Constant Change in the Canadian Review Process

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While the pharma industry is no stranger to change…and lots of it, the various reforms within the regulatory and reimbursement pathway may result in a system that is unlike what we know today. Not only could the road to approval from a regulatory and health technology assessment (HTA) perspective change, but the parameters for pricing medicines may take a drastic turn.

Over time the pharmaceutical industry has witnessed change in the review process of new and existing medications in Canada, such as the alignment of the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) under the Canadian Agency for Drugs and Technologies in Health or CADTH. There have also been the consistent updates to the Health Canada review policies, the design of a more formalized structure and process of the pan-Canadian Pharmaceutical Alliance (pCPA), and a drastic change in Quebec regulations to allow for product listing agreements, to name a few.

More recently, we have watched the federal government swoop in to change the course of direction with the Patented Medicines Regulations. Just as the Patented Medicines Price Review Board (PMPRB) was carrying out consultations on its Guidelines Modernization Discussion Paper, the Feds announced in May 2017 amendments to the Patented Medicines Regulations which will directly impact the rules and guidelines of the PMPRB.

CADTH, also, is not one to sit idle. The agency is continually analyzing and updating its processes and, as such, is looking to expand its Scientific Advice program that provides manufacturers with a fee-for-service consultation on their drug-development program with advice from a health technology assessment point of view. CADTH is also currently piloting a project with Health Canada whereby the two agencies will collaborate on specific oncology drug submissions to "explore opportunities to develop a more integrated model for drug review in Canada."[1]

These initiatives strive to enable faster access for patients to new medicines. Will the industry be moving to an authorization system based on safety, efficacy and economic value all in one concurrent process? Will manufacturers

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only require one submission package to move from Notice of Compliance (NOC) to reimbursement?

The federal health technology agency has also stated that it will be evaluating a prioritized system in place of the current first-in, first-out process. As manufacturers plan several years into the future, this modification will have a huge ripple effect in a pharma company's pre-launch and launch plans. While companies try to navigate the current system, they must also plan for the future despite the fact that there may be many more questions right now than answers. What criteria would be used for prioritization, how would the timelines be adjusted *etc.*?

Most recently, the new federal Minister of Health, Ginette Petitpas Taylor, announced a review of the eight federally funded pan-Canadian health organizations (PCHOs) that address specific aspects of the health care system including CADTH, the Canadian Institute for Health Information (CIHI), and Canada Health Infoway, among others. This review will be carried out by two health policy experts, who have been asked to "explore the future role of these organizations in light of a number of critical challenges and priorities facing the health system."[2]

Given the complexities within the "Approval to Reimbursement Pathway" and the numerous moving parts within this multifaceted system, it can become a challenge for industry, patient groups, and other stakeholders to navigate. How does a manufacturer prioritize its energy and efforts with all these shifting components? As strategies, forecasts, and timelines are developed, more contingency plans may be required given the ripple effect of new programs within this pathway.

While our industry has always been fast paced and not one that cowers from change, some certainty or even probability would be valuable. However regarding predictability… there is none!

Appendix

1. CADTH. CADTH Drug Portfolio Sessions. Available at www.cadth.ca/events/cadth-drug-portfolio-information-sessions-2017. Accessed November 2017.
2. Health Canada. External Review of Pan-Canadian Health Organizations: Guidelines and Questions for Stakeholders. Available at www.canada.ca/en/health-canada/programs/external-advisory-body-pan-canadian-health-organizations/external-review-stakeholder-guidelines-questions.html. Accessed November 2017.

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