

#### Summary

The integration of pharmaceutical advances is a major scientific, social and economic challenge. For patients and their families as well as health care providers, access to the latest treatments offers hope for a better quality of life. Since its creation, the Institut national d'excellence en santé et en services sociaux (INESSS) has been examining the optimal way to introduce new treatments. In early January 2012, it therefore established an innovation review committee to identify potential solutions for improving access to drugs deemed promising for end-of-life cancer patients, while ensuring that this access remains fair and reasonable for all patients and the population as a whole.

#### The role of the Institut national d'excellence en santé et en services sociaux

INESSS' mission is to promote clinical excellence and the efficient use of resources in the health and social services sector.

Part of its mission is to assess drugs for coverage by the province's drug insurance plan. The evaluation process considers five criteria as established by the Institute's founding Act: therapeutic value, reasonableness of price, cost effectiveness, and the advisability of entering the drug on the list and its impact on the health and social services system. The drug's therapeutic value is a prerequisite to consideration of the other four criteria. This appraisal is part of a deliberative process involving clinicians, researchers, ethicists, pharmacoeconomists and citizens. Following this deliberation, INESSS communicates its recommendations to the Minister of Health and Social Services.

#### Why cancer drugs?

The leading cause of death in Québec and the rest of Canada, cancer is both a major social concern and a government priority. The Québec Cancer Control Program (Programme québécois de lutte contre le cancer) and the Direction québécoise du cancer, created in April 2011, are evidence of the importance attributed to providing effective care to individuals suffering from this illness. Furthermore, recent research advances have led to the development of promising, though costly, new drug molecules, such as targeted therapies.

#### How Québec compares with other Canadian provinces

With regard to listing drugs, Quebec stands out for the speed with which it evaluates new drugs and for the number of molecules recommended for the list. However, there do seem to be differences when it comes to anticancer drugs. To find an explanation for these differences, INESSS has reviewed the drug listing processes in other jurisdictions. It was found that many provinces and countries have developed different mechanisms and programs to increase access to specific, often costly, drugs that could offer a breakthrough in the treatment of diseases such as cancer.

To maintain an appropriate balance between drug accessibility and system sustainability, innovative models must be established to introduce drugs deemed promising. This approach represents a landmark achievement for Québec cancer patients.

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#### Bibliographic notice

Institut national d'excellence en santé et en services sociaux (INESSS). Accessibilité à des médicaments anticancéreux à caractère jugé prometteur. État des lieux et bilan du projet pilote : synthèse. Québec, Qc : INESSS; 2012.

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## Financial impact of cancer drugs on health care institutions

In 2010-2011, Québec's health care institutions spent a total of \$606 million on medications. Drug expenditure has been increasing at an annual rate of approximately 5% for the past ten years.

In the case of antineoplastic drugs, health care institution spending on antineoplastic drugs is increasing by an average of 15.5% every year. The increased use of medications and the entry of costly drugs on the market partially explain this phenomenon. For Québec hospitals, the class of antineoplastic medications represented 35.5% of total drug expenditures in 2010-2011.

On the one hand, Québec would like individual end-of-life cancer patients to have the best possible access to therapeutic advances. On the other hand, the province must endeavour to introduce these new drugs at an affordable price to society as a whole.

Consequently, to maintain an appropriate balance between drug accessibility and system sustainability, innovative models must be established to better assess the added value of these drugs.

## Pilot project to review cancer drugs

In November 2011, INESSS launched a pilot project to explore new ways of assessing seven cancer drugs deemed promising: Afinitor®, Alimta®, Iressa®, Erbitux®, Herceptin®, Revlimid® and Zitiga®. Thanks to this project, an estimated 1,500 cancer patients were given access to these therapies. Based on pharmacoeconomic standards and experimental agreements outside Québec, INESSS estimated that if the risk-sharing agreements recommended in the pilot project had been entered into, substantial savings of nearly \$10 million would have been achieved.

## Findings of the Comité d'évaluation des innovations – Volet cancer en fin de vie

The Comité d'évaluation des innovations – Volet cancer en fin de vie, with members from several milieus, namely researchers, ethicists, oncologists, citizens and patients, began reviewing the framework for assessing drugs for listing purpose, in addition to examining mechanisms developed in other jurisdictions to promote the introduction of innovative drugs. Based on the committee's findings, INESSS has drafted nine recommendations, grouped into three major categories, as follows: broaden the current framework for assessing drugs for listing purposes, develop new approaches to ensure that innovative drugs are introduced in a coherent manner and improve information management in Québec.

