Canada's Access to Medicines Regime

Consultation Paper

Comments by

Canadian Generic Pharmaceutical Association ("CGPA")

GENERIC DRUGS.

CGPA

SAME QUALITY. LOWER PRICE.

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General Comments

The Canada's Access to Medicines Regime ("CAMR") has proved unworkable in practice, as predicted by the Canadian Generic Pharmaceutical Association (CGPA).

Major changes are required. The minor amendments implied by the questions in the Government of Canada's November 24, 2006 consultation paper are insufficient.

For example, Apotex's lamivudine/nevirapine/zidovudine combination product is now approved by Health Canada for export for humanitarian purposes, yet Apotex's application for a compulsory license has bogged down in the morass of confused and unnecessary steps in CAMR.

The 30 August 2003 Decision of TRIPS Council (the "Decision") calls for a system that will work quickly in view of "the importance of a rapid response" if an importing country gives notice that it needs a drug.

To ensure a rapid response, the Decision puts only four straightforward requirements on the government of an exporting country, such as Canada. The exporting country must:

(1) satisfy itself that the importing country has made the required "notification" to TRIPS that it needs the product. (See Decision, s. 2(a)). This can be easily done by looking at the WTO website (See Decision, footnote 5);

(2) ensure that the compulsory license contains three conditions (see Decision, s. 2(b)(i), (ii), and (iii)). This obligation is met by including the three conditions in the standard form compulsory license issued by the Commissioner;

(3) notify the Council for TRIPS of the grant of the license, and provide the required minimal details of the license (see Decision, s. 2(c)); and

(4) ensure that "adequate remuneration" is paid to the patentee (see Decision, s. 3). This is already achieved by existing s. 21.08 of CAMR and the regulations thereunder.

Canada's statute should not impose more onerous requirements than the Decision.[1] The many steps in CAMR that go beyond the requirements of the Decision are unnecessary and counterproductive. CAMR has been drafted to satisfy the demands of patentee companies, not to ensure drugs are exported for humanitarian purposes.

[1] Although more streamlined than CAMR, even the comparatively simple Decision process has proved onerous and unworkable, particularly for importing countries. See "Neither Expeditious, Nor a Solution: The WTO August 30 Decision is Unworkable", Medecins Sans Frontieres. Prepared for the XVI International AIDS Conference, Toronto, August 2006.

CAMR as presently drafted appears to be based on a misapprehension the Decision requires Canada's government to set up complex procedures to enforce compliance with the terms of the compulsory license, and protect the patentee's rights.

This is the wrong approach. The patentee, not the government of Canada, is the appropriate party to enforce its own patents.

If the patentee believes a generic manufacturer is stepping outside the terms of the license, the patentee can seek its remedies under the *Patent Act*.

It is counterproductive to impose unnecessary restrictions on the generic manufacturer. That approach is not only at odds with the Decision, but also impractical. It deters generic manufacturers from participating, and perversely penalizes the generic manufacturer for doing charitable work for humanitarian purposes.

Required Changes to CAMR

The following are examples of provisions in CAMR that should be eliminated or changed, in light of the above comments:

It is impractical to require the applicant to apply for a licence for every "patented invention to which the application relates". Patentees will assert there are dozens or hundreds of patents "to which the application relates", owned by many patentees, resulting in confusion and delays. The licence should allow the licencee to make, use or sell any patented invention reasonably related to the export of the drug product specified in the notification (See s. 12.04(1), 12.04(2)(d)). The Decision requires the licence to be for a "product" (see paragraph 2 and 2(a)).

Streamline or eliminate the requirement to negotiate with the patentee before seeking a compulsory license (s. 21.04(3)(c)(i) and (ii))): This provision allows patentee companies to delay by disputing details of the application, and demanding further information. This unclear and unnecessary requirement has proved insurmountable for the Apotex licence application referred to above. No such provision is required under the Decision or TRIPS.

Requirement to provide notices to patentee should be removed: Notices to the patentee at various stages of the process (see ss. 21.07, 21.15, 21.16) are unnecessary. The Decision requires only that the wording of the compulsory license contain a condition that the licencee post certain information on a website (Decision, paragraph 2(b)(iii)).

