Health Canada Santé Canada

Notice

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Subject: Guidance Document: Classification of Products at the Drug-Medical Device Interface

This guidance document was first published on January 30, 2013 as "Factors Influencing the Classification of Products at the Drug-Medical Device Interface." The present revision is intended to reflect the recently implemented Ministerial Schedule, enacted through the *Budget Implementation Act* (BIA) in 2019. The new authorities allow the Minister to determine a single set of regulations that would apply to a health product that simultaneously meets more than one of the definitions outlined in the *Food and Drugs Act* (F&DA) (i.e., drug, food, device, or cosmetic). The new Schedule is intended to improve consistency, predictability, and transparency of classification decisions for industry stakeholders.

The classification of a health product determines which set of regulations will be applied. The majority of products can be readily classified according to the definitions in section 2 of the F&DA and its associated regulations. Although, it is sometimes difficult to determine which set of regulations apply. Classification guidance documents describe the factors that influence these decisions made by Health Canada, and are intended to increase transparency and predictability.

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This document addresses the classification of two health product groups (i.e., medical devices and drugs). It complements other guidance documents, including *"Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats"* and *"Guidance Document: Classification of Products at the Cosmetic-Drug Interface,"* which address Health Canada's classification of products at other interfaces. This document reflects an approach that considers the F&DA definitions of "device" and "drug" in a contextual manner.

For questions on classification of products at the drug-medical device interface, please contact the Office of Science in the Bureau of Policy, Science and International Programs (BPSIP) of the Therapeutic Products Directorate at drug.device.classification-drogue.instrument@hc-sc.gc.ca.

Canada

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Guidance Document

Classification of Products at the Drug-Medical Device Interface

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Ligne Directrice : Classification des produits situés à la frontière entre les drogues et les instruments médicaux

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Document change log

Date	Change	Location (section, paragraph)	Nature of and/or reason for change
2021-07-16	Clarifications made to increase transparency, clarity, and consistency of criteria used in classification decisions at the drug-medical device interface.	Sections 2.1, 2.2, 2.3, 2.4, 2.5, 2.6	Changes reflect the new Ministerial Schedule enacted through the *Budget Implementation Act* in 2019. Other changes are intended to further enhance clarity with respect to product classification.
2018/02/07	Modified definition of (medical) device in the Food and Drugs Act and respective guidance.	Section 1.3	Changes reflect the enactment of the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* on November 6, 2014.

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 programme 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 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 used in the classification of a health product as either a device or a drug.

b. To facilitate consistent and predictable decision-making when determining the regulatory pathway for devices and drugs.

1.2 Scope and Application

This guidance is intended to assist stakeholders in the classification of products at the drug-medical device interface when the appropriate regulatory framework is not immediately evident. Products at the drug-medical device interface are those that do not readily fall within the definition of "device" or "drug" as set out in section 2 of the *Food and Drugs Act* (F&DA). Therefore, these products present a challenge when determining which set of regulations apply.

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

1.3 Background

In Canada, medical devices and drugs are regulated under the F&DA and its associated regulations. Section 2 of the F&DA defines a device and a drug as follows:

- "Device" means an instrument, apparatus contrivance or other similar article, or an in vitro reagent, including a component, part or accessory, of any of them, that is manufactured, sold or represented for use in

    a. diagnosing, treating, mitigating or preventing of a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
    b. restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
    c. diagnosing pregnancy in human beings or animals,
    d. caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or,
    e. preventing conception in human beings or animals;

- however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

- "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,
    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.

In most cases, the distinction between devices and drugs is clear and these products can be easily classified according to the definitions. However, as new health products and technologies emerge, it can be difficult to determine the classification and appropriate regulatory framework for certain products. In circumstances where a product does not clearly fall under the existing definitions, guidance is warranted on how classification decisions are likely to be made by Health Canada.

2 Guidance

The definitions of "device" and "drug" in the F&DA provide the basis for Health Canada's classification of these two product lines (i.e., drug and device). Health Canada interprets the definitions of device and drug in a manner that considers not only how a product achieves its therapeutic/health effect, but also how its composition, characteristics, and intended use are represented and perceived in the marketplace and by its users. The list of factors provided in this section is based on these two definitions.

At Health Canada, classification of devices and drugs is based on the definitions outlined in the F&DA. Nonetheless, the emergence of new scientific and/or other evidence may prompt the reconsideration of previous classification decisions. As such, previous classification decisions are not always reflective of how a given product is to be classified. In cases where the classification of a product or group of products is to be changed, the affected sponsors are informed in advance of the change to allow them time to obtain the necessary market authorization under the appropriate set of regulations.

2.1 Health Claims

To determine the classification of a health product and which regulations would apply, Health Canada considers the product's associated claims, and how they align with the definitions in the F&DA. Claims can be explicit or implicit. Explicit claims are clear and direct; there is no ambiguity with regard to their meaning or intent. In contrast, implicit claims are conveyed through a product's representation, and may indirectly suggest a health benefit. Product representation includes (but is not limited to) the appearance, labeling promotion, and advertising of a product.

