

## Pharma in brief - Canada

### Health Canada to amend *Food and Drug Regulations* to require notification of drug shortages and zero sales of DIN products: draft guidance documents issued for stakeholder input

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#### Summary

The *Regulations Amending the Food and Drug Regulations (Shortages of Drugs and Discontinuation of Sale of Drugs)* were published in the Canada Gazette, Part II on June 29, 2016, and will come into force in the spring of 2017. These amendments will require a manufacturer to notify Health Canada within 30 days when a drug has not been sold for 12 consecutive months. Further, these amendments will require a manufacturer to publicly report drug shortages or discontinuations of a drug through a new third-party website.

Health Canada has released two draft guidance documents pertaining to the proposed amendments to the *Regulations*: (a) “Cancellation of a Drug Identification Number (DIN) and Notification of the Discontinuation of Sales,” and (b) “Draft – Guide to reporting drug shortages and discontinuations.” Both are open for consultation until **September 28, 2016**.

#### The zero sales notification requirement

In the spring of 2017, section C.01.014.12 of the *Food and Drug Regulations* will come into force requiring drug manufacturers to notify Health Canada within 30 days when a product has not been sold for 12 consecutive months. Initially, this requirement was only anticipated to apply to select categories of drugs. However, Health Canada recently announced its intention to amend the *Regulations* to require all products with a Drug Identification Number (**DIN**), including non-prescription products, to comply with this section of the *Regulations*.

The purpose of the provision is to allow Health Canada to assign a new “dormant” category in the Drug Product Database (**DPD**) to better enable users to determine which drug products are presently available on the Canadian market. However, this would not affect the DIN for the product. Currently, if a manufacturer stops sales of a product without cancelling the DIN, the drug is still listed as “marketed” on the DPD even though it is not available on the Canadian market.

#### Reporting on drug shortages and discontinuations

In the case of an actual or anticipated drug shortage, the amendments to the *Regulations* will require an authorization holder to report the anticipated start and end dates of the shortage, and the actual or anticipated reason for the shortage within six months of the anticipated start date, if known.

In the case of a discontinuation of a drug, a DIN holder will be required to report the DIN, the date on which the person discontinued the sale of the drug, the latest expiration date of the drug sold and the lot number of the drug to the Minister of Health within 30 days after the day on which the sale of the drug was discontinued. Further, a DIN holder will be required to post information related to the discontinuation of its drug on a third-party website at least six months before the day on which the sale of the drug will be discontinued, if known, or within five days after the day on which

the decision to discontinue the sale of drug is made, if the decision is made within six months or less. Previously, the *Regulations* only specified that a DIN holder notify Health Canada within 30 days of discontinuation of sale of the drug.

### **Consultation on proposed amendments to the *Regulations***

Health Canada has released two draft guidance documents pertaining to the proposed amendments to the *Regulations*: "[Cancellation of a Drug Identification Number \(DIN\) and Notification of the Discontinuation of Sales](#)" and (b) "[Draft – Guide to reporting drug shortages and discontinuations](#)." Both guidance documents are open for consultation until **September 28, 2016**. A copy of the "[Draft – Guide to reporting drug shortages and discontinuations](#)" can be obtained by contacting Health Canada.

### **Link to *Regulations***

[\*Regulations Amending the Food and Drug Regulations \(Shortages of Drugs and Discontinuation of Sale of Drugs\)\*](#)

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