

Quebec's Science and Technology Ethics Commission and Expanded Uses of Psychotropics: Ethical Issues and Recommendations

Me Edith Deleury, LL.M

President of Quebec's Science and Technology Ethics Commission, Professor Emeritus at the Faculty of Law, Université Laval

Marie-Claude Côté, B.A.A., B.Sc., M.A., Ethics Advisor at Quebec's Science and Technology Ethics Commission

ABSTRACT

If the new and rapidly expanding discipline of neuroethics Recently, the use of psychotropic drugs has increased in Quebec. Several factors may explain it, including expanded uses which aim to improve cognitive function in the absence of known mental problems. These uses involve ethical and social choices, which go beyond the medical setting and include the public participation of experts and citizens.

This article lays out the position of the Quebec's Science and Technology Ethics Commission, which has addressed this issue and published a position statement in autumn 2009. We present two categories of expanded uses, namely the "Medical" and the "Lifestyle". Then we focus on values and ethical issues related to expanded uses. These ethical issues pose a challenge for the individual, the State, the media and the pharmaceutical industry; and they play out in the short, medium and long term. In addressing these issues, the Commission makes several recommendations.

Key words: ethics, psychotropics; off-label.

Introduction

The Commission, established in 2001 by the Government of Quebec, has a twofold mission. It is firstly to inform, raise awareness, gather opinions, foster reflection and organize debate on the ethical development of science and technology; and secondly, to propose general guidelines for stakeholders to refer to in their decision making.

In November 2006, the Commission decided to produce a position statement on psychotropic drugs. Several factors have motivated the Commission's interest. The leading factor is that Canadians

and Quebecers are large consumers of psychotropic drugs. For example:

- In 2002, Canadians were among the leading users of psychotropic drugs worldwide (Rehm & Weeks, 2005).
- During 2000, 19.4% of Quebecers over 65 years of age received at least one prescription for benzodiazepines (RAMQ, 2001).
- Among minors, between 1993 and 1999, prescriptions for psychostimulants increased by over 200% (Collège des médecins du Québec & Ordre des psychologues du Québec, 2001).

Among other factors which have attracted the attention of the Commission may be noted: the popularity of nonprescription products that stimulate cognitive functions ("smart drinks", Omega-3, etc.); the development of this branch in the pharmaceutical industry; the immense hopes, both in people suffering from mental disorders and among "healthy" people, to maintain or enhance the cognitive functions, or to regulate their moods; and finally, the incomplete information on long-term side effects on the nervous system.

This article presents a part of Commission's position statement. It is divided into two parts. First, we will describe the state of the Commission's reflection on ethical issues raised by the expanded uses of psychotropic drugs. Then, we will explain the recommendations and cautionary notes that have emerged from this reflection.

Two Types of Expanded Uses

It is important to clarify what is meant by "expanded use". For its part, the Commission has defined the term "expanded use" as use going beyond the scope of established practices, and has for this

reason identified two types of “expanded uses”: the “Medical” type and the “Lifestyle” type.

These two categories are not completely independent of one another. On the one hand, several stakeholders and contextual elements are common to both categories. On the other hand, scientific research and applications are guided by standards which are culturally determined. However, the two categories have been distinguished for the purposes of demonstration.

Expanded Uses of the “Medical” Type

This kind of use is primarily within the sphere of expertise of physicians and in a context of professional practice which is perhaps not unique to Quebec, but is nonetheless part of the set of problems at issue here: the non-optimal organization of health-care network and the emphasis on the concept of prevention resulting in individuals taking medication. Some aspects are more common: scientific uncertainty due to lack of knowledge about brain function and the modes of action of psychotropic drugs; diagnosis of a mental or neurological disease may be harder to establish on an objective basis than a physical disorder; the well-known but nonetheless real difficulty of distinguishing between “therapy” and “enhancement”.

