presenting DSM-III as atheoretical and promoting neutrality about possible causes of mental illness diminishes the meaning of the symptom itself. Indeed, the symptom arises in a relational and socio-cultural context which should be considered when determining treatment. Finally, DSM-IV-TR states that the concepts that define the mental disorders are, *inter alia*, “distress, dysfunction, dyscontrol, disadvantage, disability, inflexibility, irrationality, syndromal pattern, etiology and statistical deviation.” These concepts are hard to define clearly and objectively. Furthermore, the last criterion – statistical deviation – denotes less a diagnosis than a relationship with a norm and normativity that are constantly changing; in this sense, it contains “a promise of perpetual adjustment.”

The emphasis on symptoms also poses practical difficulties. First, the way symptoms are set out varies from person to person. Resistance to pain, fear of stigma, lack of vocabulary, comorbidity and the relationship of trust with the health professional are all elements that come into play in the recognition and formulation of symptoms. Second, a symptom may occur in more than one mental or neurological disorder. For example, aggression can be found in depression, alcoholism, dementia and schizophrenia. Third, a disease may have a multi-factorial etiology, i.e. it may be caused by the presence of several biological social and environmental factors. These factors can lead to symptoms of varying degrees of severity, which can be noted on an objective basis or not besides, some symptoms are not treatable by pharmacology. The choice to treat or not should take the whole context into account.

Mental health diagnosis may therefore be difficult to establish, especially for general practitioners. To overcome this difficulty, several practitioners formulate a “diagnostic impression” rather than a diagnosis. However, this impression is of little help, given that the physician needs to answer several crucial questions: does the individual suffer from mental illness or not? If so, how severe is the illness? What treatment should be offered?

265 MÉOS, op. cit., p. 32.
266 DEROUESNÉ, op. cit.
270 Ibid.
272 OTERO, op. cit., p. 76 (our translation).
273 COMITÉ DE TRAVAIL SUR LA SANTÉ MENTALE DES JEUNES SUIVIS PAR LES CENTRES JEUNESSE, op. cit., p. 10 (our translation).
These problems, coupled with the importance of professional judgment and a certain degree of subjectivity, are real, as is shown once again by the example of ADHD:

In practice, the number of children and, more recently, of adolescents and even of adults labelled with ADHD is growing, because of the great variability in the use of diagnostic criteria. In fact, the prevalence of ADHD varies considerably, on account of cultural diversity and the different methodologies used in studies.274

Therapy or Enhancement?
Given the suffering and hardship experienced by people with a mental or neurological disorder, the difficulties of diagnosis should be kept to a minimum. In this respect, new psychotropic drugs which cause less severe negative side effects give physicians additional flexibility. Indeed, when a physician is faced with diagnostic doubt, it may be more appropriate to prescribe a new generation psychotropic drug – resulting in less severe adverse drug reactions. Accordingly, the degrees of severity of symptoms for which medication is administered tend to decrease.275 In turn, lower diagnostic thresholds of these diseases could also help transform a condition previously considered “normal” into a condition which has become “medical.”276

Psychotropic medications with lesser adverse drug reactions are opening up new possibilities, and this in turn highlights the need to distinguish between therapy and enhancement. Therapy aims to prevent or heal a known or anticipated health deficit in a person, i.e. a recognized medical condition or physiological dysfunction. Enhancement seeks to boost a function beyond a person’s usual capacity, without any dysfunction being identified.277

The difference between “therapy” and “enhancement” usually lies in the grey zone of the “health/well-being-disease” continuum, and a significant conceptual difficulty arises at this juncture: how is one to draw a distinction between an enhancement and a treatment? A narrow definition of the term “enhancement” is of little use, partly because the concepts of disease and health are linked on the continuum and are part of a cultural and historical context, which is based on compromise and social values. Accordingly, the meaning accorded the term “enhancement” varies considerably, depending on the value system(s) in place. The meanings ascribed to a single reality may be articulated within a single society, particularly a pluralistic society like Quebec’s.

However, on the practical level, a modus operandi lies in “determining an optimal state, which varies according to time and place, and then intervening based on normal functions.”278 The question of what is normal is therefore central to the concept of enhancement: the attempt to enhance a function is related to personal or social criteria. Noting this fact, however, does not answer the question: enhanced compared to what? Or in relation to whom? As a result, in clinical practice, the unique character of each individual, professional judgement and other factors entering into the decision mean that what will be a therapy for one person will be an enhancement for another.

The concept of enhancement can also be confused with that of prevention. By enhancing a cognitive function that is functional or a behaviour deviating from certain norms, one may avoid what are considered more harmful consequences, such as difficulties at school, negative evaluations in a professional setting or stigmatization by one’s peers. In these situations, some people invoke prevention instead of meliorism.
In addition, the line between enhancement and therapy is blurred by the literal interpretation of WHO’s definition of health (“Health is a state of complete physical, mental and social well being and not merely the absence of disease or infirmity”),279 which has inspired definitions used by Quebec and Canada. Indeed, the notions of “well-being” and “completeness” are hazy, so it is relatively easy not to feel in the best of health.280 Thus, an intervention for the purposes of enhancement could be presented as therapeutic if it served to ensure an individual’s well being.

These elements can, on the one hand, give rise to new demands on the part of individuals and, on the other, justify physicians in seeking the welfare of people and in responding to the patient’s expectations – whether those expectations are real or are perceived as such by physicians.

Some Factors Involved in Prescribing Practices

The Commission has taken a special interest in four factors likely to influence the prescribing practices of physicians, namely the limits of knowledge about psychotropic medications as well as mental and neurological illness, the influence of the pharmaceutical industry, the organization of the health and social services system, and patient demand.

The Limits of Knowledge about Psychotropic Medications as well as Mental and Neurological Illness

Guidelines and Clinical Practice

In general, guidelines and good practice guides are based on evidence. However, the evidence itself is drawn from clinical trials which take place in contexts replicating little of everyday reality and of the unique character of individuals. As a result, evidence and evidence-based standards are not always very useful in medical practice, a situation the director of the National Institutes of Mental Health in the United States described as “the unfortunate state in psychiatry [...] where too many research studies have little immediate relevance to practice, and too little practice is based on research evidence.”281 Other clinical researchers reach the same conclusion: “In the era of evidence-based medicine, the scarcity of high quality evidence for mental health is striking. Mental health practitioners often cannot obtain useful information to guide their clinical decisions.”282

274 COLLÈGE DES MÉDECINS DU QUÉBEC and ORDRE DES PSYCHOLOGUES DU QUÉBEC (2001), op. cit., p. 4.
275 POST, op. cit., p. 2.
276 Ibid.
277 BMA, op. cit., p. 5.
278 BAERTSCHI, op cit. (our translation).
279 Underlining by the Commission.
280 OTERO, op. cit., p. 68.
282 SHUCHMAN and HÉBERT, op. cit., p. 1257.
Scientific Journals

Scientific journals are the main source of evidence and information for health professionals. Their credibility and independence are values crucial to the current system of scientific information.

However, journals are not immune to fraud or publication bias, which may in turn affect their reputation and diminish the confidence of their scientific readers, as is demonstrated by the case of the virtual absence of studies showing negative results discussed previously.\(^{283}\) Even so, there is a need for the knowledge arising from publication of all studies, since a negative result in itself is a source of information. In addition, access to this information prevents the repetition of the same experiences – resulting in gains of valuable time and money for researchers – and providing policy makers and clinicians with more complete information for the approval of medical indications of a given drug.

It is therefore important to remember, first, the importance of reliable and comprehensive information and, second, the need for control mechanisms as a way of ensuring reliability.

The Influence of the Pharmaceutical Industry

The use of advertising and promotional items as well as the use of sales representatives are excellent promotional tools. These are recognized techniques, found in all spheres of trade in goods and services. However, certain practices raise questions, some of which are discussed below.

The Scale of Investments in Promotion and Marketing

Data on corporate spending on sales and marketing are difficult to obtain and analyse. The greatest amounts of data have been collected in the United States. The main sources of information are financial statements, the reports of associations and of IMS Health, a firm specializing in pharmaceutical marketing and recognized as a credible source.

As discussed in chapter one,\(^{284}\) the sums invested in 2004 in sales and marketing services were almost equivalent to those invested in R&D. Quebec and American researchers have analysed publicly available data and have come up with a different interpretation of the situation.\(^{285}\) Taking into account other promotional costs, the promotional activities of pharmaceutical companies amounted to US$57.5 billion, almost double the amount allocated to the R&D.

Canadian and Quebec data are not available, but there can be little doubt about the reality of promotional activities targeting drugs, because this phenomenon is observed at the international level and pharmaceutical companies are multinational entities present here and elsewhere in the world. There is reason to believe pharmaceutical companies accord great importance to sales and promotional activities, but the Canadian context is different from the American context in two main respects. First, direct advertising in Canada is strictly regulated, which in turn has the effect of limiting the content of messages and possibly also the sums allocated to advertising. The second difference relates to industry associations of pharmaceutical companies. In the United States, pharmaceutical companies are brought together within PhRMA, an association which has developed guidelines and statements of principles relating to clinical trials and marketing practices.\(^{286}\) In Canada, the national association Rx&D brings together more than fifty companies involved in pharmaceutical research and development and representing 90% of drugs currently on the market, and has also developed a code of ethical practices.\(^{287}\) This self-regulatory normative framework is not immune from criticism but it testifies to a desire to scrutinize the professional activities of association members. In the event of non-compliance with established rules, the code provides for penalties ranging from fines to expulsion from the association.
The Impact of Promotional Activities on the Provision of Therapies

Most promotion and marketing expenses target physicians; promotional activities consist for example of sales representatives visits to physicians in private practice and in public facilities, the distribution of free samples, continuing education seminars and advertising in medical journals.

However, relationships between health professionals and the pharmaceutical industry are two-fold in nature. On the one hand, codes of ethics require that health professionals should not enter agreements that would jeopardize their professional independence.288 On the other hand, pharmaceutical companies invest time and money on promotional activities in order to obtain tangible results.

It is well-known that some health professionals may be subject to pressures on their professional practices, including their decision to prescribe (or not) and the choice of medication prescribed. For example, according to a Quebec study, physicians pointed out that pharmaceutical companies exert pressure on them to increase sales of their products and that these practices are exacerbated by a context of strong competition, which increases the influence of these companies on physicians.289 Another study describes different types of contacts and activities organized by pharmaceutical companies in order to reach physicians from the time of their university training onwards, and then through continuing education and their research activities (mainly clinical trials).290 Finally, in a literature review analysing the results of 29 studies on the relationship between physicians and the pharmaceutical industry, the author established some detailed aspects of these relationships.291 These relationships start at the time of academic training and continue on a monthly basis throughout professional practice. Visits by pharmaceutical representatives are perceived as requests to modify prescribing practices and to adopt new drugs in the facility where physicians practice. Sponsored continuing education also focuses more on drugs by sponsoring companies than on other drug treatments.

The influence of promotional activities on the availability of therapies is therefore discernible at two levels. The first consists in favouring certain drugs at the expense of other potentially effective and/or less expensive drugs. The second consists in promoting drug treatment potentially to the detriment of other possible forms of therapy.292

Pharmacists are also targeted by promotional activities of pharmaceutical companies. However, while physicians are the main customers of research-based companies, pharmacists are the clients of generic drug companies and wholesalers.293 In this respect, the Quebec Drug Policy has set a cap on professional allowances294 given to owner pharmacists. The cap currently stands at a maximum of 20% of the value of sales of each manufacturer.295

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283 See Chapter 1, section The Media: Information and Critical Space.
284 See Chapter 1, section The Pharmaceutical Industry: R&D and Financial Interests.
285 GAGNON et LEXCHIN, op. cit.
286 For more details: http://www.phrma.org/principles_and_guidelines/.
288 For example, according to the Code of ethics for physicians: “A physician may not be party to any agreement or accept any benefit that could jeopardize his professional independence, particularly in the context of continuing medical education activities.” (R.S.Q., chapter M-9, r.4.1, art. 80).
289 GARNIER and MARINACCI, op. cit., p. 197.
292 LEXCHIN, op. cit., p. 1450.
294 “A professional allowance is a reduction as a discount, rebate or premium, good, service, gratuity or any other benefit granted, paid or provided, directly or indirectly, by a generic drug manufacturer to an owner pharmacist” (Regulation respecting benefits authorized for pharmacists, chapter A-29.01, r.1.01, art. 2). These amounts are used to cover current expenses related to operation of a pharmacy and to services offered to the public.
The Organization of the Health and Social Services System

Some items related to the current organization of the health and social services network have been referred to in a previous chapter, including the shortage of staff for several occupational groups in health and social services.

Other organizational factors also contribute to expanded uses of psychotropic drugs. For example, general practitioners provide care for the majority of cases of mental illness. However, the complexity of these pathologies and the difficulty of establishing diagnosis imply a pressing need for knowledge and clinical expertise which may prove insufficient.

Next, the silo structure of various different components of the health and social services system makes it more difficult to do patient follow-up. By favouring isolated professional contacts to the detriment of a continuum of care and an integration of services, this organizational model does not allow for optimal access to a range of services (diagnosis, monitoring, drug compliance, different skills of health professionals and social services, etc.) and creates conditions for expanded uses. For example, the Collège des médecins du Québec and the Ordre des psychologues du Québec make the following comment about the use of Ritalin®:

"Use of this drug is often denounced by the media and is seen as an “institutional pill” prescribed as a way of compensating for gaps in the follow-up of these children, whether on the medical or the educational level, and for the lack of resources that would enable combining several methods of intervention."

It should be noted that this situation is changing. New models of care based on multidisciplinary teams or networks of institutions are growing in Quebec and are improving the accessibility and continuity of care required by people with particular mental or neurological illnesses.

Patient Demand

The Commission wishes to stress this aspect, which has already been described in chapter one, but is too often ignored.

In general, the values of “autonomy” and “self-care” and “taking personal responsibility” are promoted by the media and social organizations. Even before consulting a health professional, an individual has access to abundant sources of information: television, the Internet, books and periodicals destined for a scientific readership or for the general public, advertisements, etc. The information available stresses the importance of health and prevention, which are in turn promoted by public health stakeholders and the media. Similarly, the promotion and marketing activities of pharmaceutical companies also aim to influence people.

Thus, the individual appearing before a health professional – a physician, nurse, psychologist, social worker, pharmacist, etc. – may have made up his mind in advance or have specific requests. In a context of relationships and medical follow-up, the health professional is not “impervious” to these requests, or even pressures. As a consequence, the therapeutic relationship undergoes an adjustment, and responsibility is now shared: although the health professional cannot of course opt out of the relationship, the individual now shares in responsibility.
The Consequences of Expanded Uses of the “Medical” Type

The demonstrated benefits and risks of psychotropic drugs were discussed in the second chapter. This subsection focuses on expanded uses of psychotropic drugs of the “Medical” type, and describes the main anticipated benefit, namely the advance of knowledge, as well as four potential consequences: the accessibility and quality of care, risks for individual safety, the trivialization of psychotropic drugs and the role played by physicians in meliorism.

