Prescription drugs: Optimizing costs and use for the benefit of the patient and the sustainability of the system

APPRAISAL REPORT ON THE PERFORMANCE OF THE HEALTH AND SOCIAL SERVICES SYSTEM

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Le genre masculin utilisé dans ce document désigne aussi bien les femmes que les hommes.

Note : La rédaction de ce document s'est achevée en janvier 2015. Toute évolution relative au domaine du médicament au Québec depuis cette date n'a pas pu y être intégrée.

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- Association canadienne des compagnies d'assurances de personnes;

- Association canadienne du médicament générique;
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- Association des conseils de médecins, dentistes et pharmaciens du Québec;
- Association des pharmaciens des établissements de santé du Québec;
- Association pulmonaire du Québec;
- Association québécoise d'établissements de santé et de services sociaux;
- Association québécoise des pharmaciens propriétaires;
- Bureau de la recherche et des relations internationales – Université McGill;
- Bureau de liaison université-milieu – Université Laval;
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- Collège des médecins du Québec;
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- Diabète Québec;
- Fédération des médecins omnipraticiens du Québec;
- Fédération des médecins spécialistes du Québec;
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- Ministère des Finances et de l'Économie;
- Montréal InVivo;
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- Ordre des dentistes du Québec;
- Ordre des ergothérapeutes du Québec;
- Ordre des infirmières et des infirmiers du Québec;
- Ordre des optométristes du Québec;
- Ordre des pharmaciens du Québec;
- Ordre des podiatres du Québec;
- Ordre des psychologues du Québec;
- Ordre des sages-femmes du Québec;
- Ordre des travailleurs sociaux et thérapeutes conjugaux et familiaux du Québec;

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- Ordre professionnel des inhalothérapeutes du Québec;
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List of abbreviations and acronyms

ADHD	Attention-deficit/hyperactivity disorder
AGQ	Auditor General of Québec
APES	Association des pharmaciens des établissements de santé du Québec [Québec association of health care institution pharmacists]
APhA	American Pharmacists Association
ASD	Autism spectrum disorder
ASSS	Agence de la santé et des services sociaux; Health and Social Services Agency
BCCA	British Columbia Cancer Agency
BNF	British National Formulary
CACDS	Canadian Association of Chain Drug Stores
CADTH	Canadian Agency for Drugs and Technologies in Health
CDR	Common Drug Review
CEP	Clinical evaluation package
CIHI	Canadian Institute for Health Information
CIRANO	Center for Interuniversity Research and Analysis of Organizations
COPD	Chronic obstructive pulmonary disease
CPDP	Council of Physicians, Dentists and Pharmacists
CRI	Clinique réseau intégrée [Integrated clinical network]
CRSP	Comité régional sur les services pharmaceutiques [Regional committee on pharmaceutical services]
CSBE	Commissaire à la santé et au bien-être; Health and Welfare Commissioner
CSEMI	Comité scientifique d'évaluation des médicaments aux fins d'inscription; Scientific Committee on Entry on the List of Medications
CSHP	Canadian Society of Hospital Pharmacists
CSSS	Centre de santé et de services sociaux; Health and Social Services Centre
DPS	Director of Professional Services
DUR	Drug Utilization Review
FIP	Fédération internationale pharmaceutique; International Pharmaceutical Federation
FMG	Family medicine group
FMOQ	Fédération des médecins omnipraticiens du Québec [Québec federation of general practitioners]
GDP	Gross domestic product
GLEM	Groupe local d'évaluation médicale [Local medical evaluation group]
HAS	Haute Autorité de santé; French National Authority for Health
HPRAC	Health Professions Regulatory Advisory Council

INESSS	Institut national d'excellence en santé et en services sociaux [National institute for excellence in health and social services]
IRSPUM	Institut de recherche en santé publique; Université de Montréal Public Health Research Institute
MR	Medication reconciliation
MSSS	Ministère de la Santé et des Services sociaux [Department of health and social services]
MTM	Medication therapy management
MUHC	McGill University Health Centre
NACDS	National Association of Chain Drug Stores
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPS	National Prescribing Service
NTA	National Treatment Agency for Substance Misuse
OECD	Organization for Economic Cooperation and Development
OPQ	Ordre des pharmaciens du Québec [Québec order of pharmacists]
pCODR	pan-Canadian Oncology Drug Review
PGTM	Programme de gestion thérapeutique des médicaments [Therapeutic drug management program]
PIP	Potentially inappropriate prescription
PMPRB	Patented Medicine Prices Review Board
PPI	Proton pump inhibitor
QLSCD	Québec Longitudinal Study of Child Development
RAMQ	Régie d'assurance maladie du Québec [Québec health insurance board]
RASNA	Régimes d'avantages sociaux non assurés; Uninsured employee benefit plans
RDGM	Regional Department of General Medicine
RGAM	Régime général d'assurance médicaments; Basic Prescription Drug Insurance Plan
RLS	Réseau local de services [Local services network]
RPAM	Régime public d'assurance médicaments; Public Prescription Drug Insurance Plan
RQDRU	Réseau québécois de recherche sur l'usage des médicaments [Québec network for research on drug use]
Rx&D	Canada's Research-Based Pharmaceutical Companies
SAP	Special Access Program
SNP	Specialized nurse practitioner
UHC	University hospital centre
WHO	World Health Organization

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Québec, le 23 février 2015

Monsieur Gaétan Barrette
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Monsieur le Ministre,

Conformément à l'article 22 de la Loi sur le Commissaire à la santé et au bien-être, je vous transmets mon rapport faisant état de la performance du système de santé et de services sociaux dans le domaine du médicament d'ordonnance. Celui-ci occupe une place centrale dans notre système et est à la source de multiples enjeux qui ont émergé dans le cadre de nos travaux antérieurs. Alors que les médicaments d'ordonnance ont contribué notamment à diminuer les hospitalisations, à accroître l'espérance de vie et à abaisser le taux de mortalité pour certaines conditions, il y a place à l'amélioration en ce qui a trait à leur usage et au meilleur contrôle des dépenses qui y sont associées. C'est pourquoi j'ai estimé nécessaire d'analyser ce domaine en vue de vous proposer des pistes d'amélioration.

Au fil des ans, les médicaments d'ordonnance ont pris une place grandissante dans l'arsenal thérapeutique. À titre d'exemple, 55 % des Québécoises et Québécois consomment au moins un médicament d'ordonnance régulièrement ou en permanence. L'augmentation de la prévalence des maladies chroniques, le vieillissement de la population et une demande accrue pour cette forme de traitement sont parmi les facteurs qui expliquent le recours croissant aux médicaments. Les dépenses qu'ils entraînent ont accaparé progressivement une proportion croissante des dépenses en santé. En effet, en raison d'un usage non optimal, de l'évolution de la pharmacopée et du fait que le Québec paie plus cher ses médicaments qu'à peu près tous les pays industrialisés, les fonds publics consacrés aux médicaments ont crû de manière très importante.

Si les objectifs d'amélioration de la performance dans ce domaine peuvent s'énoncer aisément, les solutions, elles, sont loin d'être simples. Il serait en effet utopique de croire qu'une solution unique ciblant un seul acteur ou une seule sphère d'activité permette d'atteindre la visée que s'est donnée le Québec au regard des médicaments d'ordonnance, soit leur accès équitable et raisonnable. Il est également nécessaire d'assurer une meilleure réponse aux besoins et aux attentes de la population québécoise. Compte tenu de l'importance des ressources publiques consacrées au financement de notre système, la population est en droit d'exiger d'en avoir plus pour

son argent. Les sommes ainsi dégagées devraient être réallouées là où les besoins sont criants, mais également là où les actions ont des retombées systémiques et durables.

Les préoccupations éthiques ont été constamment présentes tout au long de nos travaux. Comment répondre aux différentes iniquités d'accès aux médicaments observées, selon le lieu où sont donnés les soins, la personne qui les prodigue, l'endroit où les ordonnances sont vendues ou encore la couverture d'assurance? Comment concilier la réponse aux besoins du plus grand nombre avec les situations rares ou nouvelles, pour lesquelles les solutions ne sont pas toujours éprouvées et parfois très coûteuses? Quelle part idéale les actions à visée curative devraient-elles occuper dans l'ensemble des dépenses de santé, comparativement aux actions à visée préventive? Avec mon équipe, nous avons tenté de faire la juste part entre ces tensions parfois contradictoires, toujours préoccupantes, et de vous proposer des pistes de solution qui sont en conformité avec les valeurs de notre société. Les membres de mon Forum de consultation ont pris à cœur ces travaux et ont démontré, encore une fois, leur capacité à s'élever par rapport à leur point de vue individuel pour considérer le bien commun. Nombre de citoyennes et citoyens ont participé à nos consultations. Des experts du domaine de même que des décideurs de divers horizons nous ont également éclairés et ont enrichi nos travaux. Tous les points de vue ont été considérés, qu'ils aillent dans une direction ou dans une autre.

Pour guider le choix des pistes de solution, les valeurs de solidarité, de compassion et d'équité ont servi de trame de fond. Les recommandations proposées dans ce rapport s'inscrivent dans l'effort collectif à faire pour reprendre le contrôle de nos dépenses en santé, mieux utiliser les ressources et assurer la pérennité de notre système public de santé et de services sociaux.

Veuillez accepter, Monsieur le Ministre, l'assurance de mes sentiments les meilleurs.

Le commissaire,

Robert Salois

Introduction

Drugs are a central part of today's therapeutic arsenal. The benefits of prescription drugs, combined with the benefits of advances in health care and public health, are undeniable: they contribute to lower mortality rates for infectious diseases; improved management of cardiovascular diseases; longer life expectancy for serious diseases, especially AIDS and cancer; reductions in hospital admissions, etc. Thus, drugs, which are necessary to maintain and improve population health, are an expenditure, but also an investment, in health. As such, optimal drug use contributes to health system performance.

Data on prescription drug use and associated spending shows how important they are. In Québec, 55% of respondents to a 2013 Commonwealth Fund survey reported taking one or more prescription medications on a regular or ongoing basis, while 27% reported taking three or more (CSBE, 2014c). The results of the online survey of 1,000 Quebecers conducted by Léger on behalf of the Commissioner in 2012 also show that most Quebecers use medications. According to the survey, 84% of Quebecers use prescription drugs on a regular or occasional basis (55% and 29% respectively) (CSBE and Léger, 2012).

Furthermore, total expenditure on prescribed drugs represented nearly 7.5 billion dollars for Québec and nearly 27.7 billion dollars for Canada in 2012. Estimated expenditure per capita on prescribed drugs was $927 in Québec and $795 in Canada in 2012. Since 1995, expenditure per capita on prescribed drugs has always been higher in Québec than in the rest of Canada. Drug expenditure has also claimed a growing share of Québec's health and social services system expenditure since the 1990s. Total expenditure on prescribed drugs accounted for more than 17% of total health expenditure in Québec in 2012 (CIHI, 2013a). Growth in the cost of drugs covered under Québec's Public Prescription Drug Insurance Plan (RPAM) was, however, slower from 2004 to 2012 than from 1996 to 2003, when it was over 10% (CSBE, 2014b). From 2010 to 2012, total expenditure on prescribed drugs in Québec rose from approximately 6.9 billion dollars to 7.5 billion dollars, an increase of 7.9% (CIHI, 2013a). However, the annual growth rate of expenditure on prescribed drugs continues to outpace that of gross domestic product (GDP) and total health and social services system expenditure.

In the past decade, the negative variation factor of drug prices (-2.7%) has mitigated the growth rate of drug expenditure. The increase in drug expenditure is due to other factors, including changes in the demographic profile of the population, the population's growing expectations as to the benefits of medication, the higher prevalence of some diseases, expanded indications for some products and the use of new drugs with special characteristics. Some of these drugs treat previously untreatable diseases, while others are used as a preventive measure. Some target specific populations or replace molecules that are still available. These new generation drugs often cost more than their predecessors, although the added value of many is questioned. In this regard, the Patented Medicine Prices Review Board (PMPRB), the Canadian body responsible for

ensuring that drug prices are not excessive, considers that, of the 109 new drugs marketed in Canada in 2011, 1% represented a discovery, 5%, a substantial improvement, 25%, a moderate improvement and 69%, a slight or no improvement (PMPRB, 2013). Moreover, entry into the market of generic drugs, at a fraction of the price of brand name drugs, is sometimes delayed, resulting in additional expenditure (for more details, see the CSBE document *Les médicaments d'ordonnance: état de la situation au Québec*) [Prescription drugs: the situation in Québec [1]].

Not only are drug use and costs increasing, but their use is not always optimal, which has an impact on the performance of Québec's health and social services system. The increased use of some prescription drugs is questioned, especially in some population groups, including the elderly and children treated for attention-deficit/hyperactivity disorder (ADHD). The elderly are overrepresented in the population of people who have a complex health problem or chronic diseases and take multiple medications. For instance, 93% of people aged 65 and over use prescription drugs (CSBE and Léger, 2012). Furthermore, inappropriate prescribing has been observed in the elderly; prescriptions either do not comply with accepted standards or the risks of adverse effects outweigh the expected benefits. Furthermore, patient use is sometimes problematic, especially with respect to non-compliance with the prescription, intentional or otherwise. The risks associated with a higher rate of drug use in this population are significant (morbidity, loss of autonomy, hospitalization, mortality, etc.), especially when their appropriateness is questioned. We can also question the increase in the number of prescriptions for stimulants in children treated for ADHD that has been documented in Québec and elsewhere in recent years. According to data for 1998 to 2010 from the Québec Longitudinal Study of Child Development (QLSCD), around 6% of 8-year-old children had taken a drug to treat attention deficit and hyperactivity behaviours in the year before the study (Cardin et al., 2011). Since 1996, double the number of prescriptions have been written for stimulants in Québec than in the rest of Canada (Currie, Stabile and Jones, 2013); children who take this type of medication are also reported to be overrepresented in disadvantaged areas, which is a matter of concern. Although this increase can be explained by a number of factors, including better screening, differences observed between countries in ADHD diagnosis and treatment rates tend to show that other causes of a cultural and social nature are also at play. This troubling data is a reflection of the behaviours our society considers socially acceptable in children. The preferred solution, i.e., medication, can also be questioned, since it implies that behaviours that are seen as disruptive are not normal and are responsible, at least partly, for health problems. While it has been clearly demonstrated that some children with ADHD benefit from medication, the significant side effects reported mean that it must not be taken lightly. In addition to suboptimal use, medication is also known to be taken for non-medical reasons: its use is sometimes expanded. In fact, it is also used to cope with life situations, such as bereavement, to manage personality traits,

[1] available in French only

such as shyness, or to deal with social pressure, for example related to sexual, professional or academic performance. Medication is also used to deal with the consequences of unhealthy lifestyle behaviours, such as a lack of physical activity or poor diet.

Drug use is therefore a highly complex health, social, economic and organizational phenomenon. It is a result of the combined actions of multiple stakeholders, including the pharmaceutical industry, governments (including regulatory authorities and agencies that review drugs for public funding), public and private insurers, health professionals (prescribers, pharmacists, etc.), health and social services network administrators, intermediaries (such as purchasing groups and distributors), patients and, more broadly, citizens. Each of these stakeholders has his own interests that are legitimate in their own right, but that may sometimes be incompatible with the public objective of providing fair and reasonable access to medically required prescription drugs. In the dynamic surrounding drugs in Québec today, each stakeholder's action potentiates that of the others, leading to actual outcomes that deviate from expected outcomes, in a social and cultural context that is conducive to this dynamic. Thus, the combined action of these stakeholders means that drug use grows exponentially, without necessarily meeting population health needs. This also calls the fair and reasonable allocation of resources into question. In this interplay of stakeholders, three groups play a key role in drug supply and demand, namely, pharmaceutical companies, physicians and patients. To improve population health, pharmaceutical companies develop and market products with the objective of making a profit, while also taking the necessary steps to maintain their viability and profitability. To meet individual health needs, physicians use the tools at their disposal in an organizational context that does not support the use of other therapeutic options. Indeed, a number of factors do not promote optimal drug use: the current organization of medical practice in Québec, the challenge of meeting a high individual and social demand for drugs and difficulty accessing valid and impartial information. For their part, patients ask for drugs, which are seen as the best way to resolve their health problems.

Growth in drug use and spending – when drugs are not necessarily used appropriately – raises the issue of the system's viability and how to maintain fair and reasonable public access to medically required drugs. Indeed, when increased spending on prescription drugs is not associated with significant population health gains and improved health and social services system performance, it could lead to problems with access and equity in other care and services offered by the system to serve different populations. Furthermore, this growth could create problems with the overall funding of the system, even going so far as to threaten sustainability and become an economic burden for Québec. This growth might mean that cuts would have to be made in other public services or might add to the overall taxpayer burden. Consequently, equity between people with different needs, health or otherwise, and intergenerational equity, could be jeopardized.

If fair and reasonable public access to prescription drugs is an objective for Québec, each stakeholder must be aware of the collective impact of his own actions and work toward developing shared responsibility. The goal of Québec's public policies is to maintain and improve population health and support the province's economic development, while acting as a public regulator and payer. The government must therefore provide clear guidance and a regulatory framework for drug use that are in keeping with social values**.**

Considerations concerning the allocation of resources and equitable access to care and services raise a number of ethical issues which, depending on how they are addressed, may call the organization of public drug insurance in Québec into question. What share of financial resources should be allocated to drugs relative to other types of health interventions? How can we leverage expertise in drug use in order to use the limited resources in the most efficient and equitable way possible? How can we improve equitable access to prescription drugs across the different patient groups covered by the public and private components of the Basic Prescription Drug Insurance Plan (RGAM) and across diverse pharmacies? How can we ensure equitable access to drugs across different institutions? How should we regulate the use of expensive drugs, especially at the end of life? How should solidarity and compassion be reflected in access to expensive drugs that involve clinical and economic uncertainties, for instance drugs for rare diseases? The answers to these key questions lie in a socially shared definition of the values of social justice, equity and solidarity underlying social choices. A trade-off must be made between individual and collective interests and requires citizens to participate in decision making. The question then arises as to how stakeholders' interests in drug development and use can be balanced to allow the expression of citizens' informed choices.

The use of medications in institutions and under the RGAM

Medications were introduced into the health and social services system under the *Hospital Insurance Act* (1964) and the *Health Insurance Act* (1970). Medications are considered medically necessary and are provided to patients as part of hospital care. The *Act Respecting Health Services and Social Services* (Québec, 1991) also sets out some of the regulations governing the use of medications in institutions.

Then, in 1997, for reasons of social justice and solidarity, the *Act Respecting Prescription Drug Insurance* created the Basic Prescription Drug Insurance Plan (RGAM), whose purpose was to ensure "that all persons in Québec have reasonable and fair access to the medication required by their state of health" (Section 2). "The term 'fair' points to the egalitarian dimension of the Plan, the word 'reasonable' qualifies this access by referring to concepts such as common sense, moderation, sound judgement, etc." [Translated from the French] (Doucet, 2006, p. 114). The RGAM must provide every person in Québec with equitable access to the most appropriate prescription drug for their disease, taking cost into account. To fulfil this requirement, the Institut national d'excellence en santé et en services sociaux (INESSS) applies review criteria to

determine eligibility for inclusion on the lists of medications provided and reimbursed by the government.

Québec's RGAM is characterized by its universality, contributory nature and mixed funding (public and private). The public component, the RPAM, is financed by taxes, the income-based premiums charged to people who are eligible for the plan and the financial contribution of the people insured under the plan. The private component is financed by the financial contribution of the people insured under the plan and third party payers of private group plans (employers, companies and unions).

The objective of the Politique du médicament published in 2007 was to ensure fair and reasonable access to medically required drugs, fair and reasonable pricing and optimal drug use, in addition to addressing the place the pharmaceutical industry occupies in Québec. It should be noted that this policy has now expired.

Some stakeholders are calling for a review of the RGAM in favour of universal coverage. This position is supported by the fact that drugs are considered to be medically required and have come to be a central part of the therapeutic arsenal, which was not always the case, in particular when the foundations of our public health system were laid. Moreover, the inequities observed between people covered by the public and private components of the RGAM are strongly criticized, especially since a significant number of people cannot afford their prescriptions unless they cut back on other important budget items, such as food. Improving equity in access under the RGAM, particularly for people covered by its private component, is imperative in the short term. The government cannot ignore arguments in favour of universal drug coverage, which are based on their importance in health care, and those related to equity. Uncertainty about the cost of universal coverage does not warrant dismissing the proposal, especially since some economic analyses claim that this type of change in drug insurance could be achieved at zero cost or even generate savings.

Moreover, some experts believe that the fact that some countries that adopted a universal public drug insurance plan (including Australia, New Zealand and the United Kingdom) pay less for some drugs supports the hypothesis that they have better control over drug prices. The form prescription drug coverage should take depends on societal choices with respect to equity and solidarity and is directly linked to the importance attributed to drugs in the range of health services offered. It is therefore an issue that must be considered in light of all the services offered, not only those related to drugs, the subject of this report. Given the legitimacy of the arguments in favour of universal coverage, it is imperative that the Minister of Health and Social Services engage in a reflection on this issue, a society-wide reflection that should ensure that all perspectives are fully considered and pave the way for the decisions to come. Notwithstanding this wide-ranging reflection, substantial improvements are required in the short term.

Optimal drug use and the performance of the health and social services system

The notion of optimal use is employed in various contexts. Thus, in a clinical setting, where drug use is patient specific, the most important rule is the “five rights” rule, i.e., right patient, right drug, right dose (or dosage), right route and right time. However, on a systemic level, the definition adopted by the Government of Québec includes a collective concern: “use that maximizes the benefits and reduces the risks for population health while taking into account the various options possible, costs and available resources, patient values and social values” [Translated from the French] (Desmarais and Robitaille, 2010, p. 1). According to this definition, responsibility for optimal use must be shared by all the stakeholders concerned.

The elements in this definition of optimal use correspond to different dimensions of health and social services system performance as defined by the Commissioner: “an effective health and social services system is a system that achieves its goals and objectives and fulfils its mandates in keeping with its underlying values, and optimizes production based on the resources available” [Translated from the French] (CSBE, 2014a, p. 11). Thus, the Commissioner considers a system effective in the area of prescription drugs if their use is optimal. In preparing this report, the elements in the definition of optimal drug use guided the Commissioner in determining which aspects of the performance of Québec’s health and social services system need to be improved. The objective of fair and reasonable access, which underpins the system’s orientations, reflects the social values underlying optimal use. These were the main values considered in this report.

Of the many subjects and issues of interest related to drugs that could have been examined in preparing this report, in accordance with his mandate to assess the performance of Québec’s health and social services system, the Commissioner limited himself to the situation in Québec. His analysis focuses on prescription drugs, a highly complex subject in itself and a very important budget item in Québec’s health and social services system. In this regard, the Commissioner decided to adopt a comprehensive approach to assessing the system’s performance in the area of prescription drugs, encompassing their development and introduction into the health and social services system, their review for reimbursement as well as their marketing, prescribing, dispensing and use. Recommendations are not made for areas under federal responsibility, such as patented medicine prices review, safety and efficacy evaluations, international trade agreements and property rights for drugs.

Moreover, the Commissioner decided not to make recommendations regarding certain areas of concern, nonetheless widely shared, if the solutions appeared to be clear and steps had already been taken to implement them. Drug shortages are an example in kind. Indeed, this clearly defined problem was the subject of analyses and recommendations by experts in the field in 2012 under the auspices of the Ordre des pharmaciens du Québec (OPQ). Despite the initiatives undertaken, the Auditor General

noted in 2014 that the response to shortages was not yet organized satisfactorily in Québec, which points to the need for urgent action (AGQ, 2014).

Lastly, topics for which the Commissioner made recommendations in recent years were not revisited in this report, such as the need to ensure access to available data and measurement indicators in order to track health impacts and the importance of health promotion and disease prevention activities, even if these topics are still relevant to the overall performance of the health and social services system.

