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January 15, 2007

Ms. Brigitte Zirger
Director, Therapeutic Products Directorate
Health Canada
1600 Scott Street
Ottawa, ON K1A 0K9

Re: Review of *Canada's Access to Medicines Regime*

Dear Ms. Zirger:

On behalf of Wyeth Canada, I am writing in response to the request for comment on *Canada's Access to Medicines Regime* (CAMR).

Wyeth Canada is a research-based pharmaceutical company with leading therapeutics in the areas of women's health care, cardiovascular diseases, central nervous system disorders, anti-inflammatory disorders, infectious disease, hemophilia, oncology and vaccines. Wyeth's products include biopharmaceutical products that are the result of significant research and development in the biotechnology field. Since 1883, Wyeth Canada has been making an outstanding, innovative contribution to Canadian healthcare. On behalf of our 2,000 employees in Canada, I would like to offer the following comments on the CAMR.

Since 1968, Wyeth has been the sole provider of oral contraceptives to USAID and has since also worked with CIDA to provide oral contraceptives to Bangladesh. In collaboration with the Global Alliance for Vaccines and Immunization (GAVI), the World Health Organization (WHO), USAID and the World Federation of Hemophilia (WHF), Wyeth:

- provides conjugate pneumococcal vaccines;
- is able to help in the development of a potential new treatment for river blindness;
- enhances maternal and child health programs; and
- has linked hemophilia treatment centers and organizations between developing and developed countries.

In 2003, Wyeth Canada and the innovative pharmaceutical industry applauded Canada for being the first country to take steps to provide local legislation that would implement the Doha Decision to facilitate the exportation of certain medicines by Canadian generic pharmaceutical manufacturers to developing and least developed countries with insufficient pharmaceutical manufacturing capacity.

Following in Canada's footsteps other countries including Norway, the Netherlands and the European Union have enacted similar legislation. However, in no country has the legislation been used, as no potential importing country has notified of a need for specific pharmaceuticals. While I appreciate that the Government of Canada is mandated to review the legislation in 2007, I would urge caution about changing legislation that has not yet been tested anywhere in the world.

The fact that the legislation is relatively new has a direct effect on the number of decision makers that are aware of the ability of this legislation to help their citizens. We understand that many of the countries, which most need help, are not even aware that CAMR is available.

Indeed, the Canadian legislation has only been in operation since May 2005. Even now, the entire system contemplated by the legislation has not yet been implemented. CAMR provides for the establishment of an advisory committee to assist on recommendations with respect to medicines that will be subject to the regime, but to date this committee has not been formed.

With the knowledge that the legislation is relatively new, and that many least developed and developing countries are unaware of it, I would urge the Government of Canada to undertake a comprehensive educational program to ensure that those who need this humanitarian aid are aware of its existence and are encouraged to use it prior to contemplating changing the regime significantly.

CAMR is focused exclusively on access to patented medicines. However, there are many other forms of humanitarian aid that are delivered to developing and least developed countries that are not under the purview of CAMR that deserve equal or greater emphasis in efforts to assist developing nations. Clinics, trained personnel, supply chain management, and access to clean water and food are all as important as access to pharmaceuticals. As the industry indicated during the C-9 discussions, without appropriate infrastructure, CAMR by itself will not fulfil the Doha Declaration goal.

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Before providing responses to the questions posed in the consultation document, I would note that respect for intellectual property (IP) rights is not only beneficial for innovators, but is also in the interest of the developing world nations intended to benefit from CAMR. Without reasonable and effective IP protection, the medicines and vaccines of the future will be delayed, or may not be developed, to the detriment of those patients who are most vulnerable to disease conditions.

I thank you for the opportunity to provide comments on this legislative review and would caution you again not to make major changes to a regime that has yet to be tested.

