PHARMACEUTICAL POLICY

CONSULTATION PAPER

Québec

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Santé
et Services sociaux
Québec

Minister's Foreword

The Basic Prescription Drug Insurance Plan (*Régime général d'assurance médicaments,* RGAM) was set up in 1997 in order to ensure that the people of Québec would have reasonable economic access to the medication they needed. The act setting up the RGAM also called for a pharmaceutical policy to be drafted.

Since the RGAM came into effect, the Conseil du médicament has been set up and partnership agreements have been struck with pharmaceutical manufacturers in order to promote optimal drug use. Last May, all concerned parties took part in a conference on optimal drug use. We have used the consensus that emerged as a base for our reflections on optimal drug use.

Today, I am pleased to present the fruit of these reflections. The publication of the draft pharmaceutical policy presents Quebecers with a global and coherent set of directions and strategies on access, price, and optimal use of medication. It also discusses the pharmaceutical industry and its importance as an engine of economic development in Québec. This document describes some of the principles that will guide our future decisions and actions.

The tabling of this report will be followed by a consultation with a parliamentary committee, including all involved players. These broad discussions will ensure that everyone contributes to the success of this policy. They will also permit all concerned to tell us their reactions and suggest improvements, in order to make Québec's first pharmaceutical policy something that everyone can support.

Philippe Couillard
Minister of Health and Social Services

Executive Summary

Before the adoption of the *Act respecting prescription drug insurance*, nearly 17% of the population of Québec were without any coverage for prescription drugs required by their state of health. The adoption of the Act in 1997 guaranteed the whole population reasonable and equitable access to drug therapy. Currently, some 3,2 million people are covered by the public insurance plan, while some 4,3 million have private coverage.

From 1997-1998 to 2003-2004, the total cost of prescription drugs purchased by beneficiaries of the public insurance plan increased by an average of 15% per year, climbing from $1 164 300 000 to $2 635 800 000. The total cost of medication purchased through the public system increased by nearly 11% during the 2003-2004 fiscal year.

Since 1997, the Basic Prescription Drug Insurance Plan (*Régime général d'assurance médicaments,* RGAM) has undergone numerous adjustments. In particular, in 2002 the government reviewed the parameters for financial contributions from beneficiaries of the public system and set up an annual indexing system for these parameters.

As for the health and social services network, costs increased an average of 11,4% per year from 1999-2000 to 2002-2003, when medication costs reached $384,0 million.

Considering the amount that the Québec government spends on prescription drugs, their crucial place in the health and social services system, the unique nature of the product and its use (which should be optimal), and the great number of parties concerned such as patients, health professionals, and pharmaceutical industry, it is important to have a coherent vision for pharmaceutical policy. The government has chosen this policy to give it a common vision and to guide its actions, in particular in finding an acceptable balance between increasing needs, vulnerable health care users who need protection, and the ability of society to support such a system.

The pharmaceutical policy contains four main themes: accessibility of medication, fair and reasonable prices, optimal drug use, and a dynamic pharmaceutical industry in Québec.

This draft project contains thirty-four ministerial proposals based on these themes. Some continue current policies, but a majority call for new concepts or new rules.

Accessibility

The draft policy suggests solutions for improving access to medication in order to offer a quality service. These suggestions are both diverse and interrelated.

Access to formularies

Access to formularies (RGAM and institutional) is an important issue because a drug must be listed on these formularies to be covered by the government. In this regard, we note that the decision to list a drug must continue to be based on scientific analysis. Furthermore, several ways to reduce delays in the listing process and to cut red tape associated with exception drugs are suggested, in order to make drugs available in a timely fashion. A better connection between health care facilities and ambulatory services is also suggested.

Several means to simplify the administrative process are identified, including more frequent modifications to the Drug Formulary to introduce list price reductions and to add new drugs, chiefly generic drugs. Various mechanisms are suggested for facilitating the Régie de l'assurance maladie du Québec (RAMQ)'s management of exception drugs, such as access to forms on the Internet. It should be noted that prescribing physicians must submit authorization requests for patients to be reimbursed for drugs; the use of the Internet could reduce the red tape that physicians so often deplore.

The draft policy proposes changing the circumstances in which an ambulatory patient in a general or specialized hospital could be administered a drug purchased in the community. This would facilitate movement of patients within local health and social services networks and service corridors by clarifying funding rules for medication.

Finally, patients with rare hereditary metabolic disorders sometimes request access to new pharmaceutical treatments before scientific analysis is complete, or despite a negative decision by the Conseil du médicament, a frequent outcome due to lack of demonstrated therapeutic value. Policy choices regarding these medications are difficult, considering their high cost for the RGAM. Therefore, the draft policy includes clear rules restricting public financing of medication for hereditary metabolic disorders to those drugs whose therapeutic value has been demonstrated to the satisfaction of the Conseil du médicament

Financial accessibility to beneficiaries

With regard to financial accessibility, particular attention has been paid to the most vulnerable groups of health care users. It is proposed that elderly people under the public system who are receiving maximum payments from the Guaranteed Income Supplement receive their prescription drugs free. These are the elderly health care users with the lowest incomes, about $12 000 per year for a single person.

Afterwards, depending on increases in efficiency obtained through optimal drug use measures and partnership agreements, it could be possible to provide medication free or reduce contributions for other groups of low-income users.

Fair and reasonable prices

The second chapter of this draft policy deals with drug prices.

Since 1994, a non-increasing drug price policy for listed medications has existed in Québec. At the same time, as stated above, costs for the RGAM have increased. An aging population, increased use of pharmaceutical treatment, and increased use of new and more costly drugs have all contributed to this rise. For the last ten years, price increases have been permitted in Québec only in exceptional cases. At the same time, the consumer price index has increased by about 20%.

The draft policy includes measures allowing the Québec government to pay a fair and equitable price. One of these measures would be to end the price freeze. However, a mechanism to control price increases is proposed. Also, to minimize the financial impact on the public prescription drug insurance plan, agreements could be negotiated between the Québec government and drug manufacturers, so as to reduce or even eliminate the cost of indexing prices.

The draft policy also suggests accelerated listing of medications that represent a significant savings potential for the RGAM. In particular, one measure proposes a maximum price for generic drugs. As for wholesalers, it is proposed to limit their mark-up to 6% in order to ensure equity among them.

Optimal drug use

The government has a primary role in the first two parts of the draft policy; the third chapter, however, concerns all partners, including health care professionals, patients, the pharmaceutical industry, and government agencies. All have an important role in working together and putting concrete measures into action.

The Conseil du médicament was created in 2002 following amendments to the *Act respecting prescription drug insurance*. The Conseil's task is to assist the Minister of Health and Social Services in updating formularies and promoting optimal drug use. To help it meet this objective, the Conseil created a round table in 2002, composed of representatives of the Ministère de la Santé et des Services sociaux (MSSS), the RAMQ, professional orders and associations, the pharmaceutical industry, and the insurance industry. It is suggested to increase this round table's role in optimal drug use by making it the primary forum on this subject, so as to increase participation from the field. More numerous optimal drug use measures that are better accepted by the parties concerned should improve both public health and public finances. To do this, it is necessary to clarify the round table's roles and responsibilities.

The draft policy calls for practices and procedures that use new information technologies to best advantage. Several other projects will be promoted, including transmission of therapeutic intent, prescribing profiles, and home prescription review. More specifically, transmission of therapeutic intent would allow pharmacists to contribute more to optimizing drug use, and would allow the Conseil du médicament to conduct studies to help plan strategies against non-optimal use. Note that some of these measures could only be implemented after modifying certain laws and regulations regarding transmission of information from patients' files. These measures are vital tools for ensuring optimal drug use.

The draft policy also proposes measures to spread awareness and information among citizens regarding optimal drug use. A broad media campaign is already underway.

Finally, drug companies must sign a manufacturer's commitment in order to have their products listed in the Formulary. This commitment could be used to control certain business practices. Among the measures provided for are clauses requiring respect for commercial practices and optimal use criteria established by the Conseil du médicament. A schedule of corrective measures in case of non-respect is also provided for. Finally, a measure requiring pharmacists to bill the RAMQ according to the actual purchase price is called for.

Maintaining a dynamic pharmaceutical industry in Québec

The pharmaceutical industry is a major player in the Québec economy. It is therefore important to link health and industrial policy in order to ensure that the government acts coherently in these fields.

The fourth chapter contains three main proposals. The first is to maintain the 15-year rule, which ensures that manufacturers of new medications are guaranteed that their product will remain fully refundable for 15 years after being included in the formulary, even if the patent expires and a less expensive generic equivalent enters the market.

The second measure is for agreements to be signed with the pharmaceutical industry in order to promote optimal drug use and reduce risks of using medications.

Finally, in order to maintain balance between health and economic development policies, a permanent discussion forum is proposed, bringing together the MSSS, the Ministère du Développement économique et régional et de la Recherche (MDERR), and manufacturers of innovative and generic drugs.

Consultation

This draft pharmaceutical policy will undergo a consultation process starting this winter. This consultation will allow all concerned players to react to the draft policy and suggest changes to it. We hope that everyone will participate, so that as many different parties as possible are satisfied with the policy and are prepared to contribute to its success.

Note:	This executive summary lays out the main lines of the draft pharmaceutical policy. To understand all the nuances of the proposed solutions, we suggest that the document be read in its entirety.

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INTRODUCTION

The current situation

Medication is the most widespread and most accessible medical treatment technology. When medications are used properly, they improve health and quality of life, with positive results for individuals' productivity.

Pharmaceuticals are not normal trade goods, in that the choice thereof often depends on the advice of a health care professional, and their use is motivated by the consumer's state of health. They must therefore be used in a controlled manner. Just as optimal drug use produces benefits, non-optimal use can be dangerous for patients' health.

Québec has a universal health care system composed of two programs: the health insurance system and the hospital insurence system. As for medication, for several years the provincial government has offered partial coverage of some sectors of the public, with other sectors being covered by private insurance. Thus, for several years, a large number of Quebecers were without any insurance for the cost of their prescription drugs. After numerous reports were published on the question, the Québec government decided during the 1990s to pass the *Act respecting prescription drug insurance,* which created the Basic Prescription Drug Insurance Plan (*Régime général d'assurance médicaments,* RGAM). Since this law was brought into force in 1997, all citizens of Québec have had access to prescription drug insurance. The government, via the public part of the RGAM, is responsible for providing prescription drug coverage to elderly people, employment assistance beneficiaries, and the nearly 1,8 million Quebecers who do not have access to a private group prescription drug insurance plan. This law also set out certain rules for group plans, regarding guarantees as well as certain parameters for co-payments. These measures all help to ensure reasonable economic access to therapeutic medication for all Quebecers. Medication dispensed in general and specialized hospitals (*centres hospitaliers de soins généraux et spécialisés,* CHSGS) and in residential and long-term care centres (*centres d'hébergement et de soins de longue durée,* CHSLD) is covered by the hospital insurance system.

From 1997-1998 to 2003-2004, the total cost of prescription drugs purchased under the public insurance system grew by an average of 15% per year, climbing from $1 164 300 000 to $2 635 800 000. Even though this growth has slowed over the last few years, total cost of medication purchased through the public system increased nearly 11% during the 2003-2004 fiscal year. To respond to these increases, the government had to review financial participation from beneficiaries of the public system and set up an annual indexing system for these.[1] In 2003-2004, more than 10% of the health care budget went to medication, counting both the public prescription drug insurance plan and costs for medication administered in health care facilities.

1. Appendix II shows the progression of total costs of the public prescription drug insurance plan, maximum premiums, and contribution parameters.

This large increase in medication costs in the health and social services network has been observed for a number of years. Annual growth was 11,4% from 1999-2000 to 2002-2003. Despite the implementation of controls on medication use by physicians and pharmacists in health care facilities, the rate of increase matched that of the public health insurance plan in 2002-2003. In that year, drug costs reached $384,0 million.

Medication has been the budget item with the highest rate of annual growth for several years; this trend seems likely to continue, owing to the aging population, the arrival of new drugs on the market, the increase in the number of prescriptions, and the rising average cost of each prescription.

The trend is similar for private insurance plans. According to the Canadian Life and Health Insurance Association, costs reimbursed by private insurers grew by an annual average of 13,3% between 2000 and 2003. This also slowed between 2002 and 2003, dropping to 9,8%.

Furthermore, Québec is host to an innovative pharmaceutical industry, an important economic engine for the province, which in turn supports it. Although this support sometimes involves costs for the health and social services system, Québec reaps direct and indirect economic benefits from this industry's presence. Québec is also home to a generic drug industry, which is however less widespread than the innovative drug industry.

Roles and responsibilities of various government bodies

The federal and provincial governments each have responsibilities in regard to pharmaceuticals. On the federal level, Health Canada is the authority responsible for certifying pharmaceutical products, including those intended for humans. To market a drug in Canada, the manufacturer must present scientific evidence of its safety, efficacy, and quality, pursuant to the *Food and Drugs Act* and its attendant regulations. Health Canada also has jurisdiction over clinical studies carried out in the country, and over the advertising of prescription drugs to consumers.

For its part, the Patented Medicine Prices Review Board (PMPRB) ensures that prices of medicines patented in Canada are not excessive. It exercises its authority under the federal Minister of Health. Another federal law, the *Patent Act*, is under the responsibility of the Minister of Industry. Duration of patent protection in the Canadian pharmaceutical industry is still a matter of public debate.

In Québec, three bodies have an important and complementary role in this matter: the Ministère de la Santé et des Services sociaux (MSSS), the Conseil du médicament, and the Régie de l'assurance maladie du Québec (RAMQ).

Laws whose application falls under the responsibility of the provincial Minister of Health and Social Services include the *Act respecting health services and social services* and the *Act respecting prescription drug insurance*. The decision to list a medication during an update to the Drug Formularies for the MSSS and institutions is up to the Minister, in consultation with the Conseil du médicament. The Minister is also responsible for managing all matters under his or her jurisdiction relating to prescription drugs. The MSSS is mandated to oversee and evaluate the RGAM, to develop directions and

strategies with regard to medications, and to maintain relations with public, parapublic, and private-sector players.

The Conseil du médicament's task is to assist the Minister in updating formularies and to promote optimal drug use. To carry out these tasks, the Conseil can undertake or support reviews of medication use; suggest and contribute to the development and implementation of training, information, and awareness activities for health professionals and the general population; evaluate problems in medication use; and oversee implementation of measures to prevent and correct these problems. The Conseil's roles also include making recommendations to the Minister as to how drug prices are set and changed as well as on any other questions the Minister submits to it.