The Advance of Knowledge

The main anticipated benefit expected is the discovery of therapeutic purposes that were not foreseen at the time of Health Canada's drug approval. This is already a well-known fact in the medical community. It should be remembered that clinical guidelines and good practice guides do not take into account all conditions of life and health in the existing population. Positive effects may emerge from clinical use, which were not foreseen initially. Subsequently, clinical studies and additional analysis may support these empirical advances with an evidence base.

Accessibility and Quality of Care

Expanded uses of psychotropic medications may create a vicious circle: a medical consultation is a precondition for a person (potentially) to get a prescription. In a context where the health and social services network is hardly able to meet demand, health professionals could promote a drug therapy “by default” so as not to leave people without care. As a result, human resources allocated to consultations and follow-up would have an even harder time meeting demand, and so forth. And, paradoxically, the increase in consultations could result in less screening and inadequate follow-up for users already diagnosed with mental and neurological illnesses. Human resources devoted to consultations and follow-up would be even less sufficient to meet demand, and so on.

Expanded uses also result in an increase in the prescription of psychotropic medications, which in turn affects the viability of the network. Indeed, whether they are reimbursed by public or private drug insurance plans, the greater use of these drugs creates a financial burden which will have to be borne by society.

As a result, expanded uses of psychotropic drugs lead to consequences for the health and social services network. They increase human and financial pressures, inhibit access to care and services and could undermine the idea of a basic basket of health and social services offered by the health-care system.

Risks to Individual Safety

Given the broadening of diagnostic thresholds of several mental and neurological diseases and the increase in approved medical indications for psychotropic drugs, the scenario of increased use of psychotropic drugs is plausible. In addition, as the use of psychotropics increases – based on the volume of drugs per user or on the overall number of users – the prevalence of adverse reactions and drug interactions in a context of polymedication or of simultaneous non-drug products also risks increasing.

297 KIRBY and THE STANDING SENATE COMMITTEE ON SOCIAL AFFAIRS, SCIENCE AND TECHNOLOGY, op. cit., p. 128.
298 ROMANOW COMMISSION, op. cit., p. 119.
299 COLLÈGE DES MÉDECINS DU QUÉBEC et ORDRE DES PSYCHOLOGUES DU QUÉBEC (2001), op. cit., p. 5 (our translation).
301 On this subject, see Chapter 1, section The Individual: Citizen and Patient.
302 For more details, see Chapter 2, sections Demonstrated Benefits of Psychotropic Drugs and Demonstrated Risks and Side Effects of Psychotropic Drugs.
The risks associated with benzodiazepines, used as anxiolytics and sedatives, and with antipsychotics are well known; risks associated with other psychotropic drugs are less well known. According to the knowledge base on benzodiazepines, two types of risks in particular attract attention, namely workplace safety and traffic safety:

- **Work Safety** - The risk of workplace accidents is likely to increase and affect the health of workers and, possibly, also that of their colleagues. Repercussions can also be expected for the employer, due for example to absenteeism, and for Quebec society, through compensation paid by the Commission de la santé et de la sécurité du travail (CSST).

- **Traffic Safety** - The risk of traffic accidents involving automobiles, trucks, bicycles, four-wheel scooters, etc. – may also increase, placing at risk the health of the driver, passengers and bystanders. The costs associated with these injuries should not be overlooked, including hospital expenses, compensation paid by the Société de l'assurance automobile du Québec (SAAQ) and wage losses related to absenteeism.

In short, the risks to individual safety stemming from the use of psychotropic drugs are likely to affect individuals, and also lead to consequences at the collective level.

**Trivialization of Psychotropic Drugs**

There are unequivocal situations where mental disorders can be diagnosed; however, in the grey zone lying between the two poles of the “health-disease” continuum, it can prove hard to characterize an individual’s mental health. In this context of uncertainty, the possibility of “overdiagnosis” of mental and neurological diseases is ever-present. The increasing prevalence of these disorders may result in an increase in prescriptions, since these diagnoses are often associated with psychotropic prescriptions.

Also, in a context of diagnostic uncertainty, and given the daily disruptions experienced by people with mental disorders, the fact of establishing a diagnosis and prescribing a psychotropic drug may be clinically justified. There exists a risk of medicalizing life events that are unpleasant, stressful or painful, but inevitable in the course of life, whereas those events do not necessarily belong to the field of medicine.

However, the fact a medical diagnosis has been made may change an individual’s perception of the gravity of his situation. When an expert establishes that a mental health state is problematic, the implication is that illness is involved. When the expert proposes that a patient take medicine, this has the effect of legitimizing treatment. This in turns diminishes the importance of the role played by the individual in his own life, for example in using personal resources to cope with life events and to develop critical thinking, since the prescription of psychotropic drugs justifies their use.

**The Role Played by Physicians in Meliorism**

When a person’s cognitive or mental capacities are functional or correspond to non-pathological physical conditions, then one may speak of prescription of psychotropics as expanded use for the purposes of enhancement. For example, age, stress, and fatigue due to long working hours are factors explaining variations in mood and cognition, without however constituting symptoms of disease. In these situations, prescribing psychotropic medications means the physician is expanding the boundaries of the traditional therapeutic relationship.

Several reasons may explain why physicians assume this role. Some have been discussed previously, including the lack of time for consultations and follow-up, and the method of billing fees for service, favouring a greater number of services. This may also be a way for physicians to maintain contact with their patients, provide valuable information and better control their use of psychotropics. In such a relational context, physicians are sensitive to the demands of patients and people legally responsible for others (parents, curator, tutor), which may influence their decision to prescribe or not. Also, at the individual level, physicians operate in a social context where they are required to perform. They may in fact identify with this value personally.
However, in prescribing psychotropic drugs for non-therapeutic purposes, physicians are contributing to the current trend of meliorism and performance as well as to the trivialization of drug use.

**Expanded Uses of the “Lifestyle” Type**

Often called “lifestyle drugs,” some psychotropic medications have effects favouring their use to meet social expectations – performance, productivity, health, “youth”, rapid change. However, using drugs in order to match a lifestyle and fulfill its underlying values is completely different from using drugs in order to heal people diagnosed with mental or neurological illness. There is little ambiguity about “Lifestyle” type uses: they are related to meliorism, confirmism or recreation.

This section discusses expanded “Lifestyle” uses, their context and some of their consequences. Several aspects will be discussed, namely the concept of “normality”, examples of using psychotropics for “Lifestyle” purposes, factors involved in individuals’ life choices as well as the consequences, whether positive and negative, of this type of expanded use.

**Towards a Redefinition of Social “Normality”**

Normality can be understood as the statistical concept of “normal distribution”. According to this concept, the characteristics of a given population can be mathematically distributed, and illustrated by a symmetrical bell-shaped curve where the mean is found in the centre. The mean is a precise figure serving as a reference point: a person will be closer to or farther from the statistical mean.

Normality may also reflect a social or subjective decision. Behaviours deviating from social expectations are evaluated positively or negatively. As a result, “normal functioning” is a social question and subject to constant redefinition:

> Being a functional human is not a matter of biology, except indirectly, since the norms of functionality depend on how we live, which in turn refers to the social understanding of man and the understanding of the individual, in short to what it means for a human to be and to act like a human.

Thus, defining a disease and determining its importance in society depends not just on biological characteristics, but also on norms and values associated with it. Several groups of stakeholders take part in defining what constitutes a “disease”: health professionals, associations and professional special interest groups and charities, citizens, the media, pharmaceutical companies and different levels of government. Given that these stakeholders influence each other, it is hard to consider the particular contribution of each in isolation; by the same token, there is no reason to obliterate their roles and responsibilities.
From Normality to Normativity

"Normality" and "norm" are intimately linked: social or axiological normality ("axiological" means "value-based") may lead to a norm, i.e. to a statement describing what to do or to refrain from doing. Normative statements generally refer to a type of action, specifying what agents should or should not do and under what circumstances.111

In general, social expectations lead to norms that in turn translate into expected behaviours ("People only wonder whether someone has a normal brain when his behaviour is not").112 According to a Quebec researcher, "the norm is always a measure used for assessing whether something conforms to the rule [...] the norm derives its value from the tension between 'what poses a problem' and 'what does not pose a problem'."113 In Western societies, the tension residing in the concept of health is primarily interpreted through a biomedical lens, but this trend does not occur in isolation from the surrounding culture. One actually feeds on the other:

Drugs are in fact powerful instruments of socialization, and for some people of compliance, in societies characterized by mass individualism, in which there is a permanent requirement to adapt to rapid change and to social normativity focused on individual responsibility, continual performance and promotion of autonomy.114

If this “social normativity” has great resonance in society, then it may result in people being ostracized when they deviate from behaviour deemed inappropriate or, more generally, when they are judged to be less "efficient".

The Impact of Psychotropic Medications on the Concept of Normality

According to two researchers, the notion of "enhancement" can be broken down into three concepts: normalization, repair and performance edge.115 Normalization is involved when psychotropic drugs are used in order to achieve a statistical average or meet a socially expected standard; repair is involved when psychotropic drugs are used for the purpose of returning to a previous level of performance; performance edge is involved when psychotropic drugs are used to improve cognitive functions in the interests of sheer performance. This conceptualization of the concept of enhancement highlights the complex interactions between the society and the individual with respect to using psychotropic drugs for enhanced performance.

The space currently accorded to values such as performance and individualism tends to make individuals deviating from these values less acceptable. Although the values of performance, efficiency and improvement have been positive ones throughout history and in different societies, the fact they are perceived in idealized terms raises questions. What ought to be “a means to an end” has become an end in itself.

This normalization of conduct, mood, and the effects of aging may lead to social homogeneity.116 The definition of normality changes, when people use psychotropic medications in pursuit of certain standards or an ideal: if it is “normal” to use drugs for non-therapeutic purposes, then normality becomes a medicated normality. The resulting normalization increases social pressure to conform and makes the consumption of psychotropic medications seem more legitimate. The ensuing normalization increases social pressure for compliance,117 and gives an air of legitimacy to psychotropic drugs.
Some Psychotropic Applications related to Lifestyle

There is nothing new about the idea of resorting to drugs or biomedical technologies in pursuit of an ideal, whether in terms of physical appearance or performance. Sports doping is prohibited, but so-called "cosmetic" applications are legally available in Quebec: breast implants to increase breast volume, Botox® injections to remove age or smile wrinkles or to treat hyperhidrosis (which is manifested by immoderate underarm sweating), smoothing of the face (facelift) to remove the age-induced sagging of skin, and liposuction to remove fat cells.

Some effects of psychotropics are of particular interest to the pharmaceutical industry and manufacturers of non-medical products (such as natural products and homeopathic products). 318 R&D departments are increasingly focusing on the development of psychotropics with a view to enhancing certain cognitive and vegetative functions among healthy people, such as:

- **Maintaining and stimulating memory and cognitive function** constitutes a market destined to develop. People over 50 years of age naturally experience a certain reduction of memory and slowing of psychomotor functions. These people are more numerous and wealthier than before, are in good physical health, are active and are willing to maintain alertness. 319

- **Enhancing attention capacity and controlling fatigue** may interest large segments of the population. 320 The possibility of increasing attention or lessening the consequences of fatigue may interest several categories of people: young people in the school environment; people working in competitive jobs or on variable work shifts; people subject to time differences; or categories of employment that require long hours of work or sustained attention – such as health care, air traffic controllers and truck drivers, etc.

- **Stabilizing and controlling moods** may provide relief for some people. 321 Their social relationships and their ability to complete personal and professional projects would be strengthened. By the same token, people around individuals who display agitated or disruptive behaviour may demand that the latter individuals receive psychotropic drugs.

- **Reducing anxiety** would seem to appeal to many people. 322 Public speaking, engaging in an interview or entering into contact with others is not always easy. Many people are afraid of not finding the right words, having no ready answer or lacking know-how, seeming ridiculous, stammering or sweating.

311 OGIEN, op. cit., p. 1111.
312 BAERTSCHI, op. cit. (our translation).
313 OTERO, op. cit., p. 74 (our translation).
314 Johanne COLLIN et al., “Le médicament, entre science, norme et culture”, in COLLIN et al., op. cit., p. 3 (our translation). Pierre-Luc ST-HILAIRE writes along similar lines: “Plastic use [...] meets the individual’s need to adjust to social demands” (“De l’usage ‘plastique’ des antidépresseurs”, in COLLIN et al., op. cit., p. 124). According to Patrick LAURE, a French public health physician: “For about a decade now, the quest of performance, of productivity and of profitability translates into a demand of ‘everything, right now’ [...]. Doping behaviours are partly associated with this frantic race towards the immediacy of results.” (“Doit-on blâmer ou encourager les conduites dopantes?”, Éthique publique, vol. 8, no. 2, 2006, p. 64) (our translations).
315 Peter CONRAD and Deborah POTTER, “Human Growth Hormone and the Temptations of Biomedical Enhancement”, Sociology of Health and Illness, vol. 26, no. 2, 2004, pp. 201-202. The authors analyse the notion of enhancement in relation to the use of growth hormone; their analysis can be satisfactorily transposed onto psychotropics.
322 GLANNON (2008), op. cit., pp. 49-50; WALSH, op. cit.
Some Factors in Life choices

Without drawing up an exhaustive list, the Commission has identified three factors that influence expanded lifestyle-related uses: the influence of the pharmaceutical industry, the media and the Internet as well as the differences between psychotropic drugs and other CNS stimulants/depressants.

The Influence of the Pharmaceutical Industry

*The Impact of Promotional Activities on the Availability of Therapies*

Pharmaceutical companies have recognized the market growth potential of psychotropic uses for the purposes of enhancement. Consequently, they are investing large sums of money in sponsorship and advertising on their websites.

Promotion of a product is intended, among other things, to reinforce a positive perception about the product or to modify behaviour in order to promote its consumption. Concerning drugs, this promotion also increases the trend of medicalization and medicamentation. These two phenomena are subjects of debate in themselves, but it is clear that the promotion of drug therapies diverts attention from other forms of existing therapies and reinforces the perception that medicines are useful, even necessary, in painful but non-medical life situations.

*The Impact of Promotional Activities on Drug Prices*

Expenses for the sale and promotion of drugs are included in the price of drugs and are therefore paid by the people who buy them. According to one author, this has particularly been the case since 1997, when several restrictions on direct-to-consumer advertising (DTCA) of prescription drugs were lifted in the United States. The difference between Canada and the United States in terms of expenditure on prescription drugs per capita rose from CA$31 in 1995 to CA$356 in 2005, although the increase cannot be explained by demographic, economic or public policy factors. In the United States, this has had a considerable impact on the financial capacity of individuals, insurance companies and public systems.

The Media and the Internet

The media are major sources of information that generally present medications in a positive and uncritical light. Their programmes and advertisements promote an active lifestyle or the importance of health and youth, reinforcing the same compelling picture of life.