Sincerely,

Arnout Ploos van Amstel
President & Managing Director
Wyeth Canada

Wyeth Canada's

Submission in Response to

Canada's Access to Medicines Regime Review

Questions

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?**

A. Yes and the specifics should include the following:

- The name of the government person or entity, or the person permitted by the government of the importing country to which the product is to be sold, and prescribed information concerning that person or entity (as per Section 21.04(f) of the Patent Act)
- The country in question recognizes that there is a humanitarian crisis (unless such crisis is decreed by the WHO as being of such magnitude that the need to act is urgent, one can think of avian flu epidemic that some countries may want to downplay in order not to affect local tourism)
- The head of that state or the Ministry of Health are the ones providing the authorization

Canada also has a moral obligation to ensure that the NGO in question abides by Human Rights as implemented through the Canadian Charter and does not discriminate on the basis of religion, ethnic origin or gender.

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

A. Since the regime is a country-to-country regime, it would appear difficult to allow for a free exchange of the products within a regional trade group.

ELIGIBLE PHARMACEUTICAL PRODUCTS

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

A. The list is extremely useful for everybody to know which products are available for use under CAMR. It provides a clear tool, which in turn helps avoid undue litigation in Canada should a company attempt to seek a compulsory license for a product not listed by Canadian authorities.

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

A. Yes it is.

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?

A. Yes with extensive consultation of the innovative pharmaceutical industry by the advisory body to the relevant Ministers.

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

A. The following criteria should be considered:

- The condition to be treated and the number of people affected;
- Whether it does indeed result in a humanitarian crisis as determined by the WHO, not only the country itself;
- Whether the innovative company is a licensee or the owner of the patents on the product – if it is a licensee, do they have the right to engage in the CAMR;
- Whether the product is under a NOCc – and whether the conditions under which it is sold in Canada can be implemented in the country to which it is to be exported.

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

A. Since the scheme is intended to provide needed pharmaceutical products to countries, which do not have the manufacturing capacity to produce the medicine, it would defeat the purpose to allow for the export of the API only. And since only generic companies are allowed to avail themselves of the CAMR provisions, and they need to demonstrate bioequivalence to the "product" being copied, there is no need to allow for the exportation of APIs. The only foreseeable scenario for the exportation of APIs would be at the request of another country's generic manufacturer to use in a different formulation than that approved in Canada. This scenario however does not fall within the purview of CAMR, which is only intended to allow for the compulsory licensing of existing Canadian products.

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?

A. Yes. Based on the answer to Question 1 the official document must bear the appropriate signatures and accompany the application.

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?

A. The CAMR requirements should apply to all listed countries whether WTO members or not. The whole CAMR scheme should not be used for any other purpose than humanitarian measures. As with any other extreme urgency, it should be attested to by the WHO.

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?

A. The countries to which these products would be exported would probably appreciate the fact that Canadian safety standards are applied to the products they are willing to buy from us. Since Health Canada treats these as priority reviews, delays would be minimal as attested by the vast improvement in approval times and the disappearance of the backlog.

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

A. Even if this would be best answered by the importing countries, since Canada's reputation is at stake, it needs to retain its obligation to review the medicines with the same exacting standards it does for the Canadian population.

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?

A. The innovator has a high stake in ensuring that a product, which it still sells on the Canadian market, is not tainted by reports that a cheap sub-standard copy is creating health problems rather than solving them in a developing country. The fact that the product in question would not be up to Canadian standards could affect public perception, sales of the product, and reputation of both the generic and innovator firms in many markets around the world. Canada has an obligation to ensure that these products are submitted to the same standards as those intended for the Canadian population. Therefore, Wyeth considers that nothing short of a mandatory review is acceptable.

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?

A. The information required constitutes in our view minimal information that should be required. Any reduction of these requirements would not be acceptable.

14. How might the application process be simplified?

A. The process does not need to be simplified at this point in time. We still do not know if it is cumbersome since it has not been used. Once experience has been had with the process, the Government can reassess and review if need be.