The RAMQ insures employment assistance beneficiaries, persons 65 years of age or older, and persons who are not eligible for group insurance or a benefits scheme.

To this end, the RAMQ keeps the public informed, manages registration of beneficiaries, and pays for prescription drugs and pharmaceutical services. It publishes the Drug Formulary and manages the exception drug procedure. It also maintains a large information bank containing data on prescription drug use by the insured population.

As manager of the Québec Drug Insurance Fund, the RAMQ prepares budget forecasts and proposes a fee structure that allows the budget to be balanced.

Finally, the government of Québec is responsible for making laws regarding professions. The application of these laws is delegated to the professional orders under the oversight of the Office des professions du Québec.

Stakes for the various parties involved

When a department proposes a policy, it affects all players in the fields concerned. It is therefore useful to identify them and the issues they face.

The Minister of Health and Social Services, the MSSS, its agencies, and its network

As specified in its mission statement, the first concern of the MSSS is to maintain, improve, and restore the health and well-being of Quebecers by offering a set of integrated and high-quality health and social services, thereby contributing to the social and economic development of Québec. For the MSSS, it is therefore fundamental that the entire population of Québec have access to drug therapy. Although not the only part, pharmaceuticals are an integral part of any health care system.

It is also fundamental for the MSSS that medications be properly used in order to maximize the intended benefits for the user.

The amount of public money devoted to medication is also an unavoidable issue. This expense is the fastest-growing section of the MSSS' budget, increasing much faster than government revenues are. This trend seems likely to continue for at least the next few years, both for the public system and

institutions and for private insurers. Costs for public and private prescription drug insurance could come to represent too large a financial burden, both for the government and for families, which could lead to severe consequences; the sustainability of the RGAM is at stake.

The citizen as user of medication

Most often, people consume prescription drugs as directed by a health care professional who is authorized to prescribe them. The patient is therefore following a decision made by a third party. However, patients are becoming better and better informed about available medications and treatments. Patients therefore have great expectations of these therapies, as they want to improve their health. The general belief is that the most recent drugs are the best, and patients therefore want these drugs to be accessible. It should also be borne in mind that more and more people are self-medicating and consuming natural products. Health care professionals involved in drug therapy are not always aware of what else a patient might be taking.

The public insurance beneficiary as funding partner

The majority of beneficiaries[2] of the public prescription drug insurance system contribute directly to funding this system by paying premiums, co-insurance, and deductibles. Any significant increase to one or more of these parameters could therefore have a direct impact on the accessibility of drug therapy for public insurance beneficiaries. If their financial contribution becomes prohibitive, they might change the medication they take.

The citizen as taxpayer

The Québec government funds the health and social services system through its general tax system, with a health tax on payrolls, and from federal transfer payments for health. Public opinion is very sensitive in this regard. It is therefore difficult to conceive of tax increases as a solution to increasing medication costs.

Health care professionals

Once the appropriate regulations are in effect, recent changes to the laws on professionals will permit health care professionals other than physicians to participate more actively in drug therapy. In particular, nurses and pharmacists will be called upon to play a more important part in drug therapy.

Physicians

Like all health professionals, physicians want to practice their vocation in such a way as to best meet their patients' needs. From this perspective, quality of care trumps cost control. Clinical decisions, such as prescriptions for drugs, do not systematically take cost into account. Also, physicians deplore the red tape created by certain administrative rules regarding payment for medication.

2. Employment assistance recipients with severe employment constraints receive their medication free, as do the children of public prescription drug insurance beneficiaries.

Pharmacists

One cannot consider medication without considering pharmaceutical services and care (e.g. identification of problems linked to drug therapy, personalized advice, monitoring of therapy, etc.) Dispensing a medication to a patient necessarily involves a pharmacy service. Conversely, professional pharmacy service does not always involve dispensing medication.

Pharmacists played a very important part in the implementation of the RGAM and its subsequent modifications. Accordingly, the time needed for administrative tasks must not intrude on their clinical work towards optimal drug use.

Nurses

Nurses are often responsible for informing and teaching patients about how to take medication and follow drug therapy. Also, new legislative dispositions added to the *Professional Code* require nurses to provide guidance to non-professionals (within the sense of the *Professional Code*) who are to be authorised to administer prescription drugs to certain users under certain conditions.

Private insurers and insurance groups

Significant increases in costs are also observed in private prescription drug insurance plans. Contrary to the public system, professional fees for pharmacists are not fixed. Premiums are adjusted according to increased spending. As demand continues to grow, it is hard to imagine that premium levels can rise indefinitely in response.

By law, a group insurance contract or a benefit plan that contains guarantees in case of illness, accident, or disability must offer the same protection offered by the RGAM as a minimum. Therefore, insurance groups that offer benefits must include prescription drug insurance.

It should be mentioned that insurers are against a universal public system, as this would mean that they would lose nearly their entire market, with the exception of complementary insurance.

The Ministère du Développement économique et régional et de la Recherche

Québec's dynamic pharmaceutical industry is an important asset. The Ministère du Développement économique et régional et de la Recherche (MDERR) is mandated to support and promote the growth of businesses in Québec in order to increase prosperity and create jobs. The pharmaceutical industry is one of the priority sectors in the MDERR's development strategy. Conditions of market access are chief among the considerations of pharmaceutical companies when making investment decisions. Health and pharmaceutical policies therefore run the risk of harming this industry in Québec.

The pharmaceutical industry in Québec and Canada

Market access is an essential concern of drug companies. Health Canada authorizes the sale of medications; however, market access is strongly influenced by coverage conditions. In Québec, the Conseil du médicament, after studying a medication, recommends to the Minister whether or not it should be included in formularies. This decision has a direct impact on drug companies' revenues, as the Drug Formulary lists drugs that must be covered by both the public and private systems.

The challenge of a pharmaceutical policy

The challenge of a pharmaceutical policy is to reconcile the often conflicting positions of those involved. For example, access to the latest medication confronts optimal drug use; increase of the RGAM's cost conflicts with the government's ability to pay; financial safety of vulnerable groups runs up against the contribution asked of others served by the RGAM; and the need to pay as low a price as possible runs counter to the interests of pharmaceutical companies. Compromises must be made in order to ensure a balanced approach for both public and private parties.

This policy will take stock of current issues to find an acceptable balance between constantly growing needs and the community's ability to fulfill them. In the end, the pharmaceutical policy will guide the MSSS's actions and those of the other parties involved, while promoting a dynamic pharmaceutical industry in Québec. The proposed solutions revolve around optimizing already available resources.

Also, the MSSS is concerned with the efficiency and effectiveness of the measures that will be put in place in the wake of the pharmaceutical policy. At the department level, the goals of these measures will be established and indicators will be decided on accordingly.

The policy aims to give Québec a more coherent vision and a strategy to ensure that medication is accessible to everyone, that it is used in an optimal way, and that the business environment is such that commercial practices, costs, and industrial development contribute to the success of this strategy.

The pharmaceutical policy

The pharmaceutical policy centres on four main themes: accessibility of medication, fair and reasonable prices, optimal drug use, and a dynamic pharmaceutical industry in Québec. Each of these points is dealt with in its own chapter.

These chapters provide context and a portrait of current problems. Next, proposals from the department are listed both for improving the current system and for reaffirming the usefulness and continuation of certain actions that have already been taken.

It should be noted that these four points are interdependent, such that an action taken in one matter will affect the other three. For example, actions taken to promote optimal drug use could affect access to certain medications and a particular pharmaceutical company's market share. Likewise, measures taken to support the pharmaceutical industry could affect drug prices or vice versa. Thus, each point must be considered with the others in mind.

Conditions for success

The Minister of Health and Social Services is determined to move the pharmaceutical policy forward. The first steps were taken at the symposium on optimal drug use held on May 20 and 21, 2004. This event brought together some 300 people from the various fields concerned with pharmaceuticals, as well as the general population.[3] The participants agreed on the importance of informing the general public, training professionals, increasing interdisciplinarity, and promoting optimal drug use through a variety of measures.

The Minister's wishes alone would not be sufficient to ensure the success of the policy's goals. All interested parties from affected fields must be actively involved and do their part, in cooperation and complementarity with the others. This will allow common goals to be shared, especially in regard to optimal drug use. This cooperation between health care professionals will require a new work organization centred on interdisciplinarity. The Minister believes that this cooperation will be the main factor in the successful implementation of the pharmaceutical policy.

3. Appendix III is a list of groups that were invited to participate in the symposium on optimal drug use.

CHAPTER I ACCESSIBILITY OF MEDICATION

ACCESSIBILITY OF MEDICATION UNDER THE RGAM

Drug therapy is an essential element of medical treatment. A very large number of medications are on the market in Canada. The RGAM ensures that everyone has access to the medications they need.

In Québec, access to medication is ensured mainly by the RGAM in its public and private sections, and by the health and social services network (including CHSGSs and CHSLDs). Other means exist to deal with particular user groups such as those covered by the Société de l'assurance automobile du Québec and the Commission de la santé et de la sécurité du travail.

Considerations of public health have led the MSSS to implement universal programs of free drugs used for treatment and prophylaxis of tuberculosis and sexually transmitted infections.

The Drug Formulary

RGAM coverage is established by the Drug Formulary. This list specifies the medications covered by the provincial system, for both the public and private sectors. The latter may, however, offer coverage of additional medications according to the contract a private insurer has with members of a group insurance policy.

In addition to medications whose cost is guaranteed by the RGAM, the Drug Formulary also lists various equipment that the Minister believes is essential to administering prescription drugs. For each drug, the Drug Formulary lists its common names, trademarks, and manufacturers. The Drug Formulary also specifies the price of each drug for the use of the public section of the RGAM. The Formulary is periodically updated by regulation of the Minister, after consultation with the Conseil du médicament. These updates are effective from the date of publication in the *Gazette officielle du Québec* or at any specified later date.

For a drug to be evaluated for inclusion in the RGAM's Drug Formulary, the product must first have been submitted to Health Canada's Therapeutic Products Programme and bear a Drug Identification Number (DIN) assigned by that body. After thus obtaining a compliance listing, the manufacturer may then submit a request to the Conseil du médicament, to decide whether to recommend the drug for inclusion in the Drug Formulary.

The Conseil evaluates medications according to a schedule for updating formularies, both that of the RGAM and those of health care facilities. The processing time of about six months from the submission of the file to the Minister's decision is the time needed for expert analysis of the data and the various regulatiory and administrative processes connected with updating the lists. However, this process can be accelerated and a drug can receive a recommendation on a priority basis, if the Conseil du médicament judges it necessary.

The Conseil du médicament is a body of experts in pharmacology, health economics, and other relevant fields that allow the Conseil to consider ethical and social factors in its deliberations. The Conseil, then, is a forum where scientific and economic data are interpreted both by experts in these fields and by people with other priorities, and where social values are taken into consideration. The *Act respecting prescription drug insurance* specifies the criteria the Conseil must use to evaluate medication for addition to the Drug Formulary. Only drugs with scientifically demonstrated therapeutic value at the right price can be paid for with public funds.

When the *Act respecting prescription drug insurance* was amended in June 2002, two new criteria were added, allowing the Conseil to take social values, among others, into account when considering new medications, especially very costly ones. Criteria 3 and 4 from the following list are not yet being applied; the Conseil plans to start applying them in October 2005.

The Conseil will then be applying the following four criteria:

1) the therapeutic value of each medication;

2) the reasonableness of the price charged and the cost effectiveness ratio of each medication;

3) the impact of the entry of a medication on the list as regards the health of the population and the other components of the health care system; and

4) the expediency of entering medications on the list with regard to the purpose of the basic prescription drug insurance plan, which is to ensure that all persons have reasonable and fair access to the medications required by their state of health.

After evaluating a medication, the Conseil can recommend that the product be rejected or added to the Drug Formulary, either in the regular or in the exception list. In the latter case, a form needs to be sent to the RAMQ to obtain an authorization for coverage of that drug. Listing in the exception section means that the drug is covered only when used for certain indications recognized by the Conseil.

In order to make these procedures less complicated, the RAMQ allows prescribing physicians to make these requests over the Internet, in the case of certain drugs.

Two methods are available. In the first, the prescriber can print the form available on the website, fill it out, and mail or fax it to the RAMQ for processing. In the second, the prescriber can connect to the RAMQ's online service using a pre-arranged password, and can fill out the authorization form online. Authorization requests received over the Internet are dealt with on a priority basis. Since June 2004, online requests for seventeen specific drugs have been electronically authorized, so that the prescriber receives a response immediately.

Evaluations by the Conseil du médicament

For confidentiality reasons, the Conseil du médicament does not release any information regarding products under study or the state of the evaluation process. When the Minister's decision is made public, a summary of the Conseil's opinion is released under the title *Capsules pharmacothérapeutiques*. These summaries are available, among others, on the Conseil's website.

The "exceptional patient" program

Another means of access to medication, the "exceptional patient" program, is currently reserved for those insured through the RGAM's public sector. It allows patients to have their medication covered if the nature and severity of their illness and the cost of the required drug therapy pose an undue financial burden.

MINISTERIAL PROPOSALS REGARDING ACCESSIBILITY OF MEDICATION UNDER THE RGAM

Ministerial proposal 1

Before 1997, a substantial portion of the Québec population, about 1,5 million people, had no prescription drug insurance coverage. The implementation of the RGAM solved this situation. However, in a situation of limited financial resources both for the state and for citizens, coupled with the aging population and increased use of medication, this social asset cannot be maintained without having to make choices about which drugs will be covered.

Listing a medication in the Drug Formulary is essential to its accessibility to RGAM beneficiaries. It can therefore be seen that this is a matter of utmost importance to all concerned, whether patients, prescribing physicians, pharmacists, public decision-makers, or drug manufacturers. The diversification and refinement of new drugs coupled with constantly increasing costs lead the Minister of Health and Social Services to reaffirm his intention to:

- **Maintain accessibility based on a drug formulary that, in certain cases, stipulates specific conditions for payment.**

Ministerial proposal 2

All medications marketed in Canada must have received a compliance listing from the federal government, attesting that they comply with standards of safety, efficacy, and quality. These listings are a minimum requirement for drugs to be listed in the Drug Formulary, which means that only drugs that are marketed and available in Canada can be considered by the Conseil du médicament.