The Internet constitutes a particular case because it is so pervasive, is used on a regular basis, conveys an enormous amount of information and ensures the relative anonymity both of sources of information and of Web surfers. Information is transmitted on the Internet without regard to its truthfulness; while some Internet sites provide information of dubious quality, there are many other reliable sites. Indeed, scientific journals have developed websites where individual articles can be read or ordered online. There are more and more exclusively Internet-based scientific journals, some of which are peer-reviewed – which gives them the same credibility as their printed counterparts. Finally, dictionaries, encyclopaedias and independent research sites are also available on the Internet.

Pharmaceutical companies have also created their own websites and offer more information online than information provided in advertisements. These sites often include tools for self-diagnosis, with the proviso that individuals should consult a health professional.
The growth of Internet has more recently been accompanied by the emergence of cyber-pharmacies. These Internet-based pharmacies are banned in Canada but, given the characteristics of the Internet, the ban is easily circumvented. Their mode of action is well-known: they use spam, that is to say junk mail and advertisements sent to email addresses. These spam messages frequently offer medications relating to “Lifestyle” enhancements, for example proposing increases in breast size or ways to overcome baldness.

The current practices of cyber-pharmacies raise several concerns. First, the validity of the information presented on the benefits of medication and on manufacturing processes, if it is presented at all, is of an uncertain or questionable nature. Second, some sites offer consultations, without the individual being able to verify the qualifications of respondents, or tools for self-diagnosis. Third, medications do not necessarily satisfy requirements for manufacturing conditions in effect in Canada. Finally, consumers are not informed that the Canada Border Services Agency can seize all medications that are purchased abroad.

The Commission is concerned about the quality of scientific information accessible on the Internet and about the activities of cyber-pharmacies. It is also concerned that people may be influenced by this information and may decide to buy medicines or medical products without having sufficient knowledge or without obtaining advice from a specialist. Decisions are taken based on inadequate information, or even minimal awareness about the real and potential risks associated with lack of knowledge of the product being purchased: the expiry date, counterfeiting, the presence of toxic ingredients, etc. The consequences can be serious for the health of these individuals.

**Differences between Psychotropic Drugs and some other CNS Stimulants and Depressants?**

There is nothing new about the desire to take advantage of the brain’s plasticity and to improve mental performance. People commonly use such substances or techniques, which may be part of everyday life.

For example, products such as ginseng, ginkgo biloba and plant infusions have been consumed for centuries and are still used today. More recently, vitamin and mineral supplements have been added to the supply of products commercially available in several kinds of institutions. Although the effects of these products are not scientifically proven, they are commonly used in Quebec. Other stimulants such as caffeine, glucose and nicotine are commonly found in food or are part of a lifestyle. More rarely, stimulants derived from transformed substances or that are chemical in nature, such as amphetamines and cocaine, are consumed in some social settings. In addition to the use of improved products, techniques such as memory training, yoga, visualization and meditation are practiced to increase cognitive abilities, even though their benefits are not demonstrated by scientific studies.
In this context, the market for psychotropic drugs has found a niche. Given this context, in terms of risk, some people compare taking psychotropic medications to taking products such as coffee and alcohol, which are nonetheless recognized to be harmful when consumed in large quantities: the consumption of these products is legal in Canada; they are safely manufactured. They may actually have effects on all people, some of whom are more sensitive than others to the strength and duration of effects. Finally, the negative effects of excessive or prolonged consumption of coffee and alcohol are well-known – and yet they remain accessible and popular – whereas in the case of psychotropics, long-term effects are poorly documented. As a result, some consider there is no demonstrated proof of the specificity and risks of psychotropic drugs, and there is no real difference between a psychotropic drug and other neurostimulants.

The Consequences of Expanded Uses of “Lifestyle Drugs”

The demonstrated benefits and risks of psychotropic have been described above. In this subsection, only the expected benefits and risks of expanded “Lifestyle” type use of psychotropic drugs will be described.

It should be noted that scientific evidence and public perceptions both play a role in shaping the character of benefits expected from a particular drug. To date, only a handful of scientific studies have focused on psychotropics used strictly for enhancement purposes. As a result, many of the hoped-for benefits of expanded “Lifestyle” uses are being extrapolated from the scientifically demonstrated benefits in the treatment of diseases; however, it is risky to transpose an evidence base onto healthy people using psychotropes. In addition, it should be remembered that the scientifically demonstrated effects vary in number and intensity for each individual, a situation which ought to apply equally to expanded uses for the purposes of enhancement.

The Enhancement of Cognitive Functions

The enhancement of certain cognitive abilities is one of the objectives pursued by consumers of psychotropic drugs. Enhancement of mental abilities that enable learning, information processing and memory is considered as a personal and social benefit.

Accordingly, from this perspective, stimulants such as amphetamines and methylphenidate (including Ritalin® and Concerta®) are useful because they can enhance memory and concentration levels. Both minors and adults are sensitive to these effects and could benefit from them. In fact, methylphenidate is particularly popular among high school and university students, especially in the United States. An American study of high school students estimated that illicit uses of neurostimulants exceed medical uses.
Methylphenidate and the Risk of Drug Abuse

Methylphenidate (including the best known brand, Ritalin®) has the distinction of having the same neuropharmacological mode of action as cocaine. This medicine is regularly used to treat ADHD, but since ADHD is primarily diagnosed in young children and adolescents, medical and public health authorities have paid particular attention to the possibility it could lead to physical dependence or favour in later life drug and alcohol consumption.

According to the recent biomedical literature, young people with ADHD who take methylphenidate do not risk dependency or conditions conducive to abuse, regardless how old minors are when they take psychotropics. For some authors, the medical use of methylphenidate would also reduce the risk that young people take drugs or alcohol later in life. Indeed, given that disturbing traits and behaviours are stabilized, life in society and at school would be more harmonious and self-esteem higher.

However, two situations promoting physical dependence have been identified so far:

- The first involves the intravenous injection of methylphenidate reproducing the quick reaction time and the effects of cocaine. This is a theoretical laboratory-based or illicit expanded use situation since there is currently no provision for intravenous therapeutic treatment.

- Strictly observing the clinically accepted dosage would not cause addiction or a person’s predisposition to abuse. However, if the doses are not respected and are taken in numbers greater than recommended dosage, the effects on the brain and their quick reaction time are similar to those induced by cocaine.

use. According to the authors, methylphenidate is perceived as a study aid, a tool, just like tutors or caffeine pills. According to this perception, it is not just used to treat individuals, but also to help them with personal development depending on their own life objectives. It is presented as an individual choice in liberal democratic societies marked by medical consumerism. (Eric RACINE and Cynthia FORLINI, “Cognitive Enhancement, Lifestyle Choice or Misuse of Prescription Drugs? Ethics Blind Spots in Current Debates”, Neuroethics (Online First), 2008, http://www.springerlink.com/content/u22547313857t607/fulltext.pdf [consulted 5 September 2008]).

335 In the Chapter 2, sub-sections Demonstrated Benefits of Psychotropic Drugs and Demonstrated Risks and Side Effects of Psychotropic Drugs were presented as an individual choice in liberal democratic societies marked by medical consumerism. (Eric RACINE and Cynthia FORLINI, “Cognitive Enhancement, Lifestyle Choice or Misuse of Prescription Drugs? Ethics Blind Spots in Current Debates”, Neuroethics (Online First), 2008, http://www.springerlink.com/content/u22547313857t607/fulltext.pdf [consulted 5 September 2008]).


Similarly, concentration and fatigue may be improved by modafinil, a stimulant used in the treatment of narcolepsy and unusual fatigue. This drug also shows significant positive effects on other cognitive functions such as speed of decision-making and greater alertness. Other classes of psychotropic drugs are able to improve memory and cognitive function, including acetylcholinesterase inhibitors. These drugs are used to delay the onset of symptoms of Alzheimer’s disease and other forms of dementia, but they may also produce benefits for people not suffering from dementia. For example, donepezil is prescribed to treat Alzheimer’s disease, and has been tested on pilots during simulations; it has improved performance in emergency situations and in landing approaches.

Enhanced cognitive functions also contribute to meeting the demands of the labour market, which represents a gain both for employers and employees. For example, neuro-stimulants may prove useful in occupations where the safety of others is crucial – pilots, air traffic controllers, truck drivers, etc. – and which therefore require constant attention. In these professions, the expanded use of psychotropic stimulants could lead to gains in terms of public safety, at least apparently and in the short term. In this regard, according to a Quebec study, respondents do not perceive that the use of psychotropic drugs by employees in the workplace poses a major problem.

Moreover, in their personal lives, people are often subject to a frenetic pace of life. For example, conciliating work and family life (a classic example in Quebec) is often accompanied by cultural outings, sports activities, volunteering, and so on. In short, for some people, psychotropic stimulants meet the needs or expectations of everyday life.

The Regularization of Mood and Behaviours

Another important category of benefits includes the regulation of behaviours, personality traits and self-image. For example, being affable and feeling comfortable in public are valued character traits; inducing or enhancing these qualities helps to better prepare individuals for dealing with the stress of their personal and professional lives. Psychotropic drugs can quickly make people feel better, while promoting better integration; at least that is what many users hope.

People take these drugs to obtain results on the personal and professional levels: harmonious personal relationships, a more attractive personality, increased sociability, better cooperation, initiatives, improved productivity, fewer absences, and so on. On the one hand, feelings of grief and sadness decrease, while on the other, self-esteem and a sense of performance and of efficiency are expected to increase. As a result, people expect to achieve a state of well-being or better well-being.

An Increased Standard of Living

There is a positive correlation between cognitive functions and the standard of living: a slight increase in cognitive functions leads to a rise in incomes and an improved quality of life. Several factors increase cognition: healthy eating, physical exercise, intellectual stimulation, satisfactory social relations, etc. However, some people have limited cognitive abilities and are unlikely to improve them; these people stand most to gain from a pharmacological enhancement of their cognitive functions.

In short, the benefits of expanded uses of almost all classes of psychotropic drugs seem to point to improved self-esteem, social validation of their achievements leading to promotion in the workplace, an improved social life, a favourable reputation, etc.
Some authors also suggest that the sum of these individual gains may increase education levels and the productivity of society, which would in turn mean that everyone would stand to benefit from this situation. For other authors, meanwhile, other consequences should also be noted, such as increased competitiveness to the detriment of other social values, or impacts on the health of individuals that could lead to an increased workload or fewer hours of sleep.

As a result, expanded “Lifestyle” uses do not just involve benefits. Risks are potentially associated with this type of use, including risks to individual safety, external pressures, psychological dependence and the trivialization of psychotropic drugs.

Risks to Individual Safety

In the short term, negative side effects may be associated with non-compliance with the indicated dosage. In addition, the use of psychotropic drugs provided by friends or bought illegally over the Internet exposes consumers to two types of risks: those associated with the use of psychotropic medications and those relating to the unknown characteristics of medications ingested. Among these risks, the Commission includes adverse drug reactions, interactions with other substances taken concurrently and the side effects which can for example be caused by traffic accidents, work accidents or aggressive behaviours. In these three examples, the safety of others comes into play.

In the long term, science cannot tell what the effects of psychotropic medications, including stimulants, antidepressants or acetylcholinesterase inhibitors, are on the brains of healthy people. It is possible that other mental states including moods and emotions could be affected, either positively or negatively, by the fact of changing or enhancing a given cognitive function. At the present time, with the exception of tranquilizers and benzodiazepines (anxiolytics), the evidence base regarding the impact and scale of these effects on the central nervous system is extremely limited. In particular, potential negative effects affecting the future of adolescents or young adults using psychotropic drugs remain largely unknown.

Expanded “Lifestyle” uses involve other risks to consumer safety. First, when psychotropic drugs are used without prior consultation with a health professional, the risks associated with their use increases. Risks also increase if the drugs are purchased outside of licensed pharmacies, in which case product reliability – the product’s ingredients, manufacturing process and expiry date – cannot be ensured. And yet, certain uses elude the oversight of health professionals. For example, medicated individuals exchanging or donating psychotropic drugs are means by which individuals can obtain psychotropic drugs by circumventing medical supervision.
In addition, certain “Lifestyle” uses may impair the physical and mental health of users. For example, the neurostimulant modafinil (marketed under the name Alertec® in Canada) is prescribed in cases of narcolepsy and severe disturbances of the sleep-wake cycle. Using modafinil for other purposes, such as performing over long periods, reducing the effects of segmented working hours and reducing attention to signs of fatigue, may affect cognitive functions. Indeed, the consequences of insomnia, including sleep deprivation or poor quality sleep, are among the first diagnostic criteria in DSM-IV-R, and ensure that people so affected may have difficulties with short-term memory or executive functions. In general, lack of sleep can lead to difficulty in functioning during the day, which translates into the presence of fatigue, sleepiness, a decrease in cognitive performance and a reduced ability to integrate emotions in decision making. Lack of sleep is also a risk factor for physical illness such as hypertension and type 2 diabetes. Sleep is therefore a physiological process vital for neuronal plasticity, for the consolidation of newly acquired knowledge and for good physical health.

External Pressures

It should be noted that social pressures, even to the point of coercion, have an impact on the process of individual decision-making.

People resort to expanded “Lifestyle” type uses in pursuit of a certain ideal, self-image and group, both in their professional and personal life. As a result, direct and indirect pressures to comply with this ideal may be brought to bear from different directions: the social network, hierarchical superiors, work colleagues, organizational culture, the family, parents, schools, the media, etc.

Psychological Dependence

It is possible to become psychologically dependent on psychotropic drugs. For people using and benefitting from psychotropic medications, the fear of losing such benefits is a powerful motivation for continuing to take the medications, even when medical conditions no longer indicate such use.

Consequently, some people may use psychotropic drugs as a strategy for confronting unpleasant or painful life events. This type of drug use can lead to perceptions that the difficulties of life could be resolved by taking medication. Faced with these situations, a chronic use of psychotropics will end up addressing symptoms instead of mobilizing the personal resources needed to cope with life. This may also cause a devaluation of other forms of therapy or ways to cope with life’s difficulties and a low tolerance of sadness, fatigue, discomfort, pain, sleep disorders, etc.

Trivialization of Psychotropic Drugs

The trivialization of psychotropic drugs was discussed above, in the section on the expanded uses of the “Medical” type. However, trivialization is even more a concern where expanded uses of the “Lifestyle” type are concerned, since in this latter case the use of psychotropic medications is designed to help fulfill idealized norms, images or values that have become ends in themselves. Also, the fact that consumers overstate the desired benefits and under-estimate the risks increases the trivialization of “Lifestyle” related uses.
A SYNTHESIS

The Commission has decided to distinguish between two categories of expanded uses of psychotropic drugs, namely expanded “Medical” and “Lifestyle” uses. Several common points of interest emerge from the expanded uses of psychotropics.

