APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY

January 23, 2007

VIA EMAIL

Douglas Clark
Director
Patent Policy Directorate
Industry Canada

Brigitte Zirger
Director
Therapeutic Products Directorate
Health Canada

Dear Director:

Re: CAMR Consultation Paper

Apotex Backgrounder:

Apotex Inc., founded in 1974, is the largest Canadian-owned pharmaceutical company with headquarters in Ontario and over 5,000 people in research, development, manufacturing and distribution facilities in its Group of Companies. In the total Group's number of employees, we have over 2,000 scientific staff including 100 PhD's. We produce more than 260 generic pharmaceuticals in approximately 4,000 dosages and formats which are exported to over 115 countries.

Worldwide sales exceed $1 billion (Canadian $) per year.

Research at Apotex and its Group of Companies includes the development of both generic and innovative pharmaceuticals, including the area of biotechnology.

R & D expenditures for Apotex in 2005 were over $183 million representing close to 18.3% of sales. This commitment for the next 10 years will exceed $2 billion (CDN).

We are not just any pharmaceutical company; we are Canada's pharmaceutical company, a leader in science and technology.

Chronology of Apotex's Experience with Bill C-9

- Started developing triple combination AIDS drug (Apo-Triavir) May 2005
- Submitted December 2005 to Health Canada
- Approved by TPD June 2006 (Patent Hold)
- August 2006 WHO prequalification
- Discussions with Brand patent holders from June 2006 on
- Because of the complexity of the process, nothing has moved since

We thank you for the opportunity to provide comments on how the regime can better deliver on Canada's commitment to improve access to less expensive medicines in developing countries. We respectfully offer the following comments for your consideration:

Eligible Importers
The guidance appears clear enough concerning products "permitted by". The issue is becoming an eligible importing country. It has been our experience that individual countries do not clearly understand the process for obtaining permission for importing eligible products. The NGOs have actually helped individual countries in this regard.

Eligible Pharmaceutical Products
Schedule 1 is a useful document. It addresses the objective of providing clarity and transparency to the identification of products that are eligible for export under the regime. We recommend that a process be put in place to allow for addition of products in a timely manner based on a clearly documented public health need.

Notification
The requirement to include the importing country's notification to WTO, in the application for a compulsory licence, is an unnecessary burden that only delays the process. The eligible countries are clearly listed in Schedules 2 through 4. A certification that the country is included on those schedules should be sufficient. There have been instances where the country does not want to be publicly identified until a compulsory licence is obtained and it is viable that the product can be exported to the country. The requirements pertaining to anti-diversion are sufficient to ensure the product is only exported to eligible countries.

Health Canada's Drug Review
The requirement for review of the pharmaceutical product by Health Canada is not a deterrent to manufacturers. Health Canada enjoys a reputation for rigorous regulatory review. This allows WHO the confidence to understand the product has been subjected to well defined regulatory requirements for safety, efficacy and quality. As such it allows WHO to accept the review for inclusion of the product on the Prequalification list. This does not put an unnecessary drain on WHO resources and allows for timely inclusion on the PQP. It also benefits the manufacturer as the product would be eligible for approval within Canada once the patent expires.

Application Process
The requirement to request a voluntary licence prior to a compulsory licence is an unnecessary burden that only results in potential delay to timely access to the pharmaceutical products by developing countries. It only adds the potential for abuse and increases the length of time it takes for the product to become available. Since the regime is in place and it is clear the desire is to have medicines available to developing countries in a timely manner, it is recommended that the process be simplified such that the first step is directly to submit an application for a compulsory license. This minimizes the cost of unnecessary litigation, that would only end up being transferred to the end purchaser, defeating the purpose of having timely access to low cost medicines.

Duration of Licence
The 2 year licence term appears to be an unnecessary requirement. The finite time required under TRIPS should be defined as the time under which the patent is still valid. The need for low cost medicines by developing countries will remain as long as the patent is in force. The requirement to renew the compulsory licence is an administrative burden to both the manufacturer and the government that only leads to increased cost of the product.

Good Faith Clause
The good faith clause is not necessary for implementation of the regime. It is a requirement that has a greater potential for abuse and increased cost to the manufacturer than addressing the potential issue it is designed to address. Only manufacturers who have the significant resources to deal with the potential litigation would even express an interest in participating in CAMR, and even those who can will be deterred due to the cost and time required to deal with the litigation. One way to ensure that CAMR is not used for commercial purposes is to include costing information as part of the application for a compulsory licence. An alternate approach would be to build in an appeal mechanism to the licence.

Quantities Exported
It is recommended that CAMR include a simplified and accelerated procedure to amend the licence when an importing country has identified a need for additional quantity of a pharmaceutical product for which a licence currently exists.

Anti-Diversion Measures
The safeguards are more than adequate to prevent diversion of exported pharmaceutical product. The requirement for each individual company to maintain a website is onerous especially for smaller manufacturers. One central website within Health Canada or the Patent Office would be an alternative.

Should you have any questions, please do not hesitate to contact me by telephone at (416) 401-7293, by fax at (416) 401-3809 or by email at jhems@apotex.com.

Sincerely:

John Hems
Director, Regulatory Affair