Given that physicians are with few exceptions the only professionals in Quebec authorized to prescribe drugs, the Commission has focused on factors likely to influence their prescribing practices, in particular:

- The limits of knowledge about psychotropic drugs as well as mental and neurological illness: this factor involves the limited nature of evidence, mostly drawn from clinical trials which replicate little of everyday reality.
- The influence of the pharmaceutical industry: pharmaceutical companies promote their products, whether targeting doctors, pharmacists or the general public.
- The organization of the Quebec health and social services system: it operates as a series of silos, and has to contend with a fairly widespread shortage of human resources; in that context, prescription drugs can be seen as tools offering temporary relief.
- Patient demand: Before consulting a health professional, an individual has access to abundant sources of information: television, the Internet, books and scientific or general-interest magazines, etc. Thus, he may have made up his mind in advance and have specific requests.

As is the case with any use of medication, expanded uses of the “Medical” type lead to consequences, one of them being a main anticipated benefit and four being potentially adverse consequences.

- The main anticipated benefit is the advance of knowledge through clinical use in a population with a diverse life and health profiles.
- Accessibility and quality of care may be reduced as a result of

expanded uses of psychotropics if physicians promote a drug therapy “by default” so as not to leave people without care. Paradoxically, the increase in consultations could result in less screening and inadequate follow-up for users diagnosed with mental and neurological illnesses.

- Individual safety is at stake, since increased use of psychotropics may be accompanied by increased risks of the prevalence of adverse reactions. Also, the safety of others is at stake since workplace or traffic accidents may increase, that could bring consequences at the collective level, given that Quebec’s social security net provides for compensation in both cases.
- Trivialization of psychotropic drugs. Given the diagnostic uncertainty and the daily disruptions experienced by people with mental disorders, there is a possibility of “overdiagnosis” and “overprescribing” psychotropics. But the fact a medical diagnosis has been made may change an individual’s perception of his situation because it implies that illness is involved. Moreover, when the expert proposes that a patient take medicine, this has the effect of legitimizing treatment. As a result, there exists a risk of medicalizing life events whereas they do not necessarily belong to the field of medicine.
- The role played by physicians in promoting meliorism. Several reasons may explain why physicians prescribe or not; however, in prescribing psychotropic drugs for non-clearly-therapeutic purposes, physicians are contributing to the trend of meliorism and performance as well as to the trivialization of drug use.

Expanded Uses of the “Lifestyle” Type

The values of performance, efficiency and enhancement have been positive ones throughout history and in different societies, although 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.

Some psychotropic medications are used to meet social expectations – performance, health, “youth”, etc. These practices necessarily involve the idea of “normality”, which can be understood as a statistical concept, or may reflect social or subjective decisions. Moreover, “normality” and “norm” are intimately linked: social or axiological normality may lead to a norm, i.e. to a statement describing what to do or to refrain from doing. People deviating from these norms, through behaviour deemed inappropriate or, more generally, who do not “perform well” may be stigmatized.

This normalization of conduct and mood 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*.

In its analysis, the Commission has singled out three particular factors that may influence expanded uses of the “Lifestyle” type, namely:

- The influence of the pharmaceutical industry: Pharmaceutical

companies have recognized the market growth potential of psychotropic uses for the purposes of enhancement. Their promotion reinforces the perception that medicines are useful, even necessary, in non-medical life situations.

- The Media and the Internet: The media are major sources of information that generally present medications in a positive and uncritical light, reinforcing the same compelling picture of life. Also, people may decide to buy medicines at cyberpharmacies, based on inadequate information or even minimal awareness about the risks associated with lack of knowledge of the product being purchased.
- Differences between psychotropic drugs and other CNS stimulants/depressants: 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 – which nevertheless remain both accessible and popular – whereas for psychotropics, the long-term effects are poorly documented.

In terms of consequences, expanded uses of the “Lifestyle” type present the same risks as of the “Medical” type, although other risks are specific to “Lifestyle” type uses. The Commission has singled out three anticipated benefits¹, namely:

- The enhancement of certain cognitive abilities. People stand to gain both personally and socially when they enhance mental abilities. In this perspective, enhanced cognitive functions also contribute to meet the demands of the labour market, which represents a gain both for employers and employees.
- The regulation of mood, behaviours and personality traits. Psychotropic drugs can quickly make people feel better, while promoting better integration; at least that is what many users hope. Feelings of grief and sadness decrease, while self-esteem and a sense of performance and of efficiency are expected to increase.
- An 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, 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.

