



Collaboration for Research Integrity and Transparency

A PROGRAM OF YALE LAW SCHOOL, YALE SCHOOL OF MEDICINE AND THE YALE SCHOOL OF PUBLIC HEALTH

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via electronic mail

Re: Public Comment on the Regulations amending the Food and Drug Regulations (Public Release of Clinical Information) and Regulations Amending the Medical Devices Regulations (Public Release of Clinical Information), posted in the Canada Gazette on December 9, 2017

The Collaboration for Research Integrity and Transparency (CRIT) at Yale University supports and applauds the effort to amend the Regulations to allow for release of clinical information in drug and device submissions following final regulatory action. The proposed policy change will expand public access to clinical trial information, helping Canadians and their health care providers make more informed health decisions. The initiative will also facilitate independent research that will generate new knowledge regarding the safety and effectiveness of drugs, biologics, and medical devices. Revisions to these Regulations will bring Health Canada closer to the proactive release policy of the European Medicines Agency (EMA).

However, we have concerns regarding the exceptions contained in the proposed Regulations, which exempt clinical trial information from disclosure that:

- (a) was not used by the manufacturer in the submission or supplement to support the proposed conditions of use for the new drug or the purpose for which the new drug is recommended; or
- (b) describes tests, methods or assays that are used exclusively by the manufacturer.

Although the Regulatory Impact Analysis Statement indicates that Health Canada intends to closely align its policy with the European Medicines Agency (EMA)'s proactive release of clinical trial information (Policy 0070), the exceptions to the Regulations would result in less



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transparency than the EMA currently provides, and could result in some information related to patient safety being exempt from disclosure. We would note that during the consultation process on the White Paper, many pharmaceutical industry respondents urged that document release should mirror EMA's Policy 0070.¹ In particular, the exception for clinical trial information not used to support the proposed conditions of use is out of step with EMA policy. This information, contained in eCTD Section 5.3.5.4, (All) Other Study Reports, is specifically subject to proactive EMA publication under Policy 0070.² The final Regulations should require Health Canada to proactively release all clinical trial data submitted by a sponsor seeking market authorization that pertains to patient safety, not just the data reviewed by Health Canada to grant or deny approval.

We are concerned that the proposed Regulations would render "tests, methods or assays used exclusively by the manufacturer" exempt from disclosure. This exemption would be detrimental to public health because it would effectively prohibit independent researchers from obtaining and re-analyzing data.³ The exemption is broad enough to cover everything from vaccine assays to modified questionnaires to laboratory tests. If submissions for regulatory approval rely on these methodological details, this information should not be kept confidential. For example, if a surrogate marker is used, any unusual modification to the collection or analysis of that surrogate marker should also be released.

We respectfully request that Health Canada substantially limit the exceptions contained in C.08.009.2(2)(a) and 43.12(2)(a), and remove the exceptions contained in C.08.009.2(2)(b), and 43.12(2)(b), from the Regulations.

We are also concerned that the Regulations do not specify how information will be released (proactively or upon review of individual request), or the conditions under which information will be released. We previously submitted comments on the White Paper requesting that the Regulations require Health Canada to proactively release clinical trial information, rather than requiring explicit individual requests, and that there be no limitation on who can receive clinical trial information, or how it will be used once it is released, other than to prohibit efforts to re-identify trial participants.

¹ Health Canada (2017). *Responses to the Public Consultation on the White Paper "Public Release of Clinical Information in Drug Submissions and Medical Device Applications."* Available at <https://www.canada.ca/en/health-canada/programs/consultation-public-release-clinical-information-drug-submissions-medical-device-applications/what-we-heard.htm>

² European Medicines Agency (2016). *External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use, EMA/90915/2016.* Available at http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/09/WC500235371.pdf

³ Herder M, Hatchette TF, Halperin SA, Langley JM. Against vaccine assay secrecy. *Human Vaccines & Immunotherapeutics* 2015;11:498-503.



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In addition, the regulations do not include a timetable for release of clinical information for medical products where a final regulatory decision predates the implementation date of the regulation, and do not include a timetable for processing for redactions and subsequent release of clinical information for newly approved products. We understand that Health Canada is currently consulting with a Stakeholder Reference Group regarding these issues. We urge Health Canada to adopt a standard of proactive release of redacted clinical information no later than 60 days after a final regulatory decision, and that a clear timetable for release of clinical information for medical products where a final regulatory decision predates the implementation date of the regulation be established.

Again, we applaud the proposed policies changes contained in the Regulations. However, we urge the agency to adopt the changes we outlined above, to increase the availability and use of clinical research data that has the potential to benefit science and public health.

Sincerely,

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