First, although the term “expanded use” is applied to both categories, the first category consists for the most part of an extension of therapeutic uses of psychotropics, while the second illustrates above all expanded uses in the absence of this therapeutic goal. Second, although some factors are specific to each class, the same stakeholders are often involved. Third, it is not always easy to distinguish between therapy and enhancement, and as a result it is relatively easy for anyone to justify resorting to psychotropics. Fourth, it seems obvious that widely available and transparent scientific information of a high quality is important; however this precondition is not always met, whether by the general population or by health and social services professionals. Fifth, the lack of knowledge of the effects of psychotropic medications on healthy individuals means that the expected benefits are held out as promises, while risks are often neglected or ignored. Finally, regardless of the categories used here, the increased use of psychotropic medications raises the broader question of the identity of the person and the normality of socially expected behaviours.

This synthesis opens up a number of ethical issues arising from expanded uses for the purposes of enhancement. The ethical questioning in the next chapter focuses on the set of problems arising from uses and prescriptions for the purposes of enhancement, which are not related to therapeutic purposes or to problems in the health and social services network.


358 Derived from GLANNON (2006), op. cit., p. 49.


360 The set of problems and a literature review are presented in MÉOS, op. cit., pp. 32-33.

361 MÉOS, op. cit., pp. 32-33; WALSH, op. cit., p. 140.

362 WALSH, op. cit., p. 140.
AN ETHICAL QUESTIONING ABOUT EXPANDED USES OF PSYCHOTROPIC DRUGS
In this position statement, the Commission considers two broad categories of expanded use, those of a "Medical" nature and those having more to do with "Lifestyle". Medical uses come within the competence of physicians who perform the regulated activity of prescribing drugs to treat diseases and are thus able to legitimize their use. The second category concerns the use of psychotropic drugs as a means of fulfilling a lifestyle need. Although these categories are distinct, they involve some of the same stakeholders; in addition, they are located along a continuum where the boundary between recognized medical treatment and expanded use can be blurred.

The previous chapter identified a number of hoped-for benefits and risks associated with expanded use of psychotropic medications. Expected benefits include the advance of knowledge, higher cognitive functions, mood regulation and improving one's personal and social standing. As for potential risks, several stand out in particular, notably the lack of safety for the person using psychotropic drugs as well as for others, access to the health and social services network, external pressures, the trivialization of medications and the medicalization of certain life events.
The analysis of these risks and these benefits raises several questions, including:

- Does the increase in expanded uses threaten the core values of the Act respecting health services and social services, such as equity, accessibility, justice and autonomy?

- Does recourse to some expanded uses of psychotropics serve to overcome shortcomings of the health and social services network?

- Do external pressures influence the choice of taking or of not taking psychotropic drugs?

- If the use of psychotropics stabilizes moods or enhances cognitive function, is a person more “himself” as a result?

- Does the expanded use of psychotropics alter the concept of identity and the concept of the human being?

Several other values underlying these issues are also at stake, including the protection of persons, freedom, responsibility, the availability of information and the quality of this information. The concept of normality is also involved.

Ethical issues related to expanded uses of psychotropic drugs are complex and it is important to state and discuss them calmly. In considering these issues, the Commission has identified four key values: the protection of individual health and safety, autonomy and the affirmation of individual freedom, equity and representations of the human being.
PROTECTION OF INDIVIDUAL HEALTH AND SAFETY

Psychotropic medications are powerful. Even under medical supervision, benefits may be accompanied by significant side effects, including dizziness, heart problems, lethargy, gastrointestinal disturbances and psychomotor disorders (including falls and difficulties with fine motor skills). In the case of polymedication, potential drug interactions add a level of risk to the person consuming psychotropic drugs. These side effects cannot be predicted with accuracy, because the brain of each individual is unique and the brain’s networks of neuronal connections change over time.

For these reasons, psychotropic medications cannot be dispensed outside of the logic of drug safety, which aims to protect persons, and is one of the fundamental values underlying the health and social services network.

Drug safety is a constant concern in our societies. Psychotropics pose special challenges because they induce biochemical changes in brain functions. They deliberately seek to change neuronal plasticity and the levels of neurotransmitters in order to alter cognitive functions, emotions, behaviour and motor skills. So far, however, the functioning of the brain is still largely unknown; as a result, potential mid-term and long-term effects induced by psychotropics are also unknown. Consequently, as the following paragraphs indicate, persons are to be protected against the unknown risks of psychotropic medications, and a greater knowledge base is needed in this field.

Improving Knowledge: an Essential Precondition

The research undertaken for this position statement shows the need for a greater knowledge base relating to both the functioning of the brain and to psychotropic drugs.

In the short term, both the risks and modes of action of psychotropics are still largely unknown. They act even though their mechanisms of action at the neurological level are not clearly understood; they sometimes produce effects that are neither demonstrated nor anticipated. Knowledge about the optimal duration of pharmacological treatments also poses a problem, because it varies from one author to the next, and guidelines do not always clearly state when and how to stop treatment. Nonetheless, the duration of treatment is an important factor in a person’s well-being and health. Indeed, if the timeframe of treatment is too short, the disease will not be controlled; if the timeframe of treatment is too long, the person will receive unnecessary medication.

The long-term effects of taking psychotropic drugs raise several fundamental questions: Will cognitive functions be affected – and, if so, by which psychotropic drug, how, and for how long? Will their effects be reversible or permanent? Will one-time use have the same effects as chronic use? Are gender or age at the time of use important factors? Is the length of time during which psychotropic drugs are consumed a key element? Will the modification of a particular function affect other cognitive functions? What physiological consequences are likely to ensue? How do biochemical changes induced in healthy individuals compare to those observed in people suffering from diagnosed diseases?
The long-term risks faced by young users of psychotropic drugs, particularly children and adolescents, raise particular concerns. Indeed, although negative impacts on the physical or mental health of young people could appear in the long term, they could occur in early adulthood, forcing these people to deal with these consequences for the rest of their lives.

To date, there is very little scientific data from longitudinal studies capable of answering these questions. The anticipated increase in the use of psychotropic medications makes the need for knowledge about these drugs even more compelling. Meanwhile, it is important to draw a profile of the use of psychotropic drugs, and to monitor their development. Indeed, in the absence of scientific and clinical data (diagnoses, therapeutic intentions etc.) a precise portrait of expanded uses in Quebec cannot be established. In order to be able to quantify and qualify the short, medium and long term effects of psychotropics in Quebec, the Commission recommends:

**Recommendation No. 1**

That the main stakeholders deepen the knowledge of psychotropic medications, namely:

a) that the Minister of Health and Social Services give the Conseil du médicament (the Medication Council) the mandate of establishing a profile of current uses of psychotropic medications in the Quebec population and of monitoring their evolution over time;

b) that Quebec granting agencies incorporate into their programming the funding of qualitative and quantitative studies on the uses of psychotropic medications and on the different types of impacts induced by them;

c) that the relevant associations and professional orders document the practices of their members where the use of psychotropic medications is concerned.

**Improving Various Modes of Information**

During a medical consultation, the physician takes into account the consequences of the use of psychotropic drugs and correlates them with the benefits which may accrue to the patient. In the case of self-medication or expanded “Lifestyle” uses, adverse drug reactions and possible risks of expanded uses of psychotropic medications are often ignored or underestimated by those people using them without expert guidance.

In all cases, people obtain information through various channels, notably through the Web and other media.

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363 See Chapter 2, sub-section *Demonstrated Risks and Side Effects of Psychotropic Drugs.*

364 On the notion of polymedication, see Chapter 2, sub-section *Some User Profiles for Psychotropic Drugs.*
Influences of the Internet

The Internet has revolutionized and continues to transform modes of communication. The rise of the Internet has made this media unavoidable in the workplace, educational networks, and interpersonal communications. Through online shopping, the Internet is also changing consumer habits. The Internet also influences the dissemination of knowledge through scientific information sites for specialists but also through sites offering popularized scientific information, discussion forums and blogs. The popularity and accessibility of the Internet offer many benefits, such as the diversity of sources and the kind of information accessed, which can be useful and educational for people consulting it.

However, the quality of this information is uneven and its validity is hard to verify. Consequently, Internet-based information may be incomplete, biased, and may even constitute misinformation. And yet, the quality of this information and its degree of popularization are particularly important when the literacy level of readers is limited.

Where information on drugs is concerned, the consequences can be serious, because websites can reach those individuals likely to use psychotropic drugs or those more vulnerable persons who are concerned about their health or who already suffer from a disease. Similarly, the rise of cyber-pharmacies and online shopping – without any after-sales service – raises the question of the validity of the information provided and the safety of drugs sold.

Given the difficulty of scrutinizing the quality of information found on the Internet and to ensure that people safely consume psychotropic medications, the Commission recommends:

**Recommendation No. 2**

That main stakeholders ensure the reliability of information transmitted to the population on the web, namely:

a) that the Minister of Health and Social Services, together with the Conseil du médicament and the relevant associations and professional orders, direct the general public to sources and Internet sites containing reliable popularized information;

b) that the Ordre des pharmaciens du Québec (Quebec College of Pharmacists) raise awareness in the general public of the risks of relying solely on information found on the Internet, and of the importance of validating this information by consulting health professionals.

Influence of Other Media

Messages in mass media and those found in the scientific literature on the concept of enhancement vary depending on the nature of the enhancements likely to be made. Accordingly, while physico-esthetic enhancements are socially accepted, physico-sports enhancements through doping are frowned upon, and cognitive enhancements such as behaviour and mood regulation through psychotropic drugs are generally presented in a very positive light.
In the scientific literature, three trends relating to psychotropic drugs are emerging. The first trend is relatively rare and sees in the development of drug use for the purpose of enhancement a biological appropriation as a means to solve social problems such as aging, which is poorly perceived and hard to live through, and socio-economic inequities. The second trend is more common and takes up the idea of using drugs to solve personal or social problems, without insisting on their biological and deterministic character, however. Finally, the third most common trend is found in the biomedical literature, and acknowledges expanded uses of psychotropic medications, but considers it unrealistic to try to ban these expanded uses: this is the argument of inevitability according to this argument, it is better to accept psychotropic drugs and to regulate them.

The mass media, whether print or electronic, reach a high proportion of homes in Quebec. In light of the many uncertainties remaining in neuroscience, particularly as regards psychotropic drugs, the mass media have an unavoidable duty to be knowledgeable about science. However, the space and treatment accorded to scientific advances, including medications, is very unsatisfactory. Given their wide-reaching influence, stakeholders in the field of information – from journalists, researchers, senior staff to owners of media organizations – have a responsibility to provide accurate information to their audiences. To this end, the members of a range of associations, such as the Fédération professionnelle des journalistes du Québec (FPJQ), the Association des journalistes indépendants du Québec (AIJQ) and the Association des communicateurs scientifiques du Québec (ACS), can rely on codes of ethics.

Finally, networks of public libraries play an important role in disseminating the knowledge since they reach 95% of Quebec’s population, about 30% of whom are members. The importance of the Grande Bibliothèque du Québec should be noted. Its national mission makes it an essential library in Quebec. Networks of municipal libraries would be strengthened if a local library served as a clearinghouse for health information, feeding other libraries of the municipality or region. This library would offer full and current scientific information, while integrating various information platforms – magazines, books and encyclopaedias, in print and online, exhibitions and Internet access, etc. Ultimately, a library devoted to health could emerge, along the lines of the Cité de la santé within the Bibliothèque de la cité de la science et de l’industrie at La Villette (Paris).
As a result, in presenting risks, benefits and questions with multiple layers of detail and meaning, the mass media and distributors of scientific information are participating actively and objectively in societal debates around psychotropic medications and their expanded uses. To this end, the Commission recommends:

**Recommendation No. 3**

That stakeholders in the field of information ensure the dissemination of critical, balanced and complete information on knowledge and uncertainties relating to mental health disorders, the use of psychotropic medications and the non-pharmacological treatments used in the treatment of mental and neurological disorders.

The Commission invites the stakeholders in the field of information to evaluate their roles and practices in providing health information. In order to do this, they may call on Quebec research groups studying psychotropic medications, mental health disorders or the influence of media on society.

**Other Stakeholders in a Global Perspective**

The Commission is of the view that the expanded use of psychotropic medication has an impact not only on protection of the individual, but also on protection of the population. Three sources of risks and social costs resulting from expanded use of psychotropics have been identified in this position statement, namely: pressures on the health and social services network, the current model of medical practice and the high proportion of certain user profiles.

- **Pressures on the health and social services network** are a consequence directly linked to individual behaviour. As mentioned in the previous chapter, increasing use of psychotropic drugs can cause an increase in road and workplace accidents, as well as impulsive or aggressive behaviour directed towards other people. And yet, the Quebec social safety net assumes responsibility for medical expenses in the event of accidents or as a result of aggressive behaviour, and provides income support in the event of a workplace or traffic accident through CSST and SAAQ benefits. This results in pressures on staff in the health and social services network, as well as financial pressures, which are borne by the community.

- **The model of medical practice**, i.e. recourse to psychotropic prescriptions as a means occasionally of getting around the problem of directing a patient to another professional such as a social worker or psychologist. The Commission is concerned about these current limits of the system, which involve medicalization, medicamentation and the trivialization of psychotropics. This model also exerts pressure on the health care network, which is illustrated by the fees of medical consultations charged for prescriptions and monitoring, pharmacists’ fees as well as the overall cost of drugs.\(^{374}\)

- **Social costs associated with the high proportion of particular user profiles** are more difficult to identify. The profiles in question are related to age, gender and economic status.\(^{375}\) As a result, minors, seniors, women and socioeconomically disadvantaged people stand out in the use of psychotropic drugs. Given this situation, what could be the impact of expanded use of psychotropic drugs on social perceptions of these groups and the self-perception of people within these groups?
In terms of the protection of “individual health and safety”, professionals in the health and social services network, the pharmaceutical industry and the State are the key stakeholders.

Professionals in the Health and Social Services Network

Physicians, pharmacists, nurses, psychologists and social workers are the health and social services professionals most directly involved in the use of medications. They practice their professions in demanding conditions. Indeed, caregivers work in a network which is not optimally organized, although that does not relieve them of the obligation to master a great deal of highly specialized information. Doctors and pharmacists are also subject to various pressures from the pharmaceutical industry as well as from patients or those closest to them. It is in this complex world that caregivers now exercise professional responsibility.

For physicians – the ones prescribing psychotropics drugs –, two new questions arise: the first is related to uncertainty concerning psychotropics and the second relates to their social responsibility.

As explained above, there are still many unknowns about issues such as molecular cascades, mechanisms underlying neuronal plasticity, the roles of neurotransmitters, the possible impacts of a psychotropic drug on other parts of the brain, potential medium and long-term effects of psychotropic drugs, etc. These uncertainties can make clinicians uncomfortable about their decision-making role, and even lead to a moral dilemma, especially for general practitioners. Indeed, general practitioners provide care for the majority of patients suffering from mental or neurological disorders; but even they find that existing information is highly complex, often scattered or difficult to access. They would benefit from improved access to more centralized and better organized scientific information. Therefore, the Commission recommends:

**Recommendation No. 4**

That the Minister of Health and Social Services, together with the Conseil du médicament, and the relevant associations and professional orders:

a) establish an accessible mechanism to disseminate information on psychotropic medications and on the state of knowledge relating to non-pharmacological treatments;

b) develop best clinical practice guidelines for mental health;

c) develop decision support tools.