Eliminate patentee's extra litigation rights: CAMR gives the patentee three separate, ambiguously worded rights to litigate against the generic manufacturer at various stages (ss. 21.08(4) and (5), 21.14, 21.17). These are unnecessary and counterproductive. They are not required under the Decision. The patentee can pursue the existing remedies under the *Patent Act* if it wishes to argue the generic manufacturer is not entitled to the protection of the licence due to some alleged breach of the licence.

Streamline the application process (s. 21.04(2) and (3): The Decision requires minimal information in the application. The Commissioner should have to do no more than satisfy himself that the importing country has made the necessary notification to the Council for TRIPS saying its needs the product (See Decision, s. 2(a)(iii) and footnote 2). Therefore, for example, the Canadian patents "to which the application relates" and information about the patent situation in the importing country are irrelevant (ss. 21.04(2)(d), 21.04(3)(d)).

Compulsory license should not be limited to four years (s. 21.12(2), (4): No such time limit on a compulsory license is required by the Decision. There is no rationale for such a time limit. Low-cost drugs may still be needed for humanitarian purposes after four years.

Do not limit the drugs to those on Schedule 1 (s. 21.03(a)): The Decision does not require the exporting country to limit the drugs to which the scheme applies. The importing country should decide what drugs it needs. The Decision says the importing country will provide notification to Council for TRIPS specifying the "names … of the products needed" (Decision, s. 2(a)).

CGPA Responses to Questions in the Consultation Paper

Eligible importers

1. NGOs may purchase products "permitted by" an eligible importing country Should CAMR provide guidance on the meaning of "permitted by" in this context?

CGPA assumes the question relates to ss 21.04(2)(f) of CAMR, providing that an application form for a compulsory license must set out:

> *(f) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and…*

There should be no such additional "guidance". The problem is there are too many convoluted and irrelevant rules in CAMR already.

Nothing in the Decision requires the exporting country to evaluate the legal and regulatory status of purchasers in the importing country. It is impractical and pointless to attempt to do so, and merely creates delays.

2. The WTO waiver also allows the export and distribution of licenced products to developing and least-developed countries that are party to a regional trade agreement. Does CAMR accommodate the purchase and distribution of licenced products by and amongst regional trade groups?

No. CAMR impedes the purchase and distribution of licensed products for humanitarian purposes to any recipient country whether in a regional trade group or not.

Eligible Pharmaceutical Products

3. Is Schedule 1 an appropriate mechanism to define the products that are eligible for export under CAMR?

No. Schedule 1 should be repealed. There should be no limit on the drugs that are eligible. The Decision does not require any such limit.

4. Is Schedule 1 necessary to avoid delays due to litigation?

No. The Commissioner should be required to issue the license if the importing country has made the required "notification" to TRIPS that it needs the drug (See Decision, s. 2(a)), and the generic manufacturer requests the license. This will solve the alleged problem mentioned in the Consultation Paper, namely, that if Commissioner has "discretion", his decisions will be attacked in court by patentees.

5. Should the government review Schedule 1 at regularly scheduled intervals to consider amendments that are in addition to requests received from interested manufacturers, importing countries and NGOs?

Schedule 1 should be abolished, as set out above. Under the Decision, it is up to the importing country to decide which drugs it needs.

6. What criteria should be considered when amending Schedule 1?

See answer to question 5

7. Schedule 1 does not currently contain any active pharmaceutical ingredients (API). Should CAMR allow for the export of APIs?

See answer to question 5.

Notification

8. Is the requirement that a certified copy of the importing country's notification be included in the application for a compulsory licence necessary to comply with the WTO waiver?

No, because it is already on the WTO website (see Decision, footnote 5).

9. CAMR requires non-WTO Member developing countries (those listed on Schedule 4) to: declare a national emergency or other circumstance of extreme urgency; agree that the imported product will not be used for commercial purposes; and undertake to adopt anti-diversionary measures. Are these requirements unduly burdensome on non-WTO developing member countries that wish to participate in CAMR?

The requirements of CAMR are too burdensome for both WTO and non-WTO members.

It should be sufficient that an importing country, whether a WTO member or not, has complied with the requirements of the Decision i.e. has provided a "notification" that (i) specifies the names and expecting quantities needed, (ii) confirms that it has insufficient or no manufacturing capacity, and (iii) confirms that it intends to grant a compulsory license.

