BILL C-398

to fix Canada's Access to Medicines Regime (CAMR)

HOW DOES THIS NEW BILL DIFFER FROM PREVIOUS BILL C-393?

In substance, this bill is the same as Bill C-393, which was passed by a sound majority in the House of Commons on March 9, 2011 during the last Parliament , but died in the Senate on the Order Paper with the Spring 2011 election call.

Please note the following about Bill C-398:

1 The definition of "pharmaceutical products" that may be exported in generic form under CAMR

The amendment proposed in Bill C-398 is *exactly the same amendment that was passed by the House in Bill C-393*. It preserves the scope of the existing definition (and the existing CAMR Schedule 1 of eligible pharmaceutical products) but adds to the definition to ensure that CAMR is not limited only to those medicines. It does this by explicitly incorporating the wording of the World Trade Organization (WTO) General Council's Decision of 30 August 2003. In that decision, Canada and all other WTO countries agreed on a definition of pharmaceutical products that could be exported under a mechanism such as CAMR to address public health problems—including, but not limited to, HIV, tuberculosis and malaria. This amendment would make CAMR properly reflect the scope of what has been negotiated internationally.

Pertains to clause 2 of the bill, amending section 21.02 of the *Patent Act*

2 Adding or removing countries to the list(s) of countries eligible to receive pharmaceutical products under CAMR

In the last Parliament, Bill C-393 was revised in Committee to combine the lists of eligible importing countries into a single list (Schedule 2). *The new Bill C-398 is identical to the previous Bill C-393 on this point*, and would ensure that non-WTO member countries that are "developing countries" are included without, for example, having to declare a "national emergency." This would eliminate an unfair double standard in the current CAMR, since WTO developing countries don't face this restriction. It would, in fact, be unethical and bad public health policy to wait until a situation is declared an emergency before getting medicines to people.

Pertains to clause 3 of the bill, amending section 21.03 of the *Patent Act*

3 "One-licence solution"

This clause in the new Bill C-398 is virtually identical to the parallel clause in the former Bill C-393. One minor change to the language was made to make it crystal clear that one licence issued to the generic manufacturer will authorize the manufacturer to sell simultaneously, under that single licence, to any of the eligible importing countries listed in the schedule (Schedule 2). Amending CAMR with this "one-licence solution" is key, because it means generic manufacturers do not have to go through a separate licensing process for every individual order of a product but instead are able to fill multiple orders under a single licence.

Pertains to clause 4 of the bill, amending section 21.04 of the *Patent Act*

4 Provision clarifying that quantities of medicines exported under CAMR licences are limited in accordance with the WTO General Council Decision

NEW

Bill C-398 would add a new subsection (5) to section 21.04 of the existing *Patent Act* (the section dealing with issuing a compulsory licence to a generic manufacturer). This new subsection did *not* appear in the previous Bill C-393 and responds to questions raised in the last Parliament. This new subsection would specify that the licence authorizes the generic manufacturer to export the product "to the extent necessary to meet the needs of any country listed in Schedule 2 [the schedule of eligible importing countries]," so long as the importing country appropriately notifies the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) Council (if a WTO member) or the Government of Canada (if not a WTO member), as required. *This provision exactly reflects the terms of the WTO General Council Decision of 30 August 2003*, making it even clearer that the proposed reforms to CAMR are entirely compliant with WTO law.

Pertains to clause 4, amending section 21.04 of the *Patent Act*

5 Transparency and anti-diversion measures

NEW

This amendment in Bill C-398, which did *not* appear in Bill C-393, further clarifies and strengthens the provisions aimed at ensuring transparency in the use of CAMR (so as to prevent diversion), *conforming even more closely to WTO rules*. It specifies that Canadian generic manufacturers must post online both (1) "the quantities being exported to each country or WTO Member" under their licence and (2) a copy of the written notification the importing country has made to the WTO TRIPS Council (if a WTO Member) or to the Government of Canada (if not a WTO Member). That notification sets out the importing country's "expected quantities" of the pharmaceutical product, which the generic manufacturer is then authorized under its licence to supply.

Pertains to clause 6, amending section 21.06 of the *Patent Act*

6 No sunset clause

NEW

The previous Bill C-393 contained a rather awkwardly worded provision imposing a 10-year sunset clause on the reforms to CAMR. This meant that the changes to make CAMR workable would automatically expire, unless renewed through a complicated Parliamentary process. *This clause does not appear in the new Bill C-398, as there is no benefit to such a limitation.*

PLEASE NOTE: Other minor housekeeping variations were made. Minor wording and grammatical changes were made to make the new bill easier to read without changing the substance.

For more information:

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