Cassels

Have Your Say on Possible Changes to the Food and Drug Regulations: Generic Drug Equivalence and Related Terminology

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Health Canada is soliciting input on possible changes to the *Food and Drug Regulations* regarding establishing pharmaceutical equivalence between a proposed generic drug product and the Canadian Reference Product ("CRP"). These proposed changes are intended to better harmonize the framework with the practices of other major regulatory bodies. Consultations, which are the first in a series of consultations, will be open until October 13, 2017.

The key concepts in the proposed changes are as follows:

(a) Establishment of pharmaceutical equivalence. The proposed changes introduce a distinction between "*pharmaceutical equivalents*", generic drug products with the same medicinal ingredient in the same dosage form, and "*pharmaceutical alternatives*", generic drug products with different salts, esters or complexes as the medicinal ingredient and/or generic drug products with different but comparable dosage forms to the CRP.

Under the proposed changes, both pharmaceutical equivalents and pharmaceutical alternatives could be considered therapeutically equivalent, if it can be demonstrated that the drugs have the same routes of administration and same safety and effectiveness as the CRP[1]. If approved, a Notice of Compliance could be issued for either a pharmaceutical equivalent or a pharmaceutical alternative[2].

(b) Definition of "medicinal ingredient". In addition to the above, the proposed changes add a definition of "medicinal ingredient" as "the active substance that contains the therapeutic moiety in the drug product that is administered to or consumed by Canadians"[3]. This is in contrast to the current approach of treating the input material as the medicinal ingredient. The proposal also indicates that the terms "therapeutic moiety" and "drug product" could also be defined to clarify the definition of "medicinal ingredient"[4].

Comments on the proposed changes must be submitted by October 13, 2017 by e-mail, fax or mail to:

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Health Canada

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Additional information can be found here.

For additional guidance and specific advice on the proposed changes to the *Food and Drug Regulations*, please contact Chandimal Nicholas or another member of the firm's Life Sciences group.

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[1]Government of Canada, *Notice to Interested Parties*, Possible Changes to the Food and Drug Regulations: Generic Drug Equivalence and Related Terminology.

[2]*Ibid.*

[3]*Ibid.*

[4]*Ibid.*