374 Financial impacts have not been demonstrated, however, at the individual level. Indeed, other types of professional care – psychologists, social workers and other experts – are mainly in the private and not the public system of services. Their fees constitute direct costs for individuals, unlike the indirect costs reflected in taxes. If these extramedical resources took up more space in the public network, it would be important to assess their net financial impact. This point will be raised below in this position statement.

375 See Chapter 2, sub-section Some User Profiles for Psychotropic Drugs.

376 In several different places, Chapter 2 addresses uncertainties related to knowledge about the CNS.
The second question refers physicians to the social dimension of their role. Their expertise in the health field confers authority and social legitimacy on their medical opinions and acts. It is important that they think about their role, or the one they recognize, in the phenomena of medicalization and medicamentation of life situations and events such as bereavement, professional failure or extreme shyness. Similarly, another aspect of their social role is the place they give to non-pharmacological therapies during medical consultations related to these events. Their role in expanding the therapeutic area and their share of responsibility for the consequences arising therefrom are elements of debate. To this end, the Commission recommends:

**Recommendation No. 5**

a) That the relevant associations and professional orders sensitize their members about the phenomena of medicalization and medicamentation, as well as the reality and potential consequences of expanded uses of psychototropic medications.

b) That the universities, associations and professional orders concerned provide integrated mental health programmes in the core curriculum and in continuing education programmes.

c) That the universities, associations and professional orders involved include non-pharmacological treatments in the core curriculum and in continuing education programs.

Finally, the Commission invites associations, federations and professional associations in the health and social services network, as well as their members, to think broadly about two dimensions of their professional responsibility.

The first is to take account of the asymmetric nature of the relationship between the professional and the layman. Indeed, when people consult experts, they acknowledge that they are somewhat vulnerable and that they lack knowledge which experts possess. Experts are invested with implicit power.

Second, certain professional practices are raising new questions. For example: is the emphasis on prevention increasing the incidence of expanded "Medical" and "Lifestyle" uses? How are health professionals dealing with the scale of expanded uses? What position should they take in terms of professional responsibility when they have to deal with patient demands to be "better than well"?
Pharmaceutical Companies

In Canada, innovative pharmaceutical companies are major sponsors of clinical trials that form the basis of drug licensing; they also play a leading role in pharmacovigilance once drugs are marketed. As a result, pharmaceutical companies are key stakeholders where information on human safety is concerned. They must therefore reconcile the imperatives of product efficiency and safety with the aim of profitability and social responsibility.

However, according to several authors, pharmaceutical companies are actively involved in the phenomena of medicalization and medicamentation (or Disease Mongering). They benefit from expanded “Medical” type uses, especially given the expansion of approved indications associated with medical diagnostic thresholds. Moreover, where approved medical indications are concerned, it should be noted that in 2009 the Food and Drug Administration (FDA, USA) published practice guidelines allowing pharmaceutical companies to use peer-reviewed scientific articles focusing on non-approved uses. In general, the approval of new medical indications, and now the publication of non-approved uses results in peer-reviewed scientific journals, for a drug already on the market have the effect of increasing the pool of consumers.

The importance pharmaceutical companies give to research activities, training, promotion and marketing of drugs is well-known. In this respect, the Commission identifies four levels of responsibility:

- **In terms of research**, drug development is subject to various regulatory processes. Phase IV clinical trials aim particularly at pharmacovigilance, i.e. monitoring of drugs and their effects after they have been marketed. Criticism is directed at the way Phase IV is conducted by industry, since it may serve as a marketing strategy. In addition to pharmacovigilance, R&D should also focus on the medium- and long-term effects of psychotropic medications reaching the market. This form of vigilance would increase the knowledge base relating to the medium- and long-term safety and effectiveness of medication – a knowledge base which this position statement deems is insufficient.

377 This power of knowledge is not restricted to the field of health and social services. One may think of lawyers, tax specialists, investment advisors, architects, engineers, etc.

378 Several philosophers have addressed this question from different perspectives, such as Michel FOUCAULT, for example in *La volonté de savoir* and *Surveiller et punir*; Hans JONAS, *Le Principe responsabilité. Une éthique pour la civilisation technologique*; Paul RICOEUR, particularly in “Postface”, dans Frédéric LENOIR (ed.), *Le temps de la responsabilité*, Paris, Fayard, 1991, pp. 251-270 and “Le concept de responsabilité. Essai d’analyse sémantique”, in *Le juste*, Paris, Seuil, 1995, pp. 41-70.


382 This aspect has been addressed in Chapter 1, section *The Pharmaceutical Industry: R&D and Financial Interests* and in Chapter 3, sub-section *Expanded Uses of the “Medical” Type – Some Factors Involved in Prescribing Practices – The Influence of the Pharmaceutical Industry*.

In terms of dissemination of results, research conducted by pharmaceutical companies is the basis for drugs licensing and for further advances in scientific knowledge. It is therefore important that information derived from this research is transparent and systematically disseminated, regardless of the findings. However, some practices undermine transparency, such as the fact negative results of clinical trials are rarely published, confidentiality clauses in contracts preventing researchers from discussing their research and delays in the disclosure of adverse events.

In terms of marketing, pharmaceutical companies should strike a balance between profit and the common good. In order to reach the level of profitability expected by shareholders, investments are made in promotional tools and training activities targeting health professionals that extol the benefits of proposed drugs. Companies also develop promotional tools for the general public. To enable professionals and individuals to make informed decisions, information on psychotropic drugs as well as associated benefits and risks, both proven and potential, should be presented in an understandable, balanced and exhaustive manner.

In terms of education and training, pharmaceutical companies are actively involved in training activities, including funding of those activities, which are in turn aimed at health professionals, especially physicians. This dimension of training given to physicians is defined in the ethics codes of the Conseil québécois de développement professionnel continu des médecins (the Quebec Council for Continuing Medical Professional Development) (CQDPCM) and the association of Canada’s research-based pharmaceutical companies (Rx&D). Given its importance for the health of the population, it is important to repeat that training offered by pharmaceutical companies should include knowledge presented objectively and exhaustively.

The State

The public has high expectations about the safety and effectiveness of medications they take. The fact that drugs are approved by Health Canada and are prescribed by physicians tends to reinforce these expectations and the perception of safety. Thus, transparency and accuracy of information about the risks and benefits of medications are central to the trust people place in monitoring authorities, pharmaceutical companies and prescribers. As guarantor of the common good, the State is a major stakeholder. It intervenes and regulates research leading to this information as well as its dissemination.

With respect to protection of the individual and the population, the Commission has focused attention on two factors relating to the regulatory framework, namely direct-to-consumer advertising (DTCA) of prescription drugs and the drug licensing process.
The current Canadian regulatory framework is not well adapted to deregulation in the United States, which allows direct-to-consumer advertising (DTCA) of prescription drugs, without major restrictions. This form of advertising is banned in Canada and is subject to several regulations. However, the ban is easily circumvented through Canadian access to American television, newspapers and magazines. Given that information easily crosses the border, there are pressures to allow DTCA in Canada. As mentioned above, one of the arguments used in support of deregulation is that DTCA makes it possible to reach people directly and to better inform them as a consequence. In this regard, the Commission distances itself from the pro-DTCA argument and, in endorsing the position taken by the Conseil du médicament du Québec, recommends:

**Recommendation No. 6**

That the Minister of Health and Social Services intervene with the Minister responsible for Health Canada,

- a) to keep in effect the ban on direct-to-consumer advertising (DTCA) of prescription drugs in Canada as long as the pharmaceutical industry or the advertisers have not demonstrated its benefits for the health of the population and for the health system;
- b) that regulations continue to preserve the unique character of the Canadian health care system, which is based on solidarity;
- c) that existing regulations concerning the prohibition of the third kind of DTCA (which mentions the medication by name, the pathologies which it addresses and the benefits associated with its use) are applied to advertisements coming from the United States.

Also, the Commission has focused attention on the drug licensing process. The complexity of the functioning of the central nervous system and the scarcity of knowledge about the medium- and long-term effects of psychotropics call for great prudence in the drug approval process. In this regard, two weaknesses are worth mentioning:

- the lack of independent audits of the results produced by pharmaceutical companies;

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386. See Chapter 1, section The Normative Framework for Medication.


388. See Chapter 1, sub-section The Challenges of the Normative Framework – Direct-to-Consumer Advertising (DTCA) of Prescription Drugs for this argument as well as counter-arguments.

389. CONSEIL DU MÉDICAMENT DU QUÉBEC (2004), *op. cit.*


The theoretical and clinical limits on which drug approvals are based, which include the small size of participant cohorts in clinical trials, the lack of drug interactions in clinical trials and the monitoring process of effects (whether positive or adverse) once the drug reaches the population.

If this process is not updated with tools and independent evaluation of the pharmaceutical industry, it may not meet the high and legitimate expectations of citizens relating to the safety of drugs they consume. In this respect, the new “progressive licensing process” proposed by Health Canada is “based on the fact that knowledge about a drug progresses over time.” This initiative that Health Canada would like to take would constitute an improvement since it takes into account several criticisms of the process currently in place.

In addition, regulators have called on pharmaceutical companies to disclose all research results in a registry. The World Health Organization launched the International Clinical Trials Registry Platform, which aims, first, to bring existing registries together into a one-stop service and, second, to propose standards for all registries. In October 2008, when the World Medical Association adopted the revised Declaration of Helsinki, it stressed the importance of publishing all results of clinical trials, whether positive, neutral or negative. In Canada, Health Canada also encourages that clinical trials be recorded and disclosed in a public registry. For its part, in its draft revision of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, the Interagency Advisory Panel on Research Ethics proposes that “all clinical trials should be registered with a recognized and easily web-accessible public registry.”

To date, these initiatives call for the voluntary participation of researchers and pharmaceutical companies. In the interest of maintaining the bond of trust, ensuring a better flow of knowledge and allowing for greater transparency, the Commission recommends:

**Recommendation No. 7**

That the Minister of Health and Social Services intervene with the Minister responsible for Health Canada, so that Health Canada makes disclosure of clinical trials and of all results compulsory, in an accessible registry, and that this registry is regularly updated.

The concern for drug safety with regard to psychotropic medications reflects a kind of prudence, and multiple stakeholders shoulder responsibility for this prudence in various ways. Nevertheless, solving the difficulties associated with risk management and improving scientific knowledge would not necessarily make expanded uses of psychotropic drugs acceptable in social and ethical terms. In fact, ethics has a much wider scope. It is concerned with the way techno-scientific progress unfolds – with uses, impacts whether actual or anticipated, the determination of issues and their regulation – and the community value of togetherness. Other ethical concerns are raised by the expanded use of psychotropic medications. One of these concerns involves autonomy and the affirmation of individual freedom.
AUTONOMY AND THE AFFIRMATION OF INDIVIDUAL FREEDOM

In a context in which autonomy, freedom and a sense of responsibility are valued, the relationship between individual choices and the limits that may be imposed on them is paramount. This question – which is central to contemporary debates – arises in a particularly delicate way in the context of this position statement.

The Moral Subject: a Thinking Being

The moral subject is endowed with reason and capable of thinking, and is autonomous and free. As a result, the moral subject is able to think out his actions and to answer for, and take responsibility for, their consequences. This responsibility of the moral subject implies a causal link, the ability to reason, awareness of one’s actions and their consequences and the freedom to act (or not to act). It is based on a premise: that the person has the ability to make choices and take decisions.

It is along these lines that the discourse of individual responsibility for one’s health has begun to take shape over recent decades. At the root of this discourse are reflected, inter alia, the recognition of individual rights, but also the significant impact of lifestyle on a person’s health. Consequently, some individuals have become more knowledgeable and also more critical. Some are also interested in self-care practices, some of which are promoted by the government agencies, or show an interest in self-medication.

The Commission considers that emphasizing the autonomy, freedom and responsibility of the subject enables him to be an actor in terms of caring for his own health. In this context, can limits be imposed, and how can they be posed, on the use of psychotropic medications which the individual deems personally appropriate? By what criteria can the moment be determined when individual needs have priority over those of the community? How can autonomy, solidarity and personal relationships be reconciled? Can limits on individual decision-making be imposed when the negative consequences (e.g. intoxication, accidents, falls) are assumed by society as a whole? What should the person be told who, in asking for psychotropics, invokes his own quality of life, which is a highly subjective concept, as well as self-determination? What should the person be told who wants a prescription for psychotropics in order to maintain or enhance personal performance?
The idea of limiting subjects in their decisions and actions conflicts with the “strong” concept of autonomy, according to which individuals are free, have the right to live their lives as they wish, and are limited only by the right of others to do the same. At that moment, if the risks of using psychotropic drugs have not been demonstrated with certainty or if the risks are accepted by users, other ethical and social issues are not considered. Yet the question of the balance between individual interests and collective interests remains to be addressed.

**External Pressures**

The person identifies with groups and shares social values. A person may be autonomous and free to choose, while nevertheless being subject to strong pressures from all directions, to comply with various group models, professional expectations, ideals of behaviour or appearance, etc. This is particularly clear in the case of expanded use of psychotropic drugs.

The expression “everybody else is doing it, so just do it yourself” provides a compelling illustration of the pressures to conform which are exerted on the individual. This expression is used in many fields of activity: at school, work, in artistic leisure activities, and in sports. The expression encourages the quest for performance, and trivializes the use of psychotropic medications as a means of leading this quest. Moreover, a person’s refusal to take psychotropic drugs may lead to negative moral judgments from his peers, while ensuring that person falls behind his peers in terms of performance.

Thus, autonomy and the freedom of choice of moral subjects present themselves in a context where expanded use for the purposes of enhancement acquires meaning and social finality. By placing too much emphasis on autonomy and individual responsibility, one risks forgetting the other factors that influence an individual’s health, such as the physical environment, the social milieu, dominant values, as well as the responsibilities of other stakeholders: government, business, the media, pressure groups, etc. In addition, some expanded uses of psychotropic medications meet the expectations of society while camouflaging the social causes of these expectations. As a result, the medicalization of social problems through expanded “Medical” or “Lifestyle” uses is not addressing the root causes of these problems.

This vision of performance and enhancement confronting society may challenge the autonomy of the individual, but it may have much the same effect on other groups “at risk” of expanded use of psychotropics, who are often vulnerable and find themselves in a power relationship which is rarely advantageous for them. One may think for example of minors, individuals with little schooling or who live in poverty, the elderly who are losing autonomy or living in isolation, and workers unable to refuse a “request” from their employer.