Anti-diversionary measures in the importing country are the importing country's responsibility under the Decision, paragraph 4, and may be reviewed by TRIPS Council under paragraph 5; they are not Canada's responsibility.

Health Canada's drug review

10. Does the requirement that pharmaceutical products be reviewed for safety, efficacy and quality promote or discourage Canadian pharmaceutical manufacturers and eligible importing countries from participating in CAMR?

Canadian generic manufacturers support the review of such products for safety, efficacy and quality. Market demand for non-reviewed products will be filled by manufacturers in low-cost countries at prices far below those at which Canadian manufacturers could supply product.

11. Would manufacturers and countries be more or less likely to participate in CAMR if this review were optional?

See answer to question 10.

12. Are there alternatives to a mandatory/optional Health Canada review process that would be acceptable to Canadian pharmaceutical manufacturers while providing safety, efficacy and quality assurance to eligible importing countries?

See answer to question 10.

The application process

13. Does the type of information that must be provided to the patentee in the request for a voluntary licence pose a barrier for the licence applicant?

Yes, the information is a barrier.

For example, the requirement that the application show the applicant sought a voluntary license has been made (s. 21.04(3)(c)(i)) is a significant barrier in practice.

The patentee can delay the issuance of a compulsory license indefinitely by demanding ever more information, and claiming it does not have enough information to decide if a proposed license is "on reasonable terms and conditions."

The requirement that there be a request for a voluntary license has allowed the patentee to obstruct the granting for a compulsory license to Apotex for a compulsory license for its lamivudine/nevirapine/zidovudine combination product.

CGPA disagrees that the request for a voluntary license is required by 31(b) of TRIPS, as asserted in the Consultation Paper.

Article 31(b) can be waived in cases of in circumstances of extreme urgency or in cases of public non-commercial use. A compulsory license under the system is granted by an exporting member such as Canada to permit public non-commercial use, therefore s. 31(b) does not apply. This is made clear by the Chairman's statement that the purpose of the compulsory license system is to "protect public health", not to pursue "commercial policy objectives". Furthermore, the purpose of the Decision is to address a worldwide crisis of extreme urgency.

In addition, omitting the request for a voluntary license is a reasonable exception under Article 30 of TRIPS. Article 30 creates limited exceptions to patent rights "provided such exceptions do not <u>unreasonably</u> conflict with a normal exploitation of a patent and do not <u>unreasonably</u> prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

The intent of the Decision is that if an eligible importing member seeks drugs under the system, a rapid response is important and consistent with the Decision (see preamble). Any conflict with normal exploitation of a patent, if consistent with that objective, cannot be unreasonable. The eligible importing member or its citizens are third parties with legitimate interests.[2]

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[2] Section 55.2(1) of the *Patent Act*, permitting "early working" of a patent, has been held consistent with TRIPS because of the Article 30 exception: *WTO, Report of the Panel on "Canada- Patent Protection of Pharmaceutical Products" (March 17, 2000) WTO Doc. WT/DS114/R*. In light of the dispute panel's interpretation of Article 30, CAMR would not be inconsistent with TRIPS if the requirement that a voluntary licence be requested was dropped. If a generic manufacturer does not seek a voluntary licence, the patentee's rights are not unreasonably prejudiced: the patentee may export drugs for humanitarian purposes, or grant a licence on reasonable commercial terms to others to do so, at any time. The access to medicines schemes of India, China and the Netherlands have no requirement equivalent to s. 21.04(3)(c)(i).

Patents "issued in respect of that invention" (s. 21.04(2)(d)): Under s. 21.04(2)(d), the applicant must include "for each patent to which the application relates, the name of the patentee of the invention and the number … of the patent issued in respect of that invention." However, patentees will argue there are dozens or even hundreds of patents on the active ingredient, polymorphs, manufacturing processes, intermediates, uses, formulations, packaging, dosing methods, and so on held by many patentees.

For example, keyword searches of "lamivudine", "nevirapine" and "zidovudine" at the on-line patent database of the Canadian Intellectual Property Office (CIPO) on January 18, 2007 turned up 152, 136 and 204 patents or laid-open patent applications containing these words, respectively. A search of chemical names and classes would turn up others.

