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Food and Drugs Regulations

C.R.C., c. 870

FOOD AND DRUGS ACT

C.01.004 (1) The inner and outer labels of a drug shall show

...

(c) on any panel

...

(iv) a quantitative list of the medicinal ingredients of the drug by their proper names or, if they have no proper names, by their common names, except in the case of a drug to which section C.01.004.02 applies,

(iv.1) despite subparagraph (iv), for drugs to which Division 8 applies, if the *therapeutically active component* as defined in section C.08.001.1 and the medicinal ingredient as determined in accordance with section C.08.001.01 are not the same, the name of the medicinal ingredient and a quantitative list of the therapeutically active components of the drug,

...

C.01.004.02 (1) In addition to the requirements of section C.01.004, the outer label of a drug for human use in dosage form shall display, either one bilingual table, placed on any panel, that contains only the following information in both English and French or one table in English and one table in French, each of which is placed on any panel, that contains only the following information:

...

(b) a quantitative list of the drug's medicinal ingredients by their proper names or, if they have no proper names, by their common names;

(b.1) despite paragraph (b), for drugs to which Division 8 applies, if the *therapeutically active component* as defined in section C.08.001.1 and the medicinal ingredient as determined in accordance with section C.08.001.01 are not the same, the name of the medicinal ingredient and a quantitative list of the therapeutically active components of the drug;

...

C.01.004.03 In addition to the requirements of section C.01.004, the inner label of a drug to which section C.01.004.02 applies shall display on any panel

...

(b) a quantitative list of the drug's medicinal ingredients by their proper names or, if they have no proper names, by their common names; ~~and~~

(b.1) despite paragraph (b), for drugs to which Division 8 applies, if the t*herapeutically active component* as defined in section C.08.001.1 and the medicinal ingredient as determined in accordance with section C.08.001.01 are not the same, the name of the medicinal ingredient and a quantitative list of the therapeutically active components of the drug; and

...

DIVISION 8 – NEW DRUGS

...

C.08.001.01 (1) For the purposes of this Division, a reference to the medicinal ingredient of a new drug is a reference to the form of the medicinal ingredient in the dosage form of the new drug as determined by the Minister, taking into account the method of manufacture and the controls to be used in the manufacture of the dosage form.

(2) If the Minister is unable to make this determination because of uncertainty as to what constitutes the form of the medicinal ingredient in the dosage form of the new drug, the manufacturer who has filed a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission or a supplement to any of those submissions, shall, at the request of the Minister, provide information and materials on the medicinal ingredient.

C.08.001.1 For the purposes of this Division, ...

~~***pharmaceutical equivalent*** means a new drug that, in comparison with another drug, contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients; (*équivalent pharmaceutique*)~~

pharmaceutical equivalent means

(a) in respect of a new drug referred to in Schedule C of the Act, a new drug that, in comparison with another drug, contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients; and

(b) in respect of a new drug not referred to in Schedule C or Schedule D of the Act, a new drug that, in comparison with another drug, contains identical amounts of the identical therapeutically active components, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients. (*équivalent pharmaceutique*)

...

therapeutically active component means a medicinal ingredient, excluding those appended portions, if any, that cause the medicinal ingredient to be a salt, hydrate or solvate. (*composant thérapeutique actif*)

...

C.08.002 (2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(a) a description of the new drug and a statement of its proper name or its common name if there is no proper name;

...

~~**(c)** a list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients;~~

(c) a list of the ingredients used in the manufacture of the new drug, stated quantitatively, and the specifications for each of those ingredients;

...

C.08.002.1 (1) ~~A manufacturer of a new drug may file an abbreviated new drug submission or an abbreviated extraordinary use new drug submission for the new drug where, in comparison with a Canadian reference product,~~

A manufacturer of a new drug, other than a new drug listed in Schedule D of the Act, may file an abbreviated new drug submission or an abbreviated extraordinary use new drug submission for the new drug where, in comparison with a Canadian reference product,

(a) the new drug is the pharmaceutical equivalent of the Canadian reference product;
(b) the new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister considers it necessary, bioavailability characteristics;
(c) the route of administration of the new drug is the same as that of the Canadian reference product; and
(d) the conditions of use for the new drug fall within the conditions of use for the Canadian reference product.

...

C.08.002.1 (3.1) If the Minister has reasonable grounds to believe that there is a difference between the medicinal ingredient in a new drug and the medicinal ingredient in the Canadian reference product, the manufacturer of the new drug shall, at the request of the Minister, provide information and materials that demonstrate that the difference, if any, is inconsequential with respect to the safety or effectiveness of the new drug.

...

C.08.003 (2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:

(a) the description of the new drug;

...

~~**(c)** the specifications of the ingredients of the new drug;~~

(c) the specifications of the ingredients used in the manufacture of the new drug;

...

C.08.004 ...

(4) A notice of compliance issued in respect of a new drug on the basis of information and material contained in a submission filed pursuant to section C.08.002.1 shall state the name of the Canadian reference product referred to in the submission and shall constitute a declaration of equivalence for that new drug.

(5) If there is a difference between the medicinal ingredient in the new drug and the medicinal ingredient in the Canadian reference product, the difference shall be stated in the notice of compliance referred to in subsection (4).

C.08.004.01 ...

(4) A notice of compliance issued in respect of a new drug for extraordinary use on the basis of information and material contained in a submission filed pursuant to section C.08.002.1 shall state the name of the Canadian reference product referred to in the submission and shall constitute a declaration of equivalence for that new drug.

(5) If there is a difference between the medicinal ingredient in the new drug and the medicinal ingredient in the Canadian reference product, this difference shall be stated in the notice of compliance referred to in subsection (4).

C.08.004.1 (1) The following definitions apply in this section. ...

~~***innovative drug*** means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (*drogue innovante*)~~

innovative drug means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient. (*drogue innovante*)

...

variation includes, for the purposes of the definition *innovative drug*,

(a) an enantiomer or a mixture of enantiomers;
(b) a polymorph;
(c) a medicinal ingredient that, when compared to a previously approved medicinal ingredient, is identical, excluding those appended portions, if any, that cause either medicinal ingredient to be a salt, ester, hydrate, or solvate; or
(d) any combination of the variations found in paragraphs (a) to (c). (variation)

Transitional Provision

13 (1) The amendments set out in these Regulations do not apply in respect of a new drug that, before the coming into force of these Regulations, is the subject of a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission.

(2) For greater certainty, the version of the definition innovative drug in subsection C.08.004.1(1) of the Food and Drug Regulations that applies is the version of that definition that was in effect at the time the new drug submission or extraordinary use new drug submission was filed by the innovator in respect of the innovative drug in question.

Coming into Force

14 These Regulations come into force 90 days after the day on which they are registered.