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

A. It is important to allow for negotiations to take place between the innovator and the generic manufacturers who will determine what the reasonable terms will be. The royalty regime for example as defined in the legislation already constitutes part of the reasonable terms.

DURATION OF THE LICENCE

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

A. It is difficult to assess in the absence of a real-life experience with the scheme. Taking into consideration that there would be a two-year period before the license would eventually need to be renewed, there is no need to actually deal with this issue for the time being. There would be ample time for a regulatory amendment should the need arise during that initial two-year period.

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?

A. The procedure as it exists is already fairly simple, it does not need to be tinkered with at this point in time.

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?

A. The initial discussions surrounding the royalty calculations found that this would be a fair approach. It remains that way today. The generic industry initially found that not being able to "make money" would constitute a hindrance and, therefore, that any royalty would act as a deterrent. Since Canadian generics have long been demonstrated as being some of the highest-priced in the world, it would be near impossible for them to lower them sufficiently to be able to compete for supply contracts with countries like China and India which have also developed their own compulsory licensing schemes and have been providers of choice for low price therapies for a number of years. This by itself might explain the non-reliance on any of the CAMR-like schemes developed by a number of countries.

As indicated by our industry over and over again, it is one thing to get the medicines to the countries in need but without the appropriate infrastructure to ensure that the medicines get to the people who need them in addition to adequate water and food supplies and support to ensure compliance – medicines by themselves would not suffice.

THE GOOD FAITH CLAUSE

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

A. It is doubtful that a clause framing the whole scheme would act as a deterrent to the use of this laudable effort.

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

A. Absolutely, since in its preamble, the Jean Chrétien's Pledge to Africa specified that the Chairperson's statement formed an integral part of the endeavour. Though other systems have not incorporated this type of clause, Wyeth believes it is a worthwhile safeguard to ensure that the system is not used for commercial purposes.

QUANTITIES EXPORTED UNDER LICENCE

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

A. The intent is to ensure that CAMR is used by Canadian generic companies, but since as mentioned above they cannot compete with India and China as far as prices are concerned – standard of living, wages. etc… are higher in Canada – there is little probability that the scheme will ever be used.

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

A. Since Canada does not allow stockpiling, it should not affect participation in CAMR. The quantities required by countries should be sufficiently important to justify production. The generic company actually benefits from being able to copy the drug ahead of the time that it will be able to introduce it in the Canadian market at which point all the pre-work will be done and the approval swift.

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

A. Wyeth supports a process that ensures that any licence that is issued is amended as soon as possible in the event the contract is concluded for a different quantity than in the original application. The application amount should also be amended on the official website to reflect reality.

ANTI-DIVERSION MEASURES

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

A. The conditions to prevent diversion are minimum conditions. There will never be a completely full-proof mechanism to prevent the diversion of pharmaceutical products. There is a need however to coordinate closely with national and international agencies to ensure that sub-standard counterfeit medications are not being used to address a humanitarian crisis.

The Chairperson's statement about "good faith" are agreed to by the direct participants in the scheme who should want to ensure as much security and integrity of their supplies as possible. This can only be done through an open and transparent system – through the use of specific websites, agreed upon quantities, distinctive features etc. – and close national and international monitoring.

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?

A. The anti-diversion provisions actually help strengthen the purpose of the WTO waiver by ensuring that the drugs intended for a specific population and country remain in that country. Acting in good faith, all stakeholders involved in the scheme should want to be able to track and demonstrate their contribution to the countries in need.

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

A. The conditions for termination are sufficiently clear.

27. Are they fair?

A. The termination provisions are ineffective since they do not prevent misuse of the system. In the event of the drugs being diverted to another country, the generic manufacturer whose product it is can still partake in the regime without penalty. The fact that the patentee has the onus of going to court to seek termination of a license while the generic continues to misuse the license is discriminatory toward the innovative pharmaceutical company. There are also no damages or other compensations available to the patentee.

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

A. Since there are minimal requirements for participating in the program, they would probably not deter participation.