No matter how many patents are included in the application, brands will argue there are others "to which the application relates", thus creating confusion and delaying the process. Furthermore, a compulsory license may be delayed indefinitely as new patents issue.

This information is not required under the Decision, which contemplates the license will be in respect of a product.

14. How might the application process be simplified?

If an eligible importing member has made a "notification" to Council for TRIPS, as set out in Decision, paragraph 2(a), the Commissioner should be required to grant a compulsory license, if requested by a generic manufacturer.

The generic manufacturer has every incentive to comply with the license because if it does not do so, the patentee can pursue remedies under the *Patent Act.*

15. Should "reasonable terms" be defined? If so, how?

Attempting to define "reasonable terms" will simply lead to more confusion and delay. There should be no obligation on the applicant to seek a voluntary license "on reasonable terms" or at all. The patentee is at all times fully entitled to grant a license to anyone on whatever terms it deems reasonable. Subsection 21.04(3)(c)(i) confers no right on the patentee it would not otherwise have, except to delay and obstruct the grant of a compulsory license.

Duration of the license

16. Is a two-year, once-renewable licence term an appropriate duration for a compulsory licence issued under CAMR?

No. The drugs may still be needed in the importing country after four years, because its people may still be poor and sick, and the importing country may still lack pharmaceutical manufacturing capacity.

The duration of the license should be until expiry of any relevant patents, or such earlier time as requested by the eligible importing country in its notification.

17. Should CAMR provide for a simplified procedure for the renewal of a compulsory licence where the conditions that gave rise to the original licence persist?

The application process itself should be simplified as set out in the response to Question 14, with no limit as to duration or number of renewals. The importing country should decide what drugs it needs, and for how long it needs them.

Royalties

18. Is there an alternative to the CAMR formula for calculating remuneration that would better encourage uptake of the regime while remaining compliant with the WTO waiver and TRIPS?

The requirement for “adequate remuneration” to the patentee (see Decision, s. 3) is achieved by existing s. 21.08 of the Amendments, and the Regulations thereunder.

“Good Faith” Clause

19. Does the prospect of litigation under the “good faith” clause discourage Canadian pharmaceutical manufacturers from participating in CAMR?

Yes. Section 21.17 confers one of at least three unnecessary litigation rights given to the patentee by CAMR (see also 21.08(4) and (5), and 21.14), in additional to the existing remedies under the Patent Act. All such additional litigation rights should be repealed. They are not among the four requirements in the Decision Canada must meet, and will lead to unnecessary litigation and uncertainty.

Section 21.17 addresses a non-problem. There is no danger that generic companies will make too much money out of licenses for humanitarian purposes. Prices on the world market will be kept low by international competition from manufacturers in countries with lower labour and regulatory costs than Canada. Participation by generic manufacturers will be in the nature of a charitable donation.

20. Is the good faith clause necessary to implement the Chairperson's Statement?

No. No other country has implemented an equivalent.

The Chairperson's statement says that the system should be used in good faith and "should not be an instrument to pursue industrial or commercial policy objectives." The perversely worded "good faith" section, 21.17, turns the CAMR into just such an instrument. It allows patentees to litigate against the generic manufacture in the hope of preventing or delaying the distribution of low-cost drugs for humanitarian purposes, thus pursuing the industrial and commercial objective of keeping profits high.

21. What alternative measures might be employed to ensure that CAMR is not used for commercial purposes?

If all of the measures recommended by CGPA in these comments are implemented, this will somewhat reduce the ability of patentees to abuse CAMR to pursue industrial or commercial objectives such as delaying the export of drugs of humanitarian purposes.

We question the interpretation of the Chairman's statement reached by the authors of the Consultation Paper: that the "good faith" called for by the Chairman requires measures aimed at generic companies. The reason the Decision, and the Chairman's statement, were necessary is that patentees have not allowed the supply of low-cost pharmaceutical to poorer countries. Generic manufacturers are the solution, not the problem.

The Chairman's statement is, as we read it, a generally worded exhortation that all affected parties, specifically exporting and importing countries, but also both patentee and generic companies, act in good faith.

