Health Canada Santé Canada

March 4, 2013

Notice

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Subject: *Guidance Document: Factors Influencing the Classification of Products at the Device-Drug Interface*

Health Canada is pleased to announce the release of the *Guidance Document: Factors Influencing the Classification of Products at the Device-Drug Interface.*

The classification of a health product determines which regulations will apply. Although the majority of products can be readily classified according to the definitions in the *Food and Drugs Act* (the Act) and its associated regulations, classification decisions become difficult when the applicable regulations are not immediately apparent. Classification guidance documents describe the factors that influence these decisions by Health Canada, and are intended to increase transparency and predictability.

This document addresses the classification of two therapeutic product groups (devices and drugs). It complements other guidance documents, including *"Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats"* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php) and *"Guidance Document: Classification of Products at the Cosmetic-Drug Interface"* (http://www.hc-sc.gc.ca/cps-spc/pubs/indust/cosmet_drug_guide-drogue-ref/index-eng.php), that address Health Canada's classification of products at other interfaces. Health Canada will continue to clarify other interfaces, as needed, as part of its commitment to operational excellence.

This guidance reflects an evolved approach that considers the Act's definitions of "device" and "drug" in a contextual manner. The factors described in this document are derived from this interpretive approach.

For questions on *Factors Influencing the Classification of Products at the Device-Drug Interface*, please email:

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Canada

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GUIDANCE DOCUMENT

Factors Influencing the Classification of Products at the Device-Drug Interface

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre : *Linge directrice : Facteurs qui interviennent dans la classification des produits situés à la frontière entre les instruments et les drogues*

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request additional information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1 INTRODUCTION

1.1 Policy Objectives

(a) To make stakeholders aware of the factors that influences the classification of a therapeutic[1] product as either a drug or a device.

(b) To facilitate consistent and predictable decision-making when determining the regulatory pathway for a therapeutic product.

1.2 Scope and Application

This guidance applies to therapeutic products at the device/drug interface when the appropriate regulatory framework is not immediately apparent.

The classification of drug/device combination products, which combine at least one drug component and one device component, is outside the scope of this guidance. In addition, this guidance is not intended to address the classification of cells, tissues and organs.

1.3 Background

In Canada, medical devices and drugs are regulated under the *Food and Drugs Act* ("the Act") and its associated regulations. Section 2 of the Act defines a device and a drug as follows:

> "device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
> (b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
> (c) the diagnosis of pregnancy in human beings or animals, or
> (d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,
> and includes a contraceptive device but does not include a drug.
>
> "drug" includes any substance or mixture of substances manufactured, sold or represented for use in
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

[1] The use of the word "therapeutic" in this guidance document encompasses all diagnostic, treatment, mitigating, and/or preventative effects associated with a health product.

(b) restoring, correcting or modifying organic functions in human beings or animals, or
(c) disinfection in premises in which food is manufactured, prepared or kept.

Classification of a therapeutic product determines whether it is regulated as a device or a drug. In most cases, the distinction between drugs and devices is clearly identifiable and these products can be easily classified according to their definitions. As new technologies and products emerge, however, it can become increasingly difficult to clearly identify the appropriate framework under which these products are regulated. In circumstances where a product does not readily fall under the existing definitions, guidance is warranted to indicate how classification decisions are likely to be made.

2 GUIDANCE FOR IMPLEMENTATION

The definitions of "device" and "drug" in the Act provide the basis for Health Canada's classification of these two product lines. Health Canada interprets the definitions of drug and device in a manner that considers not only how a product achieves its therapeutic function, but also how its composition and characteristics are both represented and perceived in the marketplace. The list of factors provided in this section is derived from an interpretation of these two definitions.

Health Canada acknowledges that its application of these definitions has evolved. Not all previous decisions will be indicative of how these products will be classified in the future. In addition, the emergence of new scientific evidence may prompt the reconsideration of previous decisions regarding the regulatory pathway for a product.

2.1 Exclusive Definitions

The definitions of "drug" and "device" under the *Food and Drugs Act* are mutually exclusive. As such, a single product cannot be classified as both as a drug and a device.

2.2 Therapeutic Claims

First, to determine if the product is subject to the Act as a health product, Health Canada considers the therapeutic claims made and how they align with the definitions in the Act.

A product may be classified as a drug or a device even when no explicit therapeutic claim is made. A therapeutic claim may also be implicit. Both types of claims are considered when a product is classified. Explicit claims are stated with no ambiguity with regard to their meaning or intent. In contrast, implicit claims made in the representation of a product indirectly suggest a therapeutic benefit. Product representation includes the appearance, labeling, and advertising of a product.