The RGAM must ensure reasonable and equitable accessibility of drugs required by patients' state of health. The Conseil uses the criteria established by the *Act respecting prescription drug insurance* in making its recommendations to the Minister. In order to ensure equity in choosing whether or not to list a product, the choice must be justified by evidence that proves not only the product's efficacy, but also its incremental value relative to existing medication, or its ability to influence outcomes of disease as to mortality and morbidity in particular. Therapeutic value, then, is the first criterion that must be met, the foundation on which all recommendations must be based. This does not diminish the importance of the other criteria, such as reasonable price and cost effectiveness ratio, but it does ensure that they do not take precedence over therapeutic value. The Minister of Health and Social Services therefore reaffirms his intention to:

- **choose medications to be listed in the Drug Formulary on the basis of evidence demonstrating their therapeutic value. Once this is demonstrated, other criteria will be taken into account.**

Ministerial proposal 3

Currently, any modification to the RGAM's Drug Formulary is the Minister's decision. Such a decision is necessary both for adding drugs (patented or generic) and for adding equipment, as well as for removing drugs that are no longer on the market or for updating prices, names, or manufacturers. In the end, all these modifications must be done during an update of the formularies or through an amendment, making the process more complicated. Quicker listing of generic versions and decreased prices would be helpful for the RGAM.

Furthermore, the paperwork for exception drugs is regularly criticized, chiefly by physicians, as too complicated. For their part, pharmaceutical manufacturers see it as reducing access to their drugs. At the same time, the number of drugs listed in the exception drugs section is increasing. If the authorization forms are not filled in or fees are required, the impact on beneficiaries can be severe.

The list of exception drugs is an essential tool to proper management of the RGAM. However, public interest requires a balance between necessary controls and accessibility.

These concerns lead the Minister of Health and Social Services to reaffirm his intention to:

- **further reduce the complexity of the administrative process relating to the Drug Formulary.**

Several means of doing this are proposed, affecting both administrative modifications to the Drug Formulary and the mechanism for authorizing exception drugs.

Means

- ✓ Modify the Drug Formulary more frequently to introduce price reductions and list new drugs
- ✓ Plan to make the Drug Formulary officially available on the Web
- ✓ Set up an administrative mechanism for rapid routine modifications to the Drug Formulary (price decreases, listing of generic drugs, administrative corrections, etc.)
- ✓ Undertake several measures with regard to exception drugs, in particular:
  - Administrative validations using the RAMQ's file;
  - Grouping together authorizations for one class of drugs;
  - Automatic authorizations for certain prescribing physicians;
  - Transmission of a code or therapeutic intent by the prescribing physician;
  - Increasing the use of online forms.

Ministerial proposal 4

The Minister of Health and Social Services wants to:

- **Regulate prescribing physicians' bills for filling out forms for exception drugs and exception patients according to whether the forms are available online.**

Ministerial proposal 5

Health professionals such as physicians and pharmacists, institutions in the health and social services network, and pharmaceutical manufacturers want to have access to the Conseil du médicament's recommendations. Prescribing physicians and pharmacists are informed of the decisions when the Drug Formulary is updated. These can include additions of new exception drugs, the transfer of a drug from the regular list to the exception list, or changes to indications for payment. The Minister of Health and Social Services announces his intention to:

- **Make the process and decisions relating to a drug's listing in the Drug Formulary more transparent.**

Means

- ✓ Make the reasons for the Conseil du médicament's recommendation available to interested parties at an appropriate time.
- ✓ Investigate the possibility of giving public updates of the progress of the Conseil du médicament's evaluations.

ACCESSIBILITY OF MEDICATION IN HEALTH CARE FACILITIES

Funding for medication in health care facilities

Medication is administered in most institutions in the health and social services network, but especially in CHSGSs, CHSLDs, and in local community service centres (*centres locaux de services communautaires,* CLSC). As funding for medication administered in CHSGSs and CHSLDs is not provided by the RGAM, rules for choice and funding of medication administered to patients may be different.

Two modes of funding coexist in the health and social services network. CHSGSs and CHSLDs are governed by the hospital insurance system, which requires these institutions to provide services to their patients or residents free of charge. The regulations of the *Hospital Insurance Act* stipulate that all medications and pharmaceutical services provided by CHSGSs are covered for hospitalized users. A directive issued in 2000 clarified CHSGSs' responsibilities toward ambulatory patients when administering medication on site.

The *Hospital Insurance Act* does not apply to CLSCs, so drugs administered at CLSCs are covered by the RGAM.

Several treatments requiring medication are now offered without requiring hospitalization. These include medication administered in outpatient clinics, ambulatory centres, day hospitals, and CLSCs. Some client groups continue to be served by CHSGSs on an ambulatory basis, but more and more services are being or will be offered by CLSCs either on site or in the home. This situation means that, for ambulatory patients, the two funding methods coexist, one providing free medication and the other requiring a contribution.

The *Act respecting health services and social services* specifies the limits within which an institution can decide on its use of medication. The act sets up the Drug Formulary for institutions, prepared by the Minister of Health and Social Services according to the recommendations of the Conseil du médicament, as the general rule for administering medications. Nevertheless, in order to better reflect the reality of medication use in institutions of the health and social services network, specific situations are provided for in which an institution can make exceptions. Some medications can be used even if they are not included in the Drug Formulary for institutions, or even if they are not marketed in Canada, especially in cases of special medical necessity or when special treatment is necessary. In such a case, the institution's council of physicians, dentists, and pharmacists (CPDP) must authorize and oversee this practice.

Institutions may choose the medications to be offered as part of the activities listed on their organization plan. The head of the pharmacy department, in consultation with the institution's pharmacology committee, chooses the drugs for everyday use in the institution from the Drug Formulary for institutions. An institution's pharmacology committee is composed of members of its CPDP and is answerable to the CPDP. The regulation's objective was originally to rationalize drug management. The local list must take into consideration both available resources and the population served by the institution according to its organization plan.

Institutions must also comply with the *Act to provide for balanced budgets in the public health and social services network*. Costs increased an average of 11,4 % per year from 1999 to 2003. In 2003-2004, a specific allocation of 7,3 % of the cost of medication was provided, in addition to general indexing. Despite these additions, management of rising drug costs remains a major challenge for institution administrators. In this situation, government authorities must consider an annual allocation specifically for health and social services institutions to defray the increasing cost of medication.[4]

Research activities

Most often, in this field, the sponsor of a research project is a drug manufacturer; sometimes, though, a research project is undertaken on the initiative of a physician, without the manufacturer's involvement. Research activities take place both in university-affiliated facilities and in regional hospital centres.

Before performing drug trials on human subjects, the study sponsor must obtain the necessary authorization from Health Canada. These research activities follow a well-defined protocol. Objectives are established, the methodology is defined, and well-structured data collection is planned. The protocol and all documents to be given to the patients must be approved by a research ethics committee.

First and foremost, it is an institution's board of directors that must be answerable for research activities that are carried out there. Consequently, they must make the necessary arrangements with the concerned parties (sponsors, investigators, physicians, etc.) to ensure that patients who have greatly benefited from a drug treatment continue to have access to it.

According to the Minister's action plan on research ethics and scientific integrity (*Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*), published in 1998, experimental drugs are subject to the same controls as prescription drugs. In light of this, the Minister is planning to evaluate this action plan. If appropriate, existing mechanisms could be revised in order to make them more efficient.

Some research on pharmaceuticals, both on the market and not, takes place outside the health and social services network. At present, the Minister's action plan applies only to institutions in the health and social services network and to institutions with research ethics committees constituted by virtue of Article 21 of the Civil Code of Québec. The MSSS is considering whether to extend its mandate.

Over the last few years, some pharmaceutical manufacturers have undertaken various activities, wrongly referred to as research activities, but involving no research protocol, ethics committee approval, or well-structured data collection. The MSSS considers these activities to be more in the nature of marketing strategies. They may result in undue pressure on funding decisions, both for institutions and for the RGAM.

4. In calculating such an allocation, the aging population and the effect of technology must be taken into account.

In some situations, pharmaceutical manufacturers have implemented programs offering free medication to certain client groups ("compassionate programs").

In either case, when these practices take place in institutions of the health and social services network, physicians involved must obtain authorization from the CPDP as required by law, even if the product is offered free.

More and more, physicians in private practice are solicited for participation in projects referred to as "phase IV clinical studies." Physicians in this situation must be cautious, as the real motive could simply be to have the new drug prescribed to a certain number of patients. Physicians should remember that a real phase IV study must be approved by a research ethics committee.

The MSSS has little data on investigational drugs used in the health and social services network. Some of them may be particularly costly when put on the market. For this reason, the budgetary impact of introducing these new products is difficult to evaluate.

MINISTERIAL PROPOSALS CONCERNING ACCESSIBILITY OF MEDICATION IN HEALTH CARE FACILITIES

Ministerial proposal 6

Each institution may choose the medications to be offered as part of the activities listed on its organization plan. Situations have been observed wherein the local formulary was used to restrict access to certain medications in order to keep the institution's budget balanced. It is acceptable for an institution to choose a preferred option among the various drug therapy options available. However, when no other treatment can be used and when the medically necessary drug is included in the Drug Formulary for institutions, there is no justification for refusing access to that drug because it is not included in the institution's local formulary.

Medications that cannot be covered by the RGAM and that are used due to special medical necessity or in special treatments must be accessible to patients, whether admitted, resident, or ambulatory, according to the specified management mechanisms. To ensure this, the Minister of Health and Social Services reaffirms that it is necessary to:

- **Ensure that patients, whether admitted or resident, have access to the medication required by their state of health, while maintaining the mechanisms for institutions to choose the drugs they use, such as the Drug Formulary for institutions;**

- **Provide access to drugs required for cases of special medical necessity or used in special treatments, within current management mechanisms.**

Ministerial proposal 7

Some difficulty is caused by the coexistence of the hospital insurance system, for patients served on site at CHSGSs, and the RGAM, which serves ambulatory patients receiving drug therapy at CLSCs, from physicians in private practice, or at home. Some adjustments are necessary in order to ensure equitable access for beneficiaries.

The reorganization underway in the health and social services network is aiming for better patient management and greater integration of care and services. This intention can be seen in, among others, the implementation of local health and social services networks.

Under this system, it would be possible, under certain circumstances, for a citizen to go to a CHSGS to be administered a drug that he or she purchased in a pharmacy in the community. Regulations concerning institutions' responsibilities regarding chemotherapy for cancer will not, however, be changed.

The Minister of Health and Social Services, then, plans to:

- **Define the circumstances in which a citizen, during ambulatory treatment in a CHSGS, could be administered a drug purchased in the community;**

- **Modify the current regulations regarding the administration of drugs to ambulatory patients in CHSGSs, in order to facilitate movement of patients within local health and social services networks and service corridors.**

Ministerial proposal 8

CHSGS and CHSLD pharmacology committees are responsible for the choice and use of medications in their facilities. Among other duties, the members of these committees must advise the head of the pharmacy department or the pharmacist of their choice of drugs and rules for their use. Each institution must therefore devote resources to evaluating medications for listing in its local formulary.

The listing of a drug in the Drug Formulary for institutions is already a recognition of its therapeutic value; however, access to part of the Conseil du médicament's opinions or deliberations is one of the planned ways to help institutions in making decisions regarding their local formularies.

The Minister of Health and Social Services wants to establish ways to:

- **Help institutions with their evaluation of drugs, in particular by making the Conseil du médicament's evaluation work more accessible at appropriate times.**

Ministerial proposal 9

The introduction of new drugs through research activities may result in undue pressure on funding decisions, both for institutions and for the RGAM. For this reason, the Minister of Health and Social Services wants to:

- **Reaffirm the responsibility of boards of directors of institutions and pharmaceutical manufacturers to maintain access to drug therapies when required, possibly even after the compliance listing is issued;**
- **Remind boards of directors of institutions and physicians working in those institutions of the necessary procedures regarding medications that could be furnished to their institution, even free of charge;**
- **Raise awareness among involved professional orders and associations of the effect of marketing strategies presented to physicians as "phase IV clinical studies";**
- **Require boards of directors of concerned institutions to inform the MSSS of research activities regarding costly medications as soon as these are undertaken;**
- **Ensure that participants in research activities are informed about the process and the criteria for drug listing used by the Conseil du médicament.**

ACCESS TO MEDICATION IN SPECIFIC SITUATIONS

Medication and hereditary metabolic diseases

Genetic diseases are those that are linked to the presence of a pathological change (mutation) in one or more genes. These mutations can be transmitted from one generation to the next by known means. The hereditary metabolic diseases are part of the large family of genetic diseases that disrupt metabolism. Although there are a large number of these diseases, they are very rare.

Over the last decade, fundamental knowledge in genetics and genomics has advanced rapidly, due in particular to work on the human genome. At the same time, in pharmacotherapy, advances in biotechnology have allowed the creation of new molecules that replace human proteins. It has thus become possible to compensate for the absence of certain enzymes in people suffering from hereditary metabolic diseases. Various efforts, often publicly funded and supported by legislation in certain countries, have assisted the development of this type of medication. For example, a replacement enzyme has been found to treat Gaucher's disease.

The rarity of these diseases greatly limits the number of people who can participate in clinical studies. This makes the quality of research protocols and all clinical trials much more important. In the case of slow-progressing diseases, prolonged studies are also critical in determining if the treatment is influencing the natural course of the disease.

The cost of these treatments is a non-trivial factor. Recent medications, especially enzyme replacement, can reach average annual costs of $300 000 per patient.

It has previously been stated that demonstrated therapeutic value is essential for a medication to be listed in the RGAM's Drug Formulary and the Drug Formulary for institutions. In the case of new drugs marketed for the treatment of hereditary metabolic diseases, drug manufacturers, practitioners working with these patients, and patients agree that this requirement cannot be demanded of these drugs. They say that all of these drugs should be covered, even without clinical studies demonstrating the ability of the treatment to really affect the course of the disease.

Ministerial proposal 10

The Minister of Health and Social Services plans to:

- **Offer public funding for medications used in treating hereditary metabolic diseases, but only for those medications with demonstrated therapeutic value according to the Conseil du médicament's evaluation.**

FINANCIAL ACCESSIBILITY OF MEDICATION

The growing range of drugs on the market, coupled with higher prices for new compounds and increased demand (due in particular to increases in the number of prescriptions), has caused a major increase in both public and private drug spending.

Given the continually increasing importance of drugs in the treatment and prevention of disease, the government agreed that it had to act to ensure that all Quebecers had equitable and reasonable access to medication. Thus, the RGAM came into effect on January 1, 1997.

The RGAM has three primary characteristics:

- It is a universal plan;
- It has a mixed character, in that it provides for the coexistence of the public system and private systems;
- It requires the financial participation of its beneficiaries. The public system is funded partly from user contributions, partly from an annual premium, and partly from a subsidy from the consolidated revenue fund. Private plans are funded according to the insurance industry's own methods.

It is unquestionable that the implementation of the RGAM improved access to medication, as it extended coverage to 1,5 million previously uninsured people. Nevertheless, cost increases raise questions about the public plan's sustainability.

