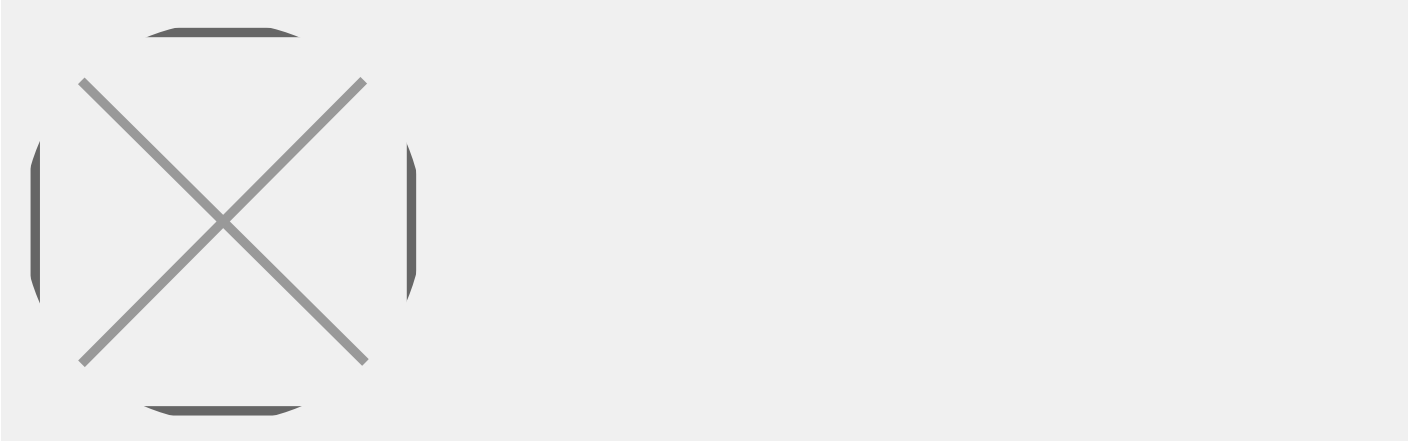
Interview: Paul Glover, Associate Deputy Minister, Health Canada



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A perspective from Canada's national health body on the future of medicine in the 21st century, from the shift to personalized medicine to streamlining regulatory and approval processes, removing duplication from international partners and utilizing modern communications technology to improve transparency and efficiency.

Could you provide a brief overview of Health Canada and its main priorities?

Health Canada has a very important mandate to protect the health and safety of Canadians. The Department has a long and prosperous legacy of fulfilling that mandate, for example through the regulation of food, drugs, medical devices and products to ensure their safety. The department also has a role in providing health information to Canadians to help them make informed choices. The other interesting aspect of Health Canada is its portfolio, working with public health agencies, health surveillance, and the Canadian Institute for Health Research (CIHR) to drive innovation and improve drug safety effectiveness.

What are some of the greatest challenges that you will be facing in the coming months and years?

The health system is changing rapidly, which creates a number of challenges in terms of keeping pace with globalization and medical innovation, such as the development of personalized medicines. To do this, Health Canada's first priority must be its employees. We must continue to

attract and retain the best and brightest minds, and give them the tools they need to work most effectively with industry. Increasingly, these tools are digital. For example, drug submissions are extremely important, and most people have no concept of just how much data is involved in a typical submission. Secure electronic exchanges with industry, and the tools to be able to plough through all that data efficiently, are both paramount. Using technology wisely and allowing Health Canada's people to interact with partners around the world is critical.

I see our second priority as maintaining our operational excellence. The Government of Canada has set out a clear priority, which Health Canada has embraced. This means cutting red tape and reducing unnecessary steps to ensure that the system is as efficient as possible. Health Canada constantly looks at the what, how and why of its operations.

Finally, the department needs to ensure a modern regulatory framework. Health Canada has taken steps in a number of areas to improve the climate for both consumers and for the industry. For example, how a drug is listed as a prescription product and moved from prescription to non-prescription was a very cumbersome process, and is now far more streamlined. Health Canada is also making progress with plain-language labeling to make it easier for consumers and healthcare professionals to understand and use health products safely and appropriately. We are also looking at an orphan drug framework that is aligned with Europe and the US. These are the changes that will improve the climate for industry, support innovation and enhance the health and safety of Canadians.