In the absence of an explicit or implicit health claim, a product may still be classified as a device or a drug if its intrinsic properties are such that it has no other use. For example, acetaminophen has no other use but as a drug. Therefore, one can conclude that it meets the definition of a drug as it is a substance that is manufactured or sold as a drug.

Even if a product adheres to one of the definitions outlined in the F&DA, the degree to which it successfully achieves its intended purpose, function, and effects in practice, would still have to be assessed. Sponsors are required to provide the scientific evidence necessary to support any of their claims. The efficacy of the product and validity of the claims would not be assessed at the time of product classification, but would be done during the review process. The purpose of classification is to provide guidance in determining the regulations that would apply to a product, whereas the purpose of the market authorization review process is to evaluate a product's efficacy, safety, and quality.

Claims that are false, misleading, deceptive, or likely to create an erroneous impression would contravene sections 20 and 9, respectively, of the F&DA. If a claim for a product is inappropriate, false or misleading, the product could also be subject to compliance actions under the *Canada Consumer Product Safety Act*, the *Competition Act,* or the *Consumer Labelling and Packaging Act*.

2.2 Product Purpose/Intended Use

The entire definitions of "device" and "drug" are taken into account when determining which is most applicable to a product and its functions. For example, a liquid for use as a body cavity filler, with no pharmacological, immunological, metabolic or chemical properties, could be classified as a drug when considering only paragraph (a) of the drug definition. However, since it is intended to play a structural role once it has filled the volume of a cavity, it is best characterized as an article that modifies a body structure. Therefore, such a product would more appropriately be classified as a device.

2.3 Product Composition and Form

The composition and form of a product also helps to distinguish a device from a drug. A device can exhibit structure in its final form (i.e., the structure of the product when it is achieving its desired effect). The structure of a device can contribute directly to its effect. In contrast, the physical structure of a drug product (i.e., in its dosage form, such as a tablet or an ointment, not its chemical structure) does not usually contribute directly to its health effect.

For 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 product form that exhibits the therapeutic effect has a defined structure, and the product is more appropriately classified as a device, rather than a drug.

2.4 Product Function/Health Effect

Consideration is also given to the health effect of a product and how this effect is achieved. In the F&DA, paragraphs (b) of the "device" and "drug" definitions differ respectively in whether a product is intended to be used to restore, correct or modify the body structure or functioning of any body part, or organic functions.

Under the “device” definition, “body structure” refers to physical components such as cells, tissues, organs, bones, muscles, tendons, etc. A “body function” generally refers to the application of some physical force or the physical movement of a body structure.

Under the drug definition, "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.

When considering a claim associated with a product, it is important to confirm whether more than one property could contribute to the overall effect of the product when used for the corresponding indication. For example, when a substance is demonstrated to modify a body structure or function as well as an organic function, then both the device and drug definitions can be satisfied. In this case, to make the necessary distinction, a comparative assessment could be carried out to determine the predominant effect and its mode of action. If the assessment determines that the predominant effect is associated with the modification of body structure or function, the product would be more appropriately classified and regulated as a medical device.

The current definition of “device” in the F&DA explicitly excludes products that accomplish their effect “solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.” This wording allows for some substances to be classified as medical devices. Specifically, a substance could be a device if its mode of action were not accomplished by pharmacological, immunological or metabolic means, or by chemical means in or on the body. However, this should not be interpreted as suggesting that every substance that does not act by pharmacological, immunological, metabolic, or by chemical means in or on the body, is a medical device. Instead, the entire definitions of “device” and “drug” must be considered when determining whether a substance is a device or a drug.

A product considered to be an accessory to a device may itself be classified as a device under the “device” definition. A device accessory is distinguished by its intended purpose/associated claim(s) to enable or support the intended use of the primary device. For example, a gel used as a lubricant to assist in the insertion and use of a probe would be considered a device accessory. Moreover, a liquid solution intended to disinfect or sterilize a medical device could also be considered an accessory to that device.

2.5 Influence of Subordinate Regulations

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

2.6 Evidence Requirements

To be granted the necessary authorization to market a health product in Canada, a sponsor must have satisfactory evidence demonstrating the product's safety, efficacy and quality, and is usually required to submit this evidence to Health Canada. The requirements for filing a device licence application, a drug submission, or a natural health product licence application are specific to each product line. These filing requirements are not taken into consideration when a health product is classified by Health Canada. First and foremost, devices and drugs are classified in accordance with their respective definitions in section 2 of the F&DA.

2.7 Product Classification by Foreign Regulatory Authorities

There are differences between the definitions in the Canadian legislation and those used by other regulatory authorities. In addition, the interpretations by other regulators of their own definitions may further affect whether they classify a product as a device or a drug.

Health Canada may consult the classification decisions of foreign regulatory authorities as a tool to assist in interpreting and applying the definitions of the F&DA. While Health Canada seeks to align device/drug classifications globally when feasible, a product would still need to meet the definitions in the F&DA and its regulations.