Quantities Exported Under License

22. How does the limit on authorized quantity impact participation in CAMR?

The application process itself should be simplified as set out in the response to Question 14, with no limit as to duration or number of renewals.

23. Should CAMR include a simplified procedure for amending the authorized quantity of a compulsory licence after it has been granted?

See answer to question 22.

Anti-Diversion Remedies

24. Are the safeguards in CAMR sufficient to prevent the diversion of exported pharmaceutical products?

Canada's measures are unnecessary. Anti-diversion remedies are the responsibility of the importing country, under the Decision, paragraph 4.

Canada's obligation, like that of any other country, is to ensure that it has in place "effective legal means to prevent the importation into, and sale in" its **own** territory of products produced under the system (Decision, paragraph 5). Canada already has such legal means available under the *Patent Act*.

Canada is required to ensure that the compulsory license issued contains a "condition", that products be clearly identified as being produced under the system through specific labeling or marking such as special packaging and/or special colouring/shaping of the products themselves, provided that such a distinction is feasible and does not have a significant impact on price (Decision, paragraph 2(b)(ii)).

The marking requirement in the present CAMR and regulations go beyond what is required by the Decision. Canada should simply include the wording of Decision, paragraph 2(b)(ii) in the standard form compulsory licence.

The Decision does not impose an obligation on an exporting country such as Canada to police or prevent diversion of exported pharmaceutical products in other countries, because it is impractical to do so, and will lead to delays.

Pharmaceutical patentee companies are large multinational companies, to whom litigation is not unfamiliar. If product produced under CAMR is diverted to a country where it should not be, patentees are capable of taking whatever measures may be appropriate in the courts in that country.

25. Do the anti-diversion provisions extend beyond the requirements of the WTO waiver in a manner that negatively impacts participation in CAMR? If so, what alternatives should be considered?

Yes. The marking requirements exceed those required by the Decision, as set out above. That negatively impacts participation.

The information that must be posted on the licencee's website should be what is required by the Decision paragraph 2(b)(iii), namely: the quantities shipped to each destination, and the distinguishing features of the products. The additional information required by ss. 21.06 of CAMR is not required e.g. "information identifying every known party that will be handling the product while it is in transit from Canada…"

Termination of License

26. Are the grounds for the termination of a licence in CAMR sufficiently clear?

There is no need for the additional litigation right conferred on patentees by s. 21.14. The patentee is entitled to pursue its remedies under the *Patent Act* if it believes the licencee has stepped outside the terms of the licence.

The licencee has every incentive to comply with the terms of the licence, in order to rely on the license as a defence in potential patent litigation.

27. Are they fair?

See answer to question 26.

28. Does the possibility of having a licence terminated in this manner deter pharmaceutical manufacturers from participating in CAMR?

It produces legal uncertainty, and is thus a deterrent to participation.

Conclusion

CAMR imposes onerous requirements on a generic manufacturer seeking to obtain and use a compulsory license, beyond what is required by the Decision. Such steps are not only unnecessary, but render CAMR unworkable. CAMR should be substantially amended to remove all unnecessary and counterproductive steps not required by the Decision.

However, even streamlining CAMR to track the requirements of the Decision may not be sufficient to ensure that low-cost medicines are distributed. No notifications by importing countries to the WTO TRIPS Council have yet been made seeking access to medicines under the Decision.[3]

As pointed out by Medecins Sans Frontieres, the Decision itself is "overly cumbersome" and has proved unworkable; "it is incomprehensible that the Canadian government included additional requirements in [CAMR] that increase the complexity of the process."[4]

The government of Canada therefore must not only address the fundamental flaws in CAMR as outlined above, but "must use its experience trying to implement the Decision as the basis to act at the WTO in order to remedy the constraints of the WTO rules governing the delivery of generic medicines to those in need."[5]

[3] WTO website: TRIPS: TRIPS AND PUBLIC HEALTH 'PARAGRAPH 6' SYSTEM. Notifications by importing WTO Members, http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm. Last visited, January 18, 2007.
[4] "Neither Expeditious, Nor a Solution: The WTO August 30 Decision is Unworkable", Medecins Sans Frontieres. Prepared for the XVI International AIDS Conference, Toronto, August 2006, p. 5.
[5] Ibid, Recommendations, p. 7.