
Classification

Drug – Device Interface

Health 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.

We are a federal institution that is part of the [Health portfolio](#).

Radon Action Month

Most requested

- [Recalls and safety alerts](#)
- [Canada's food guide](#)

Product Safety

Recalls and alerts. Standards and regulations for consumers. Health risks for pest control and chemical products.

Food and nutrition

Information on Canada's food guide, food labels, food recalls and outbreaks, food safety, how we monitor and measure food and nutrient consumption.

Healthy living

Supporting your physical, mental and spiritual health through healthy eating, physical activity and more.

Drugs and health products

Regulating drugs and health products to support public safety.

Health care system

Our health care system, including commissions and inquiries, eHealth, pharmaceuticals, legislation and guidelines.

Health science and research

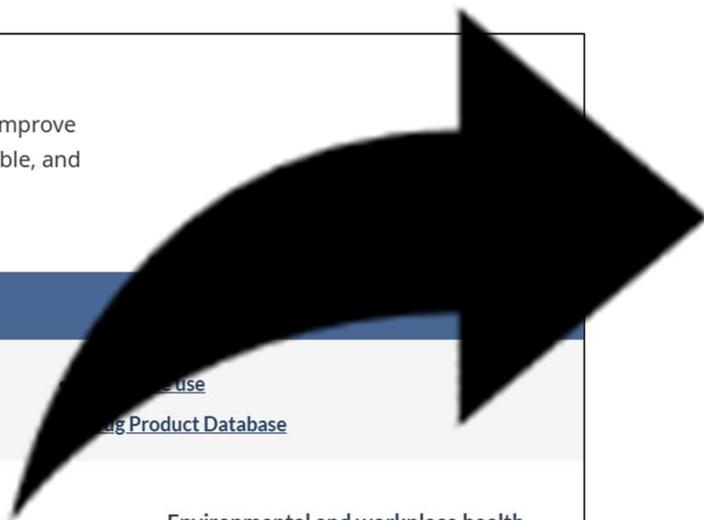
Helping you make informed decisions about health through science, research and testing.

Environmental and workplace health

Health effects of environmental and workplace factors including air, noise, soil and water pollution.

Health concerns

Preventing health problems by educating the public on drugs, diseases and more.



Subjects

- [Advisories, Warnings and Recalls](#)
- [Biocides](#)
- [Biologics, Radiopharmaceuticals and Genetic Therapies](#)
- [Compliance and Enforcement](#)
- [Device Drug Interface](#)
- [Drug Products](#)
- [Funding and Fees](#)
- [Hard surface disinfectants and hand sanitizers \(COVID-19\)](#)
- [International Activities](#)
- [MedEffect Canada \(adverse reactions\)](#)
- [Medical Devices](#)
- [Medical Use of Marijuana](#)
- [Natural Health Products](#)
- [Public Involvement and Consultations](#)
- [Regulatory Requirements for Advertising](#)
- [Special Access to Drugs and Health Products](#)
- [Surface disinfectants for emerging viral pathogens](#)
- [Veterinary Drugs](#)
- [Legislation and Guidelines](#)
- [Reports and Publications](#)
- [Improving the regulatory review of drugs and devices](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/classification-health-products-device-drug-interface.html>

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Health products at the drug-medical device interface are those that do not readily fall within the definition of "drug" or "device" in section 2 of the Food and Drugs Act (F&DA).

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<https://www.canada.ca/en/health-canada/services/drugs-health-products/classification-health-products-device-drug-interface.html>

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When the classification of a health product is not evident, the [Office of Science](#) of the [Therapeutic Products Directorate](#) is consulted. The Office of Science provides recommendations on the classification of products as either drugs (i.e., pharmaceutical, biologic, or natural health product), medical devices or drug-medical device combination products. Health product classification involves rigorous research, analysis, and consultation as necessary.

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drug.device.classification-droque.instrument@hc-sc.gc.ca

<https://www.canada.ca/en/health-canada/services/drugs-health-products/classification-health-products-device-drug-interface.html>

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In rare cases, the Office of Science may pursue additional consultation with the Therapeutic Products Classification Committee (TPCC). The TPCC includes representatives from various areas of Health Canada, within and outside of HPFB.

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The guidance document titled, "[Guidance Document: Classification of Products at the Drug-Medical Device Interface](#)" describes the factors considered by Health Canada in the classification of health products as either devices or drugs.

