




SUMMARY AND
RECOMMENDATIONS

POSITION
STATEMENT

PSYCHOTROPIC
DRUGS AND
EXPANDED USES:
an Ethical
Perspective



COMMISSION DE L'ÉTHIQUE
DE LA SCIENCE ET DE LA TECHNOLOGIE



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The French
version
prevails

**Commission de l'éthique
de la science et de la technologie**
1200 route de l'Église
3rd floor, office 3.45
Quebec (Quebec)
G1V 4Z2
www.ethique.gouv.qc.ca

PRODUCTION SUPPORT

Meeting secretary
Marie-Claude Côté
Research and writing
Marie-Claude Côté, with contributions from Marie Demers

TECHNICAL SUPPORT

Secretariat
Annie St-Hilaire and Louise Trudel
Documentation
Annie Lachance and Patricia Keable
Editing supervision
Marie-Claude Côté
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Le Graphe
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Matteau Parent graphisme et communication inc.
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MEMBERS OF THE WORKING COMMITTEE

M^e Edith Deleury, Co-Chair

Professor Emeritus
Faculty of Law
Université Laval
President of CEST

Hubert Doucet, Co-Chair

Researcher
Bioethics programmes
Université de Montréal
Member of CEST

MEMBERS

D^e Denise Aubé

Medical Examiner
Directorate of Health-Care Systems and Public Policy
Institut national de santé publique du Québec

M^e Danielle Parent

Lawyer
Director, Directorate of Legal Affairs,
Transport and Notarial Affairs,
Ministry of Justice of Quebec
Member of CEST

Danièle Cartier

Neuropsychologist, Private Practice
Inspector-investigator of the Professional
Inspection Committee of the Ordre
des psychologues du Québec

Éric Racine

Bioethicist and Assistant Research Professor
Director of the Neuroethics Research Unit, IRCM
McGill University and Université de Montréal

Johanne Collin

Professor – Sociology of Health
Faculty of Pharmacy
Université de Montréal

Lucie Robitaille

Executive Director
Conseil du médicament

Stéphane Côté

Pharmacy owner
and Clinical Professor
Faculty of Pharmacy
Université Laval

Martine Simard

Associate Professor
School of Psychology
Université Laval

COMMISSION SECRETARIAT

D^r Serge Gauthier

Neurologist and Principal Investigator,
Research Study in Alzheimer's Disease,
McGill Centre for Studies in Aging
Douglas Mental Health University Institute

M^e Nicole Beaudry, notary

Secretary General of CEST

Jocelyne Moisan

Professor and Director of the Réseau québécois
de recherche sur l'usage des médicaments
Faculty of Pharmacy
Université Laval

Marie-Claude Côté

Ethics Advisor and secretary
of Working Committee

27 août 2009

Monsieur Clément Gignac
Ministre du Développement économique,
de l'Innovation et de l'Exportation
710, place D'Youville, 6^e étage
Québec (Québec) G1R 4Y4

