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Data Protection: a winning policy for research, innovation and patients

Life sciences research and innovation in Canada was given a significant boost by the federal government recently when it amended the *Food and Drug Regulations* to provide eight years of data protection of clinical test data generated to approve a new medicine in Canada. This approval can also include six months of additional data protection for medicines that have been the subject of paediatric clinical trials.

Canadians may not have fully realized it, but the lack of data protection in Canada stifled life sciences innovation, penalizing both patients and the development of new and improved medicines.

This action by the federal government appears to meet Canada's obligations under the *Trade-Related Aspects of Intellectual Property Rights* (TRIPS) and the North America Free Trade Agreement (NAFTA). It also represents the first major step forward for innovation in Canada in more than a decade.

Rx&D member companies will be evaluating the impact these changes will have on bringing new medicines and vaccines to Canadian patients. We are also hopeful that these improvements to data protection will foster innovation in the biopharmaceutical sector, and provide the incentive to biopharma companies to commercialize their products in Canada.

As the federal government points out in its analysis, providing eight years of data protection will ensure that both innovative and generic pharmaceutical companies know the rules, which in turn will ensure that the "costs associated with litigation would decrease significantly."

Opponents of these proposed new rules may try to tell you they will extend the patent of medicines and make it more difficult for non-innovators to copy drugs. This is simply not the case. Providing real data protection will not extend patent life by one day and will still allow generic companies to copy medicines discovered by innovative companies.

A strong signal to the world – Canada is serious about attracting life sciences R&D

New data protection regulations, which were in development for more than two years and close a glaring loophole in law that has meant innovative companies received no effective data protection in Canada for their intellectual property, sends a strong signal to the world that Canada is serious about attracting research and development (R&D) in a globally competitive market.

These new regulations will give Canada the ability to compete with other major countries in the global competition for jobs, prosperity and better quality of life that the life sciences industry creates.

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It will also give our best and most creative minds the opportunity to conceive and develop the latest treatments that improve and save lives and make them available to Canadians.

We will still have less data protection than the European Union (ten years), but we will be able to compete with developed countries like the U.S. as well as emerging economies like China and India.

A patent lasts for 20 years in Canada. However, it takes on average twelve years or more for a new medicine or vaccine to go through all the trial and approval stages which leaves innovative companies eight years to recover their investment.

Developing the latest treatment to fight diabetes, heart disease or cancer is extremely expensive, time consuming and risky. It costs about \$1 billion to develop a new medicine. Only one in every 10,000 new molecules actually makes it to market and only three out of ten of those medicines will recoup their investment.

The federal government has sent a strong message to the world that Canada wants to attract more high paying jobs, investment and a better quality of life and create a climate that will improve access to new therapies, treatments and cures.

As a result of the approved data protection regulations, Canada has taken a significant step forward for patients by implementing a winning policy for research and innovation.

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