Health Canada Santé Canada

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Future Considerations for Drug Regulating

David K. Lee
Health Canada

Drug Pricing Summit, November 15, 2016

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Introduction

Current climate for regulating drugs:

- Questions about the sustainability of the present model, with most emphasis on pre-market and increasing availability of on-market information.
- Challenges related to incoming trends (precision medicine) and science (new technologies, new data architectures; new statistical models, analytical frameworks).
- Few formalized engagement opportunities with patients throughout the federal review cycle.

What might the future look like?

New International models?

- Evolution from a verification role to a more active role for regulators worldwide, one that is more iterative and collaborative with other decision-makers, and deepens the focus on improving patient outcomes?

- Regulators, among others, have available the new science, technology and opportunity to more actively take measures to **optimize the benefits and minimize the risks of drugs** throughout the lifespan of a product, from trial design to the eventual removal or abandonment of the market.

- Strengthening orientations to ensure drugs are directed to those who best respond therapeutically and are not given to those experiencing no benefit or worse, suffering harm instead of benefit. The model is collaborative and adaptive in the sense that it reduces uncertainties about who benefits from a drug and who does not throughout the lifecycle of the product.

What can we do together?

- International pilots are placing emphasis on up-front planning and more collaborative discussions between drug developers, regulators, payers so that the most important questions can be answered when the drug is studied -- at the centre of this should be meaningful engagement with patients.

- **Ensure that clinical trials** for important new therapies are discussed early to get as much as possible out of studies. This means careful exploration to sensitize clinical trials to the most optimal population, not necessarily the broadest possible one.

- **Authorize market entry** with meaningful questions and commitments (proactive questions, evidence cycle, managing uncertainties).

- **Gather and use reliable on-market evidence**: additional studies, reporting, including patient reporting, federated data models, querying capabilities, to keep optimising benefits and minimizing risks.

Looking at possibilities 2017

- **Questions and opportunities:**
  - Current pilot work and large policy discussions (e.g. Notice of Intent to implement key authorities under *Protecting Canadians From Unsafe Drugs Act* (Vanessa's law) http://www.gazette.gc.ca/rp-pr/p1/2016/2016-06-18/html/notice-avis-eng.php#nl6) creates an opportunity to discuss future amendments that are crucial for safety and implementation of a new regulatory model.
  - What discussion forum or pilot work can be explored to help all of us understand how to participate in a practical way? Willing to bring back suggestions!