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**Commission Cautionary Note on External Pressures**

The Commission is concerned that the pressures exerted in many social spheres and activities that aim to homogenize behaviours will lead to the regular use of psychotropic drugs.
EQUITY

Equity can be understood as a quality consistent with the ideal of justice, considered independently of laws currently in effect. In the context of this position statement, equity means that people receive care and services which they require because of their physical and mental health needs. This implies their right to and the personal sense of having access to care and services, access to care which is required by their specific health status, and continuity in care, for all user groups.

However, the development of expanded uses of psychotropic medications in turn raises questions about equity.

On the one hand, the use of psychotropic drugs is increasing. Starting in 1992, the Ministry of Health and Social Services focused in its health and welfare policy on the objective of reducing use of certain psychotropic drugs among specific client groups. However, the 2001 revision of the policy notes that this objective had not been achieved and the situation had even deteriorated. Quebec and Canadian data on the prevalence of depression and the consumption of antidepressants and psychostimulants illustrate the predominant place currently held by psychotropic drugs. Recent statistics from current forecasts of the use of psychotropic drugs suggest that use will continue to grow.

Moreover, it is clear from the scientific literature consulted that new psychotropic drugs are more expensive than drugs previous used. Consequently, even if the use of psychotropics does not increase, the overall cost expenditure related to psychotropic drugs will increase.

Commission Cautionary Note on the Accessibility of Medications

Given the likely increase in the use of psychotropic drugs caused by expanded “Medical” and “Lifestyle” uses, the Commission is concerned about the impact of this increase on access to medications. It is concerned about the impact this increase may have on the list of medications eligible for reimbursement, the affordability of drug insurance plans and the possibility that persons suffering from pathologies could be faced with unmanageable financial obligations.


405 RACINE (2002), op. cit., p. 89.

406 LEMIRE, op. cit., p. 135.

407 Ibid.


413 See Chapter 2, sub-section Psychotropic Drugs – Contextual Factors.
On the other hand, disruptions in the continuity of care and services would contribute of expanded “Medical” and “Lifestyle” uses. Walk-in clinics, for instance, are the appropriate venue for brief consultations and emergencies, but are not designed to address complex mental health problems or to ensure regular monitoring of chronic or recurrent health problems. Usually this need is met by an appointment with a general practitioner or specialist, but is confronted headlong by the reality of waiting times. The psychotropic drug can become a means of camouflaging the problem, rather than of treating it. In this situation, patients do not then receive the appropriate care.

A vicious circle is being created, which in turn highlights a tension regarding access to the health and social services system: the shortage of health professionals and the organization of the network would seem to facilitate the expanded use of psychotropic medications; since expanded use requires a prescription written by a physician, the number of medical consultations is increasing, which in turn reduces the availability of these professionals; it becomes impossible to escape this vicious circle. As a result, disruption in the continuity of care sets up conditions leading both to more frequent expanded uses and to less accessibility to the health network.

Given the challenge of coordinating care and sharing information, the Commission recommends:

**Recommendation No. 8**

That the Minister of Health and Social Services continue to implement integrated mental health practices to ensure better continuity of care and services and to help reduce expanded uses.

With regard to relevant non-drug therapies, such as consultations with psychologists, social workers or speech therapists, the costs of consultations are not covered by the public system when they take place in private clinics; however, this situation frequently arises, given the shortage of these professionals in the public network. Some private insurance plans reimburse a portion of these costs, but not all Quebeckers have access to these plans. This situation leads to unequal access to care and services for non-medical services.

This inequity in access to care is particularly disturbing, given that in the case of several mental and neurological diseases, the combination of “drug therapy/psychotherapy” provides better short-term results for suffering individuals. Some studies show that in the long term, non-drug therapies – including psychotherapy, a healthy diet and exercise – lead to lasting positive results for several mental or neurological disorders such as depression, anxiety and diseases linked to the reduction of cognitive functions.
To ensure the equity and accessibility of the health-care network and of the different drug insurance plans, which are fundamental values at the heart of the Quebec health care system, the Commission recommends:

**Recommendation No. 9**

That the Minister of Health and Social Services:

a) establish the conditions for improving service delivery within the public system of services offered by professionals for non-pharmacological therapies used in the treatment of mental and neurological disorders;

b) study the conditions for reimbursement by the Régime d’assurance maladie du Québec of professional services provided for private non-pharmacological therapies used in the treatment of mental and neurological disorders.

The positive impacts on the network of increased access to non-drug therapies have yet to be demonstrated, both in terms of the health-care network and of individual health and well-being. Indeed, it is possible that the overall effort expected of health and social services professionals will not diminish, or that the budgetary appropriation for the Ministry of Health and Social Services will not be adjusted downward. However, the Commission considers it would be interesting to explore this avenue in order to see whether efficiencies can be identified in terms of the network’s human and financial resources. In addition, more systematic and accessible recourse to non-pharmacological therapies could demedicalize and demedicate certain life events that are not necessarily within the medical sphere. This repositioning of various stakeholders could also reduce the frequency of expanded “Medical” type uses. In order to characterize the possible effects on the public network of access to non-pharmacological treatments, the Commission recommends:

**Recommendation No. 10**

That the Quebec granting agencies include in their programming the funding of qualitative and quantitative studies on the impacts of increased use of non-pharmacological therapies on the public health and social service system.

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**REPRESENTATIONS OF THE HUMAN BEING**

Psychotropic drugs influence the functioning of the brain, which is the organ representing the higher faculties, the seat of the spirit, of the soul, and of personal identity. Consequently, the symbolic effects on the symbolic relationship with the “self”, the identity and the concept of the human being are different from those induced by other classes of drugs. Given the many advances of neuroscience, psychotropic medications are provoking philosophical debates about human nature.\(^{416}\)

Here are some of the questions being raised: Are we truly “ourselves” when we act under the influence of drugs that alter our thinking, our behaviours, our mood and our cognitive functions? To what extent do these drugs change the identity of the person and transform that person’s relationship to the world? Will our thoughts and acts then be perceived as authentic? Does limited use, over a short timeframe, differ from regular use which modifies habitual functions in a durable way? Should we use different criteria to judge the morality of acts committed in a context of expanded use of psychotropic medications?

These issues are not solely related to expanded uses of psychotropics. They also arise, but with less intensity, in cases where drugs are used for therapeutic purposes, which aim to restore or maintain health, which is not the case of all the expanded uses of psychotropic drugs.

**Human Nature and Meliorism**

The desire for improvement is part of the human condition, which includes the enhancement of cognitive functions. In fact, “having a better memory, being more capable of attention and concentration, are enhancements of our natural abilities, and one can hardly claim that they alter the sense of being a human being.”\(^{417}\)

The question of enhancement by means of psychotropic medications leads to debates on the nature of the human being, on what it means to live a successful life and on self-realization. In this regard, the Commission has already addressed the relationship between the techno-scientific advances of neuroscience and the questions they raise about the ontological status of the human being.

Certain developments – even if mostly involving physical interventions intended to offer therapeutic benefits – raise a number of fundamental questions with regard to the personal and social aspects of human identity: what we understand and consider to be human, what is deemed normal (or acceptable) and what is not.\(^{418}\)

Indeed, Western societies situate the brain at the centre of what it means to be a person and to have an identity. The brain is the organ of thought, of consciousness, of acting or not acting, of memories, of individuality.\(^{419}\) Losing one’s cognitive abilities – including memory – can alter what defines us as individuals.\(^{420}\) However, psychotropic medications affect the chemical and biological foundations of the brain, and therefore involve what or who we are at the deepest level possible, at the human essence. The development of genetics has already launched the debate about human nature, but psychotropics are actually easier to use than genetic engineering and have a more direct relationship with our “self.”\(^{421}\)
Human nature and enhancement –
humanism and transhumanism/posthumanism

The modern humanism introduces a radical break: it distinguishes Man from Nature and places the first over the second. Man becomes an end in himself and cannot be instrumentalized, even for purposes of enhancement. The human being is thus invested with “authenticity” and the integrity of human nature must be respected.

Transhumanism and posthumanism postulate the physical and neurological plasticity of the human being. The human can use existing technologies to enhance physical and cognitive capabilities and accelerate evolution, particularly through gene therapy, psychotropic drugs, brain implants, and so on. The difference between these two ideologies is one of degree: transhumanism uses techniques to enhance physical, intellectual and psychological characteristics of the human, while posthumanism aims to transform and overcome human nature to the point where, conceivably no physical characteristic currently defining a human being remains.

These two concepts, humanism and transhumanism/posthuman are openly opposed to each other.

The claims made on behalf of psychotropic drugs to enhance cognitive functions run head-long into the belief that human nature is based on natural and gradual evolution. For proponents of “authentic” human nature,
psychotropic drugs can be used to treat and relieve people suffering from disease; cognitive enhancements from use of psychotropic drugs are not natural, and hence are unacceptable. Moreover, such enhancements upset the natural order of things and, therefore, the human being “takes himself for God” – beyond the religious sense given to this phrase, the attitude denotes a lack of humility and non-respect for the way things are; further, it should be understood that the human being enhancing his cognitive functions has little control of tools beings used and will face unknown consequences.

For transhumanists/posthumanists, the human being is not content with his natural limitations. Rather, the human being seeks to overcome these limitations and does not hesitate to use external techniques. For example, the human being hunts with weapons invented and forged by human hands, and wears glasses fashioned by humans to improve eyesight. According to transhumanist and posthumanist perspectives, psychotropic drugs are part of human evolution; they have therapeutic uses, and must also be accessible for the purposes of enhancement albeit under supervision so as to reduce risks to health.

These two concepts of the human being are not easily reconciled. For some, the manipulation of the biological foundations of life represents an affront to our humanity; for others, this possibility is an integral part of our nature.

Some Representations of the Human Being

In modern societies, three representations of the human being stand out and modulate the dimensions of responsibility, free will, conscience and spirituality.

- The first representation of the human being is religious in nature. According to this representation, humans are God’s creation. Stemming from this is a first interpretation: that using the enhancing functions of medication in order to change human nature is tantamount to changing God’s creation, and even to play God. When human beings seek scientific advances that seem to exceed the normal course of things, then they no longer recognize their own limitations: they are assuming the place of God and are thus committing an act of idolatry. This is not the only concept found in religious traditions. A second concept acknowledges that the evolution of life and humanity takes place slowly and naturally, without external recourse to nature. A third concept holds that in improving the conditions of human life, humans collaborate with God in fulfilling the work of creation: are humans not created in his image?

- The second representation of the human being is based on a kind of naturalism. Various forms exist of naturalism, the best-known of them postulating that human beings are biologically and genetically determined. Thoughts, decisions and actions are the exclusive products of interneuronal connections and chemical concentrations of various neurotransmitters.
The third representation, dualism, consists in acknowledging that the brain and mind, although connected, are nevertheless different in nature: the brain is material while the mind is immaterial. For example, it is possible to deduce the functioning of the brain using functional magnetic resonance imaging equipment (fMRI), but no one has ever seen a thought. Thus, according to this school, the “human being” includes the biological dimension, but goes beyond that to include consciousness, thoughts, memories, anticipation, and behaviours. Where the biological dimension is concerned, this representation recognizes the partly deterministic character of human decisions and actions.

These representations are being rocked by advances in neuroscientific knowledge. As a result, it is important to pay close attention to drug uses that are designed to enhance or regularize functions, whether of the “Medical” or “Lifestyle” type, since they influence the foundation of concepts of the human being and of life in society, including normality, suffering, performance and effort.

Normality

What does it mean to be “normal”? As has been shown above, responses vary over time, and depend on individuals, groups and societies. In statistical or social terms, being “normal” means meeting a standard. However, human diversity is such that it is difficult to imagine a standard benchmark for cognitive function. Any definition of normality is bound to be complex, subjective and evolutionary in nature.

Accordingly, a trait considered “normal” for a person or a physiological process such as aging may turn into an anomaly in need of treatment, based on “an ideal target.” However, does the person involved consider this trait to be abnormal? And how do external pressures alter his perception or behaviour with a view to complying with pressures?

If the use of psychotropic medications to enhance performance and present regulated behaviours and moods is becoming trivialized, this medicated normality risks favouring the homogenization of diversity and the social ostracization of “deviants”. The effects of this homogenizing trend have yet to be demonstrated in detail, but it does not seem possible to mitigate personal and cultural differences without incurring consequences: a loss of cultural and social diversity, a lack of openness to differences that could lead to an attitude of intolerance, coercion – whether mild or otherwise – and thus an assault on the autonomy of moral subjects, and moralization with respect to individual behaviour (for example, the moral subject himself or parental authority).


431 Some people also consider that evolution is part of an “intelligent design” in the mind of God (or Intelligent Design). The Intelligent Design website provides more detailed information about this trend: http://www.intelligentdesign.org/


434 LEVY, op. cit., pp. 9-10; FARAH (2004), op. cit.


437 See Chapter 3, sub-section Expanded Uses of the “Lifestyle” Type – Towards a Redefinition of Social “Normality”.

438 TURNER and SAHAKIAN, op. cit., p. 117.


Suffering

The use of psychotropic medications as a means of maintaining or achieving a level of performance, efficiency and mood stability does not necessarily mean that users will be happier or more satisfied as a result. Whether these objectives are met or not may lead to helplessness, and even to physical and mental suffering.

On the one hand, the perception of pain varies from person to person. The perception of pain follows a path between two extremes: the value assigned to it by certain people, religions, spiritual traditions and societies, and the intolerance of pain: why suffer when you can avoid it? Between these two extremes are a range of subtle gradations.

On the other hand, the cause of this suffering is often overlooked: a hectic rhythm of work and life can cause physical health problems, and harm interpersonal and family relationships. This would seem to militate in favour of psychotropic medications as a means of correcting a mental health problem caused by this rhythm of work and life. However, the consequences for individuals and their environment cannot be ignored: such people are suffering and, hopefully, they are receiving appropriate assistance. Should they be left without care simply because the cause of their suffering is related in part to a social level and not to a proven pathology? The Commission does not believe so, but considers that this form of suffering should lead us to question an emerging social trend.

Performance

In an earlier position statement, the Commission raised two questions that remain relevant today: “How far are human beings prepared to go in the pursuit of perfection? How much freedom is society willing to give individuals in this pursuit?”

The importance of the values of performance and self-realization in society cannot be ignored. These values can be found at various levels and are expressed in various ways across the ages and in different societies. Personal satisfaction and public recognition provide a sense of achievement and strengthen the positive perception of performance, which are powerful and creative forces driving personal and collective well-being.

The potential role of psychotropics in fulfilling these values should not leave one indifferent. In industrialized societies, performance, efficiency and going beyond one’s personal limits are all important, and contribute to self-realization. However, these values may be diverted from their objective once they become ends in themselves. People turn to psychotropic drugs for the purposes of enhancing cognitive and physical capacities, in order to perform “better” and to realize themselves; these expanded uses are found in different life environments: the school sector, the workplace and in leisure activities. This concept of self-realization depends on the trivialization of psychotropic drugs and leaves little room for different interpretations of what it means to “realize oneself” and of the various ways to bring about this self-realization. As a result, taking psychotropics in order to attain this objective of self-realization ends up normalizing expanded uses of psychotropic drugs for the purposes of enhancement. In cases like this, the end justifies the means, regardless of one’s health or critical reflection on the values at stake.
Effort

The issues of effort and cheating are relevant to concepts of performance, enhancement and self-realization. Indeed, the result of an action will often be considered in a favourable light if it is the result of effort, of personal investment. In addition, many societies and spiritual traditions value the use of personal resources, effort and discipline.