The government's financial capacity

Regardless of how one measures the Québec government's capacity to absorb the increasing cost of drug insurance, there is little room to manoeuvre. The health and social services sector already represents 43% of the Québec government's program spending for 2004-2005. Furthermore, demographic changes, technological progress, and trends in medical practice will all increase the share of public spending going to health and social services. Spending increases to defray rising health and social services costs, including drug insurance, will have to be limited.

The Québec government's per capita program spending already substantially exceeds that of other provinces. In 2003-2004, program spending was $6 357 per capita, comparing to $5 985 for the other provinces combined. At the same time, Québec's collective wealth remains less than that of the rest of Canada; Québec's gross domestic product in 2003 was $33 936, compared to $39 657 in the rest of Canada. In 2001, Quebecers' tax burden was heavier than that of any other province. In this situation, defraying increasing drug insurance costs by raising taxes is not an option.

It therefore seems necessary to maintain the principle of cost-sharing between the government and drug insurance beneficiaries, and to put in place necessary measures to promote more efficient drug use.

Financial capacity of beneficiaries

Unlike private plans, which must make up their costs out of premiums and contribution, the public system was founded with a double purpose: insurance and assistance.

From the start of the RGAM in 1997, lawmakers recognized the need for special financial assistance to the most vulnerable populations covered by the public system, in order to guarantee equitable and fair access to medication for all citizens.

For this reason, the maximum contribution was set at a lower level for elderly people who are receiving maximum payments from the Guaranteed Income Supplement, for elderly people receiving partial payments from the GIS, and for employment assistance beneficiaries. Children and students whose parents are insured under the public system have been exempt from contributions; since October 1999, the same has been true for employment assistance recipients with severe employment constraints. Also, the annual premium, which is paid through annual tax returns, was calculated from the start on a sliding scale based on the income of adult beneficiaries, a form of assistance done directly within the insurance group.

As a result of these various forms of assistance, 41% of total drug costs in the public system are paid by users and 59% by the government (2003-2004 figures). The annual indexing formula for financial participation parameters, introduced by an amendment to the law in June 2002 and effective July 1, 2003, aims to keep this division of costs relatively stable.

Over the last few years, certain social groups have called on the government to make the funding of the public system more equitable. Two kinds of measures have been proposed: decreasing the share of funding provided by low-income beneficiaries, and replacing the current mixed (public-private) system altogether with a universal public system.

- Although it is appopriate, in developing this policy, to examine the RGAM's formula for cost-sharing between the government and the beneficiaries, this cannot be done without taking into account the ability of all Québec taxpayers to pay (i.e. the government's financial capacity) and the necessity of guaranteeing equitable treatment among the various categories of beneficiaries of the public system, and between holders of public and private insurance. For this reason, it appears preferable to limit free medication to the most vulnerable populations, and to tie beneficiaries' maximum contributions to their income.

- As to the advantages of a universal drug insurance system, it should be recalled that a committee, chaired by Prof. Claude Montmarquette, was struck to examine this question in 2001. The committee recommended maintaining the RGAM's mixed public-private nature, for a number of reasons.

  First, the Montmarquette committee highlighted the fact that the assistance provided by the RGAM to vulnerable populations is paid for by the consolidated revenue fund and thus by all taxpayers, not only by beneficiaries of the public system. The committee also found that administrative costs of private insurance plans do not differ significantly from the public system, and thus that a universal public system would not produce major savings for those who currently hold private policies. The abolition of private plans would also mean the end of employers' contributions, thereby necessitating tax increases. Finally, private plans permit workers and employers to agree on coverage that exceeds the public system, according to their preferences and their needs.

MINISTERIAL PROPOSALS CONCERNING FINANCIAL ACCESSIBILITY OF MEDICATION

Ministerial proposal 11

The Minister of Health and Social Services wants to:

- **Keep medication financially accessible, taking into account the citizens' ability to pay (deductibles, co-insurance and premiums);**
- **Provide free access to drugs for elderly people who receive the maximum payment from the GIS;**
- **Later, depending on improvements to efficiency through optimal drug use and partnership agreements, reduce or eliminate contributions, as the case may be, from low-income insurees.**

CHAPTER II ESTABLISHING A FAIR AND REASONABLE PRICE

This chapter is divided into two parts: drug prices and wholesalers' mark-ups.

DRUG PRICES

As mentioned in the introduction, the Québec government's net spending on the RGAM has increased at a rate of nearly 15% per year since 1997. Although this increase has slowed over the last few years, it remains high enough to cause concern, having reached nearly 11% in 2003-2004. However, projections for long-term growth in the government's own-source revenues are 3,1% per year at most. This wide gap between the cost of the public system and the growth of the government's revenue is a substantial obstacle to the program's survival in its current form over the long term.

This growth in costs is due to three factors:

- **The number of people insured by the public system who are actually consuming drugs.** The aging of the population affects the number of people insured by the public system and, consequently, the number of people taking drugs. Bad economic circumstances can also add to the number of people insured.

- **An increasing number of prescriptions per person insured who is consuming drugs.** This increase is caused by the release of new medications that treat illnesses that were formerly untreatable, as well as by increasing use of medication for preventive reasons or for increasingly common chronic conditions.

- **An increasing average cost per prescription**. Due to increased costs for research and development of new medications, products that arrive on the market are usually more expensive than those already on the market. When prescribing physicians choose these medications instead of older ones (therapy switching), the result is that the average cost per prescription grows year by year.

The question of medication use has been studied, and measures to favour better drug use were included among the legislation passed by the National Assembly in June 2002. Optimal drug use will be discussed as the third point of the policy.

As for the average cost per prescription, it is evident that the problem is much different depending on whether innovative or generic drugs are at issue.

Note that several conditions are necessary for a drug manufacturer or wholesaler to be recognized by the Minister of Health and Social Services under the *Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized.*

Also, when a manufacturer wishes to have a medication listed on the RGAM's Drug Formulary, it must submit a price that it will commit to guarantee: the guaranteed selling price.

This chapter will discuss these two realities and explore the current drug cost situation in health care facilities.

QUÉBEC'S INTERVENTIONS IN REGARD TO DRUG PRICES

The 15-year rule

The lowest price method stipulates that when there are more than one manufacturer of a single drug (same chemical identity, same form, and same strength), the public insurance system reimburses the lowest price. This rule thus only concerns drugs that have at least one generic form on the market besides the brand-name drug.

In practice, this rule means that reimbursement is established according to the price of the least expensive generic version, as brand-name drugs usually stay at a higher price.[5]

Unlike public systems in other Canadian provinces, Québec's system does not apply the lowest price method universally. Before the lowest price rule can be applied in Québec, a period of fifteen years must elapse after the drug is first listed on formularies (either the RGAM's formulary, or the Drug Formulary for institutions).

This unique rule, called the "15-year rule," allows the manufacturer of the brand-name drug to keep a portion of the market even if a generic drug is available at a better price. Québec chose to implement this rule in 1994 as part of its industrial development strategy.

The non-increasing drug price policy

In order to better control the government's rising medication costs, a non-increasing drug price policy was implemented in 1994. According to this policy, no increase in price is permitted for drugs already listed in the Drug Formulary, except in very unusual circumstances.[6] This policy includes wholesalers' mark-ups.

The financial impact of this measure, though real, is difficult to quantify due to the continual growth in consumption of medications throughout the period; to replacement of existing drugs with newer and more expensive products; and to higher initial prices for newly listed drugs.

5. When the patent on a brand-name drug expires, the manufacturer rarely drops the price, even if generic drugs entering the market are less expensive. This decision is due to several factors, including the fact that the Patent Medicine Prices Review Board usually uses the price of the brand-name drug to evaluate the appropriateness of prices for similar products that may come on the market later.
6. For example, a sharp rise in the cost of products used in manufacturing the drug.

Price disparity with the United States

With the arrival of the Internet, the American population became aware that it was paying more for brand-name drugs than Canadians were. For certain drugs, price disparity between Canada and the United States can reach 40%, 50%, or even 60% or more (for Americans without insurance).

The Internet also reduced transaction costs, making it easier for Americans to access Canadian drugs.

Over the last few years, numerous online pharmacies have opened in Canada to profit from the price disparity for brand-name drugs between Canada and the United States.[7] This phenomenon does not exist in Québec, because it would contravene the rules of the *Ordre des pharmaciens du Québec* and the *Collège des médecins du Québec*.

The situation quickly became intolerable, both for pharmaceutical companies, whose profits suffered, and for American citizens without easy access to Canadian drugs. The political situation in the United States only put more pressure on American politicians to find a solution to the problem of price disparity.

For their part, makers of brand-name pharmaceuticals sought to reduce the price disparity between the two countries by increasing their prices in Canada as permitted by the rules of the Patented Medicine Prices Review Board. Thus, all provincial drug insurance systems were confronted with requests for substantial price increases in early 2004.

Eight out of ten provinces accepted these requests outright. Ontario refused them, but prices increased nevertheless. Using the mark-up available to them,[8] pharmacists were able to absorb part of these increases; the Ontario public system paid for the rest owing to an administrative provision on the actual purchase price. For its part, the Québec government categorically refused these increases, invoking its non-increasing drug price policy, which had been in effect since 1994.

Makers of brand-name medications remain firm in their desire to reduce price disparity between the United States and Canada. More requests to the provinces for price increases are on their way over the next few months, and Québec, like the other provinces, will have to take a position.

7. It should be noted that the situation of generic drugs is altogether different. There are more manufacturers for a given compound in the United States than in Canada, resulting in greater competition and a lesser price disparity between the two countries. In several cases, American prices are actually lower than Canadian prices. However, this comparison is highly variable due to fluctuations in exchange rates.
8. Note that Ontario has applied up until now a policy similar to Québec's, except that Ontario gives pharmacists an extra margin for absorbing price increases. Until the beginning of 2004, the other provinces applied certain non-increasing drug price policies based mainly on prices in Québec and Ontario.

Generic drugs

Whereas the brand-name drug market is characterized by a kind of monopoly for the manufacturer, provided it has a patent in force and there are no similar medications (so-called "me-too drugs") on the market, the generic drug market is more competitive. When a patent on a brand-name drug expires, generic drugs are free to enter this new market. Owing to the small size of the Canadian market, the number of manufacturers is limited and the market is less competitive than in the United States.

However, the brand-name and generic drug markets have one thing in common: it is very difficult for an outside observer to determine what would be a fair and reasonable price, because it is impossible to get precise and reliable information on the cost structure of pharmaceutical companies. Nonetheless, as regards generic drugs, two things seem certain:

- Manufacturers of generic drugs do not have to make major investments in research and development to create a new product. For this reason, these businesses ought to be able to put up with lower prices than manufacturers of brand-name drugs, and still make a reasonable profit. With this in mind, the government of Ontario has decided that in the province's public system, the price of the first generic drug must not exceed 70% of the price of the corresponding brand-name drug, and subsequent generic drugs entering the market must be priced at no more than 90% of the price of the first generic drug. Québec benefits from this measure because manufacturers must guarantee the Québec public system the best price in effect in public systems in Canada in their manufacturer's commitment.

- If some manufacturers of generic drugs have given large discounts to pharmacy proprietors, this would demonstrate that these products are clearly profitable and that manufacturers can afford to reduce the price of some of their products while still remaining profitable.

The generic drug market does have one important difference from the brand-name drug market: generic drug manufacturers are very reticent about asking for price increases. Since the Québec public system applies the lowest price method in setting reimbursements for generic drugs, a manufacturer who asks for a higher price than its competitors risks losing much of its market share, as pharmacists will not keep that product in stock since the consumer must pay the difference between that product's price and the lowest price.

Another important point about the generic drug market is that it is difficult for manufacturers to distinguish themselves from the others, as they all manufacture identical products. Some use discounts, which contravenes the definition of the guaranteed selling price.[9] In fact, a strict reading of the law shows that any discount offered by a manufacturer to a pharmacist must be transferred to to the public system through an adjustment to the guaranteed selling price, and therefore cannot profit the pharmacist.

9. The guaranteed sale price is the sale price submitted by the manufacturer, without any kind of rebate, discount, or premium.

HEALTH CARE FACILITIES

Increase of global cost of medication

Unlike the public drug insurance system, health care facilities are not subject to the non-increasing drug price policy. Since purchases are carried out via calls for tenders, prices have increased over time according to market conditions. This increase has contributed to a general rise in drug costs in health care facilities.

Like the public drug insurance system, the health and social services network has also experienced an increase in drug consumption, which has contributed to the increase of global drug costs.

- The number of people suffering from certain age-related pathologies has increased. For example, the number of cancer patients has increased significantly. Moreover, with the arrival of much more expensive medications, some the fruit of biotechnology, the cost of treatment has increased from hundreds to thousands of dollars.

- Reduction in the length of hospital stays has also contributed to increased global drug costs in health care facilities. This is because treatment costs are higher in the first few days of a care episode. Furthermore, facilities where patients have shorter stays can treat more patients.

In this regard, it should be remembered that costs have continued to rise despite intensive efforts to limit this increase, such as measures by pharmacists to encourage optimal drug use in health facilities.

MINISTERIAL PROPOSALS CONCERNING DRUG PRICES

Ministerial proposals 12 and 13

Québec has, of course, implemented certain measures to control the amount spent on medication. It should also be noted that since the non-increasing drug price policy came into force in 1994, there has been an approximately 20% increase in the cost of living, as measured by the consumer price index (CPI). Québec recognizes that a price readjustment is justified to allow pharmaceutical companies to charge a fair and equitable price. However, it is clear that the requirements of the budget are real and unavoidable. Any increases must therefore have a minimal effect on the cost of the health and social services system.

Therefore, the Minister of Health and Social Services wants to:

- **End the non-increasing drug price policy and set up a mechanism to manage drug price increases;**

Means

- ✓ Authorize drug price increases only at a specific time of year, during updates to the Drug Formulary.
- ✓ Restrict price indexation to products that have been listed on the Drug Formulary for five or more years.
- ✓ Limit the average price increase of all products in a manufacturer's line to the CPI increase rate minus a 0,5% correction factor.
- ✓ Limit the rate of price increase for each product to no more than 1,5 of the previously defined maximum rate.
- ✓ Allow for greater increases in special cases when, in the opinion of the Conseil du médicament, the number of people affected and the financial impact are both small. In all cases, the drug must remain more cost-effective than its alternatives.
- ✓ Allow for greater increases in very special cases of products whose removal from the Drug Formulary could have serious consequences for patients' health.
- ✓ Allow pharmaceutical companies to accumulate the indexing permitted by the third and fourth points above for a maximum of three years, not counting time before January 1, 2005.
- ✓ Give the Minister the ability to fix a maximum allowable cost in the following special situations:
- ✓ – if the price increase requested by the manufactuer is greater than the maximum rate listed above;
- ✓ – if it is impossible to reach an agreement with the manufacturer on financial compensation.