### INESSS considers a drug to be promising if:

- It can offer the patient with a clinically significant benefit in comparison to existing therapeutic options, that is, a major health improvement or a favourable adverse events profile.
- It is indicated for an illness that currently has no treatment or it represents a clinically significant improvement compared to existing treatments.
- It has a high potential for improving the treatment of a disease for which existing treatments are unsatisfactory.
- It has the potential to improve the organization or efficiency of the health care system.

## 1. Broadening the framework for assessing drugs for listing purposes

Based on these deliberations, INESSS reviewed its assessment framework, compared its procedures in place in other organizations and recommended new approaches. Some proposals have already been adopted.

One such innovation is the addition of meetings with manufacturers to discuss the coherent introduction of innovative drugs, including the feasibility of a risk-sharing agreements. Manufacturers will also be invited to submit arguments on ethical and social concerns, which INESSS would like to analyze in greater depth.

Increased citizen participation is another improvement that INESSS would like to make to its evaluation process. Citizen members have already begun sitting on INESSS scientific committees since September 2011. INESSS is also collaborating more with other relevant organizations.

### For patients

- Faster access to drugs
- Wider selection of available treatments
- Analysis enriched by more accurate knowledge of patient and citizen values and expectations

The use of medications in compliance with best evidence-based clinical practices is an INESSS priority. There is an ongoing need for Québec to equip itself with standardized tools to learn how cancer drugs are used and ensure their optimal use. For this reason, the province must set up administrative mechanisms for monitoring drugs, particularly those associated with rules governing their use.

## 2. Develop new approaches to ensure that innovative drugs are introduced in a coherent manner and provide access to certain drugs

When INESSS compared the various drug assessment bodies, it noted that most of them had developed mechanisms for the introduction of innovation, including evidence development and financial risk-sharing agreements.

As part of its evaluation review, INESSS has introduced the innovative concept of “drug deemed promising.”

A risk-sharing agreement can either cover financial parameters (financial risk-sharing agreement) or the addition of clinical data (evidence development).

Though the therapeutic value of promising drugs is recognized, they are often costly and sometimes associated with uncertainty regarding the extent of the clinical benefits. As a result, when supplementary data, such as data concerning quality of life or overall survival, are required for the pharmacoeconomic assessment, INESSS proposes suggesting that an agreement to develop evidence is reached prior to recommending the drug’s listing. Following an INESSS recommendation that a file remain under study, the manufacturer may submit a protocol specifying evidence development terms and conditions, which follows predefined guidelines (research questions, indicators, expected clinical outcomes, etc.) that have been previously determined by INESSS and clinicians in the health care network.

### For clinicians

- More treatment options
- Increased participation in drug assessment

When the cost-effectiveness ratio of a drug deemed promising prevents INESSS from recommending it for the list of medications, the drug may be the subject of a financial risk-sharing agreement, that is to be negotiated by the Ministère de la Santé et des Services Sociaux (MSSS). Such agreements can cover various situations, notably a price reduction, a fixed cost per patient, or a given price for a specific volume. As is the case for evidence development, INESSS recommends that the product remain under study. INESSS will then present the Minister with a potential strategy for allowing limited access to the targeted drug. It will also offer to support the MSSS, at the minister’s discretion, by supplying the target parameters needed for such agreements to succeed.

Through the implementation of these new mechanisms,

innovative drugs can be introduced for the benefit of Québec patients while ensuring efficient use of resources in an ongoing effort to preserve the sustainability of the public plan.

## 3. Improve information management in Québec

Drugs deemed promising are often costly, and the issues associated with them require access to data that enable monitoring of in real-life conditions. It is therefore advisable to set up information systems for collating reliable, valid, quality data. Consequently, Québec should have databases for gathering information (molecules, therapeutic use, dosage, duration of therapy, etc.) to promote the optimal use and systematic monitoring of drugs. Finally, in the case of specific drugs associated with uncertainty when it comes to the extent of the recognized benefits, data collected in a clinical setting could contribute to evidence development.

## Conclusion

With the completion of the pilot project and given the findings of the Comité d’évaluation des innovations – Volet cancer en fin de vie, INESSS proposes that Québec adopt mechanisms, like those used in other Canadian provinces, to promote access to innovative drugs for end-of-life cancer patients, while while being equitable and taking available resources into account. The primary mechanisms proposed by INESSS to achieve this are the following:

- Broaden the framework for assessing drugs for listing purposes, a process INESSS has already begun.
- Develop new approaches to ensure that innovative drugs are introduced in a coherent manner, such as financial risk-sharing agreements or evidence development with the collaboration of the health care system partners.
- Improve information management in Québec.

The fight against cancer is a government priority. INESSS hopes that its proposals will help Québec maintain its leading position in drug accessibility.

The introduction of these new mechanisms—financial risk-sharing agreements and evidence development—is a breakthrough that will provide end-of-life cancer patients with access to drugs while ensuring the sustainability of the drug plan.