Approach adopted by the Commissioner and benefits of the work

To carry out his work, the Commissioner did an extensive literature review. He also analyzed public data from organizations such as Health Canada, the Régie d'assurance maladie du Québec (RAMQ) and the Canadian Institute for Health Information (CIHI). In addition, he consulted over one hundred people (clinicians, decision makers, patients, researchers and experts in the field), representing some sixty organizations (pharmaceutical industry, government departments and bodies, professional associations and orders, patient groups, etc.). Furthermore, he commissioned an online survey of 1,000 citizens representative of Québec's population, requested testimonials online, receiving responses from 300 citizens, and held a public debate that brought one hundred people together. The Commissioner was also accompanied by an advisory committee to support him in focusing the report and inform his reflection. Lastly, he consulted his Consultation Forum throughout the course of his work (for the list of Consultation Forum members, see Appendix I).

The Commissioner's Consultation Forum

Under his incorporating Act, the Commissioner must, in exercising his functions, consult his Consultation Forum. Established under the same Act, it is a permanent deliberative body composed of 27 members, including 18 citizens from each of the regions of Québec and 9 experts in the field of health and social services. Members are appointed for a three-year term. The Consultation Forum's mandate is to give the Commissioner its opinion on issues the Commissioner submits to it. It enables the Commissioner to collect various types of information, such as citizen concerns, expectations, needs and values that will influence the nature of the recommendations made by the Commissioner, and to identify the conditions that must be taken into account when formulating recommendations to facilitate their implementation.

In addition to the present report, the Commissioner published a status report on prescription drugs and a consultation document detailing his consultative processes will follow shortly. A research report on a new descending price schedule for generic drugs, commissioned by a pan-Canadian team of researchers, was also produced. Following

the publication of this research report, Alberta made changes to its generic drug pricing practices based on the proposals. These changes are part of a Canada-wide trend to adjust generic pricing. Since Québec applies the “most-favoured nation clause”, as provided for in the *Act Respecting Prescription Drug Insurance*, it benefits in some cases from the prices in effect in the provinces with the lowest prices in public drug plans in Canada. Indeed, this clause stipulates that the price offered to a provincial drug plan by a manufacturer for a given product must be lower than or equal to the lowest price charged to other provincial plans elsewhere in Canada. Québec benefits indirectly from pricing policies in other provinces, including changes in generic pricing.

Despite the benefits for Québec, taking a proactive stance through pan-Canadian collaboration would show greater leadership in defining the place drugs should occupy in our health systems if we are to improve performance in this area. It should be noted that generic drug prices in Canada are much higher than in other countries. Reductions in the prices of generic drugs in Canada in recent years are, according to the PMPRB, mainly due to collaborative efforts between the provinces. Québec’s quasi-systematic exclusion from various working groups and tables on prescription drugs or Canadian committees has also contributed to the difficulty of sharing information and evaluating drug use on a pan-Canadian or international scale. Québec also participates less frequently than others in various partnerships or agreements, at a time when the pharmaceuticals sector is increasingly one that must be considered on a global scale. As such, the government’s announcement of its intention to join national initiatives in 2015 is to be commended, such as the pan-Canadian Pharmaceutical Alliance, which covers brand name and generic drugs.

The Commissioner used an approach that combines scientific evidence, performance indicators and numerous consultations, allowing him to make recommendations that he considers relevant, feasible and socially acceptable in Québec’s context. Furthermore, these actions were selected because they are levers with potentially system-wide impact and, as such, can have an impact on the overall performance of the health and social services system. The report presents ten recommendations grouped under four objectives: 1) Promote the use of drugs that are best able to meet health needs while controlling costs; 2) Ensure fair and reasonable access to drugs that do not meet standard review criteria; 3) Improve prescribing practices, pharmacological management and drug use; 4) Reduce inequities among people covered by the public and private components of the RGAM. The recommendations concern the introduction of drugs into the health and social services system, the review mechanism used to determine their eligibility for inclusion on the lists of publicly funded drugs, prescribing practices and pharmacological management, drug use and some of the provisions of the RGAM. Many of these actions call for greater transparency. The Commissioner believes these recommendations lay the foundations for a new drug policy.

Objective 1: Promote the use of drugs that are best able to meet health needs while controlling costs

Drug use and spending are a matter of concern due to their importance in our health and social services system. This is why several regulatory mechanisms have been put in place, including laws, regulations and codes of ethics, professional oversight and drug guides, lists of publicly funded drugs, access criteria or exceptional access mechanisms. However, these regulatory mechanisms have limitations and the Commissioner makes two recommendations to further encourage optimal drug use. The first concerns the pharmaceutical industry's vital role in developing new drugs, introducing them into the health and social services system and promoting their use. The second relates to the inclusion of drugs on the lists of medications that will be reimbursed for ambulatory care or provided in institutions under the public drug plan.

1.1 The pharmaceutical industry's presence in the health and social services system

The pharmaceutical industry plays a leading role in access to and use of drugs. It is involved in Québec's health and social services system in different ways: drug manufacture; funding and implementation of clinical trials; free drug supply schemes; continuing education and distribution of informative and promotional material; funding of institutions' foundations; distribution of samples; funding, organization and delivery of specific health care programs; provision of professional resources.

The positive effects of this role can be seen, in particular, in the development of new therapies and in institutions' ability to provide more patient support services for specific conditions (for example, diabetes or asthma). Furthermore, the financial and human resources provided by the industry supplement public resources which are sometimes unable to meet patient needs. Lastly, the information and training provided by the pharmaceutical industry fill a need among health professionals and patients.

However, the extent of the pharmaceutical industry's presence in the health and social services system can adversely affect costs, the organization of services, optimal drug use and hence the system's overall performance. Many examples were given during the consultations held by the Commissioner. Thus introducing drugs into an institution that have not yet been approved or that are not normally provided by the institution can influence drug supply regardless of official selection mechanisms (*List of Medications – Institutions*, purchasing groups and selection in each institution) and thereby affect the institution's budget. In his 2014 report, the Auditor General made the troubling observation that, contrary to applicable regulations, drugs that were not on the *List of Medications – Institutions*, or that had not yet been approved, were on the local formulary of audited institutions, with the approval of councils of physicians, dentists and

pharmacists (CPDPs) (AGQ, 2014). Drugs that had not been reviewed or that did not meet standard review criteria were on a list that allowed them to be used regularly. It should be noted that these drugs may be requested by both patients and physicians, especially those participating in clinical trials. Furthermore, the uncontrolled introduction of drugs into institutions can, in some cases, result in substantial unforeseen costs. It can also influence decisions as to which drugs will be prescribed for ambulatory care. These effects have repercussions on the RGAM and on individuals, since the drugs prescribed in institutions often continue to be prescribed outside institutions. More specifically, as the Auditor General pointed out, it is important to be aware that the samples supplied by the industry are intended to change physicians prescribing practices and stimulate demand for a particular product. This can encourage poor prescribing practices, which run counter to optimal use and can potentially generate additional costs (AGQ, 2014).

While the pharmaceutical industry's involvement in funding institutions' foundations, supplying human resources and managing care can support clinical settings, it can also have a negative impact on the independence of health professionals, institution directors and committee members (such as the pharmacology committee or the CPDP). Moreover, should the services provided under a care management program be interrupted by the company that instituted the program or the human resources withdrawn, the care settings concerned are not always able to continue the initiatives without there being a negative impact on the provision of these services or the organization of other services.

The pharmaceutical industry is highly regulated, be it with respect to clinical trials oversight, intellectual property protection, commercial activities, advertising, etc. In Québec, for example, the *Act Respecting Prescription Drug Insurance* requires manufacturers to establish rules to govern their commercial practices in order to be accredited by the Minister of Health and Social Services. Their drugs comply with the prerequisites for inclusion on the RAMQ's lists of publicly funded medications. In this regard, Canada's Research-Based Pharmaceutical Companies (Rx&D) have developed a detailed, exhaustive code of ethical practices that addresses their interactions with health professionals, information tools, funding of activities, etc.

However, as with any form of regulatory framework, the practical implementation of the guiding principles and rules, regardless of their scope and specificity, can be open to interpretation. Moreover, the Commissioner's consultations highlighted the fact that the existence of rules does not protect against real or perceived influences. Managers have reported the implicit pressures exerted by the industry, which ties the provision of funding for their foundation to the introduction of certain products into their institution. Other stakeholders consulted confirm what is reported in the scientific literature, namely, that some drug companies work with patient interest groups – or use lobbies, the media or other means – to try to influence government priorities, for example drug funding decisions (Hughes and Williams-Jones, 2013). The citizens consulted by the

Commissioner also said they would like to be informed about the lobbying done by interest groups, which indicates a certain unease about the lack of transparency regarding these sources of influence.

The Commissioner's survey – Results for how respondents rated the importance of being informed about lobbies*

Please rate how important you think it is to be informed about the following.

- The **interests of lobbies** that influence public decision making on drugs
  Total important: 69% Very important: 42% Quite important: 27%
  Total not important: 25% Not very important: 16% Not important: 8%
  Don't know / Decline to answer: 6%

Source: CSBE and Léger, 2012.

*Due to rounding, the total of the percentages may be slightly above or below 100%.

The Commissioner's Consultation Forum also expressed similar concerns.

What Consultation Forum members think[2]

"[…] citizen responsibility regarding drugs goes far beyond the individual scope of action and extends to drug companies […] Drug companies, in particular, should […] be subject to legislative and regulatory measures that require them to show greater transparency […] Agreements concluded between industry and the government should be disclosed […]"

Report of the Consultation Forum's deliberations, March 2012 session.

[2] It should be noted that the reports of the Forum's deliberations have been translated from the French and that the original reports were not revised.

Furthermore, the vocabulary used in normative frameworks, such as the Rx&D Code of Ethical Practices, can obscure commercial goals by promoting compliance with principles of conduct that are in line with the applicable regulations and, what's more, under the guise of irreproachable behaviour. One example is the terminology used when referring to the distribution of samples, or "clinical evaluation packages" (CEPs); a clinical evaluation package is defined as "a package containing a limited quantity of a pharmaceutical product sufficient to evaluate clinical response; distributed to authorized Health Care Professionals through different methods of distribution, free of charge, for patient treatment" (Rx&D, 2012, p. 58). This definition tends to emphasize only the clinical benefits of sample distribution, whereas this practice may change prescribing practices and encourage the use of a particular product.

The distribution of samples

Drug samples are distributed regularly and extensively in health care institutions and medical clinics. To improve oversight of this multitude of samples, many institutions have introduced management policies. However, the existence of a sample management policy does not guarantee that it will be applied. At the Sainte-Justine University Hospital Centre (UHC) in 2007, the total value of the samples found in patient care units was $48,783. In comparison, the value of authorized drugs in these units was $21,813 (Soucy et al., 2009). In 2012, only 19% of the doses found were listed on the hospital's formulary. Moreover, 4% of the doses had expired. Despite the existence of an electronic form to record samples, most doses were not reported to the hospital pharmacy (Barthélémy, Lebel and Bussières, 2013).

According to prescribers and patients, the distribution of samples can have benefits, such as the rapid initiation of therapy, the provision of patient teaching on how to use the product, the provision of necessary drugs to patients who are less well off or increased patient satisfaction, with this easier access seen as a privilege (Soucy et al., 2009; Malo and Goulet, 2005). Nevertheless, in addition to influencing prescribing practices, the distribution of samples can have negative effects on safety, for example by increasing the risk of unintentional duplication of therapy, allergic reactions, intolerance, drug interactions or the use of contraindicated drugs (Shnier et al., 2013; Soucy et al., 2009; Malo and Goulet, 2005).

Thus the distribution of samples warrants special attention. The issues it raises are so important that the Association des pharmaciens des établissements de santé du Québec (APES) recommended creating a legal framework to ban the use of drug samples in health care institutions (APES, 2014). To be accredited, health care institutions in Canada must comply with several standards, required organizational practices and criteria regarding drug use, including a standard on sample management (Accreditation Canada, 2013). Moreover, in Québec, in 2007, the Politique du médicament recommended regulating the distribution of samples on Québec's territory by means of a manufacturer's commitment (MSSS, 2007a).

Available options

All the contributions made by the pharmaceutical industry to the health and social services system must be considered in order to bring the multiple consequences of these exchanges to light. This is why the Auditor General, in his 2014 report, called for greater transparency in the following terms: "Guidance and monitoring are needed, in particular with respect to the management of conflicts of interest, donations and rebates, visits from pharmaceutical sales representatives and the distribution of samples to professionals" [Translated from the French] (AGQ, 2014, p. 28). The Commissioner's Consultation Forum expressed similar concerns.

What Consultation Forum members think

In December 2011, the members said they were "concerned about the balance of power between the different stakeholders in the drug chain and more specifically by the pharmaceutical industry's influence throughout the chain. Furthermore, the independence of decision makers and the scientific community with respect to this industry is a central issue for them. This is why they argue in favour of a clear division of responsibilities […]", especially between the government and the pharmaceutical industry, "and a clear definition of the behaviours expected from drug companies, especially with respect to social responsibility. The members also call for greater transparency in political decisions and actions and would like these decisions and actions and the resulting choices to be governed by equity".

"In regard to negotiations between the government and the industry, the members believe that they must first promote the pursuit of the common good and must therefore be consistent with an approach that promotes sustainable development, transparency, access to information, a return on investment and coherence in the overall allocation of resources."

"While aware of the need to work with the pharmaceutical industry in a spirit of openness, the members call for vigilance and a lack of complacency when conducting negotiations with companies […]"

Report of the Consultation Forum's deliberations, December 2011 and June 2012 sessions.

A number of solutions were proposed by the people consulted by the Commissioner to satisfy the need to increase the transparency of associations between the pharmaceutical industry and the health and social services system. They include increased government oversight of promotional practices and the creation of drug sample registers or directories listing associations between physicians and the industry. The United States considered this issue so important that they introduced the *Physician Payments Sunshine Provisions* (*Physician Sunshine Act*) in 2010 to ensure transparency in relationships between physicians and manufacturers of drugs, medical devices and medical supplies.

Physician Sunshine Act

The *Physician Payments Sunshine Provisions* (*Physician Sunshine Act*) was adopted in the United States in 2010. It is one of a number of statutes (*Sunshine Laws* – as of 1970) intended to increase transparency in decision making in the government, the federal administration and the states. Under the *Physician Sunshine Act*, any manufacturer of drugs, medical devices and biological and medical supplies that provides a payment or other transfer of value to a physician or teaching hospital must submit various information in electronic format to Health and Human Services.

What the Commissioner recommends

Given the pharmaceutical industry's impact on optimal drug use and drug spending, the Commissioner urges the Minister of Health and Social Services to prioritize transparency in interactions between pharmaceutical companies and the health and social services system (institutions, clinics and patient associations). Given the possibility of acting more directly within institutions and family medicine groups (FMGs), the Commissioner's recommendation focuses on these organizations, although the pharmaceutical industry's contributions are not limited to these alone and also concern medical clinics.

Recommendation to the Minister of Health and Social Services

1. Submit an annual report to the National Assembly on all pharmaceutical industry contributions to health care institutions and FMGs, including samples.

1.2 The lists of medications covered

The majority of OECD (Organization for Economic Cooperation and Development) countries apply various regulatory mechanisms to promote the optimal use of prescription drugs and improve spending control (Lamothe, 2006; Jacobzone, 2000). These include positive lists (drugs that are covered) or negative lists (drugs that are not covered) as well as reference pricing and maximum price systems. For example, public drug insurance plans in Australia and New Zealand have positive lists, whereas that of the United Kingdom uses a negative list.

For its part, Québec opted for using positive lists of generic and brand name drugs. The *List of Medications* is a list of drugs that are covered by the public component of the RGAM (RPAM) and for which private group plans must provide a minimum level of coverage. The *List of Medications – Institutions* is a list of drugs that are provided in institutions. These lists are intended to maintain fair and reasonable access to medically required prescription drugs as well as to support optimal drug use, in addition to being a tool for controlling drug spending (MSSS, 2007a and 2002).

Before they are entered on Québec's lists of medications, generic and brand name medications are reviewed by INESSS based on five criteria. The latter "are intended to guide health system decision makers, who must ensure optimal and appropriate drug use, while guaranteeing equitable access and the sustainability of the health system in a context where resources are limited" [Translated from the French] (INESSS, 2012b, p. 3). The first criterion concerns the therapeutic value of the medication. Once this has been demonstrated, the remaining four criteria are assessed:

i) the reasonableness of the price charged for the medication;
ii) the cost-effectiveness ratio of the medication;
iii) the impact that listing the medication will have on the health of the general public and on the other components of the health and social services system;
iv) the advisability of listing the medication, given the purpose of the RGAM.

Once the review process has been completed, INESSS sends a notice setting out its recommendations to the Minister of Health and Social Services, who decides whether or not the medications should be included on the lists of medications covered.

At present, the lists of medications are updated regularly to add new generic and brand name medications or lower prices. Since the RGAM was created, the number of products listed has continued to grow, even if this upward trend has sometimes been punctuated by temporary decreases, largely due to delisting requests from manufacturers. Moreover, no legislative or regulatory provision requires a manufacturer to keep a medication that is not yet obsolete on the list. A manufacturer may even

decide to cease production of a medication that is still valid and whose use is recognized.

The number of medications on the *List of Medications* covered by the RGAM

The *List of Medications* covered by the RGAM included over 7,000 prescription medications in 2014. From 2004 to 2009, Québec was the province with the highest number of new drugs on its list of reimbursed drugs, that is, 52 of 87 (60%) new drugs that had received a notice of compliance from Health Canada. Of these, 36 (69%) were given an exceptional medication listing. This type of listing allows, in exceptional situations, payment for certain medications considered effective for limited indications, since their effectiveness or the cost of treatment cannot justify their regular and continued use for other indications (Gamble et al., 2011). Furthermore, 12 of 29 (41%) drugs given a "do not list" recommendation by the Common Drug Review (CDR) – a process conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH) to provide formulary listing recommendations to publicly funded drug plans in Canada, excluding that of Québec – were listed on the *List of Medications* covered by the RGAM. Again, from 2009 to 2011, Québec was notable for the number of drugs that received a listing recommendation. During this period, the listing rate for new drugs was 46% (45 out of 98 newly approved drugs listed). Québec also had the shortest time-to-listing (INESSS, 2012a).

The processing times for listings or revisions for generic drugs were recently reduced and manufacturers may file submissions more frequently during the year. In some cases, especially for economic or medical reasons, submissions may be given priority status. Since 2012, submissions for inclusion on the list of medications covered by the RGAM are given priority status if the potential savings generated by the arrival of a new medication are $200,000 or more for each month of early listing (INESSS, website).

Constantly growing health needs, when resources allocated to this sector must be contained, makes it is increasingly difficult to reconcile meeting needs with the imperatives of spending control. It is therefore legitimate to question the added value of medications already on the lists. Indeed, while a medication may show it is useful by producing the desired therapeutic effects, its relative effectiveness may, however, gradually diminish compared with new drugs, even rendering it obsolete. Moreover, the scientific community regularly shows that a significant proportion of prescription drugs are inappropriate, not very effective, inefficient or simply not safe enough, which brings up questions about how their use is monitored. As yet, there is no regular mechanism for revising drug listings and INESSS'S current drug review framework was not designed for this purpose. Thus, if there is a change in the evaluation of a medication's therapeutic value, it remains on the lists of medications and continues to be prescribed, unless the manufacturer asks for it to be delisted or if there is a safety issue with the product.

Available options

Many private drug insurance plans revise their lists of medications regularly. Similarly, public drug insurance plans in many European countries revise their lists of reimbursed medications (Thomson and Mossialos, 2010; Raftery, 2008; Morgan et al., 2007; Sundakov and Sundakov, 2005). The mechanisms for revising drug listings vary widely between countries and may concern all the drugs listed or only certain classes or types of drugs. For example, Sweden's public drug insurance plan covers a positive list of generic and brand name drugs that includes some 5,000 products. Considered too long, a comprehensive revision of the list of medications approved for reimbursement was initiated in 2003. Since then, the list has been revised regularly by drug class. Over the years, some drugs have lost their reimbursement status (Anell, 2008; Moïse and Docteur, 2007; Redman and Magnus Koping, 2007; Anell, 2005). In other cases, the drug guides were modified.

How drug listings are revised in France

France applies a policy whereby a systematic revision of reimbursed drugs is conducted every five years (Franken and Le Polain, 2012). The Haute Autorité de santé (HAS) is France's independent public authority whose responsibilities include evaluating publicly funded drugs based on medical and economic criteria. An independent scientific commission of the HAS determines the level of medical service provided by existing drugs. This allows it to assess the drug's therapeutic value and how it compares with existing therapies, while taking into account the severity of the disease for which it is indicated. It also refers to data on the drug for a given indication, such as effectiveness, adverse effects and its importance in the therapeutic strategy, (HAS, n. d.).

In the past decade, a revision of reimbursed drugs, by therapeutic indications, identified drugs that were providing an inadequate level of medical service. Based on this reevaluation, it was concluded that these drugs had no place in a therapeutic strategy to treat or relieve the medical condition they were indicated for. Following this revision, public funding and prices for some drugs decreased, some were delisted, while others were made available without a prescription (HAS, 2006).

The process used to update the British National Formulary

The British National Formulary (BNF) is updated every two years by a group of editors from the Royal Pharmaceutical Society and the British Medical Association. Changes are discussed first by expert advisors (physicians, pharmacists, nurses and dentists), then by the Joint Formulary Committee. This committee, composed of physicians, pharmacists and representatives of the Medicines and Healthcare Products Regulatory Agency and departments of health in the United Kingdom, makes decisions on policies and changes to the national formulary based on new evidence and expert opinion. If the

changes concern drugs used by professionals such as dentists or nurses, representatives of these professional groups are consulted. In addition to scheduled updates (of the entire formulary or predetermined sections), regular updates are carried out to reflect new evidence and can be accessed online (BNF, website).

In addition to revising formularies, some governments use a reference pricing system, also called flat-rate reimbursement, based on drug class. In this system, a price is determined for a given drug class and patients pay the difference if they want a more expensive product. For example, in the early 1990s, British Columbia's public drug plan began to manage public expenditure on drugs using various measures, including the reference pricing policy for select drug classes (Morgan and Cunningham, 2008). In Québec, the example of proton pump inhibitors (PPIs) illustrates the potential savings that can be generated by revising the list for a drug class.

The case of PPIs in Québec

The use of PPIs has raised concerns for many years in Québec. Since 2001, criteria have been established – and revised – and optimization measures have been proposed and updated following the signing of a partnership agreement between the Government of Québec and PPI manufacturers. Other questions have been raised as to the actual impact of the optimization strategies deployed thus far on the use of PPIs in the RGAM as well as the resources allocated to them. In March 2013, at the request of the Minister of Health and Social Services, INESSS recommended implementing measures to ensure optimal use and better oversight of the cost of PPIs (INESSS, 2013a). New reimbursement rules for PPIs, based on the reference pricing system, then came into effect. Since then, a maximum allowable price has applied to some products in the PPI drug class. Anyone who does not want to pay extra can choose to receive a generic version. In other words, a person covered by the RPAM must pay the difference between the price of the prescribed drug and the maximum allowable price, unless the prescription is marked "no substitution". According to a follow-up report, the total cost of reimbursing proton pump inhibitors (PPIs) decreased significantly for the RPAM from a monthly average of $16.5M in January 2012 to $8.9M in March 2014 (INESSS, 2014).

What the Commissioner recommends

In a context where drug use and costs are constantly growing and where the government wants to provide access to those that are best able to meet population health needs, effective regulatory mechanisms must be put in place to regulate the prescription and use of reimbursed drugs. The prescription and use of drugs are social and ethical acts insofar as the resources allocated to them cannot be used to meet other basic needs of our society. The allocation of resources is based on social choices. Moreover, drugs are an important budget item for the Government of Québec and should be the subject of an in-depth analysis. The periodic revision of drug listings may

be an effective lever in this respect. Indeed, it could prevent continuing coverage for obsolete drugs and ensure that listed drugs always have their place in the therapeutic strategy both with respect to other drug therapies and within the same drug class.

