

**Notes for Remarks by
Representatives of
Canada's Research-Based Pharmaceutical Companies
(Rx&D)**

**Appearance before the
Commission des affaires sociales**

Projet de Politique du médicament

**Quebec City, (Quebec)
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Mr. Chairman, Minister and Honourable Members of the National Assembly.

On behalf of Canada's Research-Based Pharmaceutical Companies, I would like to thank the *Commission des Affaires sociales* for giving us the opportunity to appear before you today and offer our observations on the draft medication policy.

Member companies of Rx&D support the historic approach taken by the Minister of Health and Social Services to provide Quebec with its first medication policy. We especially emphasize the fact this approach is holistic in that it looks at the overall impact of medicines, not only from a health viewpoint but also from the perspective of examining the economic benefits and spinoffs that are attributable to the presence of a dynamic pharmaceutical industry in Quebec.

Specifically, this approach encapsulates both the value of medications in terms of positive health impacts for Quebecers and the augmentation of our collective national wealth.

Rx&D is a national association representing nearly 22,000 men and women who work for about 50 research-based pharmaceutical companies in Canada. Comprised of companies of all sizes, Rx&D member companies are part of the global pharmaceutical industry whose members are responsible for developing in excess of 90% of the medicines available today.

Member companies of Rx&D are very active in Quebec where we invest 49% of our collective R&D budget in research and development ... this is more than any other jurisdiction in Canada. In addition, we estimate that the biopharmaceutical sector provides more than 30,000 high-level jobs. In terms of economic development, the biopharmaceutical sector is one of the primary drivers in the Montreal area which in turn makes a major contribution to the collective wealth of Quebecers.

The business environment and government policies favorable to pharmaceutical investments that Quebec had adopted over the years have played an important role in the nurturing of the biopharmaceutical sector. This climate has clearly contributed to the many research and production activities performed today by our members in Quebec. At a time when worldwide competition is getting more and more intense between countries wishing to attract part of these international investments in biopharmaceutical R&D, Quebec has no choice but to maintain improve its approach that has promoted its social and economic interests so well until now.

We believe that by maintaining such a balanced approach, we will manage to improve the business climate that has deteriorated in our sector during these last few years.

This deterioration is primarily attributed to the long-term effects that stem from:

- the systematic price freeze that has been in effect since 1994,
- the major reduction in the listing rate of new medications reimbursed by the general drug insurance plan; and
- a deterioration of the relative competitive value of Quebec's R&D tax credits.

These are basic aspects of the business environment in our field and their impact on the investment capacity of our companies is decisive.

We generally agree with principles underlying all four components of the consultation document and we readily support a large number of the government's proposals.

To start, we are delighted that this draft policy acknowledges the important role of medications in our health system and the desire to ensure the sustainability of our drug insurance plan. Access to medications, which is the first component of the draft policy, is essential for each and every citizen.

Drugs are one of the main technological breakthroughs of our health system. They control and prevent disease and their appropriate use also avoids more costly and invasive medical treatments such as hospitalization and emergency room visits. Innovative medicines greatly improve the quality of life of patients and also allow them to live longer and healthier lives.

As with other leading-edge technologies, drugs can be costly and these costs must be managed as efficiently as possible. However, innovative medicines are special in that they are one of the medical technologies that are among the easiest to isolate and analyze within the paradigm of budgetary silos. However, this approach is fraught with much risk as such an analytical framework discounts and ignores the cost-beneficial impact of medicines in other areas of the overall health system. Yet drug plan cost progression is often the object of intense debates in society, more so than other health technologies.

Due to budget pressures, the government has tried to limit provincial plan costs by reducing the number of new medicines added to the list of medications for reimbursement. According to the latest statistics that were published after we wrote our memorandum, the proportion of new medications reimbursed by the plan decreased on average from 80% between 1996 and 1998 to 36% between 2003 and 2005.

As the Commission has already heard, health professionals and patients are greatly concerned by this trend. While the *Liste de médicaments du Québec* is the least restrictive in Canada, the recent trend shows a tendency to limit access to new drugs in the rest of Canada. If these trends continue, Quebecers will no longer be the jurisdiction adding the largest number of new medications to the list.

This trend was revealed in the latest updates (February and June) that included 40 decisions regarding medication listing. Only seven (7) products were added to the regular list and one of those is a new formulation of diltiazem, a cardiotropic drug listed since 1982.