In the scientific literature, many authors draw a parallel between cheating, effort and the use of psychotropic medications to enhance cognitive and emotional performance, usually accompanying this parallel with a comparison to sports doping. An observation can be made at this point: sports doping is universally discredited, whereas cognitive “doping” is better accepted or is interpreted with more layers of detail. This observation is even more easier to make in the case of methylphenidate consumption. Indeed, taking this medicine is not perceived to be a form of cheating. According to Canadian and American articles on the expanded use of methylphenidate, this neurostimulant is not considered a drug but rather as a tool, whose consumption through expanded uses has reached and even surpassed its medical use.

It is beyond the scope of this position statement to reflect on the importance of “effort” in Quebec society. However, research suggests that it would be appropriate to reflect on the place and interpretations of “effort” in different dimensions of our social and personal life.

Recent discoveries tend to reinforce a radically materialist, if not determinist vision of human nature. This is not surprising in itself since these discoveries result from deployment of technoscientific tools to examine the brain and the genes believed to be involved in its functions. However, questions remain unanswered, such as the predictability of thoughts and actions. Furthermore, according to some authors, this type of analysis, although quite relevant in its own way, may not take into account “the rich psychic dimensions of the integral being.”

In sum, diverse conceptions of the human being and of the cultural, religious and traditional aspects associated with the human being coexist in modern societies. This very plurality militates in favour of broadening the debate on the role of psychotropics and on the place of expanded uses in Quebec.

441 CEST (2006), op. cit., p. 66.
444 RACINE et FORLINI, op. cit.
446 According to Paul RICOEUR in his interviews with Jean-Pierre CHANGEUX (Paul RICOEUR and Jean-Pierre CHANGEUX, Ce qui nous fait penser. La nature et la règle, Paris, Odile Jacob, 1998, p. 89) (our translation).
When it comes to defining what is meant by health, disease, therapeutic use and cognitive enhancement, there is a lot of debate but not much consensus. For this reason, several questions arise: Who can draw the line between the medical and social dimensions of health? Is self-transformation a moral duty, in the interests of self-enhancement (cognitive functions, stable behaviours and mood)? Is it desirable to use psychotropics without any restriction for escaping physical and cognitive boundaries? Who should decide whether a specific enhancement of cognitive functions is acceptable or not? What criteria should be used for decision-making? What means should be taken to communicate these criteria and arguments?

Given the democratic and pluralistic nature of contemporary societies, it is difficult to invoke a single overarching vision of the common good. Indeed, developing social projects, deciding what action to take and determining the risks involved, going in the case from a passive definition of “acceptable risk” to a legitimated definition of “accepted risk”, represent collective goals to realize together as a society:

Political authorities are well-suited to arbitrate between different visions. Indeed, elected officials bear the responsibility of defining the common good and of ensuring that the community values are not subordinated to the interests of the few.

A better assessment of the “technical” risks and benefits of psychotropic drugs and their expanded uses requires the expertise of health professionals – including physicians, pharmacists, nurses, psychologists and social workers. Moreover, scientists acknowledge the existence of expanded uses and the ethical issues to which they give rise. A reading of the biomedical literature indicates a common position: expanded uses exist, they are here to stay and they will become more significant as new molecules with fewer adverse drug reactions are discovered and act on healthy individuals. Moreover, most authors do not support the idea of resignation in the face of a fait accompli: expanded uses for the purposes of enhancement must be supervised, regulated, and the social and ethical issues discussed. However, this task does not devolve on health professionals alone; dialogue with experts in the humanities and social sciences helps to broaden perspectives.
Accordingly, expanded uses go far beyond these frameworks of expertise and are part of a dynamic involving citizens. The decision-making process that defines the choice of issues, should go beyond the “expert-political class” relationship. Several other stakeholders are concerned, starting with the citizen-as-user, and should participate in social and ethical debates on expanded uses of psychotropics. In this regard, people who are not necessarily familiar with technical language and expert knowledge should also participate in discussions about expanded uses. Excluding them would undermine the legitimacy and effectiveness of decisions taken by others.

Integrating a diversity of views will promote conditions for the greater social acceptability of issues and decisions, while reducing the risk of paternalism, whether on the State’s part or on that of groups of health and social services experts. To this end, the Commission recommends:

**Recommendation No. 11**

a) That the Minister of Health and Social Services and the Minister of Education, Recreation and Sport promote the participation of civil society in discussions and decisions related to the place of medications, and particularly to the expanded use of psychotropic medications.

b) That the Commissaire à la santé et au bien-être (the Commissioner of Health and Welfare) lead a public debate on the expanded uses of psychotropic medications.

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447 Lexchin, op. cit., p. 1449.
449 Baertschi, op. cit. (our translation).
People suffering from mental and neurological health problems and those closet to them are obtaining real relief thanks to the progress in therapeutic treatments brought about by psychotropic drugs. However, increases in diagnoses of certain mental and neurological disorders as well as in prescriptions for psychotropic drugs do not rest solely on medical grounds. Several factors are involved in these increases, but the Commission is focusing on the expanded uses of drugs, on the motives underlying strictly non-therapeutic uses as well as the consequences of such uses.

It has rapidly become clear that the phenomenon of expanded uses is complex and goes beyond the medical setting alone. The lack of a consensus definition of “expanded use” of psychotropic drugs does not call into question the reality of expanded use. However, it highlights different perceptions of the same reality as well as major differences in terms of language, the assessment of risks as well as ethical issues raised by the expanded uses of psychotropic drugs. This pluralism is a fundamental characteristic of the ethical context surrounding the expanded use of psychotropic drugs and represents an additional challenge for the articulation of ethical issues.

Indeed, the place of psychotropics and of their uses in society is shaped by the presence of numerous social actors, with diverse interests, by the complexity of their interrelationships and by the social and economic influences they exert. Illustrating the complexity of the phenomenon, the Commission has become aware through its work of the multiplicity of perceptions. In perceptions of risks and benefits, some people minimize risks and invest too much hope in benefits. In perceptions of value concepts such as performance...
and self-realization, these essentially creative values may be pushed to the extreme, trivializing the use of psychotropics and instrumentalizing the brain. In perceptions of the effects of time on the body and cognitive functions, decreases in activity may be accepted, assumed or rejected. In perceptions defining individual responsibility, which is necessary when the individual is able to contribute in his own way to solving a problem, this individual responsibility may be diverted from its original meaning if it is invoked in order to solve a problem whose roots are social.

Similarly, the difficulties of delimiting the boundaries between concepts as essential as “health” and “disease”, “therapy” and “improvement”, “use” and “expanded use” are real. However, these concepts are needed in order to map out the debate.

Likewise, consensus about the expanded uses of psychotropic medications is emerging in several areas. First, psychotropic medications are absolutely essential in the treatment of people diagnosed with mental or neurological illness. Second, expanded “Medical” and “Lifestyle” uses are currently a reality in Quebec and constitute a well-established trend. Third, knowledge of the functioning of the brain is still limited, and the medium- and long-term effects of use of psychotropics remain largely unknown. Fourth, the claims made about the benefits and risks of expanded use of psychotropic medications are supported by very little scientific data and are instead of a rather speculative nature. Fifth, the idea of altering the brain, the seat of thought and a symbol of the “self”, rarely leaves people indifferent. Finally, the expanded uses of psychotropics affect both individual values, such as autonomy, well-being, self-confidence, performance and safety, and collective values, such as solidarity and accessibility.
The Commission is focusing on three potential kinds of drift related to expanded uses of psychotropic drugs. The first kind of drift is made up of external pressures bearing on the individual as well as incomplete and even partial information on psychotropic medications and their benefits. The Commission sees in this drift a risk both of homogenizing moods and behaviours and of intolerance towards people who depart from “normality” which has become a medicated normality. The second kind of drift is related to trivialization of expanded “Lifestyle” uses, and to a lesser extent of expanded “Medical” uses. The Commission notes that life situations arise that unambiguously require the use of psychotropes. However, some uses are considered as means to achieve personal and professional goals, or to cope with painful but inevitable life events; as such, they mark a shift towards the maximization of quick results and the minimization of personal resources. Finally, the third kind of drift challenges the notion of personal identity and the representation of human beings. Self-realization includes success and performance, but are all means to achieve these goals desirable? Is the human brain an object liable to be turned into an instrument, or is it a feature distinguishing a human being not only from other animals, but also from every other human being?

The ethical issues raised by the expanded use of psychotropic drugs are numerous, complex and topical. In order to address the issues, the Commission is making recommendations that several revolve around the need for information. There is a need for new knowledge about brain functions, the modes of action of psychotropic drugs and current uses of psychotropics. Moreover, teams from various scientific backgrounds should undertake studies over a long timeframe, collecting data on the medium- and long-term effects of psychotropic drugs. Finally, validated information should be transmitted to health professionals as well as to decision-makers and the general public.
The ethical issues discussed in the position statement reflect the mission of the Commission which consists, on one hand, of informing, raising awareness, gathering opinions, fostering reflection and organizing debate on the ethical issues raised by developments in science and of technology, and, on the other hand, of proposing general guidelines for stakeholders to refer to in their decision-making. It is therefore in fulfilment of its mission that the Commission is publishing its recommendations and issuing its cautionary notes, and that it proposes the rapid development of spaces for public debate, in order to keep up with the evolution of expanded uses, especially in terms of the objective of regulation. The Commission sees this public space as an ideal place for multi-stakeholder reflection and concerted decision-making, since "these issues [...] are likely to arise with increasing urgency in the years to come." The Commission does not claim to have answers to the many questions raised in this position statement, but believes that many of these questions are fundamental and need to be subjected to public debates.

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452 According to Patrick Robert, former Vice-Rector of Public Affairs and Development at the Université de Montréal, in an interview in 2004: "In genetics, for example, progress is so rapid and far-reaching that it challenges the very basis of human existence. Given this situation, scientific and technical advances will naturally involve a greater participation of social sciences in the future." (quoted by Jean-Guillaume Dumont, "Le Québec des sciences humaines – Bilan positif, avenir incertain", Le Devoir, 29 May 2004, p. H-3) (our translation).

453 Anne-Catherine HATTON, Neurosciences, nanotechnologies et éthique : un état des lieux, unpublished manuscript, Faculty of Law, Université Laval, April 2004, p. 26 (our translation).
Glossary

ACTION POTENTIAL: see Nerve impulse.

ADVERSE DRUG REACTION: Effect of a drug outside of the area for which it is administered; the effect being bothersome or dangerous, or limiting the use of the drug. (CEST, derived from OQLF)

AXON: A single projection of a neuron, which may or may not include a myelin sheath, and which conducts nerve impulses away from the cell body. It is divided into axonal terminals that transmit nerve impulses to other neurons (see Synapse). (CEST, derived from MCGILL UNIVERSITY and OQLF, op. cit.)

BLOOD-BRAIN BARRIER: Anatomical barrier formed by blood vessels isolating the brain from the bloodstream. These vessels control the exchanges between the brain and blood, carrying oxygen and nutrients to the brain and blocking undesirable substances. (CEST, derived from OQLF, MCGILL UNIVERSITY, op. cit.; Thierry BUCLIN and Jerome BOLLUAZ, “Regards récents sur la barrière hémato-encéphalique”, Revue médicale suisse, vol. 14, 2005, http://titan.medhyg.ch/mj/formation/article.php3?id=30272 [consulted 2 October 2008])

CELL BODY: Part of the neuron containing the nucleus, which processes information from other neurons or other cells (nerve cells, muscle cells, etc.). (CEST, derived from MCGILL UNIVERSITY and OQLF, op. cit.)

CENTRAL NERVOUS SYSTEM: Part of the nervous system formed by the brain (in the skull and consisting of the brain, cerebellum and brainstem) and spinal cord. (CEST, derived from OQLF)

COGNITIVE FUNCTIONS: There are four classes of intellectual functions: 1) receptive functions allowing the acquisition, processing, classification and integration of information, 2) memory and learning allowing the storage and retrieval of information; 3) thought and reason allowing the mental organization and reorganization of information, 4) expressive functions allowing communication or action.

DENDRITE: A short projection, divided into many tree-like branches, of the neuron. Dendrites are very numerous, and receive nerve impulses coming from outside the neuron (see Synapse). (CEST, derived from MCGILL UNIVERSITY and OQLF, op. cit.)

DIAGNOSTIC THRESHOLD: A value beyond or below a given threshold, which can demonstrate the existence of a disease, lead to a diagnosis and justify a therapeutic treatment. (CEST)

ELECTRICAL IMPULSE: See Nerve impulse.

EPISODIC MEMORY: Memory that mainly indexes only biographical characteristics, special events or episodes in the life of an individual which can in no way be considered as general knowledge.
EXECUTIVE FUNCTIONS: Functions which are nonspecific but essential for all directed, autonomous and adapted behaviour. They are included in cognitive functions and affect abstract thinking and the ability to plan, initiate, order, control and inhibit complex behaviours (Derouesné, op. cit.). Examples are: anticipation, goal-setting, planning, process organization, evaluation of results, formulation of assumptions, self-criticism, self-correction, mental flexibility, task persistence, mid-course adjustment and adaptability to change. (CEST, derived from OQLF)

GENERIC DRUG: Copy of a medication marketed after the expiry of a patent granted to an innovation-based pharmaceutical company. This copy is subject to Health Canada’s licensing process, in order to ensure that the generic medication and its pharmacological and pharmacokinetic effects are the same as those of the original medication. (CEST, derived from MSSS [2007], op. cit., p. 39)

GENERIC PHARMACEUTICAL COMPANY: A pharmaceutical company producing copies of a medication after the patent granted to an innovation-based pharmaceutical company has expired. This copy is subject to Health Canada’s licensing process, in order to ensure that the generic medication and its pharmacological and pharmacokinetic effects are the same as those of the original medication. (CEST, derived from MSSS [2007], op. cit., p. 39)

INNOVATION-BASED PHARMACEUTICAL COMPANY: A pharmaceutical company engaged in the research, development, manufacture and marketing of a new medication. (CEST, derived from MSSS [2007], op. cit., p. 60)

ISSUE: What is at stake (what can be gained or lost) in a project, conflict, election or event.

LITERACY: The ability to understand, use and process written information necessary to function in society, achieve personal goals, develop skills and acquire knowledge. (CEST, derived from OQLF)

LONGITUDINAL STUDY: A study measuring an event in a group of subjects at different points in time.