What Consultation Forum members think

"[…] in the same way as when a drug is included on the list of medications covered by the RGAM, several members question the criteria that justify taking an effective drug off the list, when some products that have been replaced by new, more effective drugs continue to "linger" on the list, not to mention the drugs that aren't available anymore […]"

"[…] the members are concerned about the increasing number of drugs without any added value on the market and especially on the list of medications reimbursed by the RGAM […]"

"The Forum reiterates that generic drugs and drugs with added value should be promoted and that the list of reimbursed medications should be cleaned up, without automatically restricting it to a single drug in a given class in order to respect the therapeutic decision."

"Some members question whether INESSS is able to delist certain medications that are already on the list of reimbursed medications and pointed out that it is easier to add a medication to the list than to take it off."

"Similarly, it is suggested that a drug can be listed for a specific length of time."

Report of the Consultation Forum's deliberations,
December 2011, June and November 2012 sessions.

This revision process should be conducted using the latest clinical and scientific data. The use and reimbursement of drugs with recognized therapeutic equivalence and which are considered to be more cost effective should be encouraged. In revising drug listings in the same drug class, INESSS could use a similar approach to that used for reimbursing PPIs in order to determine the incremental therapeutic value. To this end, a pilot project could be undertaken by selecting drugs from a drug class, for example nonsteroidal anti-inflammatories.

The decision to take some drugs off the lists of medications is a difficult one, given resistance to change and the multiple pressures at play. Indeed, the legitimacy of these decisions can be questioned by manufacturers, prescribers and users. Few citizens (28%) surveyed by the Commissioner saw this as the best way to ensure the sustainability of the RGAM, which shows how difficult delisting would be to do (CSBE and Léger, 2012). In this type of difficult situation, citizen participation in decision making may be in order, for example by means of an interdisciplinary decision-making committee.

Decisions by INESSS'S review committee and experts regarding the revision of drug listings should be made public in the same way the notices sent to the Minister of Health and Social Services setting out listing recommendations are. Lastly, it would be important to set up mechanisms for managing the transition when a drug is taken off the list, for example with respect to manufacturers' commitments for their product listings, pharmacy inventory management and information given to prescribers and citizens.

Recommendation to the Minister of Health and Social Services

2. Periodically revise the *List of Medications* covered by the RGAM and the *List of Medications – Institutions*.

Objective 2: Ensure fair and reasonable access to drugs that do not meet standard review criteria

The review processes for public reimbursement of drugs in many countries and Canadian provinces base their decisions on different criteria. Limited public funds and the need to select drugs for funding that will have the greatest impact on population health are among the justifications given for employing review processes that focus on the cost-effectiveness ratio of drugs.

Applying the criteria in the drug review framework used by INESSS (for the list of criteria, see the previous section on the lists of medications covered) poses several challenges, for interpretation is not always simple and the criteria may be conflicting (see box below) (INESSS, 2011b; Desmarais and Robitaille, 2008; Doucet, 2006).

Review criteria for listing decisions and challenges to their application

A drug's therapeutic value is assessed based on scientific evidence of safety and efficacy. This evidence is usually provided by the product manufacturer when he files his submission. The nature and quality of available data, biases in the data or the clinical significance of statistically proven gains raises questions at this stage. For example, it is difficult to provide evidence of efficacy for some drugs if the number of people affected is low.

Pharmacoeconomic studies, used to assess the fairness of a drug's price and its cost-effectiveness ratio, compare the cost, benefits and safety of a drug with those of a comparator. The benefit of a drug can be assessed in different ways, in particular using economic models and the cost/QALY (quality-adjusted life years) ratio. Although they are codified and technical, these studies integrate clinical, economic and social considerations which are reflected in the results. It is difficult to review drugs when no comparable drugs are available, for example when there is no treatment for a disease. Moreover, if a drug has a high cost-effectiveness ratio, decisions are more complex, especially since thresholds are used in Québec practices even though they are not official.

Other pharmacoeconomic studies focus on the health system and population health, especially the budget impact of reimbursing or providing a drug, such as the additional costs or savings generated by medical visits, laboratory tests and hospital admissions. Data for these analyses is not always available and, when it is, may contain uncertainties regarding, for example, the number of cases that may benefit from a drug, how it will actually be used or the difference between conditions in clinical trials and use in real life.

The last criterion in the review framework is intended to ensure fair and reasonable access to medically required drugs, in particular by balancing collective and individual

interests. Reasonableness can vary depending on different parameters, including advances in knowledge, such as evidence of efficacy, or social values, while the fairness dimension refers to the allocation of resources in a context where they are limited. The intangible nature of this criterion makes it difficult to apply and requires the mobilization of non-scientific information to develop an argument to support important social and ethical choices.

In drug development, manufacturers currently rely on a personalized response to health needs. Thus many of the latest products are intended for small patient groups rather than the population as a whole. Knowledge of pharmacogenetics and pharmacogenomics means that drugs can be developed for select groups based on their genetic profile. Furthermore, biotechnologies are increasingly used in the development of drugs referred to as biologicals.

These relatively recent changes in drug development create new challenges with respect to their evaluation. Indeed, a growing number of drugs do not meet standard public review criteria, mainly because evidence of efficacy is hard to obtain or they are expensive. This is the case, for example, of some costly drugs used to treat rare diseases, such as certain cancers or hereditary metabolic diseases. In cases where drugs target fatal or highly debilitating diseases for which no treatment exists, these drugs offer hope and there may be a shared sense of urgency about making them accessible despite their high cost or incomplete evidence as to their efficacy. This can raise concerns about fairness and equity with respect to the reasonableness of non-reimbursement.

Listing such drugs on formularies based on their promising nature without putting mitigation or monitoring mechanisms in place to manage the risks and costs, given the uncertainties surrounding them, can, however, result in high costs for the system. Indeed, some drugs could ultimately prove to be ineffective or too costly for the benefits they bring. The costs they generate represent a suboptimal allocation of resources and run counter to more equitable access to drugs. This is why some governments implement various approaches to ensure greater oversight of decision making that allows access to these therapies, in addition to exceptional access measures that allow drug plans to fund these drugs partially or fully.

Since resources are finite, allocating public funds to increase access to exceptional drugs raises concerns. For example, in Québec, the exception patient measure cost nearly 68 million dollars in 2011. The variable application of review practices can lead to disparities in access depending on the patient's pathology, his insurance plan, the attending physician or the institution where treatment is dispensed. Transparency is necessary regarding the review criteria used in decision making.

Moreover, European authors studied the processes used to review drugs for reimbursement in different countries. They showed that transparency could be increased

in the decision-making process in different countries for both general and exceptional access to drugs (Le Polain et al., 2010). Indeed, the obligation to make notices and recommendations produced by review agencies public once they have been sent to the decision-making body was put forward as a basic principle to strengthen the accountability of review agencies and the reasonableness of their decisions (Schlander, 2007; Daniels and Sabin, 1997). While the pertinence of this principle is widely recognized, it remains difficult to put into practice.

The Commissioner makes two recommendations to achieve the objective of improving access to drugs that do not meet standard review criteria. The first concerns the adaptation of review mechanisms, while the second is intended to harmonize exceptional access measures.

2.1 Drugs that do not meet standard review criteria

Drug review agencies around the world face challenges when dealing with drugs that do not meet standard review criteria, be they drugs for rare diseases, including certain cancers and rare hereditary metabolic diseases, or biologicals. In Québec, the challenges surrounding these drugs were brought to light in 2011 following a request from the Minister of Health and Social Services. In a pilot project, INESSS reevaluated four promising cancer drugs whose cost-effectiveness ratio had not been demonstrated during the initial review. This situation highlighted "the difficulty, in the current legislative framework, of managing new promising drugs appropriately, especially when there is considerable uncertainty as to the extent of their actual benefits for patient and population health as well as the economic and organizational benefits for the health system" [Translated from the French] (INESSS, 2011a, p. 1).

In this context, INESSS carried out an exhaustive analysis of its methodological framework for the review process. This analysis led INESSS to gradually integrate new methods, including multivariate analysis by considering new indicators, such as cost per life year gained or cost per event prevented, if they are provided by manufacturers. INESSS also explored new approaches, including listing with evidence development and the negotiation of risk-sharing agreements, approaches that will be described in detail further on (INESSS, 2012a, 2012b and 2011a).

Cancer drugs in Québec

Cancer is the leading cause of death in Québec and Canada. Advances in research in this field have resulted in the emergence of many cancer drugs that offer hope, but are increasingly specific and costly. Antineoplastics (all cancer drugs) saw the highest increase in costs from 2003-2004 to 2010-2011 (for both the RPAM and institutions). During this period, spending on antineoplastics increased from $97.3M to $315.4M, an

annual growth rate of 18.3%. The growth in spending was higher for RPAM beneficiaries, reaching 27.2% during this period (spending rose from $18.6M to $100.3M). For health care institutions, costs rose from $78.6M to $215.1M, an annual growth rate of 15.5%. INESSS forecasts for the 2011-2012 to 2015-2016 period show that, based on a steady annual growth rate, spending on antineoplastics could total $302.7M: $166.3M for institutions and $136.4M for the RPAM (INESSS, 2012a).

Available options

Different mechanisms have been put in place internationally to review drugs for reimbursement that do not meet standard review criteria.

Different drug review frameworks

For therapeutic innovations that involve clinical and economic uncertainties, the methodological frameworks used for the review process vary between review agencies. In this regard, the experiences of review agencies in Ontario, Sweden and the United Kingdom are interesting.

Different evaluation approaches

Ontario, Sweden and the United Kingdom have implemented interesting evaluation approaches.

A working group in Ontario

The strategy adopted to evaluate rare diseases in Ontario relies on the development of a new evaluation framework that considers the best available clinical evidence, patient needs and available resources. To this end, the Ministry of Health and Long-Term Care established a working group comprised of clinicians and economists to predict the potential benefit or lack of benefit of a drug treatment in a specific group of patients (Elger, 2011; Ministry of Health and Long-Term Care, 2010).

The weight of different review criteria in Sweden

The Dental and Pharmaceutical Benefits Board uses the same criteria to evaluate all drugs: the cost-effectiveness ratio of the product, the human value principle and the principles of need and solidarity. While the cost-effectiveness ratio is an important criterion, the human value principle may take precedence, irrespective of the drug. Cost effectiveness must be proven; however, since the cost-effectiveness ratio threshold is higher for more severe diseases, greater uncertainty is accepted if there is no possible way of obtaining data due to small patient groups. Thus the inherent limitations of using pharmacoeconomic studies to estimate the cost-effectiveness ratio are taken into account in the evaluation process by Sweden's review agency because its weight in decision making can be counterbalanced by other considerations (Denis et al., 2009).

The cost-effectiveness ratio and other arguments used in the United Kingdom

To make its recommendations to the National Health Service (NHS), the National Institute for Health and Clinical Excellence (NICE) uses different cost-effectiveness thresholds (£/QALY) to assess the need to take other criteria into account, such as the innovative nature of the technology, the specific characteristics of the condition and the population receiving treatment and, where appropriate, the societal costs and benefits. For drugs with a cost-effectiveness ratio higher than £20,000/QALY, funding decisions refer to these other criteria, in addition to considering the degree of uncertainty surrounding the calculation of cost-effectiveness ratios. For drugs with a cost-effectiveness ratio higher than £30,000/QALY, these other criteria become increasingly important in the evaluation. The reasoning for the committee's decision is then explained with reference to the criteria that were taken into account (Denis et al., 2009).

Integration of different perspectives

The integration of different perspectives in review processes provides a comprehensive view of what is being evaluated, mobilizes and balances various arguments in the decision-making exercise and limits practices that are discretionary, arbitrary or that favour the interests or perspectives of a particular group. Meetings between manufacturers and reviewers, for instance, allow manufacturers to explain the data submitted for review and improve their understanding of review processes. Moreover, the perspective of the patients concerned by a drug must be considered to better understand their needs and how they experience their disease. Indeed, the integration of input from patient associations or from patients themselves as well as the results of quantitative or qualitative research into the information to be examined during the review process or meeting with certain patient representatives in person informs this perspective. While the patient perspective is essential, it must not be confused with that of citizens, who do not have any bias as to the decision. Indeed, unlike patient participation, citizen participation can help balance stakeholders' multiple interests and preferences.

Some procedures implemented at INESSS to integrate different perspectives

Listing recommendations are made by INESSS'S Scientific Committee on Entry on the List of Medications (CSEMI), which is made up of citizens and members with expertise in various fields. These members examine drug manufacturers' submissions with the support of INESSS professionals, external experts and, since 2013, members of the Comité d'évaluation des pratiques en oncologie pour les médicaments anticancéreux [Committee for the review of practices in oncology with respect to cancer drugs]. INESSS relies on greater citizen participation to better integrate societal, civic and ethical values, especially within the CSEMI. To ensure the new drug product is introduced coherently, INESSS has organized "manufacturer appointments", which are meetings held before submissions are filed to address the clinical, economic and

pharmacoeconomic aspects of drug review submissions. Moreover, INESSS would like to develop mechanisms to systematically incorporate patient and patient group consultation and participation into drug review work.

Some formulary decision-making processes reflect important social and ethical choices that involve value judgements, in a context where resources are limited. This is why the exercise to mobilize arguments and different perspectives in order to make a decision must be based on a deliberative approach that emphasizes the citizen's perspective. These deliberations would balance the weight given to the multiple sources of information and inform resource allocation decisions so that they are aligned with objectives that reflect their values and preferences. Citizens' contribution to supporting decision making on issues that underpin social choices is illustrated in some of the answers to the Commissioner's online survey.

The Commissioner's survey – Results for the publicly funded reimbursement of a cancer drug

The following question was asked in the survey conducted by the Commissioner: "Would you be for or against the publicly funded reimbursement of a drug used to treat terminal cancer (i.e., a drug used at the end of life), whose cost is considered high by some people, if the drug…" In response to the question, most Quebecers were in favour of reimbursement if the drug improved quality of life without prolonging life (85%). However, they were less in favour if they were told that the drug would prolong life by a few months (42%) or a few weeks (37%) without improving quality of life. A very small minority were in favour of reimbursing a drug if it prolonged life by a few months or a few weeks, but reduced quality of life (19% and 17% respectively).

Source: CSBE and Léger, 2012.

The type of methodological approaches employed, be they surveys, deliberative approaches or other means, to allow citizens to participate in decision making is important insofar as it determines the nature of the results obtained. A permanent deliberative process can help ensure a more appropriate decision is made by revealing the values and motivations behind choices and the social acceptability of drug reimbursement proposals, as well as encouraging greater ownership of complex subjects and the development of an institutional memory. It must, however, be provided with adequate resources. Lastly, the presence of citizen representatives on scientific committees allows citizens' concerns to be voiced during the committee's deliberations, provided that this expression of views is supported and facilitated. The input of these representatives can be increased tenfold if they are selected by means of a deliberative process that brings citizens together, conducted in parallel and independently. Moreover, citizen participation in INESSS'S decisions through a deliberative process was strongly supported by the members of the Commissioner's Consultation Forum.

What Consultation Forum members think

"Several members believe the INESSS should establish a permanent advisory committee made up of citizens who are independent of all corporatism and consult it systematically during the drug review process to gauge the reasonable or equitable nature of the decisions to be made instead of basing decisions on complicated application criteria."

"[…] citizen involvement at decision-making tables is invaluable because it makes reflection easier, providing the emotional distance needed for effective decision making, an exercise that is clearly more difficult for a user addressing a situation that concerns him."

"[…] the members believe that INESSS should increase citizen participation in the drug review decision-making process. While they don't necessarily agree on whether it would be better to select only citizens who do not represent specific interest groups – which might exclude patients, for example –, they believe, on the other hand, that the selection of these citizens must be supported by a well-structured process, somewhat similar to the process used to select Forum members."

Report of the deliberations of the Consultation Forum, March and November 2012 sessions.

Similarly, experiences in other countries and elsewhere in Canada can serve as an example and an inspiration for practices in Québec.

The Citizens Council in the United Kingdom

To support them in their appraisal exercises, some agencies, such as NICE, decided to increase citizen participation in their own organization (United Kingdom, 2010; NICE, 2008). The NICE board considered that it was not legitimate for the organization and its advisory bodies to determine the social values used to develop its guidance (Rawlins and Culyer, 2004). In 2002, the board established a citizens council that meets once a year to examine issues that underpin value judgements and that arise from appraisal exercises (NICE, website).

A citizens' council to develop drug policies in Ontario

To increase transparency and accountability to the public, the Ontario government created a citizens council, the Ontario Citizens' Council, to include citizens and patients in the development of the province's drug and health policies (Ministry of Health and Long-Term Care, website-b). Since 2009, the Council, made up of 25 Ontarians appointed for 3 years, has produced reports on different topics related to drugs,

including the following: Values Framework; Private Drug Insurance in Ontario; Drugs for Rare Diseases; Managing the Drug Formulary.

The need for deliberations by a group of people from diverse backgrounds in order to make formulary decisions based on various types of data is recognized around the world. The multidisciplinary nature of the committees and teams responsible for formulary decision-making processes allows perspectives to be balanced in order to make a judgement. For example, some studies suggest that medical specialists may consider that high cost-benefit ratios for the drugs used in their specialty are the norm (Hughes and Williams-Jones, 2013). In this regard, it is important to recognize that the methods used to assess the cost-effectiveness ratio of drugs not only have limitations, but do not necessarily reflect the value people place on ensuring everyone has equitable access to drugs (Ontario Citizens' Council, 2013; Schlander, 2007). Thus, even if other criteria regarding the fairness and reasonableness of decisions have not been objectivized in the same way, they can be given the value they deserve during deliberations by a group of people, especially in cases where promising drugs are costly and involve clinical and economic uncertainties. It is important to explain the arguments put forward and to clarify their relative weight in decisions so that any "fair-minded person" can understand and judge the merits of the decision and thereby increase transparency (Daniels and Sabin, 1997).

Interprovincial collaboration and cooperation

Elsewhere in Canada, the provinces work together on drugs that do not meet standard review criteria, including cancer drugs**.**

The pan-Canadian Oncology Drug Review (pCODR)

With the exception of Québec, the Canadian provinces have participated in the pCODR, now an integral part of the Canadian Agency for Drugs and Technologies in Health (CADTH), since 2011. Made up of specialists, researchers, managers and patients, this special committee reviews emerging cancer drugs. The objective is to eliminate duplication in review processes and the scattered results that might come from the different provincial scientific and economic reviews in order to align coverage for the same cancer drug across the country. pCODR reviews and recommendations on the clinical efficacy and cost-effectiveness ratio of drugs incorporate input from patient groups being treated. They are intended to inform provincial review agencies about how these drugs are used, their funding and the impact of their use on provincial health systems. Based on this data, provinces can decide to provide a cancer drug by negotiating risk-sharing agreements, pricing agreements or agreements that determine costs based on the drug's therapeutic benefits for the patient's health by including an evidence development mechanism (pCODR, website).

Conditional approval

As one of the conditions imposed to provide access to drugs that do not meet standard review criteria, governments have concluded risk-sharing agreements with manufacturers. Moreover, some agree to list the drugs concerned provided data continues to be collected on them (coverage with evidence development).

Negotiation of risk-sharing agreements

There are many types of risk-sharing agreements that can be categorized as follows (Bourassa-Forcier and Noël, 2012):

i) *clinical risk-sharing agreements*: contracts between a manufacturer and the government to reduce clinical uncertainties associated with drug reimbursement, such as uncertainties regarding drug efficacy;

ii) *financial risk-sharing agreements*: contracts between a manufacturer and the government to reduce financial uncertainties associated with drug reimbursement by controlling prices, societal costs or budget impact by means of rebates, direct or indirect discounts, etc.

Price-volume risk-sharing agreements can involve, for example, discounts, volume and price caps, free drug schemes or outcome-based payments.

The number of risk-sharing agreements concluded has grown significantly in recent years. According to some analysts, this is probably due to pressure on governments from various stakeholders, including patients, physicians and the industry, to fund an increasing number of new drugs that involve clinical and economic uncertainties (Cheema et al., 2012). Risk-sharing agreements are concluded between governments and drug manufacturers in England, France, Australia, Germany, Sweden, Italy and in some Canadian provinces, including Ontario and Alberta. The impact of these agreements is being evaluated. According to various sources, negotiating financial risk-sharing agreements could reduce costs by 5 to 30% of the value of the drug covered in the agreement (Bourassa-Forcier and Noël, 2012).

However, it is difficult to accurately determine the costs that could be avoided, for the terms and conditions of agreements with manufacturers are confidential. Confidentiality is required by manufacturers because it allows them to maintain higher official drug prices, official prices on which price evaluations between countries are based as well as the pricing of new comparable products and generic drugs.

INESSS'S reflection on risk-sharing agreements

INESSS attempted to estimate the budget impact that signing risk-sharing agreements for seven cancer drugs listed by the Minister of Health and Social Services in 2011 and 2012 could have had. It was calculated that annual savings of $10M could have been

made for the RPAM and Québec's hospitals (INESSS, 2012a). INESSS is in favour of signing risk-sharing agreements as a condition that would allow drugs that do not meet standard review criteria to be listed.

There are advantages and disadvantages to signing risk-sharing agreements (Bourassa-Forcier and Noël, 2012). The advantages of these agreements include allowing more rapid access to certain promising drugs, better management of the costs associated with clinical uncertainties, optimizing drug use and promoting innovation. The disadvantages include a lack of transparency as to the content of the agreements, the creation of an artificial market due to the confidentiality of the agreements, the potential negative impact for people covered by private group plans insofar as these agreements mainly apply to drugs that are covered by the RPAM and hospitals, the complexity of administrative procedures and the cost of setting up a structure to manage such agreements.

Different measures can be taken to limit the negative impact associated with the confidentiality of such agreements. For example, only information about the drug price could be kept confidential. This could be an acceptable compromise to increase access to some costly drugs and better control rising drug spending.

To date, with the exception of financial drug price adjustment agreements concluded with some manufacturers (RAMQ, 2012b), no clinical or financial risk-sharing agreements are known to have been concluded by the Government of Québec. The addition of the risk-sharing agreement mechanism to INESSS'S formulary decision-making processes is still being studied. Bill 28, tabled at the National Assembly in 2014, provided for the signing of risk-sharing agreements, which shows the government's openness in this regard and to the associated confidentiality requirements. However, in signing such agreements, the principle of transparency should always take precedence and information that is not made public kept to a minimum. Citizens want transparency, as shown in the deliberations of the Commissioner's Consultation Forum and the survey results.

The Commissioner's survey – Results for how important respondents rated being informed about agreements

Please rate how important you think it is to be informed about the following.

- The **terms of agreements** between drug suppliers and the government / purchasing groups
  Total important: 74% Very important: 39% Quite important: 35%
  Total not important: 21% Not very important: 17% Not important: 4%
  Don't know / Decline to answer: 5%

Source: CSBE and Léger, 2012.

To this end, the government should allow itself the necessary leeway to negotiate these agreements so as to make as much information as possible about them public and not legally restrict the information that will be made available.

Coverage with evidence development

Coverage with evidence development allows drugs that do not meet standard review criteria, but which have promising results for serious clinical conditions, to be reimbursed under certain conditions. The mechanisms established for this purpose "provide for a sharing of responsibilities between manufacturers and jurisdictions, even between clinicians and patients, in the dynamic development of evidence" [Translated from the French] (INESSS, 2011b, p. 21). The Commissioner's online survey seems to show that citizens would be in favour of listing a drug whose effects are uncertain and for which scientific evidence is lacking if it were listed for a limited time.

