

FRAMEWORK AGREEMENT FOR ACCESS TO PRESCRIPTION DRUGS AND INNOVATION IN QUEBEC

CIRANO note based on a report by Mélanie Bourassa Forcier, November 2013

In order to expedite access to drugs and foster innovation in Quebec's pharmaceutical sector, a framework agreement is proposed to elaborate the conditions for risk-sharing arrangements between the Ministre de la Santé et des Services sociaux (the Minister) and the manufacturers of cutting-edge drugs.

By providing for reasonable and equitable access to prescription drugs and encouraging their optimal use, this framework agreement will maximize the reach of Quebec's prescription drug plan and stimulate the bio-pharmaceutical industry. According to a report published by the Institut d'excellence en santé et en services sociaux (INESSS), risk-sharing agreements can generate savings ranging from 5% to 30% for listed drugs. Currently, Quebec is the only province that has not signed any such agreement.

The framework agreement is designed to create an efficient and transparent process for negotiating and concluding arrangements between the Minister and manufacturers. In implementing it, Quebec will be the first province to have adapted a complete and transparent mechanism for establishing this type of agreement.

Here are the ten key points in the proposed framework agreement:

- (1) Only drugs with a proven therapeutic utility will qualify for risk-sharing agreements;
- (2) The INESSS' current process for evaluating drugs remains in effect. Agreements will be negotiated when this evaluation gives rise to uncertainty;

- (3) In the interest of equity, risk-sharing agreements are not limited to cancer-treating drugs;
- (4) An evaluation committee will be set up that is independent of the INESSS;
- (5) The proposed agreement must be initiated by the manufacturer and accompanied by all the data required to assess its social impact;
- (6) A Website listing all drugs covered by an agreement, and the type of agreement, must be available to the public;
- (7) Agreements that provide for rebates are prohibited;
- (8) Agreements may provide for recognition of expenses into an independent account earmarked to fund innovation in the bio-pharmaceutical sector and the development of university research (this is the only proposal that requires an amendment to the law);
- (9) Agreements may provide for recognition of expenses into an independent account earmarked to fund the creation of programs to promote the optimal use of drugs;
- (10) At the Minister's discretion, an agreement may be re-evaluated when a competing version of the drug covered by it is brought to market.

The full study is available on CIRANO's Website at:
<http://www.cirano.qc.ca/pdf/publication/2013RP-18.pdf>