Notice: Guidance Document: Classification of Products at the (Medical) Device-Drug Interface

February 7, 2018
Our file number: 18-101137-616

This guidance document was first published on January 30, 2013 as “Factors Influencing the Classification of Products at the Device-Drug Interface”. The present revision is intended to reflect the changes to the definition of (medical) device made to the Food and Drugs Act (the Act) following the enactment of the Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law) on November 6, 2014, and to bring greater clarity to the description of how Health Canada classifies health1 products at the device-drug interface.

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


This document reflects an approach that considers the Act’s definitions of “device” and “drug” in a contextual manner.

For questions on the classification of products at the device-drug interface, please email: Drug-Device.Classification.Drogue-Instrument@hc-sc.gc.ca

---

1 In this guidance document, the use of the word “health” encompasses all diagnostic, treatment, mitigation, and/or preventative effects. In addition, since the Act now defines “therapeutic product” as a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the Natural Health Products Regulations, the use of “health product” is meant to include devices, drugs and natural health products.

2 In this context, drugs include those for human use (pharmaceutical, biologic, natural health product), veterinary use, radiopharmaceutical use, and disinfectant use.
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

© Minister of Public Works and Government Services Canada 2018

Également disponible en français sous le titre : Ligne directrice : Classification des produits situés à la frontière entre les instruments (médicaux) 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, Health Canada reserves the right to request additional information or material, or define conditions not specifically described in this document, in order to adequately assess the safety, efficacy or quality of a health 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.
# TABLE OF CONTENTS

1 INTRODUCTION ...................................................................................................................... 1  
  1.1 Policy Objectives ........................................................................................................... 1  
  1.2 Scope and Application ..................................................................................................... 1  
  1.3 Background ..................................................................................................................... 1  

2 GUIDANCE ............................................................................................................................... 3  
  2.1 Health Claims ................................................................................................................ 3  
  2.2 Product Purpose / Intended Use .................................................................................... 4  
  2.3 Product Composition and Form ...................................................................................... 4  
  2.4 Product Function / Health Effect .................................................................................... 4  
  2.5 Influence of Subordinate Regulations .......................................................................... 5  
  2.6 Evidence Requirements ................................................................................................. 6  
  2.7 Product Classification by Foreign Regulatory Authorities ........................................... 6
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 in the classification of products at the device-drug interface when the appropriate regulatory framework is not immediately evident. Products at the device-drug interface are those that do not readily fall within the definition of “device” or “drug” as set out in the Food and Drugs Act (the Act), and therefore present a challenge when determining which set of regulations apply.

The classification of device/drug 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 Act and its associated regulations. Section 2 of the Act defines a device and a drug as follows:

---


4  Note that, by policy, unlike devices and drugs as single entities, a device/drug combination product is regulated under the regulatory framework that applies to its component that provides the greatest contribution to the desired effect with respect to an indication. Information on the classification and regulation of combination products is available on the Health Canada website under the Policy on Drug/Medical Device Combination Products - Decisions (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/policy-drug-medical-device-combination-products-decisions.html) and Drug/Medical Device Combination Products (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/drug-medical-device-combination-products.html).
• “device”\(^5\) means an instrument, apparatus, contrivance or other similar article, or an \textit{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 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\(^6\) 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,

---

\(^5\) On November 6, 2014, the Food and Drugs Act was amended following the introduction of the Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law). Among the changes introduced, the definition of “device” has been slightly revised; the last paragraph of this definition helps distinguish between “device” and “drug” by listing drug indicia.

\(^6\) The Drug/Medical Device Combination Products policy document defines these terms as follows: Immunological: An action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction. Metabolic: An action which involves an alteration of the normal chemical processes participating in, and available for, normal body function. The fact that a product is itself metabolized does not imply that it achieves its principal intended action by metabolic means. Pharmacological: An interaction between the molecules of the substance in question and a cellular constituent usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent and, for the purposes of this policy, includes anti-infective activity.
(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. As new health products and technologies emerge, however, it is sometimes difficult to identify the appropriate regulatory framework that applies. 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 Act provide the basis for Health Canada’s classification of these two product lines. 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.

Health Canada acknowledges that its classification of devices and drugs has evolved. Additionally, the emergence of new scientific and/or other evidence may prompt the reconsideration of previous classification decisions. As such, previous classification decisions may no longer reflect how a given product is to be classified. In these cases where the classification of a product or group of products is to be changed, the affected sponsors are provided with advanced notice 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 if a product is subject to the Act as a health product, Health Canada considers its associated claims and how these align with the definitions in the Act.

A product may be classified as a device or a drug even in the absence of an explicit health claim. Explicit claims are stated with no ambiguity with regard to their meaning or intent. In contrast, implicit claims in the representation of a product indirectly suggest a health benefit. Product representation includes the appearance, labeling, promotion, and advertising of a product.

In the absence of either an explicit or implicit health claim, a product may still be classified as a health product if its intrinsic properties are such that it has no other possible use. For example,
acetaminophen has no other use but as a drug, so the absence of a health claim would not change its classification as a drug as one can still conclude that it is manufactured and sold as a therapeutic product.

Conversely, the presence of a health claim would not necessarily result in a product being ultimately considered meeting the definition of a device or a drug as that health claim may be either nonvalid or not supported by sufficient evidence. Claims that are false, misleading, deceptive or likely to create an erroneous impression cannot be associated with devices and drugs by virtue of sections 20 and 9, respectively, of the Food and Drugs Act. If a health 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 or the Competition Act.

2.2 Product Purpose / Intended Use

The entire definitions of both device and drug are taken into account when determining which is the most applicable to a product and how it works. 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 which is consistent with paragraph (b) of the device definition. Therefore, such a product would more reasonably 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. As an example, solid substances formed by polymeric reactions, such as dental cements, or by evaporation, such as with liquid bandages, are initially applied to the patient in a liquid or semi-solid state. In each case, however, the final therapeutic form exhibits a definable structure and the product would be more appropriately classified as a device rather than as 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 Act, paragraphs (b) of the device and drug definitions differ respectively in whether a product is 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 shown to modify a body structure or function as well as an organic function, then both device and drug definitions can be satisfied. In this case, to make the necessary distinction, a comparative assessment could be carried out. If it 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 Act 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 entirety of the respective definition 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 Act, 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 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 to the NHPR. For example, Echinacea is a drug under the Act 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 submit to Health Canada satisfactory evidence demonstrating the product's safety, efficacy and quality. 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; devices and drugs are classified, first and foremost, in accordance with their respective definitions in section 2 of the Food and Drugs Act.

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 in the Act. While Health Canada seeks to align its device/drug classifications globally when feasible, a product still needs to meet the definitions in the Act and its regulations.