- **Allow agreements for setting up compensation measures to minimize or prevent the impact of price increases on the public system, and give more latitude to manufacturers in the case of drugs that represent a significant innovation.**

Means

- ✓ Allow agreements negotiated by the MSSS to take a variety of forms, according to the situation:
  - a price decrease;
  - payment of an annual financial compensation to the government;
  - reimbursement to the government according to growth in the sales of a product;
  - assumption by the manufacturer of part of the wholesaler's mark-up, etc.
- ✓ Make the content of agreements on compensation measures public.

- ✓ Fix the term of agreements and specify precise and verifiable result indicators for all parties.
- ✓ Include periodic readjustment measures in the agreements, so as to take market changes into account.
- ✓ Ensure that proceeds from compensation agreements relating to users of the public system are returned to the Fonds de l'assurance médicaments, in particular to fund accessibility measures for various client groups.
- ✓ Take the necessary measures to guarantee equitable treatment of private insurees relative to users of the public system.

Ministerial proposal 14

As mentioned, it is difficult to establish a fair and equitable price for generic drugs. Despite this, the Minister of Health and Social Services wishes to:

- **Regulate prices of generic drugs.**

Means

- ✓ Limit the price of the first generic drug to 60% of the price of the brand name drug, and of subsequent generic drugs to 54% of the brand-name drug.

Ministerial proposal 15

A drug's file can receive a priority decision if the Conseil du médicament believes that patients who are meant to receive the drug could suffer a rapid, irreversible, and severely damaging progression of the disease during the evaluation period, and that no other possible drug therapy is listed on the RGAM's Drug Formulary or the Drug Formulary for institutions. In order to promote access to medications that have a potential to save money for the public system, the Minister of Health and Social Services wishes to:

- **Add "potential for significant savings for the RGAM" to the Conseil du médicament's grounds for priority evaluation of drugs.**

WHOLESALERS' MARK-UPS

Summary of the facts

From the beginning of the drug program on August 1, 1972, up to December 31, 1992, the price payable for medications was the price submitted by the manufacturer, plus a percentage (12,5% from 1972 to 1976; 9,0% since 1976) to defray certain acquisition costs incurred by the pharmacist, without regard to the pharmacist's actual costs. In other words, until December 1992, the price listed in the Drug Formulary contained an amount to cover the wholesalers' mark-up.

In the early 90s, the guaranteed selling price method was adopted for all drugs paid for by the RAMQ. This method aimed at promoting greater transparency in setting drug prices, and at ensuring that the RAMQ was not paying more than was necessary for the wholesalers' mark-ups.

Thus, the wholesalers' mark-up is no longer included in the price listed on the Drug Formulary, and is only payable if the drug was in fact purchased by the pharmacist via a wholesaler. This wholesaler must be recognized by the Minister of Health and Social Services, and must declare the percentage of the mark-up to be added to the manufacturer's guaranteed selling price set by agreement with the government. The regulation stipulates that the mark-up submitted by the wholesaler cannot exceed 9%.[10]

The mark-ups applied today are the same ones that the wholesalers submitted in 1993. As determined by the wholesalers' initial request, mark-ups range from 5,00% to 7,15%. In accordance with the non-increasing drug price policy in effect since 1994, this has not been increased since, despite requests from certain wholesalers.

Since January 1, 1997, manufacturers have been able to have different guaranteed selling prices for sales to pharmacists and to wholesalers. This came about when the Conseil consultatif de pharmacologie (today the Conseil du médicament) heard that certain manufacturers, particularly of generic drugs, were offering discounts on the order of 5,00% to wholesalers in other provinces.

To be able to take advantage of these discounts, the regulations were changed to allow manufacturers to offer a lower price to wholesalers than to pharmacists.

These discounts, given almost exclusively by generic drug manufacturers, now act as the wholesaler's mark-up, so that the RAMQ pays only the price listed on the Drug Formulary, resulting in a savings for the government. As for manufacturers of generic drugs, they say that as a result of this policy, they absorb the wholesalers' mark-up. It is important to note that the current regulations permitting different guaranteed selling prices for wholesalers and pharmacists are not exclusive to manufacturers of generic drugs.

Since the beginning of 1997, the regulations have allowed wholesalers' mark-ups to be limited to a maximum amount for certain expensive drugs. In the first situation, the maximum mark-up is $20 for products whose smallest package size or indivisible multiple is priced at $400 or more. When billing, the pharmacist indicates whether the drug was purchased directly from the manufacturer or from a wholesaler. In the latter case, the price listed in the Drug Formulary is increased by the wholesaler's mark-up identified by the pharmacist.

10. *Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized; Act respecting prescription drug insurance* (R.S.Q., c. A-29.01, s. 80).

The situation and its development

For the 2002-2003 fiscal year, the sum of transactions in the public system represents earnings of $1 751 000 000 for the pharmaceutical companies (drug costs minus pharmacists' fees). Wholesalers' mark-ups were $89,2 million for the same period. These amounts are not paid entirely by the RAMQ since, on one hand, the user pays a contribution, and on the other hand, some manufacturers give wholesalers discounts that substitute for their mark-ups.

- The RAMQ reimburses pharmacists for wholesalers' mark-ups in two different ways:
    - According to the mark-up percentage submitted by the wholesaler: the RAMQ pays for a mark-up of between 5,00% and 7,15%. This amounts to $76,6 million and makes up 85,9% of wholesalers' revenues. The weighted average mark-up for all wholesalers is 6,1%.
    - According to the maximum allowable wholesalers' mark-up: a fixed amount of $20 for products whose smallest package size or indivisible multiple is priced at $400 or more. This amounts to $3,4 million and represents an average mark-up of 2,9%. This method allows the RAMQ to save $3,8 million that it would have to spend if the normal mark-ups were applied. This method accounts for 3,9% of wholesalers' revenue for drugs covered by the RAMQ.
- Manufacturers' discounts for certain products:
    - Wholesalers receive a discount, almost always 5,00%, from the manufacturer.

      The weighted average rate is 5,00% (ranging from 1,74% to 8,25%), for a total of $9,2 million. For wholesalers, this makes up 10,4% of their revenue for drugs covered by the RAMQ. In return, they give up the mark-up that would have been paid them if there had been no discount (5,00% to 7,15%, depending on the wholesaler). This represents a savings of $11,2 million for the RAMQ.
- Even though wholesalers' mark-ups have stayed the same, their revenue has increased due to increases in total sales.

MINISTERIAL PROPOSAL REGARDING WHOLESALERS' MARK-UPS

Ministerial proposal 16

There are significant differences in mark-ups between different wholesalers, ranging from 5,00% to 7,15%, differences that do not necessarily represent different levels of service. This situation has existed for ten years and may have created market distortions. Furthermore, Schedule II of the *Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized* stipulates that wholesalers' mark-ups cannot exceed 9,00% of the manufacturer's guaranteed selling

price for a given package size. The rates requested by wholesalers in 1993 were all below the maximum, and have stayed the same due to the non-increasing drug price policy (which included wholesalers' mark-ups), despite requests for increases from some of them. Therefore, the Minister of Health and Social Services wishes to:

- **Tighten the rules governing wholesalers so as to ensure equity among them.**

Means

✓ Unfreeze wholesalers' mark-ups, and establish a maximum mark-up of 6,0 %. Place a ceiling of $24 on products costing more than $400.

CHAPTER III OPTIMAL DRUG USE

PATIENTS AND HEALTH CARE PROFESSIONALS

The topics dealt with in the first two parts of this draft policy primarily concern the government. The decision of whether to list a drug in the RGAM's Drug Formulary or the formulary for institutions is up to the Minister of Health and Social Services, as are measures to ensure a fair price for listed drugs. However, the situation is much different in regard to ensuring optimal drug use. Here, other players have the main role.

Optimal drug use begins with whether it is appropriate to use a given drug. This question can be raised by patients themselves or by prescribing physicians. The appropriateness of a drug should be based on the patient, taking into account effectiveness, side effects, the ability of the patient to manage his or her treatment, etc. Cost should also be considered. Optimal use, then, means that the patient acquires the product and takes it according to the prescription or instructions he or she has been given.

Although the primary responsibility for optimal drug use rests with the trio of the patient, the physician, and the pharmacist, it is not limited to these three players. Universities, professional associations and orders, pharmaceutical manufacturers, insurers, public agencies, the health and social services network, and the media should all promote, encourage, advocate, and support optimal drug use. Access to quality information and training is also essential.

The impact of the pharmaceutical industry on continuing professional education must be noted, as must the media's influence on patients who request new "wonder drugs" after hearing them touted in the press. All these players have their own particular responsibility with regard to optimal drug use. Improvement in this regard can be obtained only by coherent messages and action by all concerned, and will benefit both public- and private-sector insurees.

There is no precise measurement of the impact of non-optimal drug use in Québec. However, data suggest that use of medication is not always optimal and that there is room for improvement. For example the RAMQ's file contains records of possibly inappropriate prescriptions, such as prescription of benzodiazepine to elderly people and in doses that are higher than recommended. The Conseil du médicament reports that in a descriptive study on the connection of nonsteroidal anti-inflammatory drugs (NSAIDS) with digestive haemorrhages and perforations, the rate of hospitalization for these problems increased 75,9% between 1999 and 2001. The rate for elderly people almost doubled, increasing by 93,2%.

Optimal drug use and potential savings

As the representative of the people, the government must strive in all its activities for the best use of the resources at its disposal, owing to their cost. This is a universally recognized principle of sound management.

In regard specifically to medication, the search for optimal use consists of determining what drug therapies allow the best possible results, taking into account available resources and costs.

The link between the benefits of a therapy and its cost is a fundamental piece of information in pharmaco-economic analysis. It should be noted that whereas the cost of a therapy is easy to evaluate (the cost of the drug and of professional labour), the benefits thereof can be much more difficult to measure.

There are numerous benefits to consider, and causal links can be difficult to establish and quantify. For example, if one therapeutic option is to be chosen over another, one must be able to foresee the effects of this decision on the patient's health (morbidity and mortality), on their future use of medication and health services (taking into account the quality of care received), on their ability to remain in the workforce, on their use of other government services (income security and disability benefits), on their need for care from family, and so forth.

Optimizing drug therapy must be based on a global perspective (including for private insurance policyholders); it should not be limited to the health sector. This means that a treatment can be optimal even if it does not generate a savings for the public drug insurance system, or even for any part of the health and social services system.

For example, better drug use in treating mental health problems can involve increased use of certain more costly medications, if the patient's quality of life and social integration are thereby improved. Preventive treatment of osteoporosis results in a medium-term decrease in morbidity, and can result in patients' staying active longer. Better testing and earlier treatment of diabetes can involve increases in certain short-term costs in the health and social services sector, but it will result in substantial savings over the medium and long term.

The Conseil du médicament

In 2002, an amendment to the *Act respecting prescription drug insurance* created the Conseil du médicament and gave it a special role in monitoring medications and their use. The Conseil du médicament therefore assumed the responsibilities that had previously been assigned to the Conseil consultatif de pharmacologie, the Comité de revue de l'utilisation des médicaments, and the Réseau de revue de l'utilisation des médicaments.

Note that although the Conseil du médicament is a government agency, its members, including physicians, pharmacists, and researchers, are external experts.

The main objectives of the Conseil were as follows:

- To bring together resources and consolidate expertise on medication;
- To encourage coordination in monitoring and promoting optimal use of medication;
- To promote more integrated action in evaluation, listing, monitoring, and optimal drug use.

The Conseil adopted the following definition as a common vision of optimal drug use:

> "Use that maximizes benefits for and minimizes risks to the health of the population, taking into account alternatives, costs, available resources, and values of the patient and of society."

The Conseil du médicament's mandate on optimal drug use allows it to:

- Undertake or support reviews of medication use;
- Propose strategies for training, information, and awareness with a view to improving prescription and dispensing of drugs, or contribute to the development and implementation of such strategies, with the cooperation or participation of the various players involved, particularly health care institutions;
- Make recommendations to concerned parties and health care professionals regarding improving drug use, with respect for their responsibilities;
- Propose or contribute to the development and implementation of strategies for informing the public and raising their awareness;
- See to the evaluation of problems in the use of medication and to the implementation of strategies to prevent and correct these problems.

In 2002, a round table was created bringing together representatives from the MSSS, the RAMQ, the Collège des médecins du Québec, the Ordre des pharmaciens du Québec, the Ordre des infirmières et des infirmiers du Québec, the Fédération des médecins omnipraticiens du Québec, the *Fédération des médecins spécialistes du Québec* (Federation of Medical Specialists of Québec), the Association québécoise des pharmaciens propriétaires, the Association des pharmaciens des établissements de santé, the Canadian Life and Health Insurance Association, Canada's Research-Based Pharmaceutical Companies (Rx&D), and the Canadian Generic Pharmaceutical Association. The mandate of this round table is to:

- Give its opinion on priorities and necessary actions with regard to optimal drug use;
- Facilitate actions to promote optimal drug use;
- Facilitate actions provided for in the agreement with Rx&D.

The commitment of all partners (professional orders, physicians' and pharmacists' associations, etc.) seems essential to any intervention to promote optimal drug use, since this is a professional field in which the Conseil cannot act alone. Only a joint effort will improve the use of drugs.

These interventions should be paid for out of the partnership fund set up through agreements between the Minister of Health and Social Services and the pharmaceutical industry. Furthermore, analyses of the impact of optimal drug use measures should be undertaken.

MINISTERIAL PROPOSALS CONCERNING THE CONSEIL DU MÉDICAMENT

Ministerial proposals 17 and 18

The Minister of Health and Social Services reaffirms his intention to:

- **Confirm the Conseil du médicament's mandate in regard to optimal drug use, in order to promote concerted action, and adopt the Conseil's definition of optimal drug use.**

The Round Table is answerable to the Conseil du médicament. Its members ought to be able to exercise a certain leadership and take on more responsibilities regarding measures that should be put in place in practice settings, becoming a primary source of support for promoting optimal drug use.

Recognizing the importance of concerted action to promote optimal drug use, the Minister of Health and Social Services wishes to:

- **Review the mandate of the Round Table, make regulations concerning its composition, and clarify its roles and responsibilities, so as to make it the primary forum on optimal drug use.**

PROMOTING OPTIMAL DRUG USE

A number of measures to promote optimal drug use are possible. The following is a non-exhaustive list of tools that will be favoured for helping the Conseil du médicament to carry out its mandate. Some seem more promising than others. Possible measures include training activities, distribution of instructional material, use of informational and decision-making tools, manuals, and academic visits.