The Commissioner's survey – Results for the degree of uncertainty associated with data

Would you be for or against the publicly funded reimbursement of a drug used at the end of life, such as a cancer drug:

- For which the **effects are uncertain and scientific evidence is lacking**, with funding provided on a **time-limited** basis**, the time it takes to confirm the drug's effect?**
  Total in favour: 54% Strongly in favour: 15% Quite in favour: 39%
  Total not in favour: 36% Quite against: 23% Strongly against: 13%
  Don't know / Decline to answer: 9%

- Whose effects (beneficial or adverse) are uncertain and for which scientific evidence is lacking, and there are no other treatment options (**last resort**)?
  Total in favour: 49% Strongly in favour: 14% Quite in favour: 35%
  Total not in favour: 42% Quite against: 28% Strongly against: 14%
  Don't know / Decline to answer: 9%

- Whose effects (beneficial or adverse) are uncertain and for which **scientific evidence is lacking?**
  Total in favour: 38% Strongly in favour: 11% Quite in favour: 27%
  Total not in favour: 52% Quite against: 35% Strongly against: 18%
  Don't know / Decline to answer: 10%

Source: CSBE and Léger, 2012.

Many issues remain to be clarified with respect to coverage with evidence development, for example the identification, using transparent criteria, of drugs that would warrant the application of such a mechanism, including the nature and degree of the uncertainties. Similarly, the mechanism, methods, conditions and expected outcomes for a specific drug must be clearly defined prior to its application, insofar as the mechanism can take different forms. Responsibility for the mechanism must also be the subject of careful consideration among the stakeholders concerned – government, researchers, drug companies, clinicians, patient groups, etc. Where will the leadership lie? What role will each stakeholder play? Who will fund the implementation of the mechanism? How will conflicts of interest be managed? The conditions of access to patient data, assurance of its confidentiality and quality as well as the possibility of linking the databases concerned, which may constitute significant barriers to effective and useful data collection, must also be considered. Furthermore, consideration must be given to the consequences of a potential termination of reimbursement for a drug following an unfavourable data analysis for patients who were using it.

INESSS's reflection on coverage with evidence development

To ensure the use of promising drugs at the end of life in oncology is monitored, INESSS proposed keeping them under review for a maximum period of six months, during which time they could be covered with evidence development or under a risk-sharing agreement. This proposal has not yet been followed up (INESSS, 2012b).

What the Commissioner recommends

Given the challenges posed by drugs that do not meet standard criteria, the drug review approaches used in Québec will have to evolve in order to maintain fair and reasonable access to all medically required drugs.

Recommendation to the Minister of Health and Social Services

3. Adapt listing processes for drugs that do not meet standard review criteria.

To this end:

- negotiate risk-sharing agreements with the pharmaceutical industry to ensure access to these drugs at the best prices, while keeping confidentiality to a minimum;
- revise the listings for these drugs in light of new data;
- establish a citizens' council to participate in the drug review process and ensure non-scientific criteria are taken into consideration.

2.2 The use of drugs in exceptional situations

Specific medical requirements and exceptional treatment in institutions

In Québec, the drugs used in health care institutions are usually procured by a public call for tenders system under the auspices of purchasing groups, non-profit procurement corporations. These purchasing groups are made up of pharmacists from the hospital pharmacies concerned. The head of the clinical pharmacy department is responsible for the movement of drugs in his institution, including access to drugs and rules for the use of pharmaceutical resources. Thus he is responsible, in collaboration with the pharmacology committee of the CPDP, for developing the formulary that is required for the proper operation of his institution from the *List of Medications – Institutions*, which is compiled based on listing decisions made by the Minister of Health and Social Services following the provincial review conducted by INESSS. Legally, each institution must dispense the drugs on its formulary to its patients free of charge. Since each institution develops its own formulary, based on local needs, the drugs provided may vary between institutions.

Some patients treated in institutions may have pathologies that are rare, complex or refractory to drugs on the *List of Medications – Institutions*, a provincial list. In this case, for specific medical requirements or for exceptional treatment, the institution's CPDP may authorize access to unlisted drugs, as provided for in the *Act Respecting Health Services and Social Services*. To meet these patients' needs, institutions can use new drugs with narrow therapeutic indications that target a very specific aspect of the pathology requiring treatment or that have few (or no) therapeutic equivalents. These new drugs, which are not on the provincial list or their institution's list, are recommended by specialists and requested by patients. While their use and provision are the responsibility of the head of the pharmacy department, the pharmacology committee of the CPDP and the institution's director of professional services (DPS), they differ significantly from those of drugs listed on institutions' formularies. In addition to variations in the formularies of different institutions, drugs may not be listed on an institution's formulary for various reasons, including the following:

- The drugs have been approved by Health Canada but are not on the *List of Medications – Institutions* because they are under review, because the manufacturer has not made a submission for listing or because the drugs do not meet this organization's standard review criteria.

- Some of these drugs have been approved by Health Canada but for different indications than those they are used for (off-label drug use). These drugs may nonetheless be part of accepted medical practice standards in some countries.

Off-label use may involve clinical uncertainties, sometimes combined with high costs.

- Some of these drugs have not been approved in Canada because they do not meet the review criteria for approval, because the approval process is ongoing or because the manufacturer has not made a submission for approval to Health Canada. Moreover, some of these drugs may be marketed in other countries or may be accessible in Canada under certain conditions, for example under Health Canada's Special Access Program (SAP).

Some of these drugs are prescribed on a daily basis. In institutions where research activities are conducted, the specialists who use them often participate in clinical trials to demonstrate safety and efficacy. These drugs are gradually finding their way into prescribing practices, despite uncertainties about their therapeutic and pharmacoeconomic profiles. The Auditor General even noted in his 2014 report that the CPDP of the audited institutions approved the inclusion in their formularies of some drugs that did not appear on the *List of Medications – Institutions* or that had not been approved (AGQ, 2014). Since the use of these drugs has not been approved for each of these patients, this practice contravenes Section 116 of the *Act Respecting Health Services and Social Services*.

The treatment costs of these drugs are usually higher than the average costs of all the drugs listed on institutions' formularies. Over the years, these drugs have been prescribed for a growing number of patients in institutions. On a financial level, using these new drugs generates substantial additional costs for the institution, which are not taken into account in the annual budget allocated by the Ministère de la Santé et des Services sociaux (MSSS). Indeed, in any institution, drug expenditures are financed by a share of the funds from the institution's global operating budget. Institutions' budgets are renewed annually on a historical basis following an annual adjustment based on criteria specified by the MSSS. There is no budget adjustment mechanism to absorb the additional costs generated by adding new drugs to the *List of Medications – Institutions* and thus to local formularies. The extent of the financial issues associated with these drugs raises questions, causes tensions between health professionals and creates budget management problems for institution directors.

The use of drugs that are not listed on institutions' formularies

In 2008-2009, 12,000 prescriptions were written for unlisted drugs that had not been approved by Health Canada – mainly accessible through the Special Access Program (SAP) in Québec's five university hospital centres (UHCs) – ,which represents 7.5% ($10.4M) of the annual global budget for drugs. At the McGill University Health Centre (MUHC), a marked increase was seen in requests for drugs not listed on the local

formulary: the number of requests increased from 213 between April 1, 2008 and March 31, 2009 to 416 between April 1, 2011 and March 31, 2012. These requests, which are made in oncology, but also in rheumatology and neurology, represent millions of dollars (Sidorowicz, 2012).

Unlisted drugs are often prescribed without there being any prescribing and drug use support tools common to all institutions. Since there are no decision-making criteria for their use, significant variations in practices are observed between prescribing physicians, institutions and regions.

Furthermore, the use of these drugs is not systematically monitored, precluding the collection of evidence of their efficacy or the development of drug guides to support listing decisions. While some institutions have information technology systems to manage the pharmaceutical resources on their formulary, no monitoring mechanism has been put in place for these as yet. Institutions' information technology tools cannot meet the specific requirements of qualitative and quantitative monitoring of data on the use of these drugs. The absence of data that would allow use to be monitored so that corrections could be made to the way drugs are used can have an impact on the performance of pharmaceutical services provided by institutions that use or would like to use them.

The variable contexts in which decisions are made as to whether or not to dispense new drugs that are not listed on institutions' formularies raise administrative, ethical, financial and professional concerns. Indeed, in some situations, their use may result in the suboptimal allocation of collective resources as well as inequitable access for patients depending on the institutions and clinicians involved.

Available options

Newer costly drugs dispensed in health care institutions and which involve clinical uncertainties account for a growing share of drug spending. Consequently, governments are implementing mechanisms to ensure these drugs provide a real therapeutic benefit that is superior to that of existing drugs and fulfil unmet medical needs. Some countries have adopted approaches to increase oversight of their accessibility, use and associated costs. Examples are presented in the boxes below.

The French government's "add-on list"

In 2004, when introducing an activity-based funding system for health care institutions, the French authorities thought it appropriate to fund some costly drugs separately, under specific terms and conditions (Bussières et al., 2010). In the future, they would be covered if they were on a list called an "add-on list", making their funding conditional upon their proper use (Duhamel and Morelle, 2012). Since 2004, spending on drugs on the "add-on list" has been extremely high, although its rate of growth has declined. To reduce the costs generated by these drugs, various measures have been implemented.

In 2009, an action plan addressed reevaluation, delisting and price reductions for some drugs on the list. Quality-of-use rules were established by regulation and a number of tools, sometimes enforcement tools, were made available to institutions to ensure better oversight of the use of these products. In 2011, the French government evaluated some drug classes that accounted for the highest share of expenditure, such as cancer drugs, which led to the introduction of an integrated policy in institutions to ensure equitable access. Furthermore, national benchmarks for proper use were produced. They required institutions to participate in a monitoring and auditing mechanism for prescribing practices. Lastly, an evaluation and observation system was introduced for the qualitative monitoring of prescribing data to increase knowledge of the actual conditions of use of these drugs. Questions were raised regarding the operability of the "add-on list" and the innovative nature and prices of the drugs on the list. The exercise led to general reflections on evaluation processes, pricing methods and regulations governing the use of costly innovative drugs as well as a thorough reshaping of French funding policy for therapeutic innovations.

The English government's Cancer Drugs Fund

One of a series of measures, England established the Cancer Drugs Fund, a national, regionally administered fund that provides funding for cancer drugs that are not listed on the list of drugs routinely used by the English health system (NHS England, website). A special list of drugs and indications was compiled by a group of experts. The fund covers the cost of using drugs on this list following applications from clinicians. Funding decisions are based on the type of cancer, the stage of the disease, the person's overall condition, previous therapies, effectiveness, the toxicity of the product, other therapeutic treatments available, etc.

Canadian cancer agencies

In the field of oncology, several Canadian provinces have created "cancer agencies" that produce drug prescribing and drug use support tools and sometimes cover the costs associated with cancer therapies and their administration. Ontario, which has such an agency (Cancer Care Ontario), pays for intravenous cancer drugs dispensed in hospitals under the New Drug Funding Program. This program was created to standardize the provision of cancer drugs in hospitals. Ontario allows drugs bought by the patient to be administered in accordance with procedures established by Cancer Care Ontario.

In British Columbia, the British Columbia Cancer Agency (BCCA) pays for all intravenous cancer drugs and practices are standardized by developing and implementing therapeutic protocols to be used in institutions.

The decision process map used by Eastern Health in Newfoundland

Eastern Health is a regional health authority that operates over 80 institutions in Newfoundland and Labrador (CADTH, website). To respond to local requests for funding and support for the use of non-formulary medications, this authority established an interdisciplinary committee with clinical, scientific and administrative expertise. In addition to identifying resources to support decision making, such as the CADTH, the committee responds to requests using a decision process map that consists of a series of questions about the product's approval status, available evidence, the exceptional nature of the case and associated costs. Additional decision support resources include conducting literature reviews, tapping into clinical expertise and considering ethical aspects.

Drug review in Québec's hospitals

The Programme de gestion thérapeutique des médicaments (PGTM) was created by Québec's five university hospital centres to promote the optimal use of new drugs in hospitals. In the past few years, the Program has developed a systematic approach to the evaluation of therapeutic innovations with the objective of adding drugs to the hospital's list (PGTM, website; Bussières and Marando, 2011). The Program proposes training activities and implements health care, research and practice evaluation activities, in addition to designing decision support tools and clinical intervention methods for clinicians. It is intended to promote the standardization of decision making in hospitals, especially for low-volume drugs with a high economic impact or drugs with a high potential for use and a potential for misuse in therapy. This work can be used to guide hospital pharmacy directors, the pharmacology committee of the CPDP and the hospital's DPS when they have to respond to requests to dispense new expensive therapies that involve clinical and economic uncertainties. As yet, the Program is a modest initiative supported by the university hospital centres. Its current financial and organizational conditions limit its activities and the number of systematic new drug reviews it is able to conduct.

Moreover, in Québec's hospitals, various types of drug reviews are conducted depending on the priority they are given by each hospital's pharmacology committee. For example, descriptive analyses and drug use reviews (DURs) are conducted to evaluate current practices. Some hospitals have taken measures to ensure compliance with the hospital's rules of use and to promote optimal use (Tétreault, Dupont and Hamel, 2012). Lastly, hospitals are tightening their decision-making processes with respect to drugs used for specific medical requirements or exceptional treatment. To achieve this, they require the consensus of a panel of local experts and include diversified expertise in decision-making groups, for example, in ethics (Sidorowicz, 2012).

The exception patient measure in ambulatory settings

Some drugs are not selected for public funding because it is hard to obtain evidence of efficacy or because they are expensive. When the diseases requiring treatment are very serious and there is no effective treatment, concerns of justice and equity may be raised regarding the reasonableness of non-reimbursement. Indeed, since some drugs do not meet standard review criteria for public funding, patients are penalized or deprived of care. This type of situation is a matter of concern. Moreover, citizens appear to consider it important to give everyone a chance at receiving scarce resources, even if it means a loss of overall efficiency in the resources invested for the population as a whole (Schlander, 2007). In this regard, it is interesting to note that most Quebecers surveyed by the Commissioner (80%) believe that the public drug insurance plan should cover the cost of drugs used to treat rare diseases (CSBE and Léger, 2012). A large proportion believes that such drugs should be covered by private insurance plans (54%) and charitable foundations (40%). A significant proportion (87%) also believes that drugs that are beneficial in treating rare diseases should be publicly funded, irrespective of the cost of individual therapies. Some of the testimonials sent to the Commissioner's website express similar opinions and stress the solidarity the Government of Québec should show towards people with serious diseases, including some rare diseases.

Testimonials sent to the Commissioner's website

- "I think that people who need drugs, especially drugs that save lives, should be fully covered." (Q9, E5E)
- "[Drugs] should be provided, no matter what they cost, for serious diseases such as cancer, diabetes, epilepsy, etc." (Q9, E89)
- "I am grateful that my specialist prescribed a drug for me that controls an extremely rare disease well. Since this drug is very, very expensive, the most expensive one. I am very grateful that a whole team of professionals, nurses and other staff, helped me get this drug which is hard to get through insurance companies, since it is not yet on RAMQ's list of exceptional drugs. I find it regrettable that we have to fight and turn to the media to get this drug which has been proven to be very effective and that prolongs our life expectancy indefinitely compared with an average survival time of 10 to 15 years." (Q4, E225)
- "Drug therapy costs less than hospitalization and disease prevention also costs the government less. New drugs are increasingly expensive and the population has to be made aware of the fact that the government will not always be able to provide free health care and drugs. A lot of education is needed about this. We also have to find ways to help patients with rare diseases that are very expensive to treat." (Q9, E91)

The Commissioner's Consultation Forum also insists on the need to do things differently to provide access to costly drugs that involve clinical and economic uncertainties.

What Consultation Forum members think

"[...] the members think that the case of cancer drugs or drugs used to treat orphan diseases should be dealt with based on the same principle of solidarity that should take precedence for all drugs, and several members think it is unfair that a few people should have to bear the consequences of refusing to list a given drug."

"[…] several members believe that we must work on containing rising costs and the increasing number of prescriptions for widely used drugs so that drugs that are expensive but that would not be used as widely by the population can be reimbursed."

Report of the Consultation Forum's deliberations, March 2012 session.

Ethical considerations call for the implementation of mechanisms that will allow both a response tailored to individual needs and a fair and equitable allocation of resources. Solidarity, compassion, individual rights and the idea of a more humane and more just society have led many governments to establish mechanisms to allow access to such drugs in exceptional circumstances. Thus they are publicly funded in many countries, but under different conditions from those that apply to other drugs (Elger, 2011; Denis et al., 2009). Many governments have regulated compassionate drug use. For example, Belgium and the Netherlands have introduced a compassionate use program. In Canada, Ontario has a compassionate use policy associated with its exceptional access program, which a committee of experts refers to to evaluate reimbursement requests on a case-by-case basis. Committees also deal with these types of requests in British Columbia and Alberta. Some countries, such as the United Kingdom, France, the Netherlands and Italy, have established procedures to regulate the off-label use of some drugs, especially orphan drugs. Moreover, Belgium and Italy have created a special fund for reimbursing these drugs. Lastly, in Italy, the use of orphan drugs must be documented in a national registry. In Québec, for the general coverage of drugs that are not reimbursed by the RGAM, the exception patient measure was introduced in 1983.

Description of the exception patient measure

The exception patient measure allows public coverage of a drug that does not meet standard scientific and economic review criteria for a specific and exceptional need for the insured person. The measure is intended for all people covered by the public and private components of the RGAM. Since 2005, RAMQ has managed the measure for people covered by the public component of the RGAM, the RPAM, while private group plans manage requests for their plan members. RAMQ physicians and consultant pharmacists evaluate drug reimbursement requests submitted by the attending physicians of people covered by the RPAM based on the following four characteristics:

- the drug requested must be eligible (it is used for a therapeutic indication other than those on the *List of Medications* covered by the RGAM (off-label use) or it is not on the *List of Medications* covered by the RGAM and conditions apply);
- the person's medical condition must be chronic;
- the person's medical condition must be serious;
- the drug must be a last-resort treatment for the insured person.

Furthermore, some exclusions apply: the drugs must not be prescribed for esthetic or cosmetic purposes, to stimulate appetite, for the treatment of infertility, alopecia, baldness, erectile dysfunction, obesity or cachexia and it must not be oxygen. Furthermore, the evaluation of the request takes the cost of the therapy into account. Nor must there be another pharmacological treatment on the list similar to the one requested. Lastly, the duration of drug coverage must not exceed one year: another payment authorization request must be submitted at the end of this period.

For people covered by private plans, the approaches adopted to authorize payment requests vary for each private insurer or employee benefit plan administrator. Attending physicians must submit a reimbursement request to one of these, which will then be evaluated by their own physicians and consultant pharmacists.

Changes in the use and cost of the measure

During the first ten years of the exception patient measure, the costs of drugs reimbursed by RAMQ were, on average, less than $5M annually and their rate of growth was relatively stable from year to year. However, starting in 2005, there was a major break in the trend, with costs rising to $67.6M in 2011. From 2007 to 2011, the average annual growth rate of costs was 38.4%: they rose from 0.7% of total drug costs for the RPAM in 2007 to 2.3% in 2011 (Simard, 2012). The number of prescriptions and beneficiaries also increased. It is still difficult to estimate the costs of this measure for all people covered by private plans; however, it is reasonable to surmise that they have evolved similarly to those for the RPAM.

In 2011, drug costs per public plan participant were $3,843 for those with access to the exception patient measure and $820 for those receiving drugs on the *List of Medications* (Simard, 2012). Moreover, the annual costs of a drug per exception patient measure beneficiary can be very high, for example if the drug is used to treat rare diseases (see Table 1).

Table 1. Cost/year/person of some drugs used to treat rare diseases – Patient exception measure (RPAM – 2011)

Brand name	Drug cost ($/year/person)	Indications*
Kuvan	$77,371	Phenylketonuria
Remodulin	$221,333	Primary pulmonary hypertension
Soliris	$217,645	Paroxysmal nocturnal hemoglobinuria
Somavert	$119,563	Acromegaly
Zavesca	$239,760	Metabolic disease (Niemann-Pick)

* Indications for exceptional drugs.

Source: Simard, 2012.

Available options

While the exception patient measure is founded on solidarity and compassion, the mechanism nonetheless calls for reflection. Firstly, the data showing the increasing use of this measure and its costs over time raise concerns. Some experts claim that policies on drugs for rare diseases around the world are used strategically as business opportunities by manufacturers, which could explain their growing number (Côté and Keating, 2010). These experts also reject the popular notion that the prices manufacturers charge for some of these drugs are largely justified by their development

and production costs. Instead they say that they are based on willingness to pay the price asked (Côté and Keating, 2010). Manufacturers' desire for profitability and the emotional aspect of some diseases and drugs also contribute to high prices. Some people believe that paying high prices for drugs, in particular those used to treat diseases that affect a small number of people, is a form of discrimination towards other patients insofar as a disproportionate amount of resources is allocated to them (McCabe, Claxton and Tsuchiya, 2005). Since many governments are facing similar problems with respect to the increase in the total costs associated with exceptional access mechanisms for some drugs, recommendations to control their prices have been proposed. These include requiring a justification for the price based on information on the investments made and the potential return at a global level or negotiating performance-based risk-sharing agreements (Denis et al., 2009).

Secondly, neither the detailed review process leading to the reimbursement of drugs under the exception patient measure, which the experts recruited collaborate on, nor its results, are made public. This lack of transparency makes any attempts to develop a better understanding of the grounds for the drug listing decision difficult, while the case-by-case approach used can lead to inequities among patients. These inequities may even be systemic depending on the profile of attending physicians, for example (INESSS, 2012a). The importance of transparency is recognized by the bodies that administer exceptional access measures, such as Ontario's Ministry of Health and Long-Term Care. Indeed, in its compassionate use policy, the Ministry announces initiatives to increase transparency (Ministry of Health and Long-Term Care, 2014).

Thirdly, it is important to point out that reimbursement decisions have to contend with the influence of the media, pressure from patient associations, political forums and sometimes even the judicial process that support access to these drugs (Côté and Keating, 2010).

Lastly, the evaluation method used for the exception patient measure does not allow use to be monitored, nor does it contribute to a better understanding of the potential of the molecule used for the therapeutic indication for which coverage is granted. Setting up a registry with data on certain diseases and the drugs used to treat them, as has been done in Italy, is intended to address this concern.

What the Commissioner recommends

Examining the appropriateness of dispensing a new drug in exceptional situations, either in an institution or an ambulatory setting, requires special clinical expertise. Indeed, in-depth knowledge about the necessary evidence of safety and efficacy, associated costs, the cost-effectiveness ratio and expected outcomes is essential. In addition, an ability to explain the uncertainties involved is necessary to ensure patients and their families are able to give their informed consent. Restricting access to these drugs, especially if they are costly, may deprive some patients of care, whereas solidarity and compassion would have it otherwise. Inequities in access observed between institutions or between the clinicians in charge also raise major ethical concerns.

Moreover, providing access to promising drugs without regulating and justifying their use has an impact on the performance and sustainability of the RGAM and the health and social services system. In this regard, decision makers must not only ensure that patients can access medically required drugs, they must also make efficient and equitable use of limited resources. It is therefore crucial to implement mechanisms to regulate the use of new drugs in exceptional situations in order to optimize their use in Québec's institutions and in ambulatory settings. Moreover, to make it easier for the process used to review drugs for reimbursement to strike a socially acceptable balance between meeting individual needs, budget constraints and the objectives of the health and social services system, the criteria applied must be in keeping with the principles of transparency, coherence and relevance; be revisable; allow their application to be monitored (Le Polain et al., 2010).

In Québec, responsibilities for the use of drugs in exceptional situations are divided between institutions and RAMQ. Existing processes are criticized for the inequities they create and their lack of transparency. In many countries, these responsibilities are centralized in order to tap available expertise, harmonize processes and promote coherent decision making. INESSS is the body responsible for making recommendations to the Minister of Health and Social Services as to which drugs to include on the lists of medications provided and reimbursed by the government. This is why the Commissioner believes it would be appropriate to transfer all drug review responsibilities to INESSS.

Recommendation to the Minister of Health and Social Services

4. Mandate INESSS to assume all responsibilities with respect to the use of drugs in exceptional situations, in both institutions and ambulatory settings.

