Avantage Québec - Times (and Timing) Are Changing

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The government of Quebec has introduced a new action plan that will drive health technology policy over the next 10 years. Innovation is the theme of the province's action plan and the government has identified various means to engage investment and accelerate the implementation and integration of health-care related innovation for the benefit of the Quebec population. A large part of this plan includes emerging drugs and their respective companion technologies.

This article will focus on the action taken to improve time to access for innovative drugs.

As of 2018, the *Institut national d'excellence en santé et en services sociaux* (INESSS) will be adjusting its review process to allow for more efficient and faster drug and medical device reviews. This significant shift for INESSS was driven in part by increasing pressure to improve access to innovation. There are several measures the agency is taking in order to achieve these goals.

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For one, the health technology agency will look to their national sister agency, the Canadian Agency for Drugs and Technologies in Health (CADTH), to find alignments. This, however, begs the question, how exactly will INESSS engage CADTH? Although INESSS recognizes the need for some collaboration, there are inherent challenges to overcome between the two agencies, such as differences in evaluation criteria and variances in timelines. As the current government intends to maintain the agency's independence, how can INESSS remain autonomous and still find ways to harmonize with CADTH given their differences in structure and process?

Secondly, while Quebec's movement to join forces with the pan-Canadian Pharmaceutical Alliance (pCPA) was carried out to improve efficiencies, the timing of INESSS's recommendations may not always coincide with those of CADTH to ensure Quebec's timely involvement in the price negotiation process.

Thirdly, in order to speed up the review process, INESSS has already confirmed initiation of a pre-notice of compliance (NOC) process for the review of a promising new drug or indication. In order to submit to INESSS while the product is still under review by Health Canada, the applicant must meet the following criteria:

- The product must address a serious disease; and
- The available evidence demonstrates that the drug significantly improves patients' health status compared to current treatment options.

The timing for this pre-NOC submission is 180 days ahead of expected approval from Health Canada for oncology products and 90 days for all other drugs.

As a result, this process would allow for a speedier (maybe immediate) listing during the early phase of the launch.

Listing schedule

In July, INESSS published its schedule of drug submission deadlines and updates for 2018. As per previous years, there will be nine scheduled updates for new drug products or new indications and for multi-source generic drugs. While all the nine scheduled updates allow for submissions of multi-source generics, only three of these dates pertain to innovative products (or indications). While INESSS plans to allow for brand reviews in all of its scheduled updates, their current structure may not be able to handle this increase in innovative drug updates. If INESSS moved from its fixed submission calendar to a more fluid and on-going process, would this allow for the review and evaluation of more products throughout the year and help Quebec meet its goal of improving the time to listing? Though this continuous approach would present a significant shift at INESSS regarding its structure and procedure, it may streamline the recruitment of expert committees and coordination, which may be sometimes challenging with the current process. Moving to a different operating structure could take time before it reaches effectiveness.

The Quebec action plan is also proposing the idea of setting up a working group that will include members of the innovative drug industry. The role of this working group will be to develop an "Avantage Québec" to attract investment and innovation while delivering faster review time and access to innovation.

So, while Quebec knows it is imperative to bring about more efficiencies and faster timelines for drug reviews in order to meet their innovation action plan, it is not yet clear on many fronts how INESSS will modify its process, build connections and collaboration with CADTH and integrate within the pCPA process.

More to come as this action plan will become the new mantra.

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Questions?
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