How do you maintain a balance between effective regulation and the best availability?

Health Canada does not look at tradeoffs but rather tries to create win-wins. We talk directly to patient groups, health practitioners, and industry. We benchmark ourselves against other international regulators and current best practices worldwide. For example, the orphan drug framework is one that will be aligned with what the United States and Europe are doing. While the number of patients suffering from rare diseases is relatively few, being able to pool data with other larger countries will not only improve the climate for researchers, but also enhance patient safety in the long run. It is a matter of regulating more smartly.

Another trend is eliminating duplication through working with international partners. Regulators need to work together to reduce the amount of overlap and to better exchange information, which will lead to real efficiencies. Where there are concerns, it is better to have all partners working together rather than pursuing solutions independently.

For example, Health Canada has recently signed joint agreements on the regulation of medical devices with ANVISA and the FDA. Health Canada also works very closely with the Pan-American Health Organization, and strongly supports its endeavors. We are also working closely with the European Medicines Agency on a wide array of issues. I hope that all of these organizations build some common platforms that everyone can share to facilitate exchanges. There is a very bright future for international collaboration.

How can Health Canada foster a regulatory environment that attracts international companies to create drugs here?

Canada already has that climate today. We have strong granting councils to support research and development. In addition, the government is committed to reducing red tape without compromising health and safety, which Health Canada has embraced. The health system in Canada is unique in its ability to work with patients and professionals, which will become more beneficial in the future. Canada is also a WHO-collaborating center for some biological vaccines. When Canada approves a product, many countries worldwide use it as a stamp of approval. That is an important competitive advantage for any company that is thinking about which market to enter. While Canada only has 2-3 percent of the global market, it has much credibility, not just in terms of regulation but the entire system. I also think that the health system will look to regulators and health technology assessment (HTA) groups to discover the incremental benefit and value of drugs. There is further work that Health Canada can do to streamline those processes. It is like a relay race at the moment: Health Canada approves the drug, which is handed over to provinces, which refer it to the HTA centers for their review. Aligning those processes will create further opportunities.

What are your goals for Health Canada in the next five years?

I believe that Canada will continue to have the best and brightest minds in the regulatory field, working both with industry and Canadians to ensure product availability, and with health practitioners to provide effective information. Health Canada must continue to be operationally excellent with the best available tools, and remain connected internationally with all of its partners. Rather than work alone, Health Canada needs to be part of a community of regulators working together. Since many drugs are allowed in multiple countries, it would be wise for all authorities to work together on the approval of those drugs and the follow-up of safety information once those drugs are on the market. This involves updating labels and providing good information to physicians who use and prescribe them for patients. I would also hope that the entire international regulatory community is far more transparent. Consumers want to know more about the drugs they

are taking, and they want to interact with their health professionals by being part of the debate on drug choice. The regulatory community at large needs to be far more transparent. Why or why not was a drug approved? Where and what are clinical trials producing? How can we make information on adverse events more available? How can drug bulk purchasers gain access to inspection reports more easily? Transparency and collaboration ground science and this needs to be communicated with Health Canada's partners.

What personal goal would you like to achieve as Associate Deputy Minister?

It is not necessarily about personal goals; the work that this organization does is incredibly important to Canadians. I feel very lucky to have worked with so many amazing people who take their roles seriously. Health Canada has embarked on a wonderful process of streamlining what it does, giving staff better tools to do their job, and aligning its work with partners internationally. I hope that that work continues, because I think it will improve the operating climate for industry and lead to better outcomes for patients in the long term.

In terms of preparing for trends, Canada needs to ask where it thinks the industry is going. Health Canada will ensure that it is ready for the regulation of personalized medicine and some of the other more complex technologies in the device world. It will be important to have the best people with the best tools with the best regulatory systems, working with the best minds globally, so that when personalized medicine comes forward Health Canada is ready to support innovation without compromising health and safety. That is the real challenge for which Health Canada is preparing. We also need to be ready to spend more time on those newer, more innovative products that we know less about and figuring out the appropriate regulation for it. This will change the way we do business, but I am very excited about it.

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