To this end:

- ensure the timely approval of routine requests for these drugs under the exception patient measure as well as requests from health care institutions, while integrating the university hospital centres' initiative, the Programme de gestion thérapeutique des médicaments (PGTM);
- establish standards for the use of these drugs;
- publish data on these drugs on an annual basis, such as the number of requests approved and denied, associated costs and the diseases concerned.

Objective 3: Improve prescribing practices, pharmacological management and drug use

As the Commissioner reported in his document *Les médicaments d'ordonnance: état de la situation au Québec* (CSBE, 2014b), adverse events are associated with drug use. They can be caused by a multitude of factors (side effects, inappropriate prescriptions, drug dispensing and administration errors, improper use by patients, etc.). These adverse events are seen in ambulatory settings, but also in health care institutions, as indicated in the report on events reported to the Registre national des incidents et accidents survenus lors de la prestation de soins de santé et de services sociaux [National register of incidents and accidents that occurred during the provision of health care and social services]. In the Register, medication errors rank second among the events reported (MSSS, 2013). Moreover, a significant proportion of hospital admissions or emergency room visits are the result of an adverse reaction related to the patient's medication. These problems are documented in some groups in particular, including people with multiple chronic diseases or who take multiple medications. In this regard, 8% of people with the greatest health needs in the past two years were admitted to hospital for adverse drug reactions (CSBE, 2012).

The Commissioner's survey – Results for adverse effects

A total of 42% of respondents reported that they had experienced adverse effects from their medication and, of those, more than three quarters (77%) said they had reported these adverse effects to a competent authority.

Source: CSBE and Léger, 2012.

Given the different health problems that appear with age, an increase in prescription medication use in the elderly may seem inevitable. Age-related physiological changes and frequent comorbidities make prescribing for the elderly more complex. The growing number of health problems, including the development of chronic diseases, sometimes leads to multiple prescription drug use in addition to more frequent use of over-the-counter drugs or natural products. Polypharmacy may result in a prescribing cascade, where a drug is prescribed to treat the adverse effects of another drug. This increases the risk of drug interactions, adverse effects and reduced patient compliance with treatment (CIHI, 2013b; Hovstadius et al., 2010). These phenomena can contribute not only to overprescribing of drugs but also to an increase in adverse events, such as risks of morbidity, loss of autonomy, hospitalization and mortality (Koper et al., 2012; Clerc et al., 2010; Grenier-Gosselin, 2008).

The situation in the elderly

- 94% of adults aged 65 and over take medications regularly or occasionally (CSBE and Léger, 2012).

- 49% of adults aged 65 to 74 take more than three medications (CSBE, 2014c). Medication use in the elderly has increased significantly in recent years.

- In Québec, from 1997 to 2012, the number of prescriptions written for adults aged 65 and over insured by RAMQ increased by 340%, while the number of insured people in this age bracket increased by only 47% (RAMQ, 2014).

- In Canada, in 2010-2011, one in 200 adults aged 65 and over was admitted to hospital for adverse reactions to drugs such as anticoagulants, glucocorticoids, antineoplastic drugs, nonsteroidal anti-inflammatory drugs and antipsychotics (CIHI, 2013b).

Given these observations, the aim must be to optimize drug use by developing intervention strategies targeting prescribers and other health professionals as well as patients.

The act of prescribing is central to optimal drug use and yet various problems are associated with it. Prescribing errors clearly do not contribute to optimal use. Errors related to indications, contraindications, dosage, formulation or an incorrect assessment of possible drug interactions have been documented. Errors can also be made when dispensing or administering drugs, irrespective of whether these steps take place in health care institutions or ambulatory settings.

The appropriateness of prescriptions, a phenomenon that is more difficult to assess, is a problem raised by some people. Indeed, prescriptions sometimes do not comply with recognized criteria or they are inappropriate (Conseil du médicament, 2009; Aspden et al., 2007). There may be a gap between the drug prescribed and patient's real need.

Overprescribing and underprescribing have also been documented, both in ambulatory settings and health care institutions (Shortt and Sketris, 2012; Grenier-Gosselin, 2008; Leenen et al., 2008; Aspden et al., 2007; Desgagné and Guimond, 2003). Off-label prescribing without the support of strong scientific data is also a troubling observation (Eguale et al., 2012). Other problems have been documented, such as overlooking clinical or laboratory results when prescribing. Problems related to the appropriateness of prescriptions are seen in the elderly in particular.

Inappropriate prescriptions in the elderly

Problems have been observed in the elderly, such as potentially inappropriate prescriptions (PIPs) or prescriptions that do not agree with accepted standards or introduce a risk of adverse effects that outweigh the expected benefits for a patient. For example, in Québec, in 2005-2006, 30% of adults aged 65 and over covered by the RPAM were reported to have had at least one PIP (Conseil du médicament, 2009). In this regard, certain psychotropics used for their hypnotic or sedative effect were prescribed for 4.2% of adults aged 65 and over covered by the RPAM. These drugs are used despite the fact that they are not recommended for this population because their use is associated with falls (Conseil du médicament, 2009). Similarly, it has been reported that the medication profile of nearly half of all elderly people includes at least one unnecessary drug (Grenier-Gosselin, 2008). Some inappropriate prescriptions could be prevented, for example if there is a more appropriate therapeutic option (Mallet and Grenier, 2003). Moreover, underprescribing or overuse of drugs that are clinically indicated are also problems seen in elderly people followed in the community. This situation is particularly troubling when it involves drugs that could prevent health problems from worsening (Hanlon et al., 2001). Lastly, a study showed that 24 to 36% of elderly people take drugs that may potentially cause interactions (Fitzgerald and Pirmohamed, 2007).

Problems with the appropriateness of prescriptions are also seen in young people, such as children with ADHD or an autism spectrum disorder (ASD).

Inappropriate prescriptions in young people

- A significant increase in drug use has been observed in Québec in children with ADHD (Currie, Stabile and Jones, 2013). The reasons for this increase vary and include early screening which results in a higher number of cases being diagnosed. Differences in interpretation have also been observed in the criteria used to assess the children affected. According to data for 1998 to 2010 from the Québec Longitudinal Study of Child Development (QLSCD), around 6% of 8-year-old children had been diagnosed with ADHD and around 6% had taken a drug to treat attention deficit and hyperactivity behaviours in the year before the study (Cardin et al., 2011).

- A high percentage of children and teenagers in Québec aged 2 to 17 covered by the RPAM who were diagnosed with ASD took medications for which the evidence supporting their use in this population is weak: "Of those insured by the RPAM who were diagnosed with ASD, 14.3% of children aged 2 to 5 years, 35.9% of children aged 6 to 9 years, 44.8% of children aged 10 to 12 years, 52.3% of teenagers aged 13 to 15 years and 50.9% of teenagers aged 16 and 17 had taken [these types of medications] in 2010" [Translated from the French] (INESSS, 2013b, p. 48).

The members of the Commissioner's Consultation Forum expressed concerns about the increase in the number of potentially inappropriate prescriptions in the elderly and young people.

What Consultation Forum members think

"According to Forum members, we are seeing an explosion in prescriptions and the use of medications, including antidepressants, psychotropics and, in children especially, Ritalin. Several members believe the situation is even more alarming for the elderly: they sometimes have to take a real cocktail of drugs, without really knowing why. This creates serious safety issues, not only because of possible drug interactions, but also because products may be used incorrectly. Given this phenomenon, several members question whether all these prescriptions are really appropriate: some see them as a quick and easy solution, often preferred – by the patient himself or by his prescriber – over a more comprehensive approach to care. Others question the societal impact of the omnipresence of drugs in our lives: in the case of antidepressants or Ritalin, for example, would the drug sometimes be used to offset or deal with emotional or other problems, such as a lack of family, school or social support, even obscuring attempts to determine the true causes of the problem?"

Report of the Consultation Forum's deliberations, December 2011 session.

The difficulties associated with prescribing practices are the result of a combination of contextual factors where there is enormous pressure to increase drug use, while prescribers do not have sufficient means to make informed decisions in this regard. Indeed, on the one hand, the pharmaceutical industry implements multiple strategies to develop and maintain markets for the drugs produced. On the other hand, demand is high among patients and society in general to have access to drugs to deal with health problems, in a context where drugs are seen as a preferred solution to the detriment of other therapeutic approaches.

Furthermore, the organizational context of medical practice in Québec's health and social services system does not appear to promote optimal drug use. The fee-for-service approach, the lack of interdisciplinarity and the low level of information technology uptake and use in the network – which would allow information sharing – as well as the limitations of publicly funded health care and services steer practice toward greater dependency on drugs.

Moreover, the growing complexity of the pharmacopoeia presents an additional challenge: the number of drugs available, diverse formulations and dosages, drug interactions, multiple treatment options for a single condition, etc. This situation is particularly problematic given the gaps in initial medical training in pharmacology, training that should allow physicians to critically evaluate data on drugs.

Furthermore, information about drugs comes from multiple sources, for many stakeholders with different interests contribute to it. Despite this abundance and increased access, the information available varies widely in terms of quality, is often incomplete or promotional in nature. Its format is often poorly adapted to clinical practice and difficult to use when time is short. Yet, to promote optimal use, prescribing should rely on objective, up-to-date information that is based on the best available evidence. Similar views were expressed by the members of the Commissioner's Consultation Forum.

What Consultation Forum members think

"The members think it is important that the attending physician be well informed about the therapeutic value of the drug he is prescribing."

"[…] the members believe the physician plays a key role in the information his patient is given about medication […] However, to give his patient the right information, the physician must have adequate documentation about the medication and it should not only come from the manufacturer."

"As for the prescribing physician, the members believe that he should have better access to information on the effects of drugs – so that he can show greater transparency towards his patient in this regard […]"

Report of the Consultation Forum's deliberations, March and June 2012 sessions.

Even with adequate initial and continuing education and appropriate clinical support tools, the clinician needs assistance and the expertise of all the health professionals concerned must be tapped. Indeed, with advances in pharmacology and the growing complexity of the health conditions treated, the prescriber, especially the general practitioner working in an ambulatory setting, is seeing an increase in the amount of information he must assimilate on pharmacology, a separate area of expertise. Responsibility for the management of patients with complex health problems must be shared in order to ensure continuity of care. To do so, all the professionals involved in the patient's treatment, including pharmacists, nurses, psychologists and physiotherapists, should have access to relevant clinical data. Professionals with the relevant expertise must all share responsibility; however, making interdisciplinary collaboration a reality in the health and social services system continues to be a challenge.

The definition of optimal drug use employed by the Commissioner includes the notion of a fair and reasonable allocation of resources in achieving the objectives of Québec's health and social services system. Giving the growth in drug use and spending, insofar

as the prescriber plays a key role in access to drugs, many stakeholders, including the members of the Commissioner's Consultation Forum, believe that it would be appropriate if prescribing practices were also guided by costs, for comparable benefits.

What Consultation Forum members think

"The members think […] that prescribers must be made aware of the costs and the appropriateness of drugs, on both the individual and the collective levels, and citizens must be informed directly about drugs and their real effectiveness."

"[…] physicians must be educated and made aware of the issue of drug costs. However, this issue raises ethical difficulties for some people […] a physician should not find himself refusing to prescribe a drug because of its cost […]"

Report of the Consultation Forum's deliberations, June 2012 session.

However, it is difficult for prescribers to integrate drug cost considerations into their practices, as they have very little information in this regard. Many people believe that prescribers are reluctant to consider drug costs in their decisions. This situation highlights the tension between the two roles that prescribers can play, that of "patient advocate", where they advocate for their patients' interests, and that of "gatekeeper", where they make sure that health resources are allocated reasonably. This difficulty is reported both in the international literature and in the Commissioner's consultations.

Lastly, better patient information would clearly contribute to better drug use, since patients are often the only ones who have all the information about their health and treatment. This situation is seen especially in people who have multiple chronic diseases or take multiple medications and is thought to be the result of a widely documented lack of continuity in the delivery of care and services in Québec. Intervention is often fragmented: several care providers may take over from one another for the same patient without, however, knowing the patient's health and treatment history. In this regard, a survey showed that 23% of Quebecers had not had their medications reviewed by a physician or a pharmacist in the year preceding data collection (CSBE, 2014c). Existing measures to inform the population about medication use, generally less diverse and more modest than those intended for prescribers, target certain categories of patients more frequently for whom compliance with treatment is considered essential to ensure safety and efficacy. The topic of drug information for patients was discussed several times by the members of the Commissioner's Consultation Forum.

What Consultation Forum members think

"[…] although people may be critical about their own use, they don't have the complete, valid and accessible information they would need to question it."

"[…] members point out how difficult it is for the consumer to make sense of the drug information available in pharmacies, mainly because of the confusion caused by using several names (scientific, generic, brand) for the same substance […]"

"Forum members believe that the patient's first duty concerning his treatment is to take his medication properly. Once this is done, however, they are quite clear: the extent of his responsibility depends on several factors. The information he has and the quality and validity of this information, his education, his level of literacy […] are all aspects that influence the patient's compliance with taking medication and the success of his treatment. The members insist on how important it is for the patient to be properly informed and made aware of the impacts of his medication choices […]"

"Several members also mention the lack of quality, validated and impartial information on drugs, since Internet is not a magic solution for finding reliable information, and suggest that this information should be provided by a government resource."

Report of the Consultation Forum's deliberations,
December 2011, March and June 2012 sessions.

The citizens surveyed by Léger Marketing on behalf of the Commissioner also gave their opinions on this subject.

The Commissioner's survey – Results for information and drug use

- 96% of respondents think that it would be helpful to inform and educate prescribers and raise their awareness in order to promote better drug use.

- 86% of respondents think that health professionals should be told how much the drugs they are prescribing cost.

- 94% of respondents think that informing citizens and raising their awareness would promote better drug use.

Source: CSBE and Léger, 2012.

Several stakeholders concerned by prescribing practices – i.e., prescribers, those who provide pharmacological management and patients themselves – have a role to play in promoting optimal drug use. This is why the Commissioner believes an action plan on prescribing practices and drug use that targets both prescribers and patients must be implemented, in addition to tapping the expertise of all the stakeholders concerned. The Commissioner also proposes improving the integration of pharmacists into primary care and introducing a standard discharge pharmaceutical care plan. Lastly, to promote access to drugs that can be prescribed by prescribers other than physicians and dentists, the Commissioner recommends simplifying the processes used to develop and update the formularies these professionals prescribe from.

3.1 Prescribing practices and drug use

Prescribers need different types of information to maximize the benefits of drug prescribing. This information may relate to the true clinical effectiveness of the drugs used, a complete description of the adverse effects as well as of all the drugs the patient is taking, the therapeutic options available or drug costs.

Pharmaceutical sales representatives are an important source of information for most prescribers. This source of information is welcome in a context where very little valid, up-to-date information tailored to each prescriber's practice is easily available. Although pharmaceutical representation is regulated, this source of information nonetheless continues to be criticized for its lack of impartiality and objectivity and its ability to influence prescribers in favour of corporate interests. In response to this criticism, a growing number of governments (including in Europe) have introduced academic detailing programs, where independent academic detailers meet with prescribers in person. While they seem relatively effective, these programs can, however, be expensive.

In addition to pharmaceutical sales representatives, other traditional sources of information inform the prescriber: scientific journals, prescribing guides and specialized websites. Participating in symposia, conferences and seminars of all kinds are also good opportunities for raising awareness among health professionals, especially if they are associated with continuing education credits. Moreover, some governments have introduced publicly funded continuing medical education programs. Health care institutions also organize scientific information sessions for their health professionals.

Many governments invest in the publication and distribution of newsletters on the evaluation of new drugs, factsheets comparing various therapeutic options, clinical practice guides and guidelines. In Québec, INESSS is responsible for this. Some governments fund technology initiatives such as putting drug comparison charts with comments online and the implementation of electronic prescribing tools (for example, care reminders, alerts, pharmaceutical advisors or e-prescribers).

Other governments have opted to send prescribers their personal prescribing profile to make them aware of the impact of their practices and to allow them to compare themselves with their peers. The acceptance and usefulness of this measure are better demonstrated when it is combined with a feedback activity on the information provided during a one-on-one meeting with an academic detailer. In Québec, the Fédération des médecins omnipraticiens du Québec (FMOQ) invites its members to consult, in strict confidentiality and on their own initiative, their prescribing profile which is prepared using data held by IMS Brogan. In the past, other initiatives to systematically send out prescribing profiles, including one undertaken by the Collège des médecins du Québec (Quebec College of Physicians), were more or less favourably received, since they were

seen as a potential control mechanism. Some groups consulted by the Commissioner believe that physicians would, however, be interested in knowing their prescribing profile and their average, in addition to being given feedback on their practice.

Moreover, the influence of peers or opinion leaders is a recognized strategy for communicating information effectively and some countries have opted to provide official peer group training to facilitate the distribution of medical and pharmaceutical reference material to physicians. This has been done in Belgium with its local medical evaluation groups (GLEM).

Available options

Apart from information about pharmacological content, costs are an additional aspect that can influence prescribing practices. For this reason, some governments, or other third party payer organizations, such as private insurance companies, have tried to raise prescribers' awareness of costs (see the description of the PCA program in the United Kingdom). While some of the strategies are solely intended to inform, others may be more coercive.

The United Kingdom's PCA program

In 1988, the United Kingdom established the PCA (Prescription Cost Analysis) program which, using nationally collated data, provides researchers, decision makers and prescribers with validated information on drug use in clinical practice. The information includes the type and number of prescriptions as well as the cost per prescribed drug, per drug class and per therapeutic area. The information is made available in the form of reports intended for different health system stakeholders, from practitioners to local and national health authorities. While the information was initially used mainly as a budget and financial management tool, it gradually came to be used to support research projects and the implementation, by both clinicians and health authorities, of strategies to improve drug use in clinical settings (Jones et al., 2002; Majeed, Evans and Head, 1997). This initiative gradually allowed the target groups to change the way they use drugs.

Experiences that have had the most success in influencing prescribing practices integrate several informational approaches. In this regard, experiences in British Columbia and Australia are worthy of mention.

The BC Therapeutics Initiative

Recognizing the need to provide physicians and pharmacists with up-to-date, evidence-based, practical information on prescription drug therapy, two departments at the University of British Columbia established the BC Therapeutics Initiative. This

independent organization is funded by the Ministry of Health through grants provided to the university. It brings together researchers and experts who analyze public clinical and research data or data produced by the pharmaceutical industry. The conclusions of their studies (pharmacoepidemiological, drug effectiveness in clinical settings, among others) are then disseminated to clinicians in various ways: bimonthly letter addressing pharmacotherapeutic issues, courses, seminars, podcasts, etc. (Therapeutics Initiative, website).

Australia's National Prescribing Service (NPS)

The NPS, an independent, government-funded not-for-profit organization was established in Australia in 1998. It provides decision makers, health professionals and the general public with evidence-based information on drugs, health problems and medical tests as well as practice support tools (NPS MedicineWise, website). Its initiatives target therapeutic areas known to be problematic (NPS MedicineWise, website; NPS, 2005; Phillips, 2002).

The NPS has implemented the following interventions for prescribers: the publication of practice guides and newsletters; the creation of continuing education workshops given by health professionals; an educational academic detailing program; clinical audits or self-assessments; prescriber feedback accompanied by educational messages; peer group meetings; case studies to facilitate problem-based learning. An educational program for graduating medical students disseminated using a Web platform was developed and is offered by most medical schools in the country.

At the same time, to raise citizens' awareness of the need for better medication use, initiatives such as training workshops given to seniors by peers, telephone drug information services, online support tools and educational campaigns were implemented (NPS MedicineWise, website; NPS, 2013 and 2005). A drug information telephone service for health professionals was also created.

In the first seven years of the NPS's existence, some 90% of general practitioners and 9% of pharmacists participated in at least one educational activity. Today, this organization is considered a valued and trusted source of reliable, independent information on drugs and therapies by the majority of general practitioners (84%) and the vast majority of pharmacists (97%). Furthermore, savings totalling an estimated AUS$235M have been generated for the national drug benefit program due to the changes in consumer behaviour that resulted from this transfer of knowledge (NPS, 2013; Beilby et al., 2006; NPS, 2005).

For their part, patients could benefit from information about drug effectiveness, drug-drug or drug-food interactions, treatment options, side effects, appropriate drug use or associated costs. Indeed, without accessible and understandable information, it is difficult for patients not only to make an informed decision about a drug therapy but also to comply with it properly. This information is especially important for patients facing challenges to optimal use, such as the elderly and people taking multiple drugs.

There are numerous patient information approaches. In Canada, as in other industrialized countries, social marketing campaigns have been held to promote better drug use. In Québec, among other initiatives, the MSSS invested in a campaign of this type, which was held from 2004 to 2008. The campaign is reported to have reached its target audience, its messages were clearly understood and the desired preventive behaviours were positively received (MSSS, 2010 and 2007b). Moreover, in Australia, an evaluation of public campaigns on antibiotic use showed that this strategy could be effective provided these campaigns were combined with other measures targeting different audiences (Wutzke et al., 2006). In addition to social marketing campaigns, the following strategies are widely used to raise awareness and inform the general public: websites; telephone lines to provide a personalized response to a citizen's specific need; leaflets and other documents in plain language; educational conferences for the general public; Web-based or computer applications.

With respect to patients, organizing motivational interviews between a health professional and a patient allows a personalized transfer of information and is a strategy that has had some success in encouraging the adoption of healthy or medically required behaviours (Guénette, Moisan and Guillaumie, 2010). However, like the actions undertaken with clinicians, the most effective interventions are often multifaceted, comprising professional education and regulatory measures, for example (Sketris, Ingram and Lummis, 2007).

A health education initiative for the elderly

The program "Les médicaments: Oui… Non… Mais!" [Drugs: yes... no... but!] was introduced by the Direction de santé publique de la Montérégie [Montérégie public health department] in collaboration with FADOQ to educate adults aged 55 and over about a number of common health problems, support them in adopting healthy behaviours and promote proper medication use. Support tools are provided and interactive group meetings led by a nurse and a peer are held to help participants gain the necessary skills.

An assessment carried out five years after the program was introduced showed, among other things, that participants felt more effective and were more positive about the role they could play in their health. They had also learned some health self-management and communication behaviours with the pharmacist. The program is now offered in health and social services centres (CSSSs) in other regions and territories (ASSS de la Montérégie, website; Moisan, 2006).

What the Commissioner recommends

Evaluation data on approaches designed to support prescribing practices and optimal use show that the most effective initiatives are multidimensional, such as the Australian NPS. Thus behaviour changes in all medication users must be supported. The Commissioner recommends adopting a provincial action plan on prescribing practices and drug use that includes information and educational interventions targeting both prescribers and patients.

The Commissioner recommends first putting a mechanism in place to produce regional and provincial overviews or portraits of prescribing practices in ambulatory settings. The distribution of these portraits could serve a number of purposes:

- provide up-to-date information on clinical practice and an opportunity to respond to it: meet emerging needs in the field, identify consumption patterns and anticipate potential problems in this regard (the risk of misuse, for example);
- provide references that can be used in clinical practice;
- identify prescribing trends more quickly and produce practice support tools that can meet clinicians' needs more quickly and accurately (reminders of recommendations or identification of therapeutic areas where generic drugs can be used);

- identify trends that might warrant further analysis and research to understand them better or their potential benefits or problems;
- provide citizens' with a simple document that is both informative and educational.

The portrait could include the following elements for each drug analyzed:

- the number of prescriptions;
- its characteristics (the drug's brand name, common name, therapeutic class and subclass, main recognized therapeutic indications, pharmaceutical form, amount of active ingredient);
- its unit price;
- the average price of all equivalent drugs (same pharmaceutical form and same amount of active ingredient) and the difference between the highest price and the lowest price for these drugs.