But expanded “Lifestyle” uses do not just involve benefits. Risks are associated with this type of use, and some social factors that contribute to this type of use also constitute issues of their own:

- Risks to personal safety: In the short term, the use of psychotropic drugs provided by friends or bought illegally exposes consumers to the risks associated with the use of psychotropics and those relating to the unknown characteristics of medications ingested. In the long term, science cannot tell what the effects of psychotropic medications are on the brains of healthy people.
- Psychological dependence: For people using and benefiting 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.

- External pressures: Social pressures, even to the point of coercion, have an impact on the process of individual decision-making. People resort to expanded “Lifestyle” type uses in pursuit of a certain ideal, self-image and group, both in their professional and personal life.
- Trivialization of psychotropic drugs: The point has already been discussed but it is even more a concern for expanded uses of the “Lifestyle” type. Indeed, in this case, the use of psychotropic medications is designed to help fulfill idealized norms, images or values. Also, the fact that consumers overstate the desired benefits and under-estimate the risks increases the trivialization of “Lifestyle” uses.

Summary

- the first category is more of an extension of therapeutic uses of psychotropics while the second illustrates expanded uses in the absence of a therapeutic objective;
- the same stakeholders are often involved;
- the motivations underlying expanded use have different purposes; as a result, there are multiple perceptions about drugs and their uses;
- 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;
- the idea of normality is central to the concept of improvement;
- a widely available and transparent scientific information of a high quality is important; however this precondition is not always met, neither for the public nor for professionals;
- regardless of the categories used here, the increased use of psychotropics raises the broader question of the identity and the representation of the human being.

Recommendations and Cautionary Notes

In considering expanded uses for the purposes of enhancement/regularization, the Commission has identified four essential values, namely:

- the protection of individual health and safety;
- autonomy and the affirmation of individual freedom;
- equity;
- representations of the human being.

These values in turn have led the Commission to make eleven recommendations.

Recommendations

These recommendations are organized around six themes:

1. Acquisition of knowledge about the current uses of psychotropic drugs and their different potential impacts on the central nervous system on the short, medium and long term.

In order to be able to quantify and qualify the short, medium and long term effects of psychotropics in Quebec, the Commission makes a three-point recommendation, calling to survey current uses and their evolution over time; to study qualitatively and quantitatively the use of psychotropic drugs and their various impacts; and to document the practices of physicians with respect to psychotropic drugs.

2. Objective and exhaustive transmission of scientific information related to the central nervous system, psychotropic drugs, recognized non-pharmacological treatments and, in general, information on mental and neurological diseases.

This theme relates specifically to the transmission of scientifically valid information. Stakeholders have different knowledge profiles and access different modes of information transmission. Given the importance of this issue, the Commission makes four recommendations concerning the Internet quality of scientific information and the general public; addressing the responsibility of the stakeholders in the field of information to disseminate critical and balanced scientific information to their audiences; relating to the modes of information transmission for general practitioners who provide care for the majority of patients suffering from mental or neurological disorders; and referring physicians to the social dimension of their role, in the phenomena of medicalization and medicamentation of life situations.

3. Regulation of direct-to-consumer advertising of prescription drugs.

The fact that drugs are approved by Health Canada and are prescribed by physicians tends to reinforce 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. In this regard, the current Canadian regulatory framework – which prohibits direct advertising of the kind found in the United States – is not well adapted, since the ban is easily circumvented.

4. The drug licensing process.

While the various initiatives of regulatory agencies regulators to have all research results disclosed in a registry are definitely a step forward, they are based essentially on the goodwill of pharmaceutical researchers and companies. A disclosure of

clinical trials and of all results compulsory, in an accessible, public and updated registry, is needed.

5. Organization of the health and social services network, particularly regarding integrated practices in mental health and service delivery.

The Commission has focused on the impact that current organization of the network may have on the value of “equity”. Three recommendations are made in this regard relating to the coordination of care since disruptions in the continuity of care and services would contribute to expanding “Medical” and “Lifestyle” uses; concerning non-drug therapies, in which the costs of consultations are not covered by the public system when they take place in private clinics, but not all Quebecers have access to private insurance plans. This situation leads to unequal access to care and services for non-medical services and 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; and to demonstrate the potential positive effects of greater access to non-drug therapies.

