Notice: Interim Policy on Health Canada's Interpretation of Medicinal Ingredient

June 16, 2015
Our file number: 15-107166-261

This Notice serves to inform sponsors of drug submissions pursuant to Division C.08 of the *Food and Drug Regulations* (that is, new drugs and abbreviated new drugs) of changes in Health Canada's interpretation of medicinal ingredient, and therefore to the assessment of pharmaceutical equivalence. The changes below form the basis of an interim policy, which Health Canada has implemented in view of a Federal Court decision (Justice Kane, 2013 FC 1217). The interim policy outlined herein supplements the existing Policy entitled, *Interpretation of 'Identical Medicinal Ingredient' (2003)*. Taken together, the interim policy and the 2003 Policy will remain in effect while the matter is being fully considered and until further notice.

The changes do not apply to biological or radiopharmaceutical products, or to medicinal ingredients which do not possess a unique chemical structure [for example (e.g.), polymers with varying molecular weights].

Following the court's decision and for regulatory consistency, Health Canada has reassessed its interpretation of "medicinal ingredient" as used in section C.01.004(1)(c)(iv) of the *Food and Drug Regulations* to mean the Active Pharmaceutical Ingredient (API) used as the raw material in the manufacture of the finished dosage form (FDF). As a result, drug labels must refer to the API as the medicinal ingredient. For drug products in which the medicinal ingredient undergoes a change in chemical form during the manufacturing process (e.g., *in situ* changes), the label should further indicate the chemical form in the FDF in brackets after the API. The source of the counter ion for a salt should not be listed as a non-medicinal ingredient.

Also, under the new interim policy, Health Canada will evaluate pharmaceutical equivalence between two drug products at the input stage (understood to mean the pharmaceutical equivalence of the APIs). However, when deciding whether the two medicinal ingredients are "identical", such that an Abbreviated New Drug Submission (ANDS) may be the appropriate route for assessment, Health Canada will also consider the manufacturing processes which can lead to variations in the chemical form of the medicinal ingredients in the FDF (e.g., in situ transformation of free base to salt). If the same medicinal ingredients at the input stage diverge into different forms, additional safety, effectiveness and quality data may be required. If the medicinal ingredients are different chemical forms at the input stage but nonetheless converge into the same chemical form, the medicinal ingredients will be considered "identical", and additional safety, effectiveness and quality data will not be required.

Further, the *Patented Medicines (Notice of Compliance) Regulations* will continue to apply where a comparison or reference is made to a drug found on the Patent Register, regardless of the question of equivalence. The application is not dependent on the determination of pharmaceutical equivalence. In addition, the established meaning of "claim for the medicinal ingredient" will continue to apply to the listing of patents on the Patent Register in accordance with section 4 of the *Patented Medicines (Notice of Compliance) Regulations*. Similarly, there is no impact on the application of the data protection provisions in section C.08.004.1 of the *Food and Drug Regulations.*

Submission sponsors are advised to discuss with Health Canada, in advance, when the "identicality" of two medicinal ingredients is in doubt for the purposes of establishing pharmaceutical equivalence.

For questions on pharmaceutical equivalence or labelling, please contact:

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Email: bps_enquiries@hc-sc.gc.ca

For questions related to patent listings or data protection, please contact:

Office of Patented Medicines and Liaison
Therapeutic Products Directorate
Health Canada
Finance Building
101 Tunney's Pasture Driveway
Address Locator 0201A1
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