As administrator of the RGAM, RAMQ has a considerable amount of data on the prescriptions written for publicly insured users and the associated costs. Yet, even if it could be useful to many people, this information is difficult to access. This is why the Commissioner recommends that RAMQ publish this type of portrait on its website, using RPAM data. However, using RAMQ data to carry out analyses with the objective of optimizing overall drug use has its limitations. Indeed, the absence of information on clinical contexts or demographic factors limits the interpretation of the data used. Moreover, this data concerns only prescriptions written for users insured by the RPAM.

The Commissioner also recommends that RAMQ send personal prescribing profiles to all prescribers. These personal profiles, combined with the regional and provincial prescribing portraits, will raise prescribers' awareness about their prescribing practices and allow them to see how they compare with those of their peers. Regional and provincial portraits produced by RAMQ would highlight prescribing trends and identify which drug classes are involved in problems with prescribing and use. Personal prescribing profiles could then focus on these more problematic drug classes.

Personal prescribing profiles could contain information such as the type and number of prescriptions; costs per prescription, per drug class and per therapeutic area; generic drug prescribing rates; therapeutic recommendations for a change in medication in specific clinical situations or improvements in compliance with practice standards. Information about the cost of each drug prescribed would raise the prescriber's awareness of the impact his practices have on the availability of resources for other health priorities and in other fields. Moreover, a trial conducted in British Columbia to assess the impact of the distribution of individualized prescribing portraits on statin prescribing in the treatment of cardiovascular diseases showed that the savings produced by reducing the number of inappropriate prescriptions exceeded the cost of the initiative (Dormuth et al., 2012).

It is important to stress that the benefits of sending out personal prescribing profiles will be greater if they are accompanied by a feedback activity under the responsibility of entities respected by prescribers. To mobilize live forces in the field, the Commissioner recommends designating regional general medicine departments (RGMDs) and regional pharmaceutical services committees (CRSPs). Although prescribers have to be encouraged to attend these feedback activities by making them eligible for continuing education credits, they should be designed to improve quality and not as a strategy for controlling prescribing practices.

The Commissioner also believes it would be appropriate to initiate a reflection on improving the initial and continuing education of future physicians in pharmacology, particularly general practitioners, whose scope of practice means they use a great number of drugs. Since drugs are the mainstay of therapy, the Commissioner believes future physicians must be better informed about various aspects of pharmacology, better supported in developing their ability to critically evaluate the pharmacopoeia and thus better equipped to promote optimal drug use.

Lastly, in order to maximize the potential benefits of the different initiatives, the Commissioner recommends that information activities in his action plan target patients. These individual or group activities should be offered to patient groups with complex health problems or problems with compliance.

Recommendation to the Minister of Health and Social Services

5. Adopt a provincial action plan on prescribing practices and drug use.

In particular, the provincial action plan should include:

- the annual publication of a regional and provincial portrait of prescribing trends and costs based on RAMQ data;
- the distribution, on a quarterly basis, of a personal prescribing profile to each prescriber;
- the organization of feedback activities on prescribing trends that can be used to earn continuing education credits;
- the improvement of initial and continuing medical education in pharmacology;
- the provision of support for educational initiatives on healthy lifestyle behaviours, medication and compliance with treatment for specific patient groups.

3.2 The role of pharmacists in primary care

Monitoring medication therapy is the legal responsibility of the pharmacist (OPQ, 2009). According to OPQ, monitoring allows the pharmacist to assess the safety and efficacy of medication therapy, ensure the medication is appropriate and effectively meets the patient's clinical needs and therapeutic objectives, prevent/detect/manage adverse effects and drug interactions and check the patient's compliance with treatment (OPQ, 2009). In Québec, the practice of pharmacists varies depending on their area of responsibility and the practice setting. There are community pharmacists in private practice, who may be employed or pharmacy owners (independent or affiliated with pharmacy chains or banners), and who work in ambulatory settings, and there are pharmacists who work in hospitals. The practice of pharmacists in ambulatory settings differs from that of hospital pharmacists.

Although the pharmacist's role is officially known, he does not always exercise it to its full extent, especially in ambulatory settings. Even in hospital settings, mainly due to the absence of adequate care coordination mechanisms, medication therapy is sometimes not monitored adequately, as indicated in the report of the Auditor General of Québec (AGQ) for 2014. This situation arises despite the pharmacist's inclusion on interdisciplinary teams. For example, a recent report of the Canadian Society of Hospital Pharmacists (CSHP) showed that in Québec, medication therapy management for patients with complex health needs is inadequate: it is provided only in around 75% of institutions (CSHP, 2013). For patients who have been discharged from hospital, it is basically not provided at all. Furthermore, communication between health professionals in the community and between institutions occurs in less than 25% of institutions (CSHP, 2013). The provision of pharmaceutical care and services needs to be reviewed, both in ambulatory settings and in health care institutions.

The pharmacist's expertise is underused in the clinical care of patients, whereas the demographic and epidemiological context makes utilizing pharmacists' expertise imperative (Bernsten et al., 2009; Ordre national des pharmaciens, 2008). Furthermore, the care and services organization model does not promote increased pharmacist involvement. Indeed, while pharmacists would need to be allowed to provide more clinical services, their increasing administrative obligations act as a brake to this extended role. Furthermore, remuneration models do not always facilitate interdisciplinary work.

The need to promote the value of and expand the pharmacist's role is recognized in many countries (WHO and FIP, 2006). In Québec, the adoption of the *Act amending the Professional Code and other legislative provisions as regards the health sector* (Bill 90) introduced increased interdisciplinary collaboration in health care, the use of collective prescriptions in ambulatory settings and the possibility for pharmacists to prescribe emergency oral contraception. Moreover, the *Act to amend the Pharmacy Act* (Bill 41) would, if it were fully applied, expand the pharmacist's role, for example, to include the prescription of medications in specific cases and the adjustment of a physician's

prescription (for more details, see the document *Les médicaments d'ordonnance: état de la situation au Québec*). The regulations associated with this Act have not yet been updated (Québec, 2013) and the fees for some services pharmacists may provide are still under negotiation. Under Bill 28, which aims at a return to a balanced budget, pharmacists may claim fees for three of these services.

The importance of expanding the pharmacist's role is also stressed for other reasons. For example, a panel of experts mandated by the MSSS in 2013 to assess drug-related incidents and accidents made a certain number of recommendations, including the direct participation of pharmacists in interdisciplinary teams working with at-risk populations (MSSS, 2014). Lastly, Québec's Impact Pharmacie website project, developed by Sainte-Justine UHC and partly funded by the MSSS, collects international experiences, studies and data on the roles and responsibilities of pharmacists to raise awareness about the estimated impact of their contribution to health care and services (Impact Pharmacie, website).

The Commissioner's survey – Results for the role played by prescribers and pharmacists

According to the Léger survey, respondents believe prescribers and pharmacists play an important role in drug prescribing and use. Ninety-seven percent (97%) of respondents believe the prescriber's role is very important, while 93% believe the pharmacist's role is very important. Furthermore, health professionals (especially prescribers and pharmacists) are the main source of information about medication for 89% of respondents.

Source: CSBE and Léger, 2012.

Consultation Forum members also gave their opinion on the role of pharmacists in primary care.

What Consultation Forum members think

"[…] the pharmacist's role needs to be valued more highly. […] in private practice, the latter, who has to combine a business activity with his scientific expertise, acts more as an adviser than a health professional at the moment. […] the pharmacist could, by working with the prescribing physician in a joint intervention with patients and users, ensure more appropriate prescribing for the diagnosis, help reduce overuse and the associated costs."

"[the members] believe we must […] value the role more highly and extend the mandates of community pharmacists by giving them incentives […]"

Report of the Consultation Forum's deliberations, June and November 2012 sessions.

Many people ask that pharmaceutical services be centred on meeting patient health and information needs instead of drug dispensing and its technical aspects alone. Indeed, the literature indicates that patient-centred pharmaceutical services can be associated with improved health and quality of life in patients, a reduction in medicine-related adverse events and reduced morbidity and mortality. They also seem to have a positive impact on a health system's economic outcomes (WHO and FIP, 2006).

Available options

The pharmacist's increased clinical intervention may take various forms depending on the needs of the setting.

A wider range of clinical services provided by the pharmacist

In 1986, an exhaustive study commissioned by the health authorities in the United Kingdom highlighted the importance of further extending and structuring clinical pharmaceutical services in primary care. This study paved the way for revising the community pharmacist's role (Harding and Taylor, 1997). More recently, the Department of Health in the United Kingdom once again examined the issue of increasing the community pharmacist's involvement in the continuum of care for patients with complex health needs, in addition to extending their scope of practice for this purpose (Department of Health, 2008).

The services provided by community pharmacists in the United Kingdom

Since 2005, community pharmacists in the United Kingdom can provide three levels of services:

- essential: fill a prescription, provide healthy lifestyle advice, refer the patient to other health services, provide support for self-care, dispose of expired or unused medications;

- advanced: review medication, intervene to ensure appropriate use and compliance with treatment, recommend changes in a patient's medication to the general practitioner;

- enhanced (based on local needs): administer drugs under supervision, support smoking cessation, prescribe emergency hormonal contraception using collective prescriptions, treat minor ailments, provide needle exchange, provide out-of-hours services.

British pharmacists can also decide to provide other services that are not publicly funded, such as diagnostic tests, home visits or home delivery. They can also have several functions: consultant pharmacist with expertise in a specialty (such as oncology), who supports pharmacists and other health professionals; specialized clinical pharmacist with special interests (such as anticoagulant therapy); prescribing adviser for prescribers; pharmacist prescriber (Bush, Langley and Wilson, 2009).

In many countries, community pharmacists have seen their range of ad hoc clinical activities expanded in recent years (for those introduced in Canada, see Appendix II). One of these activities is medication review for specific patient groups, such as the elderly or those with multiple health problems.

Ontario's MedsCheck medication review program

Following the adoption of the *Transparent Drug System for Patients Act* in 2006, MedsCheck was launched and is one of the services that has been funded under the Ontario Drug Benefit Program since 2007. The service is provided by community pharmacists in ambulatory settings to patients with a complex medication profile (for example, someone who is taking three or more medications for one or more chronic conditions). Through one-on-one meetings (usually annual), the pharmacist reviews and assesses patient's health and medication profiles and then makes recommendations for medication and lifestyle changes as well as actions to optimize their compliance with treatment (Ministry of Health and Long-Term Care, website-a and 2008). The program is currently under review. It should be noted that most Canadian provinces now have a similar program, as do a number of industrialized countries.

Other activities added to the pharmacist's range of services are more informative and educational and are intended to help patients adopt healthy lifestyle behaviours or support their compliance with treatment or management of their health condition (Mossialos, Naci and Courtin, 2013; Van Wijk et al., 2005). Sometimes, the pharmacist plays the role of coordinator to ensure better continuity of care for patients with complex health needs. Some governments have expanded pharmacists' role by giving them the right to prescribe: Florida was one of the first to do so (Emmerton et al., 2005). Thus some pharmacists are dependent prescribers, i.e., the act of prescribing is delegated by an independent prescriber and is done in accordance with detailed predetermined protocols. Other pharmacists are independent prescribers: after a clinical assessment of the patient, they can select the appropriate medication therapy and are responsible for its management. They can exercise this right in specific situations or they must prescribe from a predetermined list of drugs or drug classes.

Expanding the range of services provided by pharmacists on an ad hoc basis without any overall planning can have some positive impact on the quality of patient care, quality of life or health, but it remains limited. Even in some settings, where pharmacists have been called on to participate in implementing interdisciplinary and multifaceted

interventions, the impact of these interventions has varied. Moreover, it is difficult to determine which interventions have the most positive impact and to isolate the impact of the intervention of a professional who is working as part of an interdisciplinary team.

The pharmacist's participation in providing follow-up for patients with complex conditions

Modelled on what is done in hospitals, where the pharmacist works closely with other health professionals, a number of approaches designed to integrate pharmacists into interdisciplinary teams responsible for managing patients in the community have been developed. One of these is the medication therapy management (MTM) model. This model, implemented in 2006 by the American Pharmacists Association (APhA) and the National Association of Chain Drug Stores (NACDS), has gradually been adopted by many governments, local or regional health care organizations and insurance plans (including Medicare and Medicaid). Although it can be adapted to the clinical context it is used in, the model promotes interprofessional collaboration centred on the patient with complex medication therapy. The model allows each team member to use his knowledge and expertise to meet the patient's needs and optimize his medication therapy (use of the appropriate medication, reduction in adverse events, etc.). The pharmacist's participation is vital and the patient support he provides includes information, counselling, education and support regarding his medication. His commitment to the prescriber means that he keeps him informed and supports him in his follow-up of the patient and in resolving any problems that might arise during therapy (McGrath et al., 2010; APhA and NACDS, 2008; McGivney et al., 2007; APhA and NACDS, 2005).

The results of assessments of some of the programs implemented show that pharmacists' interventions frequently lead to the detection of medication-related problems, problems that can then be resolved quickly. Furthermore, pharmaceutical interventions to improve patient compliance with therapy and the effectiveness of therapy (based on costs) are particularly common (de Oliveira, Brummel and Miller, 2010).

Another approach relies on integrating pharmacists into FMGs that are comparable to the FMGs in Québec in some countries, such as the United Kingdom and Australia, and in some Canadian provinces. In Ontario, pharmacists are now part of some FMGs to optimize medication and reduce medication therapy problems in patients followed in clinic. A pharmacist's contribution to this type of team is diverse: review medication and detect medication-related problems, promote patient adherence to therapy, inform prescribers about medication therapy options or make recommendations to them, etc.

The TEAM study: a Québec study of physician-pharmacist collaborative care

The TEAM research study was implemented to provide physician-pharmacist collaborative services. The services were described in a protocol given to patients with dyslipidemia (abnormal levels of lipids in the blood) who were treated in an ambulatory setting. When the physician prescribed a drug from the statins class, he included relevant clinical information about the patient (such as laboratory results) for the pharmacist in the prescription. During an initial meeting, the pharmacist provided the patient with counselling about treatment and the patient participated in developing his treatment plan. The pharmacist then followed the patient until lipid test results showed that target levels had been achieved. During the follow-up, the pharmacist assessed the patient's tolerance of and adherence to drug therapy and adjusted the statin dosage if necessary. After each consultation, the pharmacist sent the physician any relevant information about the patient's follow-up. One year after the project's inception, more patients were initially given a prescription for a lower potency statin and had fewer laboratory tests ordered, achieved their target lipid levels, made lifestyle changes (ACCP, 2013; Lalonde et al., 2011; Villeneuve et al., 2010; Équipe de recherche en soins de première ligne du CSSS de Laval, 2008; Villeneuve et al., 2007).

Montreal's pharmaceutical model

To promote improved collaboration and coordination between hospital and community pharmacists, the Agence de la santé et des services sociaux (ASSS) de Montréal adopted a model in recent years to integrate pharmaceutical services into primary care throughout the Montreal area. In this model, pharmacists fulfil the following responsibilities:

- **a pharmacist coordinator** at the ASSS supports the implementation of the proposed model;
- **a network pharmacist** establishes, in each CSSS, intra- and interprofessional lines of communication, aligns the pharmaceutical services offered in the local services network (RLS) with general CSSS programs (such as home support) and develops a continuum of pharmaceutical services between health care settings;
- **a clinical pharmacist** associated with the CSSS works in integrated network clinics (CRIs) or FMGs. He provides clinical services, assists interdisciplinary teams (for example by reviewing patients' medication records) and acts as a liaison with patients' community pharmacists;
- **the community pharmacist** acts as liaison with primary care, for example by being more involved in the patient's treatment plan or by exchanging information about patients.

Since this model was adopted, local pharmaceutical services tables have been established in most of Montreal's CSSS territories. These tables are predominantly comprised of community pharmacists, clinical pharmacists working in CRIs or FMGs, clinical hospital pharmacists, CSSS program managers, physicians, specialized nurse practitioners (SNPs) and clinical nurses. Their objective is to promote information sharing and discussion on issues affecting the CSSS territory and to allow collaboration between the stakeholders concerned (ASSS de Montréal, 2013; Tassé, 2013; ASSS de Montréal, 2010).

In short, comprehensive, multifaceted interventions centred on both patients and prescribers and carried out by pharmacists working closely with prescribers and health care teams demonstrate the potential for significant impact on health outcomes, while contributing to continuity of care.

What the Commissioner recommends

In light of the literature review, international experiences and the consultations held, the Commissioner considers that the integration of the pharmacist's expertise into the clinical care provided by primary care teams in the network must be improved. Indeed, the provision of care in ambulatory settings to patients with complex health needs, whose drug therapy needs to be closely managed and monitored, makes it imperative.

In some regions of Québec, a few FMGs already have a pharmacist (usually a hospital pharmacist) on their team. This pharmacist participates in interdisciplinary case discussion meetings and contributes to the management of specific patient groups, such as people who receive home support, the elderly, patients on anticoagulant therapy or patients with chronic obstructive pulmonary disease (COPD) or other chronic diseases. He can provide more extensive services based on the needs identified.

However, standardizing the integration of pharmacists into FMGs presents a number of challenges with respect to the availability of trained resources. Ideally, hospital pharmacists interested in this type of practice should be integrated into FMGs. These pharmacists are already employed by CSSSs and are therefore accountable to the CPDP. They are not only required to respect the procedures and protocols used at the CSSS, but they are also familiar with the care, services and programs deployed by the CSSS and available in the local services network (RLS). Moreover, the education that hospital pharmacists receive gives them the competencies they need to work in clinical settings, since they usually have a master's degree in pharmaceutical care. In regions where fewer pharmacists have the necessary training to practice in hospital settings, there should be some flexibility when recruiting pharmacists to work in FMGs. Should it prove impossible to deploy hospital pharmacists in FMGs, an appropriate mechanism should be created to allow community pharmacists to become members of the CPDP of the CSSS.

To ensure effective interdisciplinary collaboration within teams, a number of elements must be considered, Firstly, mechanisms must be implemented to allow the pharmacist to access and enter relevant clinical data about the patient, such as laboratory results, medication history, diagnosis, treatment goal, medical history, health goals or therapeutic targets (CSHP, 2009). Furthermore, the pharmacist must be able to communicate effectively with other health professionals involved in the patient's care. This is facilitated by information technology. An agreement between the professionals concerned as to the nature of the information to be communicated would make communication more effective.

Secondly, consideration must be given to implementing regional and territorial support mechanisms, for example by deploying or extending local and regional interdisciplinary tables, the presence of pharmacist coordinators and network pharmacists in CSSSs and ASSSs and by implementing effective communication mechanisms in the local services network (RLS).

Thirdly, organizational conditions to support interdisciplinary work and the integration of pharmacists with clinical expertise into FMGs are necessary. These conditions relate to the financial support mechanisms for FMGs and remuneration methods for clinical pharmacists. Also, continuing education for professionals should be adjusted to these new realities.

Lastly, pharmacists must be able to rely on more support, both administrative and clinical, so that they can delegate some tasks and free themselves up to provide clinical services that require them to spend more time with patients.

Some of the factors that facilitate the gradual implementation of a pharmacy practice in FMGs, include the following: the legal recognition of CRSPs, which recommend mechanisms to optimize regional pharmaceutical services; the existence of FMGs in several regions of Québec that already have close ties with a CSSS, for example FMGs in family medicine units or in local community services centres (CLSCs). Other factors could support this type of practice, for example the identification, on a provincial level, of the basic pharmaceutical services that pharmacists would provide in FMGs. The services provided should, however, be tailored to regional population needs. It would also be valuable to continue to reflect on what type of training would be necessary to ensure the practice of pharmacy in primary care.

Recommendation to the Minister of Health and Social Services

6. Integrate clinical pharmacists into health care teams in FMGs.

3.3 The transfer of pharmacological information at patient discharge from hospital

Most adverse drug events (inappropriate prescription, drug interaction, etc.) occur at patient admission, transfer (change in department or health professional) or discharge from hospital, for these are stages where there is a higher risk of discontinuity of care. The phenomenon of polypharmacy is especially prevalent in elderly people who have been discharged from hospital and those followed in the community (for further details, see *Les médicaments d'ordonnance: état de la situation au Québec*). Thus monitoring the medication therapy of inpatients with complex health needs could be improved with respect to continuity of care during transitions (OPQ, 2013; CSHP, 2009).

The transfer of relevant information about the patient's condition and medication is crucial during care transitions. This transfer is often ineffective, sometimes completely lacking, which further hinders the coordination of care. Furthermore, this transfer of clinical information is often more challenging when patients have complex health needs, with multiple health professionals involved and a complex drug regimen (Picton and Wright, 2012). A number of factors interfere with the effective transfer of clinical information. On the one hand, relationships between hospital and ambulatory settings are usually tenuous and communication mechanisms lacking. On the other hand, the inadequate uptake and use of information technology in Québec's health and social services network, especially in ambulatory settings, creates a barrier to clinical data sharing between professionals. While community pharmacies use IT systems, more extensive uptake of IT systems in medical clinics has been slow despite the advances of recent years.

In Québec, considerable efforts have been made to improve the safety and continuity of pharmaceutical care between care episodes, in particular by introducing medication reconciliation (MR). This is in fact required by the accreditation process for health care institutions and, from now on, all health care institutions in Québec must be accredited by a recognized agency. The use of MR is increasingly recognized as a strategy to prevent or minimize the impact of gaps in services for patients on drug therapy. Evidence tends to show that the pharmacist, with his knowledge and expertise, is best placed to perform medication reconciliation and to do so when the patient first arrives in the hospital (ACCP, 2013; Group de travail sur le BCM de l'APES, 2009). Pharmaceutical resources in hospitals – which are sometimes limited in certain regions – are therefore heavily solicited to participate in this task, for coordination of the activity is usually the responsibility of the pharmacy department. While some institutions have introduced this tool, the situation varies across regions and institutions. The status of information technology uptake and use in the health and social services network, among other things, makes the introduction of MR more complex.

Information about medications is usually collected and reconciled when the patient is admitted to hospital. At this stage, the community pharmacist may be asked to provide his patient's medication record, an activity for which he receives payment if the request is made by emergency room staff. The transfer of information regarding the patient's medication profile when he leaves hospital is, however, difficult. Therefore, when a patient is discharged, he is often given a new prescription, without any particular indications, to give to his community pharmacist. Yet, patients are not always able to understand, remember and give clinicians all the relevant information about their condition and their treatment, especially when they have multiple health problems and multiple medications to manage. This makes it difficult for the pharmacist to make informed decisions about the new medications prescribed and their compatibility with the patient's medication profile, for example. It is also complex for the pharmacist to monitor his patient's drug therapy properly.

Available options

Although in hospitals the pharmacist's work is already integrated into that of health care teams, many people maintain that more intense pharmacist intervention is required (OPQ, 2013; CSHP, 2009). Some people believe the pharmacist should be involved at every stage of the care pathway of a patient with complex health needs, from admission to discharge, and be responsible for managing his entire drug therapy. Others believe he should at least monitor complex drug therapy more closely for the duration of the patient's hospitalization (Rennke et al., 2013; American College of Clinical Pharmacy et al., 2012; Mayer and Bussières, 2011). Thus there are diverse visions of the extent of the pharmacist's involvement in the continuum of clinical care. The CSHP defines monitoring drug therapy as the "ongoing monitoring of the whole patient, reviewing pertinent patient data, speaking with other caregivers and/or the patient, and evaluating patient response to therapy", whereas managing medication therapy encompasses a broad range of professional activities and responsibilities that allow the pharmacist to provide more comprehensive drug therapy management (including, for example, selecting, initiating, modifying, or administering medication therapy, performing a comprehensive medication review and coordinating medication therapy management services) (CSHP, 2009, p. 9).