In the absence of either an explicit or implicit claim, a product still may be classified as a drug or device if the intrinsic properties of the product are such that there is no other possible use. For example, acetaminophen has no other use but as a drug, so the absence of a claim would not change its classification as a drug.

Conversely, the presence of a health claim may not be sufficient to classify a product as being subject to the Act. For example, health claims associated with a consumer product or textile may be inappropriate, false or misleading. This could lead to compliance action in accordance with the provisions of the *Canada Consumer Product Safety Act* or the *Competition Act*, rather than classification of the product as a health product subject to the *Food and Drugs Act*.

2.3 Product Purpose

The entireties of both drug and device definitions are taken into account to determine which one is the most applicable to the product and how it works. For example, a liquid for use as a body cavity filler could be classified as a drug when considering only paragraphs (a) of the two definitions. However, its purpose is clearly best characterized as **to modify a body structure** and act as a structure once it has filled the limited volume of a cavity. Therefore it is more reasonably classified as a device.

2.4 Composition and Form

The composition and form of a product also helps to distinguish a drug from a device. A device exhibits **structure in its final therapeutic form,** that is, the structure of the product when it is achieving its effect. With a device, its structure contributes directly to its effect. In contrast, the physical structure of a drug product (that is, in its dosage form, such as a tablet or an ointment, not its chemical structure) does not usually contribute directly to its therapeutic effect.

As an example, solid substances formed by polymeric reactions, such as dental cements, or through evaporative mechanisms such as with liquid bandages, are initially applied to the patient in semi-solid or liquid states. In each case, however, the final therapeutic form exhibits a definable structure and the product is more appropriately classified as a device, rather than a drug.

2.5 Therapeutic Effect

Consideration is also given to the therapeutic effect of a product and how this effect is achieved. In the *Food and Drugs Act*, paragraphs (b) of the drug and device definitions differ respectively in whether a product is used to restore, correct or modify **organic functions** (as with a drug) or a **body function** or **body structure** (as with a device).

Under the drug definition, an "organic function" is generally interpreted as including the various "functions of life" that occur without conscious assistance, such as digestion, metabolism, growth, secretion, excretion, circulation, and respiration. Effects that modify an organic function may be either local or systemic in nature.

Under the device definition, "body structure" refers to physical components such as bodily cells, tissues, and organs, such as bones, muscles, and tendons. A "body function" refers to the physical movement of the body structure. Effects that modify a body function or body structure are strictly local.

When considering the claim made for a product, it is important to note whether more than one property could contribute to the overall effect of the product when used for this indication. For example, if a therapeutic substance is shown to modify an organic function as well as a body function or body structure, then both drug and device definitions could be satisfied. To make the necessary distinction, a comparative risk assessment could be made. Specifically, if it is determined that the greater risk is associated with the modification of an organic function, then the safety and efficacy of the product would be more appropriately assessed under the drug framework.

The effects of a therapeutic product to restore, correct or modify organic functions, body functions or body structures may suggest that the product achieves an effect by a mode of action (for example, pharmacological, mechanical, etc.). However, it is not a necessary condition that a device or drug has a particular mode of action, as this concept does not appear explicitly in either definition.

Under the device definition, a product that is considered to be an "accessory to a device" is itself classified as a device. Before such a decision is made, however, it must be confirmed that the product does not meet the definition of a drug under the recommended conditions of use. A product considered to be an "accessory to a device" does not possess therapeutic properties of its own related to the purposes of the device: its use is solely to assist in the therapeutic function of the primary device.

2.6 Influence of Subordinate Regulations

Once a product has been classified as a drug and not a device at the level of the Act, further classification is required to determine whether the product is a drug subject to the *Food and Drug Regulations* or a natural health product (NHP), a subset of drugs under the Act, subject to the *Natural Health Products Regulations* (NHPR). This further classification is guided by the definition of an NHP in section 1 of the NHPR, the exclusion of prescription drugs in section 2(2), and the inclusive and exclusive lists of substances set out in Schedules 1 and 2 to the NHPR.

2.7 Comparative Standards of Evidence

The respective requirements for filing a drug submission or a device licence application are not considered when classification decisions are made. Data requirements may differ when demonstrating safety, effectiveness and quality. There is, however, some flexibility at both the regulation and policy levels to assure that evidence sufficiently demonstrates that the benefits of the therapeutic product outweighs its risks.

2.8 Decisions by Other Regulatory Authorities

Differences remain in the definitions adopted by Canada and other jurisdictions. In addition, the respective interpretations of these definitions could further affect whether a product is classified as a drug or device in different jurisdictions.

Health Canada may consider the classification decisions of other federal regulatory authorities as a tool to assist in its interpretation and application of the definitions in the Canadian legislation. Considerations that are not supported in the *Food and Drugs Act*, however, are not taken into account.