



Ottawa, May 27, 2014

# Memorandum D10-14-30

## Tariff Classification of Medicaments Including Natural Health Products

### In Brief

This memorandum has been updated to reflect the current version of the [Customs Tariff](#), additional jurisprudence, a decision of the Harmonized Systems Committee of the [World Customs Organization](#) related to medicaments, and changes to the Canada Border Services Agency's organizational structure.

This memorandum explains the Canada Border Services Agency's (CBSA) policy for the tariff classification of medicaments, including natural health products, under headings 30.03 and 30.04 of the [Customs Tariff](#). The policy is based on jurisprudence for classifying medicaments resulting from decisions of the Canadian International Trade Tribunal (CITT) and the Federal Court of Appeal.

### Legislation

#### [Customs Tariff](#)

#### Legal Notes

#### Section VI

##### Note 1.

(a) Goods (other than radioactive ores) answering to a description in heading 28.44 or 28.45 are to be classified in those headings and in no other heading of the Nomenclature.

(b) Subject to paragraph (a) above, goods answering to a description in heading 28.43, 28.46 or 28.52 are to be classified in those headings and in no other heading of this Section.

##### Note 2.

Subject to Note 1 above, goods classifiable in heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of the Nomenclature.

#### Chapter 30

##### Note 1.

1. This Chapter does not cover:

(a) Foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (Section IV);

(b) Preparations, such as tablets, chewing gum or patches (transdermal systems), intended to assist smokers to stop smoking (heading 21.06 or 38.24);

(c) Plasters specially calcined or finely ground for use in dentistry (heading 25.20);

(d) Aqueous distillates or aqueous solutions of essential oils, suitable for medicinal uses (heading 33.01);

(e) Preparations of headings 33.03 to 33.07, even if they have therapeutic or prophylactic properties;

- (f) Soap or other products of heading 34.01 containing added medicaments;
- (g) Preparations with a basis of plaster for use in dentistry (heading 34.07); or
- (h) Blood albumin not prepared for therapeutic or prophylactic uses (heading 35.02).

### **Heading 30.03**

Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale.

### **Heading 30.04**

Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.

## **Guidelines and General Information**

1. A product can be classified as a medicament under heading 30.03 or 30.04 if it satisfies the following:
  - (a) meets the terms of the heading and any relative legal note; and
  - (b) evidence attests to the product's therapeutic or prophylactic use; and
  - (c) the goods are presented as a therapeutic or prophylactic product.

### **Guidelines**

2. The following information will help in determining the tariff classification of medicaments consistent with decisions of the Canadian International Trade Tribunal (CITT) and the Federal Court of Appeal. In this memorandum the word "medicament" may include natural health products.

3. Definitions:

"ailment" – an illness of a trivial nature

"curative" – having remedial properties, helping to cure

"dietetic foods" – foods prepared to meet the particular nutritional needs of people whose assimilation and metabolism of foods are modified, or for whom a particular effect is obtained by a controlled intake of foods or individual nutrients. They may be formulated for people suffering from physiological disorders or for healthy people with additional needs

"disease" – an unhealthy condition; a particular malady

"food" – substance(s) taken into the body to maintain life and growth

"medicament" – [a] substance used in curative treatment

"prophylactic" – tending to prevent disease or other misfortune

"therapeutic" – curative; of the healing art

4. In their decisions, the CITT and the Federal Court of Appeal made a number of observations and drew certain conclusions in order to classify medicaments in the Harmonized System (HS) as follows:

- (a) There is no requirement in the Harmonized System's legal notes, in the provisions of headings 30.03 and 30.04, or in the supporting Explanatory Notes, that a certain level of medicinal ingredients must be in a product in order for it to be classified as a medicament. Furthermore, there is no burden to scientifically prove that the product actually cures a disease, illness, or ailment. The terms of the heading do not require scientific proof of medical efficacy. However, the intent of headings 30.03 and 30.04 is to provide for goods that are in the nature of medicaments. In accordance with the terms of the headings, there must be some therapeutic or prophylactic

(medicinal) use for the product. Simply declaring that a product is a medicament does not qualify it for classification under heading 30.03 or 30.04.