A pharmacist-physician collaboration at Hôpital Brome-Missisquoi-Perkins

In 2010-2011, the Hôpital Brome-Missisquoi-Perkins implemented a project to create teams consisting of a family physician and a hospital pharmacist at a time when the hospital was facing a problem of a shortage of pharmacists. The objectives were to optimize pharmaceutical care by improving the allocation of resources, improve the pharmacist's knowledge of the patient's health and the physician's treatment goals as well as raise the patient's awareness of the importance of the pharmacist's role in working with him. When the patient arrived at the emergency room, a medication record request was sent to the patient's community pharmacy. In light of this record, after a discussion between the physician and the pharmacist, the two professionals met with the patient and initiated his management together. While the former conducted the physical examination, the latter focused on the drug therapy history using a tool designed for this purpose. The health professionals held a second meeting to discuss the treatment plan and medication-related issues. The pharmacist was then involved at every stage of the case on a daily basis in collaboration with the physician and the health care team. At discharge, the pharmacist participated in writing the prescription and informed care providers in the community about all the medications the patient would have to take from that point on. Thus the community pharmacist received the patient's complete up-to-date medication profile as well as additional patient data (laboratory results, allergies, etc.). The hospital pharmacist acted as a liaison with the community pharmacist. The patient was counselled by the hospital pharmacist. The community prescriber also received the patient's updated medication profile along with follow-up recommendations (St-Amand and Dupont, 2013).

Several options exist to promote continuity of care: implement continuums of care between hospital and community settings, develop clear protocols to define each stage of patient care and the specific role of every care provider involved or ensure there is a dedicated transition provider to ensure continuity between the patient and his care setting outside the hospital. Tools and procedures to support follow-up between episodes of care also exist. Thus, some physicians send a patient's hospital discharge summary to their ambulatory care colleagues, while liaison nurses in hospital centres are responsible for transferring information for patients who receive home support from a CSSS or who live in a residential and long-term care centre (CHSLD).

A care transition model for patients with complex health needs: the RED model

Initially implemented by the Boston Medical Center, the RED (Re-Engineered Discharge) model was designed to facilitate the care transition of patients after their discharge from hospital. A nurse case manager prepares the transition to community care: she reviews the patient's record, prepares or updates the list of medications to take, informs the patient about his condition, helps arrange follow-up appointments, acts as a liaison with the family physician, etc. To prevent hospital readmissions and emergency room visits, a number of medication-related interventions are performed: the list of medications is confirmed, the prescriptions are checked to make sure they are appropriate for the main admission diagnosis and the patient's health information, the list of medications taken before and after hospitalization is reconciled, this list is reviewed in detail with the patient to explain it to him and assess his understanding, etc. This is often done in collaboration with the pharmacist. A copy of the hospital discharge plan is sent to the main care providers who will be following the patient in the community. This plan includes the diagnosis, the care provided in hospital and the reconciled medication list. A few days after discharge, a hospital pharmacist contacts the patient to make sure the medication is being monitored properly and is not causing any adverse effects or problems, in addition to providing reinforcement if necessary. He then follows up with the family physician and nurse case manager. An evaluation of the project showed that the medication-related interventions had prevented medication-related problems or complications and reduced potential hospital admissions (Project RED, website; Rennke et al., 2013; American College of Clinical Pharmacy et al., 2012; Jack and Bickmore, 2011; Jack et al., 2009).

What the Commissioner recommends

The Commissioner believes that a standardized discharge pharmaceutical care plan (including MR) should be developed and implemented in all hospitals in Québec. This plan would facilitate the transfer of relevant pharmacological information between hospital and community settings and ensure continuous and safer follow-up for patients with complex health needs and a high risk of adverse events. The hospital pharmacist would be responsible for preparing the plan, although he would do so in collaboration with prescribers. The hospital pharmacist would make sure that the new drugs prescribed are entered in the plan along with any relevant information so that the community pharmacist is able to understand and monitor the patient's new medication profile. When the patient is discharged, the document would be sent directly to the patient's community pharmacist and family physician.

Proposed content of the discharge pharmaceutical plan

The pharmaceutical care plan could include the following:

- a section with diverse patient health information and clinical data, such as weight, allergies, drug intolerances, the problem or diagnosis at admission and relevant laboratory results;
- a section on medication that includes the medication history and admission orders, discharge orders and reasons for treatment, medications to be continued, adjusted and discontinued and the reasons for doing so;
- an individualized section with recommendations for therapeutic targets, monitoring or follow-up in the ambulatory setting.

The name of the hospital pharmacist who prepared the document would also be noted. He would then act as the reference professional for the community pharmacist. A summary version of the document, along with relevant information to promote understanding of and compliance with treatment (the main adverse effects, contraindications, etc.), would be given to the patient and explained to him.

The effective implementation and transmission of a pharmaceutical care plan would require a hospital pharmacist to be available, the identification of patients who would benefit from this type of service and improvements in communication methods between hospital and community settings. The considerable administrative burden and the current shortage of hospital pharmacists are obstacles to implementing this type of measure. Indeed, the shortage is already affecting drug distribution and the response to consultation requests from physicians. This has resulted in the removal of some pharmacists from health care teams, patient care units and clinical programs (Bussières and Tanguay, 2013; APES, 2012). It is important to take hospital pharmacists' workload into account and to free them up from more technical and administrative services (for example, data collection and entry into the computer system) to allow them to contribute to ensuring continuity of care for patients with complex health needs. Technical and administrative support is therefore crucial.

Moreover, in order to prepare a discharge pharmaceutical care plan for patients with complex health needs, hospitals will need a tool to identify these patients (Bayley et al., 2007). Clear identification criteria must be determined, some of which will have to be provincial to ensure a certain uniformity in supply. However, these criteria must be able to adapt to the context and hospitals must be able to add to them to meet the needs of the population being served. The hospital must also implement a mechanism to ensure the names of the patients identified are relayed quickly and effectively to the pharmacy department.

The electronic medical record systems that have been implemented in health care institutions and which include a specific pharmacy component are usually able to generate pharmaceutical care plans, at least a generic version that can be adapted if necessary. Thus some hospitals in Québec have integrated the preparation of discharge pharmaceutical care plans into their practices for some groups of patients. If necessary, providers may be asked to integrate a pharmaceutical care plan model into the existing software. The hospital pharmacist must be able to access all the necessary information in the patient's medical record.

Lastly, it is important to ensure a two-way communication mechanism is put in place between hospital and ambulatory settings. In this regard, electronic prescriptions are an asset, but in addition to technological considerations, introducing this type of mechanism may require the involvement of the administrative centre of the CSSS or ASSS, as well as that of pharmacy director tables in CSSSs and regional departments of general medicine (RDGMs). The complete deployment of the Québec Health Record should support this process and allow the relevant clinical data that community health care providers require to work with their patients to be transmitted. It should be noted that legislative provisions apply in Québec's case with respect to confidentiality and the transfer of patient information between health care providers, making data transmission somewhat cumbersome.

Recommendation to the Minister of Health and Social Services

7. Implement a standard discharge pharmaceutical care plan to facilitate the transfer of information from the hospital pharmacist to the community pharmacist and attending physician.

3.4 Prescribing by specialized nurse practitioners, midwives, optometrists and podiatrists

Prescribing medications is an activity reserved to certain health professionals. In Québec, only physicians and dentists may independently prescribe[3] all the medications on provincial lists (RGAM and institutions) following a diagnosis or assessment in accordance with their competence and expertise. Other professionals, in addition to pharmacists, discussed in the previous section, are also authorized to prescribe independently from a restricted list of drugs or drug classes determined by regulation under certain conditions. They are specialized nurse practitioners (SNPs), midwives, optometrists and podiatrists.

The lists that midwives, optometrists and podiatrists can prescribe from are determined by collaboration between various stakeholders following a complex and protracted regulatory process (Québec, 1986 and 1973a). The Office des professions du Québec is mandated to develop and update these lists, in the interests of public protection, in keeping with the actual evolution of the profession concerned. To fulfil this mandate, the Office consults various stakeholders: INESSS, OPQ, the Collège des médecins du Québec and the professional orders concerned by the regulation.

The list that SNPs in primary care can prescribe from is an appendix to a regulation associated with the *Medical Act* (Québec, 1973b). Updates to this appendix must first be approved by the Collège des médecins du Québec. As in the case of the lists for the prescribers mentioned previously, this is followed by several stages of approval (Durand, 2013; Québec, 1986 and 1973a). The prescribing practice of SNPs in hospital settings (neonatology, nephrology and cardiology) is primarily regulated by the rules for drug use in effect in the hospital centres they practice in.

Depending on the type of professionals concerned, the format of the list varies. Podiatrists, nurse practitioners specializing in neonatology, cardiology and nephrology as well as midwives each have access to a list containing only the drugs they are authorized to prescribe. Nurse practitioners specializing in primary care and optometrists with the required permit prescribe from a list drawn up by drug class. According to the stakeholders consulted, the right of these professionals to prescribe is hindered by a number of constraints caused by the complex nature of the development, approval and updating processes for their respective lists:

- it takes a long time (sometimes years) for the initial version of the lists to be approved;

[3] There are also dependent prescribers, who are authorized to prescribe in collaboration with an independent prescriber and are usually required to use protocols, lists or other similar tools, such as collective prescriptions. This recommendation does not concern dependent prescribers.

- they are very often limited, that is, they allow neither the needs of the patient group concerned to be properly met, nor an equivalent drug to be prescribed if a drug is out of stock, discontinued or if provincial lists of medications have been modified;

- they quickly become outdated, often even before the initial approval process has been completed, if we consider the rate at which drug therapy and clinical practice are evolving;

- they are not updated regularly, for there is no provision for a clear revision schedule. Since it can take nearly two years to obtain approval for a revision, some professional orders have to negotiate administrative agreements with orders of medical prescribers to prescribe new medications considered indispensable.

Consequently, the professionnels concerned cannot fulfil their role in an optimal manner. This situation means that patients face additional delays in obtaining care that is not always appropriate for their clinical condition, which is an issue of equitable access and choice of care provider. It also generates additional costs for the health and social services system due, for example, to the duplication of services provided. Furthermore, this situation runs counter to interdisciplinary collaboration between health professionals, a known performance improvement lever, as well as the proper use of physicians' time and expertise.

To improve performance, the system would thus benefit from less complicated development, approval and updating processes for the lists of medications governing prescribing practice. While some people may express concern about potential misuse, the Commissioner believes that the regulations governing professional practice in Québec, including the codes of ethics of professional orders, offer a guarantee in this regard insofar as professionals are obliged to act within their area of expertise.

Available options

In some industrialized countries (the Netherlands, Finland and New Zealand, for example), the authority of non-medical prescribers to prescribe has changed very little over time: it remains restricted to specific fields of practice, limited formularies or protocols. However, faced with problems in access to care, some countries evaluated the value of advancing prescribing practice and have acted accordingly, in particular with the advent of nurse practitioners (Kroezen et al., 2012; Kroezen et al., 2011). This is the case of the United Kingdom, which is now one of the countries that grants the most prescribing privileges to these professionals, despite not giving them the legal authority to prescribe until the turn of the 21st century. Other countries or provinces, such as Ontario, plan to simplify development, approval and updating processes for their designated drug lists.

The granting of authority to non-medical prescribers to prescribe from the British National Formulary in the United Kingdom

In 2001-2002, in the United Kingdom, legislation expanded nurse prescribing with the addition of a limited formulary; this was followed by the introduction of supplementary prescribing in partnership with an independent prescriber. An evaluation conducted in 2005 on behalf of the Department of Health showed that the existing prescribing framework imposed significant limitations on their practice, for instance, because the formulary contained a limited number of drugs from drug classes routinely used in practice (for example, antibiotics). Furthermore, updating the formulary was an intensive process with changes sometimes taking nearly two years to put into effect (Department of Health, 2006; Latter et al., 2005). In 2006-2007, pharmacists, nurses and midwives could qualify as independent prescribers: they were authorized to prescribe from the British National Formulary (Hacking and Taylor, 2010). The United Kingdom now has three types of non-medical prescribers:

- **community practitioners** (nurses or midwives) can prescribe appliances, dressings and medicines listed in an appendix to the national formulary;

- **supplementary prescribers** (nurses, midwives, pharmacists, chiropodists, podiatrists, physiotherapists, radiographers and optometrists) can prescribe in partnership with an independent prescriber (doctor or dentist), who is responsible for the initial diagnosis. They can prescribe any medicine named on the clinical management plan of the patients they are following together;

- **independent prescribers** (nurses, midwives, pharmacists, optometrists, physiotherapists and podiatrists) can prescribe from the national formulary, with some restrictions, where clinically appropriate (Department of Health – Social Services and Public Safety, website; Department of Health, website). Like doctors or dentists, other independent prescribers must only prescribe within their area of competence and expertise. They are responsible for the clinical decisions taken and patient interventions. They are responsible for the assessment of patients with diagnosed or undiagnosed conditions, for establishing a diagnosis and for decisions about the clinical management required for these patients (NTA and NHS, 2007).

Simplification of development, approval and updating processes for designated drug lists in Ontario

To better meet its population's health needs, several years ago Ontario decided to allow non-physician professionals to prescribe drugs from designated drug lists. While the regulatory framework provides for mechanisms specific to each profession, in recent years these prescribers have reported the restrictions they faced in their prescribing practice.

The Health Professions Regulatory Advisory Council, an independent agency created to provide advice to Ontario's Ministry of Health, considered that the existing development, approval and updating process was protracted and hindered the use of less expensive innovative medications, while also interfering with interdisciplinary collaboration in clinical practice in accordance with current standards. This situation put the population being served at risk. The Council then made the following recommendations:

- the process for approving designated drug lists for non-physician prescribers must be examined, must be more rigorous and efficient, must engage experts in pharmacology, representatives of the professional order concerned and representatives of various professions;

- these lists must be developed by class instead of by drug, as was allowed by legislation;

- an agency charged with making recommendations to the Ministry of Health must be established, comprising an independent objective panel of experts that, on the one hand, would examine the validity of requests to add drugs or drug classes to each profession's designated drug list of drugs, based on the scope of practice concerned, and, on the other hand, would determine their conditions of use (HPRAC, 2009 and 2006).

What the Commissioner recommends

The Commissioner considers it necessary to review the approval process for drugs that professionals other than physicians and dentists are authorized to prescribe, as well as pharmacists whose prescribing authority is regulated by another process. The complex process involved in developing, updating and approving these lists is an impediment to the optimal performance of the system and thus to meeting the population's needs. However, reviewing these processes will necessitate legislative and regulatory changes, which will involve many stakeholders, including the departments, agencies and professional orders concerned.

The expected benefits of reviewing the approval process are numerous. Indeed, it would improve access to drug therapy for the population, while respecting patients' personal choices and the competencies of professionals recognized under Québec's professional system. There would also be a positive impact on continuity of services and interdisciplinary collaboration. Thus, in the health and social services system, we can expect to see a de-bottlenecking (particularly in primary care and services) as well as a reduction in repeat care and associated costs. Lastly, for the patient, it would mean not only easier access to the medications he needs, but also a timely response to his clinical needs, as far as possible, by the health professional of his choice.

Recommendation to the Minister of Health and Social Services to call upon the Minister Responsible for the Administration of Legislation Respecting the Professions

8. Simplify the process used to develop and revise lists of medications that regulate the prescribing practice of SNPs, midwives, optometrists and podiatrists.

To this end:

- update lists at a rate that allows the timely inclusion of drugs required for the practice of each of these professionals;

- allow midwives and podiatrists to prescribe from lists drawn up by drug class.

Objective 4: Reduce inequities among people covered by the public and private components of the RGAM

The RGAM provides basic coverage to every person in Québec for the cost of pharmaceutical services and prescription drugs. It is a mixed system, comprising a public component (RPAM), administered by RAMQ, and a private component, administered by private group plans. In recent years, slightly more than 40% of people eligible for the RGAM were covered by the RPAM and slightly less than 60%, by private group plans. It should be noted that the *Act Respecting Prescription Drug Insurance* stipulates that any eligible person must be insured under one of the components. The current mixed nature of the RGAM results in various forms of inequities between the people covered by the RPAM and those covered by private group plans, for example with respect to the cost of drugs purchased in pharmacies and the premiums charged by private group plans.

The difference in cost for the same prescription for people covered by the public and private components of the RGAM illustrates a first form of inequity. Indeed, the bills of people covered by private group plans vary between pharmacies. Furthermore, the lack of transparency about dispensing fees compounds the problem.

Increases in premiums charged by private group plans, which cannot be controlled, unlike the premium for the RPAM, are also problematic. Indeed, private group plans cannot put a cap on coverage for drugs, since they must reimburse prescriptions as they are invoiced. Thus, even if brand name drugs can be replaced with less expensive bioequivalent generic drugs, the drug that was prescribed must be reimbursed, regardless. Furthermore, private group plans must reimburse the cost of the prescription, including the owner-pharmacist's fees, which he determines based on his assessment of the profitability of his business. This situation is compounded by the fact that insurance premiums for private group plans are not income based, unlike those for the RPAM.

Lastly, the fact that people who are covered by private group plans cannot opt only for coverage equivalent to that offered by the RPAM can create financial pressure for some people, since private plans offer premiums that cover drugs and a wide range of health services.

Many people are calling for universal drug coverage owing to the problems of inequities caused by the mixed plan. For example, the Consumers Union has been running a campaign for several years now to introduce a wholly public drug insurance plan, which is drawing an increasing number of supporters. The Commissioner believes this consideration should be part of a broader reflection on all publicly funded programs. While the Commissioner has chosen to focus on the improvements to be made to the existing system by recommending immediate concrete solutions to address problems of inequities, he believes that a broader reflection on the form the RGAM should take must

be undertaken. The members of the Commissioner's Consultation Forum also discussed the matter: their deliberations illustrate their difficulty in taking a position in this regard.

What Consultation Forum members think

"Before even giving an opinion on the appropriateness of opting for a universal plan or keeping the plan in its existing hybrid form, some members said that we would maybe need to review some insurance premium payments (deductibles) for people with lower incomes or adjust the amount of premiums based on income. […] In line with these nuances, most Forum members believe that adopting a universal plan, augmented compared with the existing public plan and that would allow the premium to be adjusted based on income, could be a solution […] These members believe this type of plan […] would be the best way to remedy the problematic situations with access and equity […]"

"Members who recommend adopting an augmented universal plan agree that the appropriateness and feasibility of doing so must first be examined, and some add that a public debate would have to be held on the potential issues surrounding this choice."

"A minority of members think it would be more appropriate to focus on improving the existing plan and maintain that this plan is good and has allowed some people […] to access expensive, yet essential, treatment. While they do not reject the idea of an augmented universal plan outright, these members are not convinced that it is a better solution. They believe that this augmented plan should include terms and conditions that are similar, even identical to those in the existing plan, which would be expensive. Moreover, the existence of the private component relieves pressure on the public component […] Members also pointed out that it would be a good idea to study successful practices in other countries with respect to public insurance plans."

Report of the deliberations of the Consultation Forum, November 2012 session.

The Commissioner believes these sources of inequities in access to drugs contravene the very spirit of the RGAM, that is, to ensure that every person in Québec has fair and reasonable access to the medication required by their state of health (Section 2 of the *Act Respecting Prescription Drug Insurance*). This objective remains, irrespective of the public or private nature of the insurance, in a context where it is mandatory for everyone to be insured. It should be noted that a tension exists between the objective of the RGAM and the business interests driving pharmacies and insurance companies. However, since Québec opted for a universal drug insurance plan with mixed funding, the precedence of the public good justifies the implementation of control measures to balance the interests at play. These measures should aim not only to reduce inequities

in the RGAM, but also to control the growth in costs of both the RPAM and private group plans.

Under the RGAM, insured people must pay a maximum annual financial contribution in the form of co-insurance (share of the bill paid by the insured person up to 32.5%) plus a monthly deductible (fixed amount paid when making the first purchase of the month). The financial contribution under the RPAM is income based, unlike private group plans. Thus the contribution paid by people aged 65 and over who receive a guaranteed income supplement and are covered by the RPAM is lower than that of people aged 18 to 64 who are not eligible for a private plan ($612 and $992 respectively in 2014) (Québec, 1996).

The private component of the RGAM is administered by group insurers or administrators of employee benefit plans. Private insurers conclude insurance contracts with employers, unions, professional associations or orders, for example, which determine the goods and services covered and the terms and conditions of coverage. Employee benefit plan administrators perform the management tasks they are assigned. In addition to offering accident/illness/disability insurance, private group plans must offer prescription drug insurance that complies with the provisions of the *Act Respecting Prescription Drug Insurance*. Coverage must at least include the pharmaceutical services and the medications on the *List of Medications* covered by the RGAM as well as exception measures (medication and patient) (Gagné, 2010). It can, however, vary between private group plans, as can the various types of coverage offered by each of these plans.

Private group plans in Québec use few cost control measures. Indeed, a significant number of private group plans operating in Québec are not regulated: administrators reimburse claims as they are submitted. These programs are often less restrictive for plan members than managed plans, which are more common in other Canadian provinces and which closely advise policyholders and plan members to help them make the best financial choices.

Discrepancies in prescription costs

The elements that make up the cost of a prescription, and thus the bill at the pharmacy, are different for people covered by the RPAM and those covered by a private group plan (see Table 2). Provincial legislative and regulatory measures regulate the elements that make up the cost of prescriptions covered by the RPAM, be they drug prices or dispensing fees. However, the cost of a prescription for people covered by private group plans, also called the usual and customary price, varies depending on the owner-pharmacist's evaluation of the profitability of his business. Under regulatory measures, the price of medications covered by the RGAM must be the price shown on the *List of Medications* covered by the RGAM, irrespective of the type of coverage. However, in the case of private group plans, owner-pharmacists freely determine the fees charged, which include a profit margin to cover the pharmacy's operating costs. The usual and

customary price charged by the pharmacy must be the same for all customers with the same prescription, but it can vary between pharmacies. Elements that influence the usual and customary price include the owner-pharmacist's commercial commitments, which can have an impact on his profit margin. Many commercial commitments are being undertaken in the context of a recent vertical integration of activities in the pharmaceutical sector. This is the result of mergers and acquisitions between generic drug manufacturers, retailers, community pharmacy chains and banners that have taken place in Québec in recent years. In this context, a pharmacist can be encouraged to purchase drugs from the so-called "preferred drug list" of a manufacturer with whom he has a commercial association.

Table 2. Elements that make up prescription cost: differences between the RPAM and private group plans

Elements that make up prescription cost	
RPAM	**Private group plans**
Cost price of the drug (regulated – *List of Medications* covered by the RGAM)	Cost price of the drug (regulated – *List of Medications* covered by the RGAM)
+ Retailer's mark-up (6.5%) (regulated)	+ Retailer's mark-up (6.5%) (regulated)
+ Dispensing fees (determined by an agreement between the Association québécoise des pharmaciens propriétaires and the Ministère de la Santé et des Services sociaux)	+ Dispensing fees including the profit margin used in part to cover pharmacies' operating costs (non regulated)
↓↓ Prescription cost	↓↓ Prescription cost or usual and customary price

Both types of coverage result in discrepancies, sometimes significant, for the same prescription. Table 3 shows the discrepancies in prescription costs for people covered by the RPAM and by a private group plan in four different pharmacies.

Table 3. Prescription cost of some generic and brand name drugs in pharmacies in the Greater Montreal Area, by type of coverage, 2012

	Beneficiaries				
		Private group plans			
Drug	**RPAM**	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4
ASA 80 (30 days)	$10.19	$3.37	$6.69	$6.69	$3.39
ASA 80 (90 days)	$30.56	$10.27	$10.89	$10.89	$10.37
Lipitor 10 (30 days)	$62.15	$69.77	$71.19	$75.59	$68.29
Lipitor 10 (90 days)	$186.34	$197.77	$201.89	$214.29	$193.39
Apo-Atorvastatin 10 (30 days)	$21.70	$30.99	$33.69	$26.29	$30.99
Apo-Atorvastatin 10 (90 days)	$64.98	$79.19	$86.79	$62.29	$79.79
Apo-Atorv 10 + ASA 80 (90 days)	$95.54	$89.46	$97.68	$73.18	$90.16
Synthroid 0.1 (30 days)	$10.16	$7.99	$8.79	$9.79	$7.99
Synthroid 0.1 (90 days)	$30.47	$17.43	$17.59	$19.29	$17.49
Altace 5 mg (30 days)	$33.58	$37.69	$38.49	$40.89	$36.99
Altace 5 mg (90 days)	$100.75	$99.07	$102.09	$108.49	$96.29
Enbrel 50 (28 days)	$1,438.51	$1,597.17	$1 551.99	$1,770.69	$1,640.17
Enbrel 50 (84 days)	$4,267.95	$4,791.49	$4,585.48	$5,288.28	$4,920.49
Sources: AQPP Symposium, May 2012, Montreal; Pharmacies in the city of Montreal.					