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Issue Identification Paper: Drug-Device Combination Products (DDCPs) Draft for Consultation

<https://www.canada.ca/en/health-canada/programs/consultation-issue-identification-paper-drug-device-combination-products-draft/document.html#a16>



This paper is intended to identify the key challenges associated with Health Canada's oversight of drug-device combination products (DDCPs) as per Health Canada's Policy on Drug/Medical Device Combination Products



What We Heard: Issue Identification
Paper on Drug-Device Combination
Products (DDCPs)



All respondents indicated their support of Health Canada taking action to provide greater detail on Health Canada's classification and regulation of DDCPs.

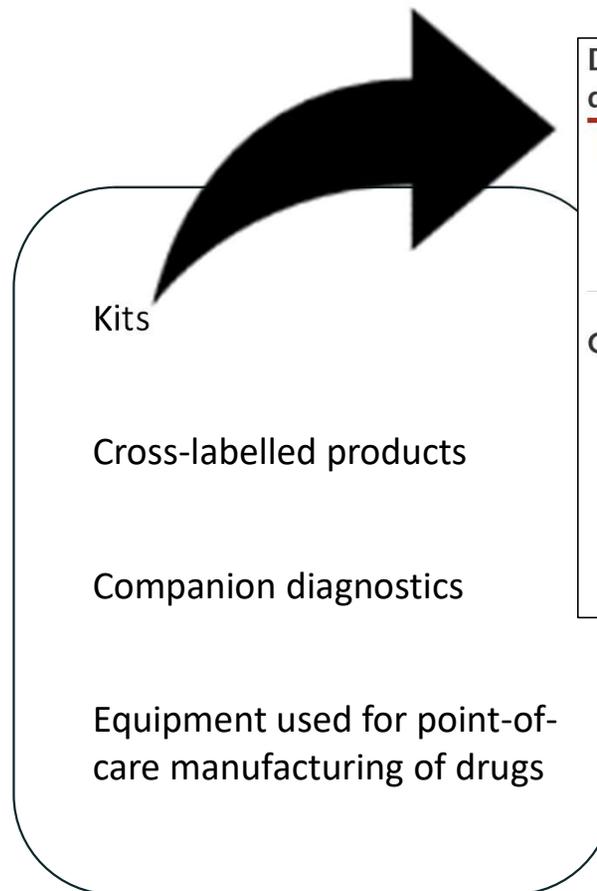
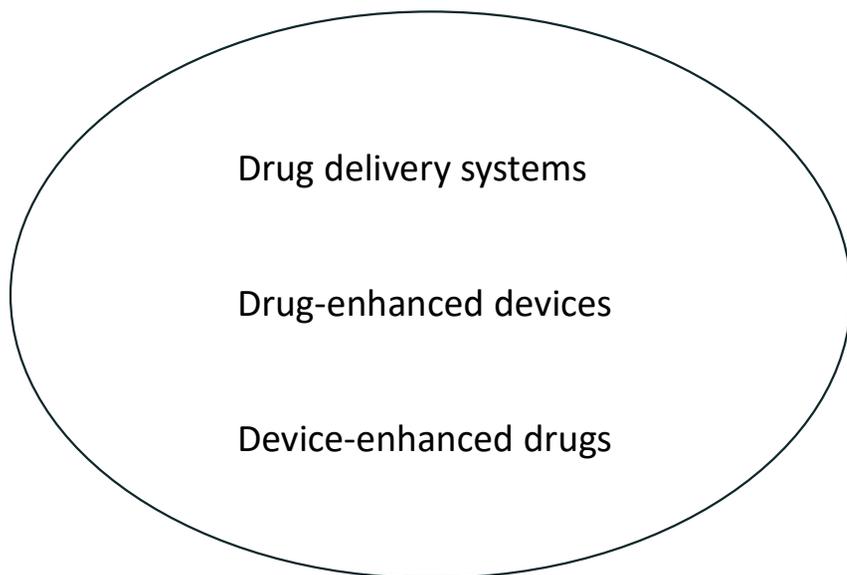


Drug-Device Combination Products (DDCPs) Issue Analysis

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Health Canada's current *Policy on Drug/Medical Device Combination Products* (the Policy) is not clear with respect to the classification of applicable products, and specifically whether some co-packaged drug-device combinations could also be subject to the Policy

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Draft guidance on co-packaged drug products: Overview

Overview

- [Requirements for drug kits](#)
- [Requirements for convenience packs and components](#)
- [Glossary](#)

On this page

- [Purpose](#)
- [Scope and application](#)
- [Policy objectives](#)
- [Background](#)
- [Types of co-packaged products: Drug kits and convenience packs](#)
- [Establishment and site licensing requirements](#)
- [Post-market reporting requirements](#)
- [Post-market safety and recalls](#)
- [Note about guidance documents in general](#)

Questions can be sent to:
meddevices-instrumentsmed@hc-sc.gc.ca

