October 17, 2014

VIA E-MAIL

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Dear Sir or Madam:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization (BIO) and the Advanced Medical Technology Association (AdvaMed), we hereby provide formal written comments in response to Canada's WTO notification, dated August 26, 2014, related to the proposed passage of Bill C-17, *An Act to Amend the Food and Drug Act* (hereinafter referred to as the "Bill").[1] While the Bill makes a number of necessary revisions to the Food and Drug Act, certain amendments proposed and passed by Canada's House of Commons in June conflict with Canada's international obligations under the WTO Technical Barriers to Trade (TBT) Agreement and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.[2]

Specifically, the provisions in question ("the June Amendments")[3] relate to the disclosure of Confidential Business Information (CBI) by the Minister of Health (Minister), to whom information can be disclosed, and the absence of confidentiality obligations or other protections to ensure that there is no unfair commercial use of the disclosed CBI (protections required under TRIPS Article 39.3). If implemented as drafted, the June Amendments could discourage innovators from seeking marketing approval in Canada, thereby impeding trade. Instead, therefore, our collective organizations implore Canada to make the appropriate revisions to the Bill so that it does not impose unnecessary obstacles to trade and respects the confidentiality of the manufacturing, research, and development information submitted to the Canadian

[1] WTO Committee on Technical Barriers to Trade, G/TBT/N/CAN/405/Rev.1.
[2] The referenced amendments also conflict with existing Canadian law. Specifically, the Bill differs in significant ways from Canada's Access to Information Act and Consumer Product Safety Act in the standard, scope, and method of disclosure of Confidential Business Information.
[3] *See* Bill C-17, Clause 3, amendments after section 21; Clause 6, amendments to section 30 after subsection 1.1.

Government for regulatory purposes, consistent with Articles 2.2, 5.1.2 and 5.2.4 of the TBT Agreement and Canada's TRIPS obligations.

The June Amendments provide overly broad discretion to the Minister of Health to divulge both CBI and trade secrets. Such disclosure would harm incentives for companies to invest in costly research and development, and then communicate detailed results, research, and manufacturing methods to government regulators. Specifically, the June Amendments indicate that:

(1) the Minister may release CBI about a therapeutic product without notifying or obtaining the consent of the person to whose business or affairs that information relates, if the Minister believes the product "may" present a "serious risk" of injury to human health; and

(2) the Minister may divulge CBI without consent if the disclosure is related to the "protection or promotion" of human health or safety and the disclosure is to a government, a person from whom the Minister seeks advice, or a "person who carries out the functions relating to the protection or promotion of human health or the safety of the public."

Finally, "confidential business information" is so broadly defined under Clause 2 of the Bill that it could extend to trade secret information, including manufacturing processes.[4]

The discretion afforded the Minister of Health under the Bill exceeds the limited instances envisaged under TRIPS Article 39.3 for the disclosure of CBI and fails to provide adequate protections to ensure that there is no unfair commercial use of the disclosed CBI. Specifically, TRIPS Article 39.3 provides:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

TRIPS Article 39.3 stipulates that CBI may only be disclosed "where necessary to protect the public" or where "steps are taken to ensure that the data are protected against unfair commercial use." In contrast, Clause 3 of the Bill provides a much lower threshold that would allow the

[4] Clause 6 of the Bill blithely states that what is not to be considered CBI will be defined by regulation after the Bill is passed.

Minister to divulge CBI if he or she ***believes*** that the product ***may*** present a serious risk of injury to human health. The restriction under TRIPS 39.3 that the disclosure must be ***necessary*** to protect human health requires more than subjective belief of a potential threat and that the CBI disclosed should be limited to that required to protect the public.[5]

Similarly, TRIPS Article 39.3 provides no basis for disclosing CBI for the undefined purpose of "promoting human health or safety." The only instance in which CBI may be disclosed under Article 39.3 is "where necessary to ***protect*** the public" (emphasis added). Nor does the Bill provide any mechanisms to ensure that there can be no unfair commercial use of the CBI divulged to a government, a person from whom the Minister seeks advice, or a "person who carries out the functions relating to the protection or promotion of human health or the safety of the public." The potential recipients of the disclosed CBI are incredibly broad, and, in turn, the Bill provides no mechanism, such as a confidentiality agreement, to ensure that those recipients (or anyone else to whom they disclose that data) are not able to use the divulged CBI to secure an unfair commercial advantage.

Given that the confidential data at issue is submitted as part of a conformity assessment procedure (to ensure the safety and efficacy of the new medicine), failure to sufficiently protect the CBI against unfair commercial use is also inconsistent with Canada's obligation under Article 5.2.4 of the TBT Agreement. That provision requires WTO members when imposing conformity assessment procedures to ensure "the confidentiality of information about products originating in the territories of other Members arising from or supplied in connection with such conformity assessment procedures is *respected* in the same way as for domestic products and *in such a manner that legitimate commercial interests are protected*;" (emphasis added). The Bill's lack of any mechanisms to ensure that the data disclosed by the Minister is not further disclosed and/or that there is no unfair commercial use of that data, does not adequately respect and protect the legitimate commercial interests of the party that originally submitted the CBI, contrary to Article 5.2.4 of the TBT Agreement.

Finally, the breadth of the proposed definition of CBI (Clause 2) to include trade secrets makes the Bill inconsistent with Canada's obligation to protect confidential information (including trade secrets) under TRIPS Article 39.2. TRIPS Article 39.2 mandates that "[n]atural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to

[5] It is noteworthy that in parallel circumstances concerning consumer safety, Canadian law appropriately limits disclosure of CBI to those instances where the disclosure is "***essential*** to address" a "serious and ***imminent***" danger to human health or the environment" (see §17(1) of the Canada Consumer Product Safety Act) or "***necessary*** to address a serious and ***imminent*** danger of health or safety of the public" (see §39(1)(b) of the Human Pathogens and Toxins Act). These examples demonstrate that, consistent with Articles 2.2 and 5.1.2 of the TBT Agreement, there are less trade-restrictive ways for Canada to achieve its legitimate goal of protecting human health or safety.

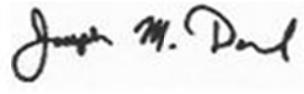
honest commercial practices ….” Since the Bill provides for potential release of trade secrets or confidential commercial information without any notification or other safeguards in place, there is a risk that companies will have no meaningful ability to prevent disclosure or otherwise protect their trade secret data before such disclosure occurs.

To ensure consistency with Canada’s WTO obligations, we would recommend the following changes to the Bill:

- The Minister should be required to notify the person to whose business or affairs the disclosed information relates before disclosure;
- Disclosure of CBI should only be permitted if essential to addressing a serious risk of injury to human health presented by the product, and the quantum of CBI released should be limited to that data necessary to address that serious risk;
- Consistent with TRIPS Article 39.3, disclosure of CBI should only be permitted where necessary to protect human health or safety of the public;
- Disclosure should be allowed only under a confidentiality agreement prohibiting both further disclosure and use of the information outside the scope of the limited purpose of the disclosure (and therefore never for commercial purposes); and
- The Minister should not be permitted to disclose confidential information such as trade secrets – including manufacturing information – relating to a therapeutic product without the owner’s consent and unless protected in a manner consistent with TRIPS.

Our industries stand ready to provide further feedback on the Bill and constructive assistance in passing a Bill that achieves an appropriate balance between protecting CBI and promoting health and safety consistent with Canada’s international obligations.

Sincerely,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