From a business standpoint, it has become increasingly difficult for Rx&D member companies to justify Canadian-based research into new therapies if the patients who will ultimately benefit from this innovative will not have access to these therapies due to silo-driven budget decisions.

One must admit that this access is increasingly jeopardized in Canada and even in Quebec where it used to be more secure.

To be clear, we are not challenging the scientific rigour robustness of the *Conseil du médicament*. As you have heard in previous testimony, the *Conseil* is carrying out its mandate rigorously and with integrity and we do not challenge this assertion. However, scientific robustness alone cannot explain the recent listing trend. Like others, we believe that the present situation owes more to the influence of budgetary pressures and to the absence, in the general drug insurance plan, of tools needed to ensure a more balanced management of the access to medication and their use.

Nevertheless, the draft drug policy specifically includes measures that should bring a balanced corrective measure to this situation while favoring optimum accessibility.

Indeed, we believe this is the case of measures defined in Proposal #3 aimed at increasing the flexibility of the administrative process surrounding the list of medications. We are in favor of keeping the List of exceptional medications that may become a useful management tool in some cases.

However, we realize that this list is now being used for purposes for which it is not suited, for example to ensure the use of new medications as an alternative when the first option is an older and cheaper medication. The actual formula of the exceptional medication is too heavy, administratively speaking, to allow us to properly adjust the therapy according to guidelines. It is a significant obstacle to the optimum use of more recent drugs and, apparently to prevent their overuse, it often promotes their underutilization. Not to mention its prohibitively high administrative cost (over \$100 per prescription), which is why private insurers avoid it most of the time. Flexible measures regarding the exception medication formula, as proposed in the policy, are a step in the right direction.

We also hope that the list will be updated again on a quarterly basis and that the waiting period will be reduced between the time when the submission is presented to the *Conseil du médicament* and the decision is rendered.

As has been suggested by other witnesses, we believe that the *Conseil* must consult on a regular basis with clinicians recognized by their peers in related therapeutic fields when evaluating new drugs. Moreover, it is important that results of these consultations be made public and, in case of disagreement, that the *Conseil* may be allowed to justify the reasons. By making this process more transparent, it can only reinforce the value of recommendations made by the *Conseil* and its reputation of scientific thoroughness.

In this spirit, we agree with Proposal #5 that strives to envelop the drug listing process and related decisions with greater transparency. We also suggest the implementation of clear rules allowing appeals.

It is of course self-evident that we support the fourth component of the draft drug policy that recognizes the importance of maintaining and further developing an innovative and dynamic pharmaceutical industry in Quebec. To this end, we are thrilled by the decision to maintain the 15-year rule that has had favorable economic consequences in Quebec, as documented by independent analysts and stakeholders.

We also wholeheartedly support the decision to reject the implementation of a reference-based pricing (RBP) system. RBP is a method of price control that fundamentally deprives doctors of the freedom to prescribe to each of their patients drugs that are, in their opinion, best adapted medically speaking. As the Minister has noted during your hearings, this measure would result in additional costs for patients. Moreover, the experience and evidence from other jurisdictions where RBP has been utilized shows that it is totally incompatible with high levels of investment in pharmaceutical research.

We also support the creation of a forum for permanent exchange to maintain a balance between health and economic development policies by involving representatives from the pharmaceutical industry, the Ministry of Health and the MDEIE. This tripartite discussion forum is being effectively used in other countries that are trying to secure and boost their share of biopharmaceutical research activities.

On another point, we would like to highlight the new name of this department following the cabinet shuffle. It has now become the *ministère du Développement économique, de l'Innovation et de l'Exportation*. The use of the term "Innovation" means, is for our industry, a very positive signal from the Quebec government.

We are wholly supportive of the fact that draft drug policy recognizes the need to remove the price freeze. Regardless of the sector in question, no innovation-based industry effectively survive over the longer term with its prices frozen for so long while the consumer price index increases by 20% over the same time period. As far as we know, whether in the private or public sector, such a constraint from the government is unprecedented.

In addition, we hope that the lifting of the price freeze can take effect this year and that a decision to this effect is announced as soon as possible.

On the other hand, we are concerned with the mechanisms presented in Proposals 12 and 13 regarding which would implement compensatory measures to coincide with a lifting of the price freeze.