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

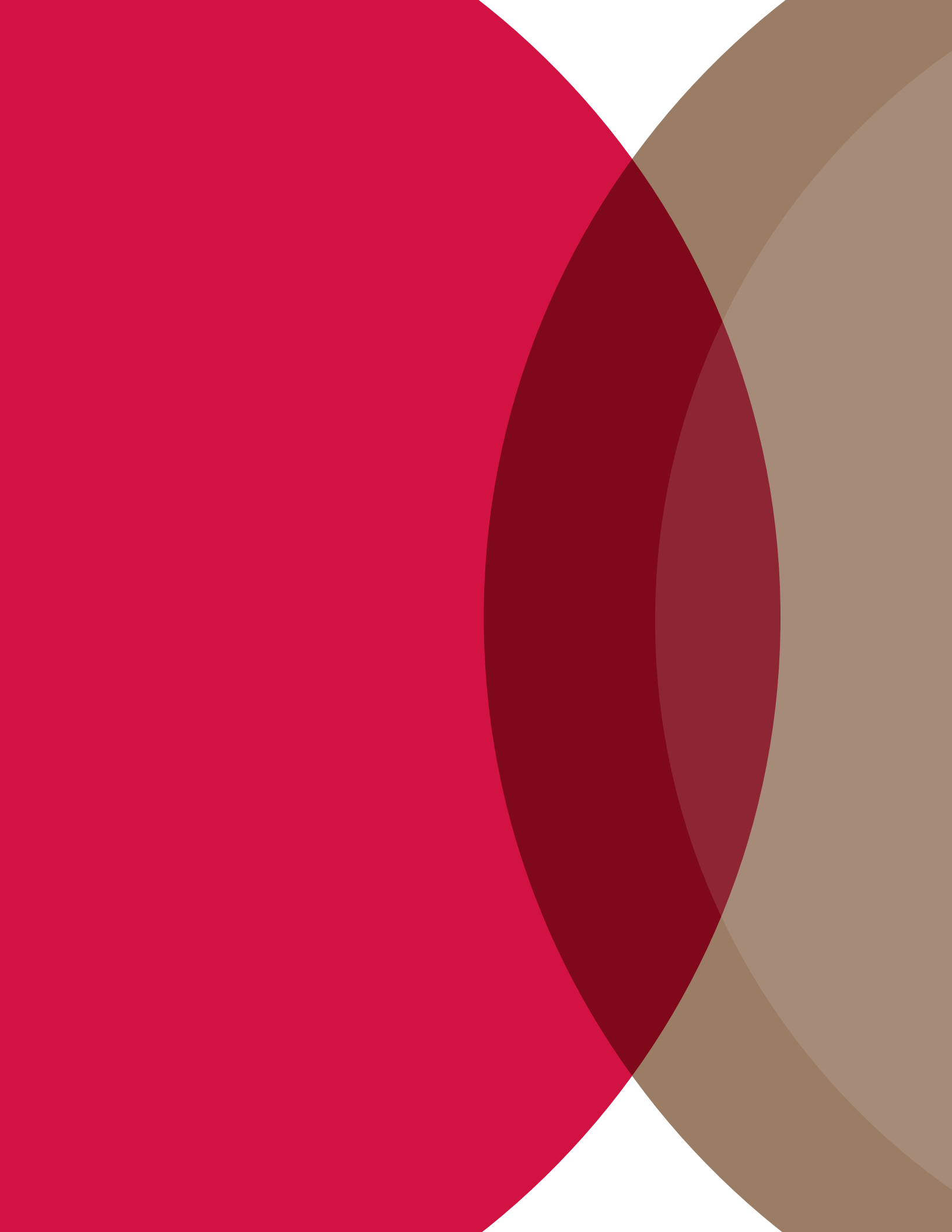


Édith Deleury

c.c. Michel Jébrak, président du Conseil
de la science et de la technologie



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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

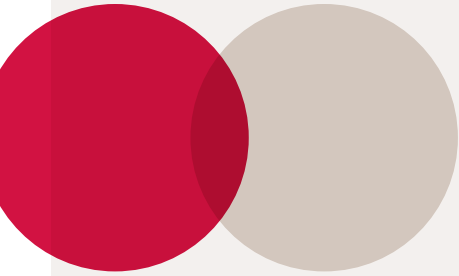
Société de l'assurance automobile du Québec
(Quebec Automobile Insurance Plan)

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 poly medication 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 a 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,¹ 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;²
- b) that regulations continue to preserve the unique character of the Canadian health care system, which is based on solidarity;³
- 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*.

1 **CONSEIL DU MÉDICAMENT DU QUÉBEC, *Publicité directe auprès des consommateurs: le point de vue du Conseil*, Québec, Conseil du médicament du Québec, 29 March 2004.**

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 previously 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 mean 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 a 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 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 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.





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THE CONSULTATION ACTIVITIES OF THE COMMISSION

The following individuals agreed to review the first draft of the working committee report in January 2009:

Henri Dorvil, professeur, Professor, School of Social Work, Faculty of Arts and Sciences, Université du Québec à Montréal

Dr. Mimi Israel, Chair of the Department of Psychiatry, Douglas Institute, and Associate Professor, Department of Psychiatry, McGill University

Bernard Keating, Adjunct Professor, Faculty of Theology and Religious Science, Université Laval

Dr. Fadi Massoud, Assistant Clinical Professor, Department of Medicine, Université de Montréal and geriatric internist at the Geriatric Service, Hôpital Notre-Dame

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.



MEMBERS OF THE COMMISSION DE L'ÉTHIQUE DE LA SCIENCE ET DE LA TECHNOLOGIE⁴⁵⁶

PRESIDENT

M^e Édith Deleury

Professor Emeritus – Faculty of Law
Université Laval

MEMBERS

Patrick Beaudin

Director General
Société pour la promotion de la science
et de la technologie

D^r Pierre Deshaies

Specialist in community health
Head of the Clinical Department of Public Health
Hôtel-Dieu de Lévis

Hubert Doucet

Researcher
Bioethics programmes
Université de Montréal

Benoît Gagnon

Researcher and doctoral candidate
International Centre for Comparative Criminology
(CICC)
Université de Montréal

Mariette Gilbert

President
Association féminine d'éducation
et d'action sociale (AFEAS)

Jacques T. Godbout

Sociologist
Institut national de la recherche scientifique
Urbanisation, Culture et Société

Françoise Guénette

Independent journalist and broadcaster

Patrice K. Lacasse

Social development coordinator,
First Nations of Quebec and Labrador Health
and Social Services Commission

Dany Rondeau

Professor
Department of Arts and Humanities
Université du Québec à Rimouski

Bernard Sinclair-Desgagné

Director, Service of Teaching International Affairs
Chair of International Economics and Governance
HEC Montréal

Eliana Sotomayor

School of Social Work
Université de Montréal


GUEST MEMBER

M^e Danielle Parent

Director, Directorate of Legal Affairs, Transport
and Notarial Affairs,
Ministry of Justice of Quebec

THE SECRETARY GENERAL

M^e 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.