Response to Health Canada on Release of Clinical Data

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Directorate Health Products and Food Branch
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Thank you for the opportunity to comment on the Health Canada white paper entitled "Public release of clinical information in drug submissions and medical device applications".1 Health Canada's proposed policy change could be a major step towards transparency. We support the public release of clinical information because Canadians and their clinicians require this information to be publicly accessible in order to make informed decisions. Greater transparency will also help Health Canada make better decisions by allowing independent scrutiny of clinical information. This ability to review the evidence will further enhance the trust that Canadians should have in the safety and efficacy of health care products. We urge Health Canada to introduce regulations under the Food and Drugs Act in a timely manner that gives legal force and effect to the policy proposed in the white paper, as modified by the changes we outline below.

We recommend the following changes, which must be subsequently translated into legally binding regulations enacted pursuant to the Food and Drugs Act, to ensure that this proposed policy will achieve its objective of greater transparency. These changes will help avoid sponsor practices that can severely restrict the release of information and subvert any attempt at transparency. Our general suggestion is that Health Canada must significantly limit the exemptions and restrictions in the proposed policy and remove barriers to accessing clinical information. Finally, there is additional information that was not mentioned in the document that must be released.

Exemptions and redactions

1. The following exemptions to the release of information must be removed from the policy because they are open to abuse: "secondary or exploratory end points which may constitute a component of an on-going development programme", "interim clinical study results" and "methodological details (e.g. in-house modifications or procedures to analytical, immunogenicity, bioassay, or sample size calculations methods not commonly used by the industry)". If Health Canada obtained this information in order

to make regulatory decisions then Health Canada has an obligation to release it. These exemptions invite sponsors who wish to suppress information–as they currently do by inappropriately labelling it “confidential” – to use these labels to subvert transparency. All aspects of the scientific methodology are key components of credible science and should be made public. Specifically, withholding methodological details may mean that information such as assays used to assess the efficacy of vaccines remain undisclosed thereby preventing independent assessment of their efficacy. Similarly, withholding information about non-conventional sample size calculations may mean that the ability to test and replicate analyses of efficacy may not be possible.

2. Health Canada’s policy must clearly state that the burden of proof is on industry sponsors to justify why certain information falls under the narrowly defined exceptions to public disclosure. In this regard, any redactions to the material that is released must be kept to a minimum and there should be written reasons given for the redactions. Experience has shown that the greater the number of redactions the more difficult it is to interpret the information and the less use the documents are in helping to understand the benefits and harms of medicines.
3. Health Canada must produce a list of the types of documents…

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