We firmly believe that the proposed mechanism should at least comply with the Canadian CPI. The price of innovative drugs is already regulated by the Patented Medicine Prices Review Board, a federal organization that allows one yearly price increase based on the Canadian CPI. Therefore, we hope that such a mechanism will apply in Quebec, with no other restrictions, such as the drug listing date.

Companies could then apply a uniform pricing policy throughout Canada while ensuring harmonization between provinces. In turn, this would be a major factor that would help maintain a dynamic pharmaceutical research industry presence in Quebec.

In our opinion, Quebec and Canada should aim in the long term at implementing a market regulated pricing system that would reflect the real cost of innovation. It is extremely important to remember that, on average, only one out of 10,000 discovered molecules will find its way to the market in the form of a product to be used by patients. The overall risks and costs imputable to the inherent attrition in these innovation efforts are borne entirely by pharmaceutical companies that invest in research. We look forward to a continuing dialogue with the various Quebec ministries concerned by this matter in order to allow the corresponding policy to evolve over time.

It is regrettable that Proposal #13, regarding the implementation of compensatory measures, would in effect cancel the impacts of the lifting of the price freeze. In addition, this proposal reflects the silo effect of examining drug insurance plan costs in isolation as alluded to earlier in our presentation. It does not take into account the fact that drugs developed by innovating companies are by themselves huge sources of savings for other areas of our health system.

In addition, it negates and disregards major contributions by Rx&D members in initiatives aimed at ensuring optimal use of medications through partnerships, continuous training or therapeutic management programs.

Finally, we believe that the massive presence of the pharmaceutical industry in Quebec, which contributes to our collective wealth, thanks to its major and measurable economic spin-offs and high-quality jobs, would largely compensate for a lifting of the price freeze.

We implore the government to ensure that modifications will be made to ensure that any terms and conditions proposed to compensate for price increases will adequately and truly reflect the value of innovation.

This is not to say that we are blind to the budgetary pressures with which the government must contend and we offer to continue to work in partnership with you in order to optimize the efficiency of our health system, namely through an optimum use of medications for the benefit of patients.

Initiatives aiming at encouraging an optimum use of drugs are undoubtedly the most interesting within the draft drug policy. These initiatives must be further developed and implemented. Their ultimate success will depend on us jointly developing a stronger partnership with government as well brand new relationship between the government and health professionals, the different associations, universities and the pharmaceutical industry.

We are proud to state that the development of such multi-partnered arrangements has been a long-standing objective and practice of Rx&D, one in which our member companies will remain at the forefront. The joint action of all key actors is essential in order to reach this objective that consists in a better usage of drugs. Incidentally, member companies of Rx&D are already deeply involved in different programs and initiatives aiming at better utilization of drugs and we would be happy to provide you with information on these initiatives if you so desire.

To bring this partnership vision to fruition, well-defined rules in commercial ethics are essential. This brings us to a very important aspect of the rules governing the commercial practice of pharmaceutical companies as described in Proposal #26. The member companies of Rx&D are already closely governed by a strict Code of Conduct covering all commercial practices.

This Code – which is a public document – must be adhered to by all Rx&D members, both in letter and in spirit. It was also recently updated in order to make it much stricter and meet, if not exceed, the needs and expectations of citizens who are rightfully demanding more when it comes to commercial governance practices. Our companies are firmly committed to this Code. Therefore, we have no objection to its being referred to in the manufacturer's commitment, provided that it applies to all manufacturers recognized by the Minister.

In addition, support for professional training is also covered in a joint Code of conduct between the Québec Board of Continuing Medical Education and Rx&D. This code was approved by the *Collège des médecins du Québec*. Very few industries in Canada can claim to be self-regulated in such a way. Our companies are aware of the importance of such self-regulation in order to reassure the public and they are ready to commit themselves positively.

In our time with you this afternoon, we have provided a brief overview of our comments and proposals with respect to the draft drug policy. Further information can of course be found in our memorandum to the Commission.

We are convinced that we can still bring an important contribution to the collective wealth of Quebecers and simultaneously to improve their health and quality of life. In addition, we believe that this draft drug policy will become the true driver of dynamic and joint action by all stakeholders involved in drug-related matters. And we intend to play an active role as an integral partner in the Quebec health system.

Thank you very much and we look forward to any questions you may have.