Ontario Public Drug Programs Division, Ministry of Health and Long-Term Care

Regulation Amendments to Streamline Submission Requirements for Certain Generic Products seeking Interchangeability Designations on the Ontario Drug Benefit Formulary

Sept 18, 2015

The purpose of this notice is to provide you with information regarding recent amendments to Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA Regulation"). The amendments have been approved by the Ontario Government and come into force **on October 1, 2015**.

A notice was posted on the ministry's website on July 23, 2015 that provided stakeholders with information on the proposed amendments to the DIDFA Regulation. Stakeholders were given a 30-day period to comment on the proposed regulatory amendments. I would like to thank all those who submitted comments and participated in the consultation process.

The amendments to the DIDFA Regulation establish the following:

- With respect to aqueous solutions that are currently exempt from the in vivo bioequivalence study requirement in section 6(1)(h) of the Regulation, the requirement that the aqueous solutions must be the "same volume" as the original product is removed, and is replaced with a requirement that the aqueous solution be the "same strength" as the original product.
- Certain dermatological products and products with a transdermal route of administration for systemic effect are exempt from the in vivo bioequivalence study requirement in section 6(1)(h).To qualify for the exemption the product must contain one or more glucocorticoids as the only active ingredient(s), and have a declaration of equivalence from Health Canada with the original product or another listed interchangeable product with which it would be designated as interchangeable.
- Products with a transdermal route of administration for systemic effect are exempt from the in vivo bioequivalence study requirement in clause 6(1)(h). To qualify for the exemption the product must have a declaration of equivalence from Health Canada with the original product or another listed interchangeable product with which it would be designated as interchangeable.

For the authoritative text of the regulation, please visit the e-Laws website at:
http://www.ontario.ca/laws

Any questions regarding the changes to the DIDFA Regulation can be directed to:

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