6. Participation of civil society in social and ethical debates related to expanded uses of psychotropic drugs.

The desire for improvement is part of the human condition, but the question of enhancement by means of psychotropic medications – influencing the functioning of the brain, which is the organ representing the seat of the soul, and of personal identity – leads to debates on the nature of the human being, on what it means to live a successful life and on self-realization. Whether representations of the human being are religious in nature, based on naturalism or based on dualism, they are being rocked by advances in neuroscientific knowledge.

When it comes to defining what is meant by health, therapeutic use and cognitive enhancement, there is a lot of debate but not much consensus. 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 and to ensure that the community values are not subordinated to the interests of the few. However, expanded uses go far beyond the frameworks of expertise of health professionals and 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. Excluding them would undermine the legitimacy and effectiveness of decisions taken by others.

Cautionary notes

In cases where it seems impossible to make a recommendation on a given issue, the Commission provides cautionary notes. Two particular factors identified as issues in the position statement:

The first cautionary note concerns the value of “autonomy and the affirmation of individual freedom”.

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 and the social milieu, as well as the responsibilities of other stakeholders. In addition, some expanded uses of psychotropic medications meet the expectations of society while camouflaging the social causes of these expectations.

The second cautionary note relates to equity and the accessibility of medications. A reading of statistics as well as scientific literature suggests 1) that expanded "Medical" and "Lifestyle" uses will continue to increase and 2) that new psychotropic drugs are more expensive than drugs previously used. Therefore, the Commission is concerned about the impact this increase may have on the list of medications eligible for reimbursement², the affordability of drug insurance plans and the possibility that people suffering from pathologies could be faced with unmanageable financial obligations.

Conclusion

Issues and ethical values associated with expanded uses of psychotropic drugs affect both individuals and society as a whole; these issues and values challenge the individual, the State, the media as well as the pharmaceutical industry, and are playing out over the short-, medium- and long-term. These issues call for ethical and social choices that go beyond the medical setting and illustrate the need to broaden the debate.

Footnotes:

1. These potential benefits depend largely on public perceptions, since the few scientific studies devoted strictly to the use of psychotropics for the purpose of enhancement do not make it possible to confirm the existence of such benefits.
2. Since 1997, all Quebec citizens benefit from universal coverage of prescription drug insurance, either through the government-run prescription drug insurance plan or a private group insurance plan.

References:

Collège des médecins du Québec & Ordre des psychologues du Québec [College of Physicians of Quebec & Order of Psychologists of Quebec] (2001). *Le trouble déficit de l'attention hyperactivité et l'usage de stimulants du système nerveux central*. Lignes directrices du Collège des médecins du Québec et de l'Ordre des psychologues du Québec. Montréal: Collège des médecins du Québec & Ordre des psychologues du Québec.

Commission de l'éthique de la science et de la technologie (2009). *Psychotropic Drugs and Expanded Uses: an Ethical Perspective*. Québec: CEST. Available at www.ethique.gouv.qc.ca.

Régie de l'assurance maladie du Québec (RAMQ) [Quebec Health Insurance Board] (2001). *Portrait quotidien de la consommation médicamenteuse des personnes âgées non hébergées*. Québec: Régie de l'assurance maladie du Québec.

Rehm, J., & Weeks, J. (2005). *Abuse of Controlled Prescription Drugs*. In Canadian Centre on Substance Abuse (Ed.), *Substance Abuse in Canada: Current Challenges and Choices*. Ottawa: CCSA.

Funding and Support: *Commission de l'éthique de la science et de la technologie (Quebec's Science and Technology Ethics Commission)*

Acknowledgements: *Hubert Doucet, Ph.D., Teacher at Université de Montréal at the Faculties of Theology and Medicine*

Competing Interests: *None.*

Address for Correspondence:

*Me Edith Deleury, President
Commission de l'éthique de la science et de la technologie 1200,
route de l'Église, bur. 3.45 Québec (Québec) G1V 4Z2 Email :
edith.deleury@ethique.gouv.qc.ca*