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Pharma in brief - Canada

"Dear Health Care Professional Letter" no longer required for Notice of Compliance with conditions (NOC/c)

Summary

Health Canada no longer requires manufacturers to prepare a "Dear Health Care Professional Letter" for drugs that have been issued a Notice of Compliance with conditions (**NOC/c**). Notification will now be provided through Health Canada's monthly *Health Product InfoWatch* publication.

Background

Drugs can be approved for sale under the NOC/c regime earlier than is normally possible. The objective is to provide early access to "promising new drugs for serious, life-threatening or severely debilitating diseases or conditions for which no drug is presently marketed in Canada or for which a significant increase in efficacy or a significant decrease in risk is demonstrated in relation to an existing drug marketed in Canada."[1] The NOC/c regime also ensures that necessary investigations on the drugs are completed while fostering transparency with the conditions of market authorization.

In the past, the manufacturer had to submit a Dear Health Care Professional Letter to Health Canada that included details of the drug, indication, disease state, the nature of the conditional authorization granted by Health Canada, and instructions to health care professionals that patients must be informed of the nature of the authorization. These letters were posted on Health Canada's website.

New process

Much of the relevant information provided in the Dear Health Care Professional Letter can be found in other accessible documents such as the product monograph. Now, in place of the letter, Health Canada will publish a notice that highlights the conditional market authorization as part of *Health Product InfoWatch*, which is a monthly publication intended to raise awareness and provide information concerning the safety of marketed health products. It is posted on the Health Canada website and distributed to key health care groups.

This change reflects Health Canada's streamlined approach to risk communication. The notices in the *Health Product InfoWatch* will include the brand and generic names, dosage form, strength and indication, along with a disclosure on the nature of the authorization granted and the need to communicate this to patients. A link to the product monograph and contact information for the manufacturer will also be included. Because publication occurs monthly, the notice will appear in the month immediately following the issuance of the NOC/c.[2]

The notices are prepared by Health Canada and provided to manufacturers for review at least two business days prior to publication in order to verify the accuracy of the information.

Updated guidance document

On September 16, 2015, Health Canada released an updated Guidance Document for Notice of Compliance with Conditions (NOC/c). The changes to this document are described above and also include certain administrative edits.

Links:

Guidance Document: Notice of Compliance with Conditions

Health Product InfoWatch Publication

Footnotes

[1] Health Canada, *Guidance Document: Notice of Compliance with Conditions (NOC/c)*, online: s 1.1 <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/compli-conform/noccg_accd-eng.php>.

[2] Ibid at s 5.3 and Appendix 3.

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