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Mr. Douglas Clark
Director, Patent Policy Directorate
Industry Canada
235 Queen Street
Ottawa, ON K1A 0H5
Canada

Dear Mr. Clark:

We are writing to you concerning the consultation on Canada's Access to Medicines Regime that began November 24, 2006. This submission contains confidential commercial information and may not be released except in accordance with the Access to Information Act. In this submission we will raise three main issues:

1) Any changes to the Regime should ensure that the integrity of the system is maintained, with no increased risk for diversion.
2) Health Canada should continue to assist developing countries by conducting health and safety reviews of drugs for export.
3) The Regime should continue to maintain a list of eligible drugs and a process to update the list when needed.

Janssen-Ortho Inc. (JOI) is a research based pharmaceutical company developing and marketing both small molecule pharmaceuticals and biopharmaceuticals. JOI is dedicated to long-term and sustainable development of patented medicines. JOI encourages efforts that will ensure that Canada has an internationally competitive intellectual property (IP) regime.

JOI fully supports access to medicines by developing countries, and appreciates the efforts Canada has made in this regard. It is our understanding that, in fact many countries that implemented systems after Canada had implemented its regime drew heavily on the Canadian system, including countries of the European Union, and Norway. As such, the various elements appear to have been accepted as the proper implementation of the regime.

It is curious however, that the review is being conducted earlier in time than mandated, and at a time when the system has not yet been used. It is not only the Canadian system which has not been used – it is our understanding that despite legislation in place in several countries, no importing country has notified the World Trade Organization (WTO) of a need for a product.

Integrity of the Regime

JOI notes that many of the questions in the consultation document pre-suppose that there is a need for change, inferring that change is needed to make the system more accessible – not that

change would be made to provide any further safeguards in the system to ensure access is provided to those in need. JOI, as a patentee, is concerned that should there be any changes to existing safeguards these changes should not be detrimental to the system overall. The current system has only minimal processes to guard against potential for diversion of products that are exported. These processes should be maintained, and could even be strengthened if the government's aim is to ensure that products in fact reach the intended recipients. These measures could include audit provisions, to ensure that the integrity of the system is maintained.

Furthermore, JOI submits that anti-diversion measures, in addition to ensuring a safe, stable and necessary supply of products for countries in need, must protect the domestic IP system and must ensure that products, which are exported under the regime, are not re-exported and sold back into developed markets.

Health & Safety Review of Products for Export

In JOI's view, a further element of the system that must be maintained is the health and safety review of products for export. The suggestion in the consultation document is that review by Health Canada is perhaps unnecessary, or that it could be supplanted by another process. JOI is of the view that Health Canada review is important. Ultimately, this is a policy question for the government; however, JOI fails to see the justification of exempting these products from a health and safety review. Many of the countries to which these products may be exported do not have their own systems of health approval. Requiring regulatory approval here means that there is a review of the product and its efficacy, thereby assisting countries in need. The Health Canada process is expedited, as particular resources are reserved to deal with the review of these products on a fast track basis. Product review cannot therefore be viewed as an impediment to access. JOI is of the view that the review requirement should not be disturbed.

List of Eligible Drugs

As a final point, with respect to the list of eligible drugs, we are concerned that there will be pressures to remove the list of eligible drugs, leaving the full scope of drugs available for access under the regime. JOI submits that having a list of eligible drugs is appropriate. Canada's system, unlike that in place in other countries, requires the Commissioner of Patents to issue a compulsory licence without any express provision for the patentee to appear and make representations. A limitation on the scope of drugs that may be licenced under the system uards against commercial uses of the system that might otherwise occur. There is a process under the regime to add products to the schedule of eligible drugs in the event it is felt necessary. It is JOI's view that the scope of eligible drugs should relate to precisely the situations which the Doha Decision was meant to address, namely, public health problems in developing and least developed countries.

We thank you for consideration of our comments. If you have any questions, or wish to discuss our submission, please contact me or Lesia Babiak. We would be pleased to meet with you to discuss JOI's position.

Regards,

Chris Halyk
President, Janssen-Ortho Inc.

cc: Lesia M. Babiak, Director, Federal Affairs & Health Policy