Technology as a tool for promting optimal drug use

In a context of integrated service delivery, information technologies are essential to success.

The participants in the May 2004 symposium on optimal drug use agreed that it is important to have access to clinical information. However, it was noted that despite the support for integrated service delivery, these clinical data are not always available when needed. For example, in the case of medication, this information, although considered essential for dealing with patients and ensuring continuity of care, is available electronically in the pharmacy but is rarely available to physicians.

The MSSS is also convinced that professionals should share information, and supported several pilot projects to this end over the last few years. However, current laws do not permit broadening these exchanges of information. Amending bills to permit better information exchange are on the agenda, and can be put into practice once they are passed by the National Assembly. Furthermore, the MSSS wishes to advance a plan to computerize both local service networks and the whole health and social services network.

In this spirit, the MSSS is moving forward with projects to develop departmental orientations on makng the whole drug distribution process computer-assisted, from prescribing drugs to administering them in health care facilities. The aim is to make the best use of human and technical resources in promoting optimal drug use.

Integration of drug information to Info-Santé/CLSC service

The popularity of the Info-Santé/CLSC system (2,4 million calls in 2003-2004) eloquently expresses the scale of the population's concern for their health.

In June 2004, a working group was mandated to review the role and organization of the Info-Santé/CLSC service. In particular, the working group aimed to adapt the services to new organizational realities in the health and social services network. New components could be added, such as integration of drug information.

Empowering citizens to maintain and improve their health by informing them about medication and its use

Optimal drug use would be impossible without citizens' taking responsibility for their use of medication. In particular, citizens must be made aware that medication is not necessarily the first or the only solution for preventing or treating a health problem. Having a healthy lifestyle can reduce or eliminate the need to use medication to treat many pathologies.

Medication is an essential resource in the therapeutic arsenal, but it must be used wisely to fully benefit from it. To do this, citizens must be aware of the risks of inappropriate use of medication and of how to use them correctly to ensure successful treatment.

Further, drug therapy cannot be totally effective without the patient's involvement, particularly in respecting clinicians' recommendations and in following the treatment faithfully. Citizens should also be made aware that the most expensive or recently released treatment is not necessarily the most effective one. In fact, in many cases, a less expensive product may be indicated.

Finally, the trend of self-medication has grown over the last few years, owing to greater access to over-the-counter remedies such as natural health products. This leads to the conclusion that citizens and health professionals must cooperate to ensure that the these practices have positive effects on health.

Therapeutic intent

One of the selected means is transmission of therapeutic intent, which the Conseil du médicament will soon be trying in a pilot project. A therapeutic intent is a note written on a prescription by the physician, specifying the health problem that the prescribed medication is meant to treat. This could be either a diagnosis (e.g. pneumonia, arthritis, depression) or a symptom (pain, insomnia, coughing).

The therapeutic intent will be transmitted to the pharmacist, who can then adjust his or her practice and personalize the advice he or she gives to the patient. This will promote optimal drug use and encourage the patient to follow the the treatment faithfully. By knowing the therapeutic intent, pharmacists will better understand physicians' objectives and therapeutic strategy, and can thus contribute more to optimizing the therapy and improving the patients' state of health.

The listed therapeutic intent could also be added to a database, which the Conseil du médicament could access in order to study medication use more deeply. It would be used in particular for aiding reviews of medication use. The therapeutic intents listed in this database might also be made available to other prescribing physicians; combined with the patient's drug profile, this information would allow other professionals, especially physicians, to make more effective interventions and thereby improve patients' health.

On another note, listing the therapeutic intent would allow administrative processing of requests for exception drugs to be simplified.

Prescribing profiles

The second selected means is feedback for physicians via prescribing profiles.

Prescribing profiles are information sent to clinicians regarding their prescription habits, allowing them to analyze their practice according to scientific recommendations for practice standards or in comparison to their peer groups. Several studies have evaluated the effects of such a measure. The efficacy of prescribing profiles varies and may be linked to differences in their development and content. Physicians must be included via their professional order or organization in developing and deploying a prescribing profile transmission project, since the success of such a measure depends on their cooperation and participation. Therefore, prescribing profiles must not be used to monitor physicians.

Prescribing profiles are an optimal-use measure that targets prescribers. The Conseil du médicament should be taking preliminary steps in this regard in the near future.

Medicine review

Finally, medicine review is a patient-focused approach aiming to maximize the positive effects of a particular patient's drug therapy. The approach applied here could draw on the Australian "home medicine review" model, while reflecting professional realities in Québec.

Home medicine review would be offered to patients living in the community. This service involves joint action by a family physician and a pharmacist. The family physician refers the patient to a pharmacist of his or her choice, who must be accredited for this service. Having received the relevant clinical information from the physician, the pharmacist reviews all of the patient's medication. He or she then presents a report and recommendations to the family physician. The resulting action plan involves both the physician and the pharmacist in their respective areas of practice. This service would be directed primarily at the most vulnerable user groups.

The current organization of family medicine groups and the government's desire to promote interdisciplinarity provide an ideal opportunity to try this kind of program. The Conseil du médicament will carry out a pilot project to evaluate the costs and benefits of such a program. This project will be financed by the partnership fund of the master agreement with Rx&D.

MINISTERIAL PROPOSALS CONCERNING OPTIMAL DRUG USE

Ministerial proposal 19

In seeking solutions for promoting optimal drug use, it is essential not to forget the importance of a joint strategy that brings together pharmacists, physicians, patients, and the pharmaceutical industry. To this end, the Minister of Health and Social Services wants to:

- **Support measures for promoting optimal drug use, such as transmission of therapeutic intent, feedback through prescribing profiles, and the home medicine review project, particularly as pilot projects.**

Ministerial proposal 20

The Info-Santé/CLSC service, provided by nurses, often receives health questions about medication and requests for information about medication. Using tools adapted to the needs of the service and the population, nurses can answer the majority of these calls. However, analysis has shown that 1,5% to 2,0% of these calls require consultation with a pharmacist for a more complete answer, especially when the caller's community pharmacist is not available. However, there is no pharmaceutical resource currently available for this service.

Having information on medication available when needed would promote optimal drug use among the population.

The Minister of Health and Social Services therefore wants to:

- **Set up a second-line drug information service via Info-Santé/CLSC, an information source already well known to the public.**

Ministerial proposal 21

The minister believes in the importance of clinical information flow. However, computerization is an existing priority of the MSSS and its network, so the issues surrounding this question are dealt with elsewhere. Although the computerization of the health and social services network is not the topic of this policy, the Minister of Health and Social Services wants, at an appropriate time, to:

- **Support favoured measures to improve the flow of clinical information among health professionals, especially with regard to medication and therapeutic intent;**

- **Help to implement computerized tools to support clinicians in promoting optimal drug use.**

Ministerial proposal 22

Citizen responsibility is essential for measures promoting optimal use to have their maximum impact.

Choosing a drug or non-pharmaceutical treatment must be an informed decision. To this end, the relationship between patients and health professionals must be reinforced to allow dialogue and receptivity, so that clinicians' recommendations and advice have their full impact.

A great deal of information on medication is available in our society, but it is not always fair or reliable. Citizens must be made aware of the importance of thinking critically about information on pharmaceuticals, and of distinguishing credible sources of information. Consequently, citizens must have access to reliable information about medication.

The rising cost of drug therapy means that citizens need to realize the cost of the drugs they use or could use. The RGAM's Drug Formulary, available on the RAMQ's website, is an ideal source of information in this regard.

For this reason, the Minister of Health and Social Services wants to:

- **Implement various awareness and information programs on optimal drug use that are appropriate and accessible to citizens and encourage them to take responsibility for their health.**

Means

- ✓ Continuing the information campaign on correct use of medication, over three years, targeting both citizens and health professionals.
- ✓ Creating and distributing informational tools, such as pamphlets, to publicize the results of the Conseil du médicaments' research activities and the recommendations stemming therefrom.
- ✓ Creating an interactive website presenting objective and accurate information on medication and its use to the population and health professionals.
- ✓ Provide easy access to information on drug costs via the RGAM's Drug Formulary on the RAMQ's website.

OTHER CONSIDERATIONS IN OPTIMAL DRUG USE

Training of health professionals

Ministerial proposal 23

University training of physicians and pharmacists is an important foundation for optimal drug use. Accordingly, starting from their training in medicine and pharmacy, this concept should be inculcated into young clinicians, and likewise for future nurses. Leaders in these professions have a role to play in this regard. To this end, the Minister of Health and Social Services wishes to:

- **Promote the integration of optimal drug use into university training of physicians, pharmacists, and related professionals.**

Ministerial proposal 24

The amounts allocated to continuing professional education of physicians, pharmacists, and nurses are difficult to calculate. Training draws on a number of different organizations, including faculties of medicine and pharmacy, professional associations, and professional orders. However, it is evident that the majority of training activities are funded by the pharmaceutical industry. Although this is an indispensable source of funding, it nevertheless raises questions about the objectivity of the training offered. The importance of impartial and objective training for health care workers should therefore be reaffirmed. In order to maintain respect for this principle, it would be useful to have another source of finances, in the form of a specific fund made of contributions from government, the pharmaceutical industry, and wholesalers among others.

The Minister of Health and Social Services therefore wants to:

- **Encourage continuing professional training and the establishment of a specific fund available both to universities and to professional orders and associations.**

Disease management

Disease management consists of providing optimal health care by increasing care quality and controlling costs effectively. It aims to improve clinical processes and integrate best practices. Disease management focuses on the need for general and specialized services for patients with chronic pathologies.

It is difficult to ignore the commercial interests of drug manufacturers when they develop and offer disease management programs targeting a particular disease and tying in their product line throughout. On some occasions, several different programs have even been developed for a single disease.

The introduction of programs offered by the pharmaceutical industry raises important questions about their value for our health and social services system, about their ability to improve care quality at optimal cost and about their effects on the organization of care.

Possible disease management initiatives must respect the policy directions and needs of the health and social services network. They must consider the patient holistically and avoid taking blinkered measures that only deal with some of the patient's individual conditions or diseases. It is also important to point out that disease management must not be limited to drug therapy.

Disease management programs must not be used to create pressure for drugs to be listed on drug formularies.

Disease management initiatives must be based on measures with evidence proving their effectiveness, and must respect the Conseil du médicament's criteria for optimal use, if applicable. Finally, from their introduction, these programs must be independently evaluated for their results and their effectiveness in increasing quality of care at optimal cost.

Ministerial proposal 25

To this end, the Minister of Health and Social Services wants to:

- **Specify the conditions for supporting disease management programs proposed by the pharmaceutical industry.**

BUSINESS PRACTICES OF MANUFACTURERS

Pharmaceutical manufacturers in Canada use a variety of strategies in their commercial practices, such as advertising to the general public, promotion to health professionals, continuing medical information, and distribution of samples. Although prescription drug advertising directed at the general public is under federal jurisdiction, the MSSS reiterates its opposition to any expansion in this field.

Other activities such as phase IV (post-market) clinical studies, pharmacoeconomic trials, or studies of medication use are among the strategies used to market medications and increase demand over the longer term. Practices common to many commercial fields, such as volume discounts, gifts, and social events, are also used.

An analysis of the current regulations and directives on commercial practices in Québec and Canada reveals that there are a number of laws, regulations, and directives dealing with certain commercial practices as well as complaint review. Mechanisms at the pan-Canadian level include the *Food and Drugs Act* and its related regulations, the Canadian Code of Advertising Standards, and the Code of Advertising Acceptance of the Pharmaceutical Advertising Advisory Board, an organization that oversees marketing to health professionals.

In Québec, these mechanisms include the *Pharmacy Act*, the *Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized*, the Conseil de l'éducation médicale continue du Québec (CEMCQ)'s code of ethics for medical educators, and the codes of conduct of the Collège des médecins du Québec and the Ordre des pharmaciens du Québec. This last code is undergoing a revision aiming in particular at improving oversight of commercial practices targeting pharmacists.

Finally, Rx&D has a code of business practices for its members. This code, of course, applies outside of Québec as well.

It should be added that this policy only deals with manufacturers' marketing practices. Those that take place between health professionals are overseen by the relevant organization, the Office des professions du Québec.

MINISTERIAL PROPOSALS CONCERNING BUSINESS PRACTICES OF MANUFACTURERS

Pharmaceutical companies spend enormous sums on marketing their products to health professionals. According to American data, this spending is equivalent to 12% of their pharmaceutical sales.[11] For their part, the majority of health professionals insist that these practices do not influence their professional judgment and their ability to choose the best treatment for their patients – despite the reservations of several authors and associations.

It seems that marketing practices encourage physicians to favour medications that are often more expensive without necessarily being more effective. This results in higher costs for all drug insurance systems.

For example, pharmaceutical companies market their drugs by distributing samples. There is reason to believe that this practice aims to modify behaviour and possibly stimulate demand for a particular product. The availability of samples makes a prescribing physician aware of new drugs sooner, encourages a preference for these drugs, and promotes their rapid adoption into prescribing habits.

11. M.B. Rosenthal et al., "Promotion of prescription drugs to consumers," *N Engl J Med* 346 (2002): 498-505.

Few Canadian data are available regarding other forms of promotional spending such as gifts, travel to conventions, samples, promotional articles, restaurant meals, and the like, and it is often this type of promotional practices that raises controversy. In 2000, an article in JAMA[12] estimated marketing expenses in the United States at between $8 000 and $13 000 US per year per physician.

At present, pharmaceutical companies' investments in medical and pharmaceutical training are usually well perceived by civil society and the scientific community. These sums help offset educational organizations' lack of funds. However, they constitute major and effective marketing campaigns for these companies.

It is noted that manufacturers of innovative drugs direct their marketing efforts mainly towards physicians, and generic drug manufacturers direct theirs mainly towards pharmacists. However, these methods could change depending on the various procedual requirements arising from recent changes to article 17 of the *Pharmacy Act,* concerning the role of the pharmacist in initiating or adjusting drug therapy.

Furthermore, the RAMQ has no way to act directly on pharmacists to prevent them from receiving discounts. In their dealings with the RAMQ, pharmacists charge the price listed in the Drug Formulary, regardless of whether they have received discounts from generic drug manufacturers. According to current administrative rules, even if a pharmacist wanted to bill a actual purchase price that was less than the listed price, this would be impossible. The RAMQ can take action only against manufacturers, and then only to enforce compliance with their manufacturer's commitment.

