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Pharma in brief - Canada

Health Canada releases white paper – Public Release of Clinical Information in Drug Submissions and Medical Device Applications

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Summary

Health Canada released the white paper – Public Release of Clinical Information in Drug Submissions and Medical Device Applications. The white paper sets out Health Canada's decision to make certain clinical information from drug submissions and medical device applications available to the public following regulatory review. Stakeholders may provide comments on the white paper using Health Canada's online form. The consultation period is open until **May 26, 2017.**

Overview

Currently, clinical information submitted by drug and medical device manufacturers used to assess the safety and efficacy of a drug or device is maintained as confidential business information. The white paper states that this information is far more comprehensive than that found in other sources such as scientific journals and clinical trial registries.

Health Canada is proposing that certain clinical information contained in drug submissions and medical device applications will be made publicly available for "non-commercial" purposes following regulatory review. The white paper defines "non-commercial" as information that "will not be used to support a marketing authorization application anywhere in the world or sold, or traded to another person."

Policy rationale

The policy rationale for the public release of information is to support the Government of Canada's commitment to transparency and accountability and to increase public confidence in the regulatory decision-making process.

The white paper states that public access to clinical information will enable independent analyses of the clinical data contained in submissions, which will (i) benefit clinical trial participants by preventing duplication of research that unnecessarily exposes participants to harm and (ii) benefit patients and healthcare providers by enabling better informed health decisions, and promoting appropriate use of the drug or device.

The public release of confidential information also brings Canada in line with other jurisdictions such as the United States and Europe, which have developed policies to share clinical trial information.

Health Canada's proposed approach

Health Canada intends to develop draft regulations that will amend the *Food and Drug Regulations* and the *Medical Devices Regulations.*

The amendments to the *Food and Drug Regulations* would provide that following a final regulatory decision, clinical summaries, reports and supporting data of completed clinical trials for primary, secondary outcomes or exploratory endpoints that are not part of an ongoing clinical development program will cease to be confidential business information.

Similar amendments are proposed to the *Medical Devices Regulations* for summaries and detailed information of all completed clinical studies or investigational testing in humans for primary, secondary outcomes or exploratory endpoints that are not part of an ongoing clinical development program.

Stakeholders will be consulted on implementation of the proposed approach, including processes for review and redaction, mechanisms for public release of clinical information and safeguards against commercial use.

Links:

Government of Canada Notice.

White Paper – Public Release of Clinical Information in Drug Submissions and Medical Device Applications

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For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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