Sources: CSBE, 2014b; Chartrand, 2012.

Another way of detecting discrepancies in prescription costs is by weighting the drug's cost price relative to the prescription cost. This approach reveals that prescription costs for people covered by private group plans can be several times the drug's cost price, 1.6 to 3.5 times in the cases shown in Table 4.

Table 4. Discrepancies between the cost prices of various generic drugs covered by private group plans and the cost charged by pharmacies for their prescriptions

	Generic versions				
	Effexor	Glucophage	Lipitor	Norvasc	Pantoloc
Cost price of the drug	$16.05	$6.70	$15.92	$12.11	$38.06
Prescription cost charged by the pharmacy to people covered by private group plans	$54.69	$29.95	$45.00	$46.99	$98.89
Differential expressed as a % by prescription*	241%	347%	183%	288%	160%

* The price differentials are calculated based on the highest prescription costs for each generic drug. Price differential calculations are based on the guaranteed selling price of the drugs on the *List of Medications* covered by the RGAM and a retailer mark-up of 6.25% (2011 rate; the rate was 6.5% in 2014). The price differential was calculated using the following formula: (prescription cost – (cost price x retailer mark-up)) / cost price.

Source: Meilleur and Lambert-Milot, 2011.

The Commissioner makes the following three observations with respect to the mixed nature of the RGAM and the methods used to determine prescription costs, which differ for the public and private components:

- The cost of the same prescription for a person covered by a private group plan sometimes varies widely depending on the pharmacy the person goes to. For people who have their prescriptions filled at pharmacies with the highest prescription costs, this means that they reach their maximum annual co-payment cap earlier than anticipated. Once these caps have been reached, the balance of the prescription cost is assumed in full by private insurance plans. At this point, incentives to reduce the usual and customary prices for these people are weak, if not non-existent;

- For identical prescriptions, the financial burden of private plans is higher than that of the RPAM. This results in higher overall costs, costs that must ultimately be assumed by individuals and third party payers, such as employers or unions;

- Due to prevailing market dynamics, the drug pricing policies applied by the MSSS are less advantageous for people covered by private group plans. Existing practices are causing spending on prescription drugs to grow, while greatly reducing the savings that individuals and third party payers could benefit from. Thus the drug price reductions in effect in Québec since 2007 have had little impact on prescription cost and have been of little benefit to people covered by private plans. On the other hand, pharmacists' dispensing fees – including the

pharmacy's profit margin, which explains the significant cost differences that still exist – benefit pharmacies and private group plans (especially those remunerated based on the amounts reimbursed), to the detriment of all individuals and third party payers.

Consultation Forum members and the citizens surveyed are concerned about drug costs and inequities among people insured under the RGAM.

What Consultation Forum members think

"Forum members are concerned about drug costs, especially their impact on Québec's health and social services system and the user's ability to pay, which is directly related to the insurance coverage provided by Québec's Basic Prescription Drug Insurance Plan (RGAM) and private drug insurance plans. Indeed, members […] are afraid that there will be inequities in access to drugs due to differences in the coverage provided by the RGAM and the different private plans."

Report of the deliberations of the Consultation Forum, December 2011 session.

The Commissioner's survey – Results for ability to pay for medication

Have you ever gone without a medication because you couldn't afford to pay for it?

According to the survey conducted by Léger on behalf of the Commissioner in 2012, 12% of respondents reported going without a medication because they couldn't afford to pay for it. Of this number, 21% of respondents represented households with an income of less than $20,000/year and 27%, households with an annual income of $20,000 to 40,000.

Source: CSBE and Léger, 2012.

To offset the inequities caused by the mixed nature of the RGAM, the Commissioner has chosen to focus on the cost of prescriptions in pharmacies and the insurance coverage offered by private group plans.

4.1 The cost of prescriptions at the pharmacy for people covered by private group plans

The mixed nature of the RGAM is a source of inequities insofar as owner-pharmacists can, under the private component of the RGAM, determine fees based on their business decisions, such as their evaluation of the expected profitability of their business. This situation raises concerns among members of the Commissioner's Consultation Forum and other citizens surveyed by the Commissioner.

What Consultation Forum members think

"commercial practices that allow the selling price of a drug in community pharmacies to vary […] should be disclosed […] and, according to some members, these practices should also be regulated."

Report of the Consultation Forum's deliberations, March 2012 session.

Testimonials sent to the Commissioner's website

• "Simplify RAMQ reimbursements, which are quite complex. Prices could be the same in all pharmacies." (Q7, E227)

• "There are also huge differences in prices between pharmacies and we don't really know if the pharmacy replaces one generic with another." (Q7, E270)

Due to increases in spending on prescription drugs in the last two decades, other provinces have implemented specific measures, including Ontario, to ensure appropriate and equitable access for the populations covered.

Private group plans in Ontario

Ontario's population is covered for prescription drugs by either the public insurance plan (Ontario's public drug programs) or by private insurance plans, as a matter of choice. It should be noted that it is not a universal drug insurance plan as in Québec, where every person must be insured for prescription drugs. The Ontario Citizens' Council is an advisory committee of citizens who provide their views on the values that reflect the needs, culture and attitudes of citizens about government drug policy. In 2012, it discussed the role that public programs should take in guiding the practices of private businesses (private drug insurance sector and pharmacies) in Ontario. Council members agreed on a number of principles that should serve as a guide when all the stakeholders concerned by public drug insurance are asked to work together to create

adequate coverage for Ontario's citizens (Ontario Citizens' Council, 2012). In keeping with the principles formulated by the Council, the approaches adopted by the Ontario government call for collaboration between stakeholders to better control monetary issues that are undermining the sustainability of the public program. In this context, to ensure that the prescription costs paid by their members remain reasonable, private group plans tend to protect their members from increases in dispensing fees and pharmacy profit margins by putting caps on the amount reimbursed for these two components of prescription cost. If the fees exceed this cap, insurers pass the difference directly on to plan members (Sun Life Financial, 2010).

Moreover, if a person gets his prescription filled at a pharmacy, he is usually given a bill that shows how much he has to pay and how much is covered by his insurance plan. The prescription cost is never broken down into its components: only the price of the drug can be found out by consulting the *List of Medications* covered by the RGAM. Thus, for people covered by private group plans, dispensing fees, including the profit margin, are neither publicly disclosed nor regulated and remain unknown. Indeed, community pharmacies do not show prescription costs, insofar as they vary depending on the pharmacy and the patient. It should be noted that the Association québécoise des pharmaciens propriétaires is trying to find solutions to this situation.

What the Commissioner recommends

The Commissioner believes that, in order to improve equity among people covered by the public and private components of the RGAM, prescription costs for people covered by the private component require further regulation. Furthermore, in the interests of transparency, bills for prescription drugs must at least clearly show the price of the product (price on the *List of Medications* covered by the RGAM) and the dispensing fees. Greater transparency will be necessary for as long as pharmacies' bills continue to vary, even if a cap were put on prescription drug costs.

Recommendation to the Minister of Health and Social Services

9. Regulate the cost of prescriptions for people covered by private group plans.

To this end:

- put a cap on the cost of prescriptions that is comparable to the price charged to people covered by the public component of the RGAM;
- make it a requirement that bills for medication show the price of the product and dispensing fees.

4.2 Coverage under private group plans

In addition to regulating the cost of prescriptions in pharmacies, actions targeting private group plans can promote equity among people covered by the public and private components of the RGAM.

Coverage for brand name drugs

Generic substitution refers to the pharmacist replacement of the drug prescribed with a bioequivalent generic option that is appropriate for the patient's condition and has the same active principles, dosage and route of administration (OPQ, 1994). When generic alternatives are available for a brand name drug, the public component of the RGAM requires an additional contribution from the insured person if he chooses to use the brand name drug, unless the prescriber has written "no substitution" on the prescription. Thus, if the person wants the brand name drug, he must pay the difference between the amount covered by the RPAM for the generic product and the cost of the prescription for the brand name drug. The additional payment does not count toward the insured person's annual contribution.

However, for private group plans in Québec, there is no provision in the *Act Respecting Prescription Drug Insurance* to encourage the use of generic products. Thus, despite the availability of generic products, private group plans reimburse the prescription cost for a brand name drug without requiring the insured person to pay an additional contribution. At most, they may occasionally encourage the use of the generic drug by covering a higher amount than is required for brand name drugs under the *Act Respecting Prescription Drug Insurance*, i.e., 67.5%.

Generic substitution

Generic substitution is a major source of savings and controls the rising drug costs paid for by insured people and third party payers, such as public drug insurance plans or employers. Although generic utilization has increased in recent years (reaching 63% in 2012), Canada lags behind other industrialized countries (CACDS, 2013). In Québec, generic prescribing rates rose from 61 to 66% from 2012 to 2013. This was the largest increase in generic utilization in a Canadian province during this period (Leduc, 2014).

Other formulas are used elsewhere in the world. For example, in Ontario, when generic products are available, the reimbursement conditions offered by private insurers for brand name drugs are less favourable than those for the generic product. Unless the prescriber has written "no substitution" on the prescription, a person insured under a private plan who wants a brand name drug must pay an additional amount that does not count toward his maximum annual contribution (Sun Life Financial, website; Medavie Blue Cross, website).

The extent of coverage offered by private group plans

The terms and conditions associated with payment guarantees for pharmaceutical services and medications for a person who is eligible for the RPAM are made public, known by and accessible to everyone (RAMQ, 2012a). The situation is different, however, for people covered by private group plans: while the premiums for each of the guarantees offered are specified in the insurance policy, the premium paid by the beneficiary for drug insurance is generally not distinguished from the premium paid for the health insurance package it is part of. Consequently, the beneficiary cannot distinguish between the premium that corresponds to prescription drug coverage under the RGAM and the premium for the additional (or supplemental) coverage offered by the plan. Furthermore, the complete list of drugs reimbursed by the private group plan, which may be longer than the mandatory list for the RGAM, is often not given to the insured person.

The case of Québec's automobile insurance plan

The case of Québec's automobile insurance plan is a concrete example that could provide inspiration for improving the RGAM. Under the *Automobile Insurance Act*, the owner of any vehicle must have a civil liability insurance contract guaranteeing compensation for property damage caused by the vehicle, with his contribution determined based on the type of vehicle and the materials transported. This civil liability insurance (required by law) is offered by private insurance companies. Once he has subscribed to the mandatory civil liability coverage, the insured person may freely choose optional additional protection to cover the perils that could affect his vehicle. Where applicable, premiums for optional coverage are clear and easily distinguished from the mandatory insurance premium.

What the Commissioner recommends

With respect to coverage offered by private group plans under the RGAM, the Commissioner makes the following three observations:

- Out-of-pocket spending for the same prescription varies depending on whether the person is covered by the public or private components of the RGAM. A person insured under the RPAM must pay more out of pocket if he wants a brand name drug than a person insured under a private group plan. Indeed, the latter does not have to pay an additional amount for it on the spot, since these additional costs are shared by all plan members.

- Coverage of brand name drugs under private group plans does not encourage the use of generics. This contributes to the growth in overall drug costs for private group plans which, ultimately, are paid by individuals and third party

payers. This growth in costs represents an additional challenge for small and medium-sized businesses.

- A person covered by a private group plan must choose between types of coverage (individual, single parent, family, etc.) that includes the guarantees required by the RGAM, but cannot distinguish them from supplemental coverage and subscribe to it exclusively.

These situations are a source of inequities. Insofar as generic utilization should be encouraged to improve the management of funds, the Commissioner believes that regulatory barriers in this regard must be removed with respect to private group plans. Moreover, he believes that anyone who is covered by a private group plan should, before subscribing to an insurance policy, be able to find out about the content, the nature of the coverage for medications and pharmaceutical services as well as the nature of the premiums charged. The information provided by the insurer should allow him to distinguish premiums for the coverage provided for under the RGAM from those associated with additional coverage. More specifically, the insured person should be able to choose between different options: purchase insurance only for the medications on the *List of Medications* covered by the RGAM, purchase insurance for additional medications or purchase insurance for other health services. This information should be available to both people covered by private group plans and policyholders or third party payers, such as employers, unions and other associations. To provide this option, amendments must be made to the *Act Respecting Prescription Drug Insurance*.

Recommendation to the Minister of Health and Social Services

10. Authorize private group plans to put a cap on the coverage of brand name drugs that is equal to the cost of the available generic product and make it a requirement for them to offer the option of subscribing only to the coverage provided for under the RPAM.

Conclusion

Prescription drugs contribute significantly to improving population health. They are a fact of life in our health systems. However, increasing drug use and spending as well as the negative impact of their use (and misuse) raise concerns. Drugs have become so important that they are nearly always offered as the answer to health problems, whereas other approaches, including health promotion and disease prevention, could also be used to great effect. Furthermore, the organization of many health systems today, as well as the social context, encourages the use of this type of treatment to the detriment of other types of care and services. This sometimes excessive use of drugs may even jeopardize the sustainability of public health systems and the budget balance of the governments that provide them. Furthermore, drugs now have an extended use that goes beyond health needs and are the preferred solution when it comes to dealing with social, family, professional or school situations, for example. For all these reasons, we must reconsider the place they occupy in the care and services provided.

To do so, it is important to recognize the multiple interests involved and the role of each stakeholder in the dynamic surrounding prescription drugs. Furthermore, information of various types that would give us insight into practices is not accessible: the pharmaceutical industry's contributions to health care institutions; review processes for drugs provided under exceptional access measures; prescribing practices and drug use; details of drug insurance policies and pharmacy billing; etc. This lack of information is an impediment to making the decisions needed to ensure fair and reasonable access to prescription drugs, an objective set out in the laws that provide for their public funding in Québec. Greater transparency in every respect is called for in the area of pharmaceuticals.

Observations and recommendations

In addition to the omnipresence of drugs in Québec's health and social services system and the fact that they account for a growing share of health spending, the Commissioner makes a number of observations based on his assessment of the system's performance in the area of prescription drugs. With respect to optimal use and cost containment, the Commissioner makes observations regarding both the place the pharmaceutical industry occupies in Québec's health and social services system and the management of the list of publicly funded medications. While it would be unfair to say the pharmaceutical industry's role in Québec is excessive, we must nonetheless acknowledge that its influence in the health and social services system is not always aligned with the public objective of providing fair and reasonable access to medically required drugs. This unavoidable presence stems in part from a sociopolitical context and industrial and scientific policies favourable to the pharmaceutical industry. Moreover, the latter has played an undeniable role in the development of Québec's economy and expertise in the field of pharmaceuticals.

As a regulatory mechanism for public drug insurance, Québec opted for a positive open list, compiled from manufacturers' listing submissions, without any limit on the number of drugs listed. Nor is there any limit on the share of the budget allocated to prescription drugs from the global health and social services budget. The *List of Medications* covered by Québec's RGAM contains a substantial number of drugs compared with formularies in other provinces or countries. There is no mechanism for revising the appropriateness of the drugs listed, while new drugs are added continually.

To ensure a fair, equitable and efficient allocation of resources and thus promote improved access to the drugs best able to meet health needs, the Commissioner makes two recommendations. The first is to increase transparency regarding all the contributions the pharmaceutical industry makes to health care institutions and FMGs, including samples. The objective of this recommendation is to make stakeholders in the health and social services system aware of potential influences and their impact on the provision of services as well as to support decision making that is in the public interest. The second calls for the implementation of mechanisms for revising the lists of publicly funded medications.

Some drugs do not meet standard review criteria for inclusion on the lists of publicly funded drugs. They may be requested under exceptional access measures. This leads to a number of troubling observations. The often high costs of these drugs and the lack of data supporting their therapeutic value, in the context of the introduction of personalized medicine and biologics, challenge traditional review processes. Requests submitted under exceptional access measures are increasing as a result, in both ambulatory and institutional settings, generating prohibitive costs. The process used to determine whether or not a drug will be covered under exceptional access measures is not made public. Moreover, the lack of aggregate data on how these measures work precludes any analysis. While the appropriateness of exceptional access measures is not questioned, their increasing use without any oversight raises concerns about equitable access, the benefits of public investments and the impossibility of monitoring the use of these drugs. To maintain fair and reasonable access to these drugs given the population's overall health needs, the Commissioner believes that review processes must be adapted. He also believes that responsibility for exceptional access measures should be transferred to INESSS, their use harmonized across the province, monitored and related data made public.

With respect to prescribing practices, pharmacological management and drug use, the Commissioner makes a number of observations. Suboptimal drug use is due in part to inappropriate prescriptions. This is the result of a combination of factors, including inadequate initial training, the inherent complexity of the field of pharmaceuticals, the continuous emergence of new drugs and new data, an organizational context of medical practice that encourages neither interdisciplinary collaboration nor the effective use of

evidence. Moreover, drug costs are rarely taken into account when prescribing drugs, whereas they have an undeniable impact on health and social services system expenditure. Suboptimal drug use can also be a result of how some patients take them, for instance due to a lack of information or by choice. Furthermore, pharmacists' clinical role is not optimized, especially in ambulatory settings. Drug therapy monitoring is inadequate, often fragmented, especially in patients with complex health needs who are taking multiple drugs and, in particular, during their care transitions. Lastly, the prescribing practices of prescribers other than physicians and dentists are hindered by complex approval processes for the drugs they are authorized to prescribe.

In response to these problems, the Commissioner believes that there is an urgent need for Québec to develop an action plan on prescribing practices and drug use. This action plan should include components relating to the monitoring of prescribing practices, continuing education for prescribers and patient education. Increased integration of clinical pharmacists into primary care and the introduction of a standard discharge pharmaceutical care plan for hospitals are also necessary to ensure continuity of care, especially for patients with complex health needs. In addition, the process and mechanisms used to develop and revise the lists of drugs that can be prescribed by professionals other than physicians and dentists must be simplified to make better use of these professionals' competencies and improve access to care and services.

A final area of concern is the inequities observed among people covered by the public and private components of the RGAM. This consideration is important, especially if we consider the significant number of people who do not take their drugs because of financial constraints. In response to these sources of inequities, the Commissioner recommends actions targeting both owner-pharmacists and private group plans. Thus transparency as to what makes up the cost of prescriptions in pharmacies and a reduction in the discrepancies in prescription costs for people covered under the public and private components of the RGAM are recommended. Furthermore, people covered by private group plans should have access to basic coverage, such as the coverage provided under the RPAM, and private group plans should be able to encourage the use of less expensive generic alternatives.

Towards a new drug policy

Québec must develop a clear vision of the place drugs occupy in the health and social services system. A new drug policy, building on the now expired policy of 2007, would serve this purpose by coordinating efforts to achieve the objective of fair and reasonable access that Québec has set for itself with respect to prescription drugs. The Politique du médicament of 2007 was a reflection of its era: while some realities have evolved, others remain unchanged and their respective orientations would need to be revisited. These included concern over the necessary reconciliation of the diverging interests of the stakeholders concerned by drugs. The growing cost burden for the Government of Québec was also considered as was the growing presence of drugs in the health and

social services system, especially when resources are finite. Of the 29 orientations set out in this policy, some were achieved within a short time, whereas others, nonetheless relevant, did not come to fruition as planned. Therefore the concerns they were supposed to address remain current.

Aligned with this objective of fair and reasonable access, the Commissioner's recommendations lay the foundations for a new drug policy. Indeed, these recommendations are levers with enormous potential for impact on the performance of the health and social services system. Were they to be implemented, they could help reduce the costs of prescription drugs, increase equitable access and improve the appropriateness, quality and continuity of care, which are different facets of the optimal use of prescription drugs and the performance of the system. In the event of a new drug policy, other fundamental orientations should be also added, addressing the uptake and use of information technology to improve health information sharing, tracking the use of drugs, generic drug pricing and solutions to problems of shortages.

The Commissioner believes that strong, proactive leadership should drive the development and implementation of this new drug policy. Broad expertise, capable of grasping the diverse facets of the reality of pharmaceuticals, is necessary and must take the rapid development of the sector into account. Increased transparency in all prescription drug decisions, a commitment to national and international collaboration as well as active citizen participation in the orientations adopted are essential to carry out this important social undertaking that concerns every one of us. Given the growing place that drugs occupy in our system, Québec must undertake this society-wide project to meet the population's health needs, while ensuring the sustainability of the system, in keeping with the values that inspire and define Québec society.

List of recommendations

Objective 1: Promote the use of drugs that are best able to meet health needs while controlling costs

1. Submit an annual report to the National Assembly on all pharmaceutical industry contributions to health care institutions and family medicine groups (FMGs), including samples.

2. Periodically revise the *List of Medications* covered by the Basic Prescription Drug Insurance Plan (RGAM) and the *List of Medications – Institutions*.

Objective 2: Ensure fair and reasonable access to drugs that do not meet standard review criteria

3. Adapt listing processes for drugs that do not meet standard review criteria.

   To this end:

   - negotiate risk-sharing agreements with the pharmaceutical industry to ensure access to these drugs at the best prices, while keeping confidentiality to a minimum;

   - revise the listings for these drugs in light of new data;

   - establish a citizens' council to participate in the drug review process and ensure non-scientific criteria are taken into consideration.

4. Mandate the Institut national d'excellence en santé et en services sociaux (INESSS) [National Institute for excellenece in health and social services] to assume all responsibilities with respect to the use of drugs in exceptional situations, in both institutions and ambulatory settings.

   To this end:

   - ensure the timely approval of routine requests for these drugs under the exception patient measure as well as requests from health care institutions, while integrating the university hospital centres' initiative, the Programme de gestion thérapeutique des médicaments (PGTM) [therapeutic medication management program];

   - establish standards for the use of these drugs;

- publish data on these drugs on an annual basis, such as the number of requests approved and denied, associated costs and the diseases concerned.

Objective 3: Improve prescribing practices, pharmacological management and drug use

5. Adopt a provincial action plan on prescribing practices and drug use.

In particular, the provincial action plan should include:

- the annual publication of a regional and provincial portrait of prescribing trends and costs based on Régie d'assurance maladie du Québec (RAMQ) [Quebec health insurance board]data;
- the distribution, on a quarterly basis, of a personal prescribing profile to each prescriber;
- the organization of feedback activities on prescribing trends that can be used to earn continuing education credits;
- the improvement of initial and continuing medical education in pharmacology;
- the provision of support for educational initiatives on healthy lifestyle behaviours, medication and compliance with treatment for specific patient groups.

6. Integrate clinical pharmacists into health care teams in FMGs.

7. Implement a standard discharge pharmaceutical care plan to facilitate the transfer of information from the hospital pharmacist to the community pharmacist and attending physician.

8. Simplify the process used to develop and revise lists of medications that regulate the prescribing practice of specialized nurse practitioners (SNPs), midwives, optometrists and podiatrists.

To this end:

- update lists at a rate that allows the timely inclusion of drugs required for the practice of each of these professionals;
- allow midwives and podiatrists to prescribe from lists drawn up by drug class.

Objective 4: Reduce inequities among people covered by the public and private components of the RGAM

9. Regulate the cost of prescriptions for people covered by private group plans.

To this end:

- put a cap on the cost of prescriptions that is comparable to the price charged to people covered by the public component of the RGAM;
- make it a requirement that bills for medication show the price of the product and dispensing fees.

10. Authorize private group plans to put a cap on the coverage of brand name drugs that is equal to the cost of the available generic product and make it a requirement for them to offer the option of subscribing only to the coverage provided for under the Public Prescription Drug Insurance Plan (RPAM).