In examining commercial practices in general, despite codes of conduct, codes of business practices, and regulations in force, it seems that certain questionable practices continue.

Ministerial proposal 26

Owing to this and to the problems mentioned, the Minister of Health and Social Services wants to:

- **Establish clear rules of business practice for all pharmaceutical companies.**

Means

- ✓ Modify the form of manufacturers' commitments by adding a clause requiring respect for existing codes of business practices and the Conseil du médicament's optimal drug use criteria in its advertisement and interventions with health professionals.
- ✓ Implement a schedule of corrective measures for infractions of codes of business practices or concerning guaranteed selling prices.
- ✓ Allow the names of contravening societies to be published at their expense.

12. Asley Wazana, "Physicians and the pharmaceutical industry: Is a gift ever just a gift?", *JAMA* 1283 (2000): 373-80.

- ✓ Specify in manufacturers' commitments that the manufacturer commits to guarantee selling prices and sufficient supplies for the duration of the Drug Formulary's validity.
- ✓ Review manufacturers' commitments and add a clause stipulating that the submitted price must be exempt of any form of gifts to health professionals and any form of discounts to pharmacists. Specify the type of benefits provided by the manufacturer that do not have to be included in the actual purchase price (e.g. certain types of funding for training, provided that the content of the training is approved by a third party; services such as Wellness Days; etc.).
- ✓ Use manufacturers' commitments to restrict or forbid the distribution of samples in Québec.

Ministerial proposals 27, 28, 29, and 30

The Minister of Health and Social Services wishes to:

- **Regulate the business practices of generic drug manufacturers.**

Means

- ✓ Support the establishment of an independent agency funded by makers of generic drugs, to oversee these manufacturers' business practices.

- **Ensure that the MSSS is represented in the pharmaceutical industry's various complaints review committees and in the CEMCQ.**

- **Encourage makers of brand name drugs and the Ordre des pharmaciens du Québec to jointly develop a code of ethics for interveners in continuing pharmaceutical education.**

- **Modify the regulation concerning the Drug Formulary to require pharmacists to bill according to the actual net purchase price, including any type of discounts other than those permitted by the above proposals.**

CHAPTER IV A DYNAMIC PHARMACEUTICAL INDUSTRY

PORTRAIT OF THE INDUSTRY IN QUÉBEC

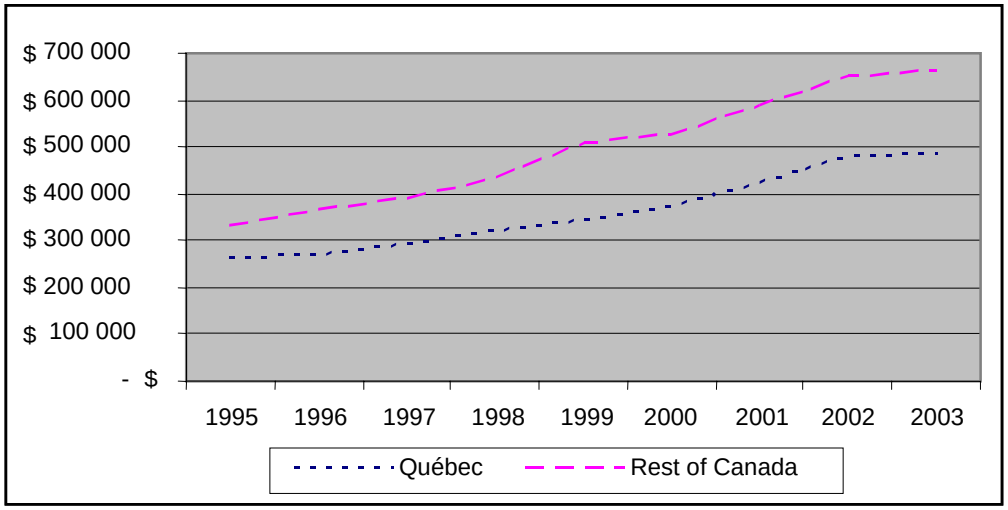
Home to some twenty Canadian headquarters of multinational brand-name drug companies and another twenty-some generic drug and contract manufacturing companies, Québec' boasts a pharmaceutical industry notable for its contribution to the province's economic development. Québec's $3,1 billion worth of shipments of pharmaceutical products represented 42% of Canadian shipments in 2002.

In 2003, 40% of Canadian pharmaceutical jobs were in Québec, and 68% of Canadian prescription drug patents were held by companies with facilities here. The Québec drug market is 25% of the Canadian drug market, equivalent to Québec's share of the Canadian population.

However, Québec's main distinction is hosting six of Canada's seven basic research centres or groups belonging to multinational innovative drug companies. Québec hosts a lesser concentration of generic drug companies.

As shown in the following graph, Québec receives nearly 42% of the Canadian pharmaceutical research industry's research and development spending. This has grown by 8% per year since 1995, both in Québec and in the rest of Canada.

Research and development spending in the pharmaceutical industry, Québec and rest of Canada, 1995 to 2003 (in thousands of dollars)



Source: Patented Medicine Prices Review Board, annual reports 1995-2003.

The economic impact of the medication field is much greater than simply that of the pharmaceutical industry. As shown below, 156 companies connected with medication were located in Québec in 2003, employing 17 500 people of whom 7 900 worked for innovative drug companies and 2 900 worked for generic drug companies and contract manufacturers.

Jobs in the Québec drug industry by type of company, 2003

Type of company	Number of companies	Jobs*
Innovative pharmaceutical companies	29	7 900
Generic drug companies and contract manufacturers	22	2 900
Medical biotechnology companies	85	2 700
Contract research companies	20	4 000
Total	156	17 500

* Estimate based on multiple sources.

Multiple sources, compilation, Ministère de l'Industrie et du Commerce, 2003.

In 2003, 64,2% of the Québec prescription drug market, by number of prescriptions, was controlled by brand-name manufacturers, and 35,8 % by generic manufacturers.

Market share of prescriptions between brand-name and generic manufacturers, Québec and Canada, 2003

	Québec		Canada	
	Brand-name manufacturers	Generic manufacturers	Brand-name manufacturers	Generic manufacturers
	(%)	(%)	(%)	(%)
2003	64,2	35,8	60,1	39,9

Source: IMS Health, Canadian Pharmaceutical Industry Review, 1996-2003, compiled by the Ministère du Développement économique et régional et de la Recherche.

COMPETITIVE ADVANTAGES OFFERED TO PHARMACEUTICAL COMPANIES IN QUÉBEC

Québec focuses particularly on businesses in the field of medication because of their promise of quality well-paid jobs. Moreover, these businesses represent an important way of adding value to research work in public laboratories and research centres.

However, with governments competing harder and harder to attract investment, vigilance is required.

As the development of a dynamic pharmaceutical industry remains a priority for the Québec government, the pharmaceutical policy is an ideal opportunity to confirm that the support given to this industry up until now will be maintained. The following section will discuss the advantages for pharmaceutical companies that come to Québec.

Tax advantages

In Québec, the two main incentives offered by various levels of government to the drug industry are refundable tax credits and tax holidays for foreign researchers. As shown in the two following tables, in 2000, the pharmaceutical industry obtained a proportionately lesser share of tax credits (5,4%) than its proportion of research spending (8,8 %); however, pharmaceutical and biotechnology companies obtain nearly 40% of tax holiday visas, allowing them to attract highly qualified workers that they cannot find here.

The pharmaceutical and biotechnology industry and tax measures for research and development

	Number of companies claiming a tax credit		Research and development tax credits granted to companies		Numbrer of visas for foreign researchers and experts
	1999	2000	1999	2000	1998—2004
	(n)	(n)	(M$)	(M$)	(n)
All companies	3 739	3 648	389	467	690
Pharmaceutical and biotechnology companies	57	43	26	25	275
Pharmaceutical and biotechnology companies as % of total	**7,0%**	**–**	**6,8%**	**5,4%**	**40%**

Source: Ministère des Finances du Québec for tax credits (Ministère du Revenu's R&D database) and Ministère du Développement économique et régional et de la Recherche for visas.

Spending on research and development for the pharmaceutical industry and for all companies in Québec, 1999 and 2000

	Research and development spending	
	1999	2 000
	(M$)	(M$)
All companies	3 047	3 555
Pharmaceutical companies	214	313
Pharmaceutical companies as % of total	**7,0%**	**8,8%**

Source: Institut de la statistique du Québec.

THE 15-YEAR RULE

Regulations on intellectual property are under federal jurisdiction. Within its jurisdictions, however, Québec has put forward a unique measure to promote the innovative pharmaceutical industry: the 15-year rule. This rule guarantees innovative pharmaceutical companies that the purchase price of their products will remain fully reimbursed for 15 years after listing on one of the drug formularies, even if the patent has expired or if there is a less expensive generic equivalent.

It should be noted that the 15-year rule does not give market exclusivity in the same way that a patent does, and does not prevent the listing of generic versions when they become available. In practice, this policy is not as strong as the exclusivity maintained by patent term restoration in the United States or the European Union. This additional protection does attract the pharmaceutical research industry to Québec, but it involves costs for the government and population of Québec. However, according to evaluations by the Ministère des Finances, the benefits of this measure for the Québec economy exceed its cost.

Ministerial proposal 31

The Minister of Health and Social Services wants to:

- **Keep the 15-year rule in its current form, instead of setting up a reference-based pricing system.**

British Columbia and certain European countries have chosen to set up a system whereby certain drugs are reimbursed according to what is called a reference-based price, chosen to provide the best cost effectiveness ratio among a single subclass of drugs with similar therapeutic effects. Although this system permits some savings for drug insurance systems, Québec has chosen not to go in this direction.

PARTNERSHIP AGREEMENTS WITH THE PHARMACEUTICAL INDUSTRY

The issues surrounding optimal drug use are generally complex and multifaceted. Cooperation and coordination of the various partners involved are prerequisites to success in this area, especially in altering medication use habits.

Various amendments to the *Act respecting prescription drug insurance* were adopted in 2002. One of these allows the Minister of Health and Social Services to sign partnership agreements with the pharmaceutical industry. In June 2002, three such agreements were signed in view of promoting optimal drug use.

The current agreement with Rx&D has, in particular, led to the creation of a partnership fund for activities promoting optimal drug use, for reviews of drug use, and for corrective measures if needed.

Two agreements have also been signed with manufacturers of proton pump inhibitors (IPPs) and selective COX-2 inhibitors (coxibs). The partner companies made financial contributions, and action plans were developed and put in motion.

These experiences with partnership agreements suggest that this approach is productive. Indeed, although the agreements are between the MSSS and the pharmaceutical industry, they involve other partners in the sector, such as physicians' and pharmacists' professional orders and associations. These have an important role to play as their cooperation is essential in implementing action plans, especially for their expertise, as well as for awareness-raising and mobilization of clinicians.

In all cases, partnership agreements are negotiated by the MSSS and managed by the Conseil du médicament. In particular, the Conseil must ensure that measures taken are evidence-based.

One condition, however, must remain in place: listing a pharmaceutical in the drug formularies must never be a condition of a partnership agreement with the pharmaceutical industry, nor may such an agreement restrict administrative measures to promote optimal drug use. Finally, these agreements must have clear objectives and provide for evaluation of their impact.

Ministerial proposal 32

Actions promoting optimal drug use can take many forms; they can be general or apply to specific classes of drugs.

Thus, the Minister of Health and Social Services proposes to:

- **Sign general partnership agreements with drug manufacturers' associations (Rx&D, the Canadian Generic Pharmaceutical Association, and the Groupement provincial de l'industrie du médicament) to allow activities such as studies, professional training, public awareness campaigns, etc.;**

- **Sign specific partnership agreements dealing with specific classes of drugs with the manufacturers involved, in order to implement measures needed to promote optimal use of those specific drugs. Such agreements will have to be signed with all manufacturers of the relevant class of drugs.**

It takes time to influence the habits of prescribing physicians and medication users, so the anticipated results will only be felt over the medium and long term. These intervention models are therefore not appropriate when short-term effects are sought.

Ministerial proposal 33

In certain cases, a product's listing in the drug formularies can raise some uncertainty about its subsequent use. It can then be useful to consider a partnership agreement to discourage non-optimal use of that product. This type of partnership, called a risk-sharing agreement, is designed for the Minister and the manufacturer to establish a way of sharing the financial risks linked to the use of the product.

Thus, a risk analysis could help determine the appropriateness of signing such an agreement with the manufacturer specifying, for example, a utilization target determined by various criteria. Beyond that target, the manufacturer would keep only a decreasing portion of the revenues according to a sliding reimbursement scale. This way, the manufacturer would have an incentive not to go beyond this target and instead to plan its marketing activities according to optimal use criteria.

Such an agreement could also be considered when a sharp increase in demand for an already listed drug suggests non-optimal use.

For these reasons, the Minister of Health and Social Services proposes to:

- **Sign risk-sharing agreements with drug manufacturers, according to study results, aiming to prevent the non-optimal use of specific drugs that they manufacture.**

PERMANENT DISCUSSION FORUM

There are several examples in the world of permanent forums for discussion between a government and the pharmaceutical industry, with the aim of making the country's business environment more attractive and competitive for the industry. These forums consist of the principal leaders of the pharmaceutical industry and the public decision-makers in the pharmaceutical field. Closer to home, Québec has set up similar groups with the petrochemical and refining industry as well as with the metallurgical industry.

Competition between different countries and sometimes even between different subsidiaries of a single company is becoming fiercer and fiercer every year. Currently in Québec, there is no single, permanent, official forum in which the innovative pharmaceutical industry can discuss its needs and expectations with the various government agencies involved. Setting up such forums could help to increase Québec's share of the pharmaceutical industry's research and development investment, or at least keep it stable from year to year.

Ministerial proposal 34

Considering the importance of the pharmaceutical industry's contribution to the Québec ecoomy, and of the intensity of international competition for research and development capital, the Minister of Health and Social Services wishes to:

- **Set up a permanent discussion forum so as to maintain balance between health and economic development policies, by bringing together representatives of the MSSS, the MDERR, and the innovative and generic pharmaceutical industries.**

CONCLUSION

The work done up to now has allowed us to make several conclusions.

First, access to needed medication is a necessity for the entire population of Québec. However, the government and its citizens have limited financial resources with which to ensure it. The draft policy proposes measures to improve access to medication in this context, thereby contributing to a quality service. Several measures to simplify the administrative process have been proposed, such as more frequent modifications to the Drug Formulary to list drug price reductions and to add new drugs, especially generic ones. Also, the draft policy proposes clear rules for public funding of drugs considered by the Conseil du Médicament to have therapeutic value in treating hereditary metabolic diseases. It also proposes changing the conditions of the public drug insurance plan to provide drugs free of charge to elderly insurees receiving maximum GIS payments. Depending on efficiency gains from optimal drug use measures and partnership agreements, free medication or contribution reductions could also be offered to low-income insurees.

