NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Proposed regulations published on additional elements of Vanessa's Law

Summary

On April 22, 2017, the Government of Canada published draft regulations *Amending the Food and Drug Regulations (Vanessa's Law)* that provide details regarding the minister of health's powers to require tests, assessments and studies of a drug post-market authorization. The draft regulations also set out additional reporting requirements for manufacturers based on the actions of foreign regulators.

Stakeholders can make representations concerning the draft regulations until June 27, 2017.

Overview

On November 6, 2014, the *Protecting Canadians from Unsafe Drugs Act* (also known as **Vanessa's Law**) came into force and amended the *Food and Drugs Act*. The amendments provide Health Canada with additional powers to regulate the safety of drugs through a life cycle approach (i.e., an approach to regulate drugs by evaluation of safety both pre- and post-market). While most of the amendments came into force immediately, some required supporting regulations.

The draft regulations are expected to achieve three objectives: (1) support the coming into force of the new powers granted by Vanessa's Law that allow the minister to require manufacturers to conduct tests, assessments and studies, and to establish standards for exercising these powers; (2) create a set of new foreign incident reporting rules to support post-market drug safety; and (3) eliminate the requirement to provide individual clinical case reports with a new drug submission.

Proposed regulations

(1) Tests, Assessments and Studies. The draft regulations are intended to define the scope of the minister's powers under Vanessa's Law to require an authorization holder to assess a drug post-market and order the authorization holder to conduct tests or studies of a drug post-market.

Under the draft regulations, to require an authorization holder to assess a drug under Vanessa's Law, the minister must have reasonable grounds to believe that the benefits or risks of injury to health associated with the drug are significantly different than they were when the most recent authorization was issued. The draft regulations also provide that a summary of the results and any actions taken as a result of the examination would be made publicly available.

To require an authorization holder to conduct additional tests or studies of a drug under Vanessa's Law, the minister must have reasonable grounds to believe there are significant uncertainties related to the benefits and harms associated with the drug, and the authorization holder must be unable to provide the minister with the information to manage those uncertainties. The minister must also consider whether there are less burdensome means to obtain the required information.

(2) Notifying Health Canada of Foreign Regulators' Actions. The draft regulations require an authorization holder of a prescription drug (or a non-prescription drug administered by a practitioner) to report certain interactions with foreign regulatory authorities related to the safety of the drug. These include: (1) any risks communicated by a foreign regulatory authority; (2) labelling changes requested by or communicated to a foreign regulatory authority; and (3) recalls, reassessments, suspensions or revocations of authorization. The authorization holder must provide such information to the minister within 48 hours of receiving it or becoming aware of it.

(3) Clinical Case Reports. The draft regulations would repeal the requirement under section C.08.005.1(1)(a) of the *Food and Drug Regulations* to provide individual clinical case reports when a new drug submission is filed with the minister. Currently, Health Canada is the only major regulator that requires this information. In order to alleviate this burden, manufacturers will only be required to provide a summary of clinical case reports when filing an NDS. The minister may request access to the individual clinical case reports when necessary.

Link

Regulations Amending the Food and Drug Regulations (Vanessa's Law)

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

For a complete list of our IP team, click here. For a complete list of our Life sciences and healthcare team, click here.