(b) Marketing, packaging, use, and other evidence (e.g. from a professional medical practitioner or a recognized text) that can attest to a product's medicinal purpose (therapeutic or prophylactic) are important determining factors in classifying the product under heading 30.03 or 30.04. There must be some indication as to the use of the product in the preventing or treating of a disease, illness, or ailment.

### Examples

– St. John's wort oil extract, mixed with olive oil, is used to treat such things as mild to moderate depression, tension headaches and insomnia. When imported in bulk it is classified under heading 30.03, or under heading 30.04 when put up in measured doses or in forms or packings for retail sale.

– Re-distilled water is classified under heading 28.51. However, when put up as a medicament in measured doses or in forms or packings for retail sale, for use in the treatment of a disease, it is classified in heading 30.04.

– Sulphur put up for retail sale for a therapeutic purpose (e.g. as a scabicide) is classified as a medicament under heading 30.04 and not under heading 25.03 or 28.02.

(c) Medicaments are generally not included in the common understanding of the term "food". However, certain nutritional dietary supplements, sometimes considered food preparations, can be classified in heading 30.04 as a medicament. This is the case when the supplement is expressly for use in the prevention or treatment of a disease, illness or ailment and put up in a form specified in that heading. For example, garlic powder packaged for use in preparing food (i.e. for flavouring) is classified in heading 07.12. However, when garlic powder is prepared as tablets (measured doses), or in another form or packing for retail sale, and sold for its curative properties (e.g. in the treatment of cardiovascular disease), the garlic is classified as a medicament under heading 30.04.

(d) Food preparations contain mainly nutritional substances; the major ones being protein, carbohydrates and fats. Therefore, products consisting essentially of one or many nutritional substances and employed in nutritional therapy, utilizing ingredient avoidance in the attainment of a particular health-related outcome, remain considered as food preparations and should be classified under their own appropriate headings despite their acknowledged therapeutic or prophylactic effect. For example, ordinary foods and beverages, as well as products such as amino acid-based powdered formulas, containing single amino acids rather than complex proteins that facilitate digestion by infants (0 to 12 months) and children (1 to 10 years) who are unable to metabolize the long chains of amino acids that comprise the standard food proteins found in breast milk, infant formulas, soy or extensively hydrolyzed protein formulas are classified in heading 21.06.

5. Throat pastilles or cough drops can be classified under heading 30.04 when put up in measured doses or in forms or packaging for retail sale provided they contain a medicinal ingredient(s) such that each pastille or cough drop has a therapeutic or prophylactic use.
6. While national health authorities may define medicaments differently, vitamins and vitamin preparations have therapeutic and prophylactic uses. Vitamins have been proven effective in the treatment and prevention of certain diseases (e.g. vitamin C for scurvy and vitamin B12 for pernicious anaemia) and can thus be classified as a medicament. The vitamins considered as medicaments do not include the goods provided for in heading 29.36, unless they are put up in measured doses or in forms or packaging for retail sale for a therapeutic or prophylactic purpose.
7. If a vitamin, or vitamin preparation, is ingested to reverse or prevent (therapeutic or prophylactic) a deficiency that may lead to a disease, illness, or ailment, it follows that the purpose of ingesting the product is to reverse or prevent that malady. It is suggestive though not conclusive in all cases that such vitamin products, intended for human or animal use, are medicaments.
8. Declaring that a product is a medicament does not make it so for tariff classification purposes. There must be some evidence to support such a claim. Trade or technical publications issued by the manufacturer or producer can help in making a determination. Similarly, technical papers published in professional journals and authored by

health practitioners may also provide information about a product's therapeutic or prophylactic uses. This includes an opinion of an expert or specialist in the particular disease, illness or ailment.

9. Goods such as certain traditional natural health products, which are considered by some to be medicaments, are excluded from headings 30.03 and 30.04. For example, diabetic or fortified foods, food supplements for general health and well-being and tonic beverages (tonic wine with herbs) etc., are specifically excluded (see legal Note 1 to Chapter 30) even though they may be considered a medicament by their use and reputation in traditional herbal medicine.

## General Information

10. If the label of a product does not provide the necessary information to determine if a product has therapeutic or prophylactic properties, or if the product's therapeutic or prophylactic benefits are not clear, the importer must provide the necessary information.