MEDICALIZATION: The process by which nonmedical problems become defined and treated as medical problems, usually in terms of illnesses and disorders, decontextualizing human problems and turning attention from the social environment to the individual. (KAWACHI and CONRAD (1996), cited by MINTZ [2002], op. cit., p. 908)

MEDICAMENTATION: The use of medication to treat medical and non-medical problems. (CEST, derived from NGOUNDO MBONGUE et al., op. cit., p. 309)

MEDICATION: Any substance or mixture of substances which may be used i) for the diagnosis, treatment, remission or prevention of any disease, ailment, any abnormal physical or mental condition, or their symptoms in man or animal, or ii) to restore, rectify or change organic functions in man or animal. (Pharmacy Act, R.S.Q., chapter P-10, art. 1 h)

MENTAL DISORDER: See Mental illness.

MENTAL HEALTH: The capacity of the individual, the group and the environment to interact with one another in ways that promote subjective well-being, the optimal development and use of mental abilities (cognitive, affective and relational), the achievement of individual and collective goals consistent with justice and the attainment and preservation of conditions of fundamental equality. (HEALTH AND WELFARE CANADA, op. cit., p. 7-8)
MENTAL ILLNESS: A recognized, medically diagnosable illness that results in the significant impairment of an individual's cognitive, affective or relational abilities. Mental disorders result from biological, developmental and/or psychological factors. (HEALTH AND WELFARE CANADA, op. cit., p. 7-8)
SYN: mental disorder, psychiatric disorder.

NERVE IMPULSE: Once a neuron receives stimulation eliciting a response, information leaves the cell body and reaches the axon to be transmitted outside the neuron (towards other neurons or muscle cells, for example). The nerve impulse travels along the neuron due to changes in the cell membrane and the concentrations of certain ions. (CEST, derived from MCGILL UNIVERSITY, op. cit.)
SYN: action potential, electrical impulse.

NEUROLOGICAL DISEASE: Any physical alteration that affects the structure or functioning of the central nervous system. (CEST)
SYN: neurological disorder.

NEUROLOGICAL DISORDER: see Neurological disease.

NEURON: The structural and functional unit of the central nervous system, consisting of a cell body and its processes, an axon and one or more dendrites. (CEST, derived from OQLF)

NEUROPHARMACOLOGY: The branch of pharmacology that studies medications affecting the central nervous system, such as modifying psychotropic mood and behaviour, anesthetics, sedatives, anticonvulsants and narcotics. (COOPER et al., op. cit., p. 1)

NEUROTRANSMITTER: Chemical substance that makes possible the transmission of nerve impulses between a neuron and another neuron or a target muscle, sensory or glandular cell. (CEST, derived from OQLF)

NON-DRUG THERAPY (TREATMENT): therapy (treatment) that does not resort to medications and whose effectiveness has been scientifically demonstrated. (CEST)
SYN: non-pharmacological therapy (treatment).

NON-PHARMACOLOGICAL THERAPY (TREATMENT): See Non-drug therapy.

PREVALENCE: The number of times an event has been observed in a given environment at a given moment or over a period of time, and without distinction between new manifestations of this event and old ones.

PSYCHIATRIC DISORDER: See Mental Illness.

PSYCHOTROPIC DRUG: Medication affecting the central nervous system and psyche. (CEST. OQLF proposes a broader definition: A substance, whether natural or artificial, able to modify mental activity and acting mainly on the central nervous system and psyche.)
SYN: psychotropic medication.

SELF-CARE: Actions by which a person takes decisions and concrete steps to prevent disease or cope with health problems in order to improve his condition.

SELF-MEDICATION: A person's use of medication without any medical prescription. (CEST, derived from OQLF)
SHORT-TERM MEMORY: Memory storing and maintaining information temporarily, for a period over tens of seconds, but which is sufficient for the performance of routine cognitive activities.

SYNAPSE: The junction point between two neurons over which passes the electrical and chemical transmission of nerve impulses. The synapse is composed of three elements: the presynaptic element (located at the axonal terminals of the neuron transmitter), the postsynaptic element (located at the dendrites of the receptor neuron) and the synaptic cleft (between the two neurons involved in the nerve impulse). (CEST, derived from MCGILL UNIVERSITY and OQLF, op. cit.)

THRESHOLD: The minimum value (low threshold) or maximum value (high threshold) ascribed to a quantity or risk factor. (CEST, derived from OQLF)

VALUE: A value is the purpose of an action. It gives meaning to the action and thus reflects the motivation to act. A value makes it possible to justify an action. Whether a value serves as a goal or as the purpose of an action, it reflects what a person or a population seeks to achieve and promote, or again to protect. (CEST [2003], op. cit., p. 54)


455 Unless otherwise indicated, all URLs were accessible 28 July, 2009, either directly or through site archives.


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RÉGIE DE L’ASSURANCE MALADIE DU QUÉBEC. Portrait quotidien de la consommation médicamenteuse des personnes âgées non hébergées, Québec, 2001, 87 p.

RÉGIE DE L’ASSURANCE MALADIE DU QUÉBEC. Tableau AM.07 – Nombre de participants et d’ordonnances, nombre d’ordonnances par participant, coût brut des ordonnances et par participant, coût RAMQ des ordonnances et par participant selon la classe de médicaments et la catégorie de personnes assurées – 2006, 2007a, Québec.

RÉGIE DE L’ASSURANCE MALADIE DU QUÉBEC. Tableau AM.10 – Nombre d’ordonnances, leur coût brut et leur coût RAMQ selon les classes et les sous-classes de médicaments les plus fréquentes et la catégorie de personnes assurées, par ordre décroissant du nombre d’ordonnances – 2006, 2007b, Québec.

REHM, Jürgen and John WEEKS. “Abuse of Controlled Prescription Drugs”, in CANADIAN CENTRE ON SUBSTANCE ABUSE (ed.), Substance Abuse in Canada: Current Challenges and Choices, Ottawa, CCSA, 2005, pp. 31-38.


CLASSIFICATION OF PSYCHOTROPIC DRUGS

List of psychotropic drugs and classifications using the Anatomical Therapeutic Chemical (ATC) classification system and the system used by the Régie de l’assurance maladie du Québec (Updated and adapted from Moisan et al., op. cit.)
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<th>International Common Denomination</th>
<th>Classification used by RAMQ</th>
<th>ATC Classification</th>
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</thead>
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<td>Sub-class</td>
<td>Chemical group</td>
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<tr>
<td></td>
<td>Class</td>
<td>Specific therapeutic use</td>
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<tr>
<td></td>
<td></td>
<td>Principal therapeutic use</td>
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<tr>
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<td>Benzodiazepines</td>
<td>Anxiolytics, sed. and hyp.°</td>
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<tr>
<td>Amtriptiline</td>
<td>Antidepressants</td>
<td>Tricyclic antidepressants</td>
</tr>
<tr>
<td>Amoxapine</td>
<td>Antidepressants</td>
<td>Tricyclic antidepressants</td>
</tr>
<tr>
<td>Busetropine</td>
<td>Other anxiolytics, sed. and hyp.°</td>
<td>Azasipredacaneide</td>
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<tr>
<td>Butoxphorol</td>
<td>Partial opiate agonists</td>
<td>Natural opium alkaloid</td>
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<tr>
<td>Chloral dioxoxside</td>
<td>Benzodiazepines</td>
<td>Derived from benzodiazepines</td>
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<tr>
<td>Chlorpromazine</td>
<td>Antipsychotics</td>
<td>Psycholeptics</td>
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<tr>
<td>Citalopram</td>
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<td>Antipsychotics</td>
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<td>Clobazam</td>
<td>Benzodiazepines</td>
<td>Anxiolytics</td>
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<td>Clomipramine</td>
<td>Antidepressants</td>
<td>Psycholeptics</td>
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<tr>
<td>Clonazepam</td>
<td>Benzodiazepines</td>
<td>Anticonvulsants</td>
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<td>Clozapine</td>
<td>Antipsychotics</td>
<td>Psycholeptics</td>
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<td>Codeine</td>
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<td>Desipramine</td>
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<td>Psycholeptics</td>
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<tr>
<td>Dexamphetamine</td>
<td>Amphetamines</td>
<td>Psycholeptics</td>
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<tr>
<td>Diazepam</td>
<td>Benzodiazepines</td>
<td>Anxiolytics, sed. and hyp.°</td>
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<td>Doxepine</td>
<td>Antidepressants</td>
<td>Tricyclic antidepressants</td>
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<td>Fluoxetine</td>
<td>Antidepressants</td>
<td>Tricyclic antidepressants</td>
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<td>Fluoxetine</td>
<td>Antidepressants</td>
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<td>Fluoxetine</td>
<td>Antidepressants</td>
<td>Tricyclic antidepressants</td>
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<tr>
<td>Fluoxetine</td>
<td>SSRI* or Tricyclic antidepressants</td>
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<tr>
<td>Fluvoxamine</td>
<td>Antidepressants</td>
<td>Psycholeptics</td>
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<td>Fluvoxamine</td>
<td>Tricyclic antidepressants</td>
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<td>Tricyclic antidepressants</td>
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<td>Fluoxazepam</td>
<td>Antidepressants</td>
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<td>Fluoxetine</td>
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<td>Fluoxetine</td>
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<tr>
<td>Haloperidol</td>
<td>Antipsychotics</td>
<td>Antipsychotics</td>
</tr>
<tr>
<td>Chloral hydrate</td>
<td>Various</td>
<td>Aldehydes and derivatives</td>
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<tr>
<td>Hydromorphone</td>
<td>Opiate agonists</td>
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</tr>
<tr>
<td>Hydromorphone</td>
<td>Antidepressants</td>
<td>antidépresseurs tricycliques</td>
</tr>
<tr>
<td>Imipramine</td>
<td>Antidepressants</td>
<td>Anxiolytics</td>
</tr>
<tr>
<td>International Common Denomination</td>
<td>Classification used by RAMQ Sub-class</td>
<td>Classification used by RAMQ Class</td>
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<tr>
<td>Lithium</td>
<td>Tranquilizers</td>
<td>Other psychotropes</td>
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<tr>
<td>Lorazepam</td>
<td>Benzodiazepines</td>
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<td>Loxapine</td>
<td>Antipsychotics</td>
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<td>Maprotiline</td>
<td>Antidepressants</td>
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<tr>
<td>Meperidine</td>
<td>Opiate agonists</td>
<td>Analgesics</td>
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<td>Methylphenidate</td>
<td>Other CNS stimulants</td>
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<td>Exception drug</td>
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<tr>
<td>Morphine</td>
<td>Opiate agonists</td>
<td>Analgesics</td>
</tr>
<tr>
<td>Nitrazepam</td>
<td>Benzodiazepines</td>
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<tr>
<td>Nortriptyline</td>
<td>Antidepressants</td>
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<tr>
<td>Olanzapine</td>
<td>Antipsychotics</td>
<td>Psychotropes</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>Benzodiazepines</td>
<td>Compactioptries, sed. and hyp.</td>
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<tr>
<td>Oxycodone</td>
<td>Opiate agonists</td>
<td>Analgesics</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>Opiate agonists</td>
<td>Analgesics</td>
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<td>Paroxetine</td>
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<td>Psychotropes</td>
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<tr>
<td>Pentazocine</td>
<td>Partial opiate agonists</td>
<td>Analgesics</td>
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<tr>
<td>Perphenazine</td>
<td>Antipsychotics</td>
<td>Psychotropes</td>
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<tr>
<td>Phenelzine</td>
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<td>Phenobarbital</td>
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<td>Pimozide</td>
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</tr>
<tr>
<td>Protriptyline</td>
<td>Antidepressants</td>
<td>Psychotropes</td>
</tr>
</tbody>
</table>

Notes:
- a: Others - Anxiolytic, sedative and hypnotic.
- b: Selective serotonin reuptake inhibitors.
- c: Psychostimulants, agents used in cases of hyperactivity and attention disorders, and as nootropics.
- d: Benzodiazepine-type medications.
### Medication for Alzheimer's Disease

<table>
<thead>
<tr>
<th>Drug</th>
<th>Category</th>
<th>Other Terms</th>
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</thead>
<tbody>
<tr>
<td>Donepezil</td>
<td>Exception drugs</td>
<td>Anticholinesterase</td>
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<tr>
<td>Galantamine</td>
<td>Exception drugs</td>
<td>Anticholinesterase</td>
</tr>
<tr>
<td>Memantine</td>
<td>Exception drugs</td>
<td>Other anti-dementia medication</td>
</tr>
<tr>
<td>Rivastigmine</td>
<td>Exception drugs</td>
<td>Anticholinesterase</td>
</tr>
</tbody>
</table>

**a:** (Others) Anxiolytic, sedative and hypnotic.

**b:** Selective serotonin reuptake inhibitors.

**c:** Psychostimulants, agents used in cases of hyperactivity and attention disorders, and as nootropics.

**d:** Benzodiazepine-type medications.
The following individuals agreed to review the first draft of the working committee report in January 2009:

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Guilhème Pérodeau, Professor and Director of the Psychology Module, Université du Québec en Outaouais

Dr. Josée Perreault, General Practice Physician, Medical follow-up care in psychiatry at Hôtel-Dieu de Lévis and General practice at Clinique Saint-Louis

Monique Richer, Secretary General of Université Laval, Adjunct Professor at the Faculty of Pharmacy, Université Laval and Bachelor of Law

The Commission thanks all of these people for their contribution to developing and enhancing the content of its position statement.
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M° Nicole Beaudry, notary

456 When the present position statement was adopted.
Drugs play an important role in therapeutic treatments since they have helped improve the quality of care and have helped make significant gains with respect to mental and neurological diseases. New generations of psychotropic drugs have raised enormous hopes, particularly for maintaining memory and cognitive function in people with dementia, for improved concentration in children with attention disorders and for emotional stability. There is also widespread public enthusiasm for over-the-counter products that produce the same effects. However, there are still limits to knowledge about the brain, the mode of action of drugs and their long-term side effects on the central nervous system.

Psychotropic Drugs and Expanded Uses: an Ethical Perspective is the sixth position statement published by the Commission de l’éthique de la science et de la technologie. In four chapters, it explains the social, socio-political and legal context in which the “drug” product exists, and describes the particular features of psychotropic drugs as well as scientific uncertainties related to the central nervous system and psychotropic drugs. The position statement analyses two broad categories of uses, namely those of the “Medical” type and those of the “Lifestyle” type. It then analyses the values and ethical issues which expanded uses put at stake, including the protection of persons, freedom, responsibility, fairness, accessibility and availability of information and the quality of this information. In considering these issues, the Commission has identified four key values: the protection of individual health and safety, autonomy and the affirmation of individual freedom, equity and representations of the human being. In its ethical assessment, the Commission addresses eleven recommendations and two cautionary notes to decision-makers in Quebec and Canada.

This position statement and other publications of the Commission are available at the following address: www.ethique.gouv.qc.ca

The mission of the Commission de l’éthique de la science et de la technologie consists, on one hand, of informing, raising awareness, gathering opinions, fostering reflection, and organizing debates on the ethical issues raised by developments in science and technology and, on the other hand, of proposing general guidelines for stakeholders to refer to in their decision-making.