Next, the rules for drug prices must be reviewed. Measures proposed to ensure fair and equitable prices include indexing the price of already-listed drugs, but also controlling the increase of drug prices. Measures setting a price ceiling for generic drugs and imposing a new maximum mark-up for wholesalers are also suggested.

There is also much to be done to optimize drug use. The draft policy favours methods and measures using new information technologies, as well as various projects such as therapeutic intent transmission, prescribing profiles, and home medicine review. The draft policy also proposes measures for raising citizens' awareness about optimal drug use, for which a broad media campaign is already in progress. To ensure that the pharmaceutical industry takes optimal drug use into account, the policy also proposes using manufacturers' commitments to control certain business practices.

Finally, the pharmaceutical industry's contribution to the Québec economy must be recognized and reaffirmed. Therefore, the draft policy proposes maintaining the 15-year rule and signing agreements with the pharmaceutical industry to implement measures favouring optimal drug use and reducing the risks associated with the use of certain drugs. Finally, in order to keep health and economic policy in balance, the policy proposes setting up a permanent discussion forum bringing together the MSSS, the MDERR, and innovative and generic drug manufacturers.

By applying these diverse and interrelated measures and thus taking on the problem in its many aspects, we hope to help improve the health and well-being of all Quebecers, while contributing to the public drug insurance program's sustainability by controlling and reducing its rising costs.

Publishing this draft policy is a key step towards joint action on pharmaceuticals. The ensuing consultations will allow all interested parties to express themselves and suggest improvements. Everyone's participation is necessary to ensure that Québec adopts a more coherent vision and a strategy to ensure that medication is accessible to all, that it is used optimally, and that business practices, prices, and industrial development all contribute to the strategy's success. These consultations will also allow the various players involved to assume their parts in ensuring the policy's success. To ensure the quality and relevance of the measures adopted, a process to evaluate their scope, their efficacy, and their efficiency will need to be developed.

The challenge is significant and expectations are great; but the solution is within our grasp.

Appendix I List of ministerial proposals

Ministerial proposals concerning accessibility of medication

Ministerial proposal 1:	Maintain accessibility based on a drug formulary that, in certain cases, stipulates specific conditions for payment.
Ministerial proposal 2:	Choose medications to be listed in the Drug Formulary on the basis of evidence demonstrating their therapeutic value. Once this is demonstrated, other criteria will be taken into account.
Ministerial proposal 3:	Further reduce the complexity of the administrative process relating to the Drug Formulary.
Ministerial proposal 4:	Regulate prescribing physicians' bills for filling out forms for exception drugs and exception patients according to whether the forms are available online.
Ministerial proposal 5:	Make the process and decisions relating to a drug's listing in the Drug Formulary more transparent.
Ministerial proposal 6:	Ensure that patients, whether admitted or resident, have access to the medication required by their state of health, while maintaining the mechanisms for institutions to choose the drugs they use, such as the Drug Formulary for institutions; Provide access to drugs required for cases of special medical necessity or used in special treatments, within current management mechanisms.
Ministerial proposal 7:	Define the circumstances in which a citizen, during ambulatory treatment in a CHSGS, could be administered a drug purchased in the community; Modify the current regulations regarding the administration of drugs to ambulatory patients in CHSGSs, in order to facilitate movement of patients within local health and social services networks and service corridors.

Ministerial proposal 8: Help institutions with their evaluation of drugs, in particular by making the Conseil du médicament's evaluation work more accessible at appropriate times.

Ministerial proposal 9: Reaffirm the responsibility of boards of directors of institutions and pharmaceutical manufacturers to maintain access to drug therapies when required, possibly even after the compliance listing is issued;

Remind boards of directors of institutions and physicians working in those institutions of the necessary procedures regarding medications that could be furnished to their institution, even free of charge;

Raise awareness among involved professional orders and associations of the effect of marketing strategies presented to physicians as "phase IV clinical studies";

Require boards of directors of concerned institutions to inform the MSSS of research activities regarding costly medications as soon as these are undertaken;

Ensure that participants in research activities are informed about the process and the criteria for drug listing used by the Conseil du médicament.

Ministerial proposal 10: Offer public funding for medications used in treating hereditary metabolic diseases, but only for those medications with demonstrated therapeutic value according to the Conseil du médicament's evaluation.

Ministerial proposal 11: Keep medication financially accessible, taking into account the citizens' ability to pay (deductibles, co-insurance and premiums);

Provide free access to drugs for elderly people who receive the maximum payment from the GIS;

Later, depending on improvements to efficiency through optimal drug use and partnership agreements, reduce or eliminate contributions, as the case may be, from low-income insurees.

Ministerial proposals concerning drug prices

Ministerial proposal 12: End the non-increasing drug price policy and set up a mechanism to manage drug price increases.

Ministerial proposal 13: Allow agreements for setting up compensation measures to minimize or prevent the impact of price increases on the public system, and give more latitude to manufacturers in the case of drugs that represent a significant innovation.

Ministerial proposal 14: Regulate prices of generic drugs.

Ministerial proposal 15: Add "potential for significant savings for the RGAM" to the Conseil du médicament's grounds for priority evaluation of drugs.

Ministerial proposal 16: Tighten the rules governing wholesalers so as to ensure equity among them.

Ministerial proposals concerning optimal drug use

Ministerial proposal 17: Confirm the Conseil du médicament's mandate in regard to optimal drug use, in order to promote concerted action, and adopt the Conseil's definition of optimal drug use.

Ministerial proposal 18: Review the mandate of the Round Table, make regulations concerning its composition, and clarify its roles and responsibilities, so as to make it the primary forum on optimal drug use.

Ministerial proposal 19: Support measures for promoting optimal drug use, such as transmission of therapeutic intent, feedback through prescribing profiles, and the home medicine review project, particularly as pilot projects.

Ministerial proposal 20: Set up a second-line drug information service via Info-Santé/CLSC, an information source that is already well known to the public.

Ministerial proposal 21: Support favoured measures to improve the flow of clinical information among health professionals, especially with regard to medication and therapeutic intent;

Help to implement computerized tools to support clinicians in promoting optimal drug use.

Ministerial proposal 22: Implement various awareness and information programs on optimal drug use that are appropriate and accessible to citizens and encourage them to take responsibility for their health.

Ministerial proposal 23: Promote the integration of optimal drug use into university training of physicians, pharmacists, and related professionals.

Ministerial proposal 24: Encourage continuing professional training and the establishment of a specific fund available both to universities and to professional orders and associations.

Ministerial proposal 25: Specify the conditions for supporting disease management programs proposed by the pharmaceutical industry.

Ministerial proposal 26: Establish clear rules of business practice for all pharmaceutical companies.

Ministerial proposal 27: Regulate the business practices of generic drug manufacturers.

Ministerial proposal 28: Ensure that the MSSS is represented in the pharmaceutical industry's various complaints review committees and in the CEMCQ.

Ministerial proposal 29: Encourage makers of brand name drugs and the Ordre des pharmaciens du Québec to jointly develop a code of ethics for interveners in continuing pharmaceutical education.

Ministerial proposal 30: Modify the regulation concerning the Drug Formulary to require pharmacists to bill according to the actual net purchase price, including any type of discounts other than those permitted by the above proposals.

Ministerial proposals concerning the pharmaceutical industry

Ministerial proposal 31: Keep the 15-year rule in its current form, instead of setting up a reference-based pricing system.

Ministerial proposal 32: Sign general partnership agreements with drug manufacturers' associations (Rx&D, the Canadian Generic Pharmaceutical Association, and the Groupement provincial de l'industrie du médicament) to allow activities such as studies, professional training, public awareness campaigns, etc.;

Sign specific partnership agreements dealing with specific classes of drugs with the manufacturers involved, in order to implement measures needed to promote optimal use of those specific drugs. Such agreements will have to be signed with all manufacturers of the relevant class of drugs.

Ministerial proposal 33: Sign risk-sharing agreements with drug manufacturers, according to study results, aiming to prevent the non-optimal use of specific drugs that they manufacture.

Ministerial proposal 34: Set up a permanent discussion forum so as to maintain balance between health and economic development policies, by bringing together representatives of the MSSS, the MDERR, and the innovative and generic pharmaceutical industries.

Appendix II Basic data on the public drug insurance system

Total cost of the public drug insurance system, 1997-1998 to 2003-2004 (in millions of dollars)

Fiscal year	1997-1998	1998-1999	1999-2000	2000-2001	2001-2002	2002-2003	2003-2004
Total cost (M$)	1 164,3	1 341,7	1 562,6	1 880,9	2 131,4	2 382,2	2 635,8
Annual variation* (%)	n/a	15,2	16,5	20,4	13,3	11,8	10,6

* Private drug insurance systems showed similar annual variations.
n/a: not applicable
Source: Régie de l'assurance maladie du Québec (RAMQ), *Rapports annuels, 1997-1998 à 2003-2004.*

Maximum annual premium in the public drug insurance system

Entry into force	Maximum premium ($)
January 1, 1997	175
July 1, 2000	350
January 1, 2001	385
July 1, 2002	422
July 1, 2003	460
July 1, 2004	494

Parameters of public drug insurance contributions *

	Elderly people			People receiving emloyment assistance without severe employment constraints	Adult clientele without access to a private plan
	Receiving maximum GIS payments**	Receiving partial GIS payments	Not receiving GIS payments		
Monthly deductible	**($)**	**($)**	**($)**	**($)**	**($)**
1997	8,33	8,33	8,33	8,33	8,33
2002	8,33	9,13	9,13	8,33	9,13
2003	8,33	9,60	9,60	8,33	9,60
2004	8,33	10,25	10,25	8,33	10,25
Co-insurance	**(%)**	**(%)**	**(%)**	**(%)**	**(%)**
1997	25,0	25,0	25,0	25,0	25,0
2002	25,0	27,4	27,4	25,0	27,4
2003	25,0	28,0	28,0	25,0	28,0
2004	25,0	28,5	28,5	25,0	28,5
Monthly ceiling	**($)**	**($)**	**($)**	**($)**	**($)**
1997	16,66	41,66	62,49	16,66	62,49
2002	16,66	45,67	68,50	16,66	68,50
2003	16,66	46,17	69,92	16,66	69,92
2004	16,66	46,67	71,42	16,66	71,42
Yearly ceiling***	**($)**	**($)**	**($)**	**($)**	**($)**
1997	200	500	750	200	750
2002	200	548	822	200	822
2003	200	554	839	200	839
2004	200	560	857	200	857

* These figures remained unchanged from January 1, 1997 to July 1, 2002. Increases took place on July 1, 2002, 2003, and 2004.

** Since March 2003, persons 65 years of age and older who receive 94% or more of the maximum Guaranteed Income Supplement (GIS) have the same contribution parameters as those who receive the maximum GIS.

*** In the public system, the contribution limit is imposed monthly.

Appendix III List of groups invited to the optimal drug use symposium

Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS)
Agences de développement de réseaux locaux de services de santé et de services sociaux
Anemia Institute
Arthritis Society
Association des CLSC et des CHSLD du Québec
Association des Conseils des médecins, dentistes et pharmaciens
Association des groupes d'intervention en défense des droits en santé mentale du Québec (AGIDD-SMQ)
Association des hôpitaux du Québec (AHQ)
Association des pharmaciens des établissements de santé, and clinical pharmacists
Association québécoise des pharmaciens propriétaires, and clinical pharmacists
Association québécoise de défense des droits des personnes retraitées et préretraitées
Auditor General of Québec
Canada's Research-Based Pharmaceutical Companies (Rx&D)
Canadian AIDS Society (CAS)
Canadian Association for Pharmacy Distribution Management (CAPDM)
Canadian Cancer Society
Canadian Generic Pharmaceutical Association (CGPA)
Canadian Institute of Actuaries (CIA)
Canadian Life and Health Insurance Association (CLHIA)
Centrale des syndicats démocratiques (CSD)
Centrale des syndicats du Québec (CSQ)
Centre for Bioethics - Institut de recherches cliniques de Montréal
Chains of pharmacies and drugstore banners
Chief executive officers and directors of professional services of university-affiliated hospital centres and institutes
Chief executive officers and directors of professional services of university hospital centres
Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-SIDA)
Coalition Solidarité Santé
Collège des médecins du Québec
Confédération des organismes de personnes handicapées du Québec (COPHAN)
Confédération des syndicats nationaux (CSN)
Conseil des aînés
Conseil pour la protection des malades
Curateur public
Diabetes Québec
Directeurs généraux et directeurs des services professionnels des centres hospitaliers universitaires
Fédération de l'âge d'or du Québec (FADOQ)
Fédération des infirmières et des infirmiers du Québec (FIIQ)
Fédération des médecins omnipraticiens du Québec (FMOQ), and clinicians

Fédération des médecins résidents du Québec (FMRQ)
Fédération des travailleurs du Québec (FTQ)
Federation of Medical Specialists of Québec (FMSQ), and clinicians
Federation of Québec Alzheimer Societies
Fonds de la recherche en santé du Québec (FRSQ)
Force jeunesse
Heart and Stroke Foundation of Canada
Institut national de santé publique
Investissement Québec
Infoveille - Léonard Aucoin
Kidney Foundation of Canada
McGill University School of Nursing
McGill University Faculty of Medicine
Office des personnes handicapées du Québec (OPHQ)
Ordre des infirmières et des infirmiers du Québec (OIIQ)
Québec Medical Association (QMA)
Ordre des pharmaciens du Québec
Regroupement des associations coopératives d'économie familiale (ACEF)
Regroupement des comités d'usagers des centres hospitaliers
Regroupement des ressources alternatives en santé mentale du Québec
Réseau québécois sur l'asthme et les maladies pulmonaires obstructives chroniques (RQAM)
Société québécoise d'hypertension artérielle (SQHTA)
Union des consommateurs
Université de Montréal - Faculté des sciences infirmières
Université de Montréal - Faculté de médecine
Université de Montréal - Faculté de pharmacie
Université de Montréal - Groupe de recherche interdisciplinaire en santé (GRIS)
Université de Sherbrooke - Département des sciences infirmières
Université de Sherbrooke - Faculté de médecine
Université du Québec à Montréal
Université Laval - Faculté des sciences infirmières
Université Laval - Faculté de médecine
Université Laval - Faculté de pharmacie
Université Laval - Unité de recherche en santé des populations (URESP)

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