11. Useful information on the therapeutic or prophylactic purpose of a medicament might be found in a recognized text, such as a publication mentioned in Schedule B of the [Food and Drugs Act](#), the Compendium of Pharmaceuticals and Specialties (CPS), the Merck Index, or a recognized peer reviewed medical paper, etc. Recognized peer reviewed papers are articles in recognized journals of medicine, such as the *International Journal of Medicine*, which have been reviewed by a qualified individual. Not all technical papers published in recognized journals are peer reviewed. Papers that are not peer reviewed may need verification.

12. For this policy, the meaning of the term "professional medical practitioner" is broadly defined. The term refers not only to physicians, but also to chiropractors, dentists, naturopaths, nurses, pharmacists, physical therapists, etc.

13. While conditions such as tension headaches, insomnia, gastrointestinal disorder, external wounds and other maladies may not be considered true diseases or illnesses, they constitute various forms of disorders or ailments.

14. Additional information, such as drug product monographs, can be found on [Health Canada's Web site](#). Drug product monographs identify the recommended use or purpose for ingredients based on [Health Canada's Natural Health Products](#) Directorate's evaluation of the safety and efficacy data.

15. In view of the CITT decisions upon which this policy is based, Canada is not able to apply the HS Explanatory Notes, relating to throat pastilles, and three Compendium Opinions, as follows:

### HS Explanatory Notes:

Heading 17.04 (v), page IV-1704-1;

Heading 30.04, page VI-3004-2

### Compendium of Classification Opinions (CCO):

**1704.90 (3)** Throat pastilles or cough drops consisting essentially of sugars and flavouring agents, e.g., menthol, eucalyptol or peppermint oil, (without other active ingredients).

**2106.90 (22)** Vitamin C preparation (500 mg per tablet) put up for retail sale in a container holding 130 tablets, containing ascorbic acid, corn starch, cross-linked carboxymethyl cellulose sodium, cellulose, rose hips, stearic acid, lemon bioflavonoid complex, magnesium stearate and acerola. According to the label, the product is not intended to diagnose, treat, cure or prevent any disease.

**2106.90 (24)** Cough syrup in the form of an aqueous solution of an alcoholic strength by volume of 1.8 % vol, put up in a container of 100 ml (130 g). The product consists of honey, plant tinctures, glucose syrup, invert sugar syrup, cherry aroma, rose oil, sodium benzoate and purified water. According to the label, the product is recommended to be used against respiratory catarrhal diseases and difficulty of bronchial respiratory catarrhal diseases and difficulty of bronchial mucus secretion. The content of active medicinal ingredients is, however, not sufficient to provide a recognisable and clinically proven therapeutic or prophylactic effect.

16. While the Harmonized System Committee of the [World Customs Organization](#) has generally classified natural health products in heading 21.06, in 2012 they classified a product based on hops and valerian in heading 30.04; this is reflected in:

**CCO:**

**3004.90 (2)** Medicament in the form of pills, consisting of plant extracts (of valerian root and hop cones), maltodextrin, colourings and excipients. According to the label, the product is recommended to be used as a remedy against agitation (two to four pills daily) or sleep disorders (one pill daily). The product contains a sufficient quantity of active ingredients to provide curative or prophylactic effect against disorders such as insomnia or sleeplessness. It is put up for retail sale in packages of, e.g., 60 pills.

**Additional Information**

17. For certainty regarding the tariff classification of a product, importers may request an advance ruling. Details on how to make such a request are found in CBSA [Memorandum D11-11-3, Advance Rulings for Tariff Classification](#).

18. For more information, call contact the [CBSA Border Information Service](#) (BIS):

Calls within Canada & the United States (toll free): **1-800-461-9999**

Calls outside Canada & the United States (long distance charges apply):

1-204-983-3550 or 1-506-636-5064

TTY: **1-866-335-3237**

[Contact Us online](#) (webform)

[Contact Us](#) at the CBSA website

<b>References</b>	
<b>Issuing Office</b>	Trade and Anti-dumping Programs Directorate
<b>Headquarters File</b>	F258860/HS 3004.90
<b>Legislative References</b>	<a href="#">Customs Tariff</a> <a href="#">Food and Drugs Act</a>
<b>Other References</b>	<a href="#">D11-11-3</a> <a href="#">World Customs Organization</a> Harmonized Commodity Description and Coding System (HS) Fifth edition (2012)
<b>Superseded Memorandum D</b>	D10-14-30 dated October 13, 2006