Health Canada Santé Canada

February 21, 2013

Notice

Our file number: 13-103005-9

Subject - Notification of Safety Labelling Changes to the Product Monographs of Pharmaceutical Drug Products

Health Canada is pleased to announce a new process that will inform generic drug manufacturers of safety labelling changes to the Product Monographs (PM) of brand name pharmaceutical drugs.

Health Canada will regularly post a table on the Department website which reflects updated and/or new safety information in PMs of brand name pharmaceutical drug products (those regulated under Division 8 of the *Food and Drug Regulations* only). This table will identify the section of the PM that was updated pursuant to a Notifiable Change or Supplemental New Drug Submission.

The issuance of this table is aimed to inform generic drug manufacturers about new safety information for pharmaceutical drug products so that they can update their PMs for health care professionals and Canadians. The table will also address Departmental commitments following the Auditor General's audit report: Regulating Pharmaceutical Drugs - Health Canada (http://www.oag-bvg.gc.ca/internet/English/parl_oag_201111_04_e_35936.html), related to improving transparency and timeliness with respect to drug safety.

Note that all manufacturers are required under the *Food and Drug Regulations* to ensure drug product labelling, including the PM, is up to date and supports safe conditions of use. The table will provide generic drug manufacturers with the necessary information about their Canadian Reference Products' (CRP) labelling to facilitate corresponding updates to generic PMs. Generic drug manufacturers are reminded of their obligations to update their PM to ensure consistency with that of the CRP; they are encouraged to review the table and submit to Health Canada according to the suggested timeline. Further instructions for generic drug manufacturers can be found below.

The table can be found on the Health Canada website (http://web.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/pm_saf_mp_innoc/index-eng.php). To access up-to-date Health Canada approved information on drugs marketed in Canada, a search of the Drug Product

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Database online can be performed at the following link: http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. As needed, Health Canada will continue to communicate new safety information to Canadians by various means including issuing warnings, advisories, and PM updates.

This initiative will be piloted starting February 2013 after which time the effectiveness of the notification process will be assessed. Comments on this pilot are welcome to the email address below.

Additional Information for Generic Manufacturers

Manufacturers of authorized generic products are expected to file submissions to update their labelling within 30 days of the posting date of the table describing the labelling change for the CRP.

Drug Identification Number (DIN) Assigned/ Non-Marketed Products

Manufacturers of generic products which are not marketed in Canada but have DINs assigned to them are also expected to file according to the above timeline.

Products on Intellectual Property (IP) Hold

Manufacturers of generic products on IP hold are also expected to file according to the above timeline, however in certain cases it may be acceptable to delay filing until closer to the date of issuance of the Notice of Compliance.

Please note that while this posting is intended to replace direct generic sponsor labelling request notifications, in some cases, Health Canada may still contact generic manufacturers directly to request PM updates. Submissions should be prepared in the usual manner as per the *Management of Drug Submissions and Post-Notice of Compliance Changes* Guidance Documents.

Sponsors are expected to file along with their submissions an attestation form certifying that the submitted PM is updated consistent with the most recent PM of the CRP. Attestation forms can be obtained on the Health Canada website at the following link: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php. Attestation templates must be used for all Notifiable Changes and Supplemental Abbreviated New Drug Submissions where a PM update is proposed, even those that do not fall under this pilot.

Questions or concerns related to this Notice should be directed to:

E-mail: Generic_Drug_Labelling@hc-sc.gc.ca