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Dear Mr. Clark and Ms. Zirger,

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

Thank you for the opportunity to comment on Canada's Access to Medicines Regime (CAMR). The EU followed Canada in being one of the first legislative authorities to introduce legislation giving effect to the WTO Decision of 2003 which was subsequently endorsed in December 2005. As the Trade Association for the European R&D-based pharmaceutical industry, EFPIA has been closely monitoring the legislative developments arising from the WTO Decision. We therefore hope our comments will be of interest to your review of CAMR.

As you are aware, under the August 2003 Decision, member countries may allow patented products to be manufactured under license by someone other than the patent holder for humanitarian purposes in response to a public request by a country which has insufficient pharmaceutical manufacturing capacity. TRIPS provides considerable latitude to requesting countries to define those situations for which compulsory licenses are the appropriate policy response and the Decision provides considerable latitude to "manufacturing countries" in determining how to implement legislation permitting exports.

That "policy space" is one element of the flexibility offered by the TRIPS agreement. EFPIA applauds the Canadian Government's own response to the Decision. In our view, the fact that the provisions set out in CAMR have yet to be used does not mean that the law has failed or that the framework it provides is somehow inadequate.

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While I appreciate that the Government of Canada is mandated to review the legislation in 2007, I would urge caution in prematurely amending legislation that has not yet been tested in Canada, especially when similar legislation has not been tested anywhere in the world. Rather, EFPIA would make two preliminary observations and draw three conclusions from the situation.

- **CAMR is not overly bureaucratic or complex**

The Canadian legislation is simple to utilise for companies that wish to do so. Once minimal formalities have been observed, there is little or no apparent discretion to refuse a licence or to argue about its terms. There is effectively no reason why a compulsory licence should not be issued quickly once the formalities have been observed.

- **It is too early to judge CAMR's "success"**

The reasons why the legislation has not been used to date are likely to have nothing to do with the legislation itself. For example, we understand that many countries are not even aware that the option to import from Canada is now available. That is presumably why, in late November 2006, the WTO held a third workshop for developing countries on TRIPs flexibilities which focussed on the Decision.

Given that the legislation is relatively new, and that many least developed and developing countries are seemingly unaware of it, an alternative to re-writing CAMR would be for the government of Canada to undertake a comprehensive educational program around it.

Turning to the wider context in which CAMR should be viewed, EFPIA would draw three conclusions.

1. Access in Developing Countries has improved – Reducing the need for CL'ed products:

The lack of use of the Compulsory Licensing (either under the Decision or more generally) underlines that WTO members have used other means to address access issues. Over the period since the legislation was passed, access has undoubtedly improved. The continued decline in the prices of both patented and off-patent medicines in the developing world irrespective of the use of compulsory licenses has been of immediate benefit to recipient countries. So are the commitments that some companies have made to continue to pass on any savings that they are able to make. The commitment of innovative companies to make their medicines available continues to be a major driver of progress.

2. Developed world generic manufacturers are unable to compete with developing world manufacturers

The WTO decision removed any legal impediment in TRIPS to the expansion of a global supply base of low price medicines for developing countries. However, removal of a legal impediment does not, in itself, ensure that that which was previously restricted will occur.

For that to happen, the economic pre-conditions need to be right. And there is significant doubt around the readiness and ability of the potential supply base – especially the supply base in developed countries - to respond to requests for cheap medicines.

The competitive factors in the global industry are such that it is manufacturers in the emerging economies (such as India) that are most strongly-placed to respond to such

requests. It is questionable to what extent developed-world generic companies would wish or be able to match suppliers from the emerging economies in a highly cost-focused tender-driven business. In this sense, the leadership shown by Canada and others is politically important, but may not have the major domestic impact in terms of supply that some have expected. This point was confirmed at a conference in Europe 18 months by representatives of European generic companies.

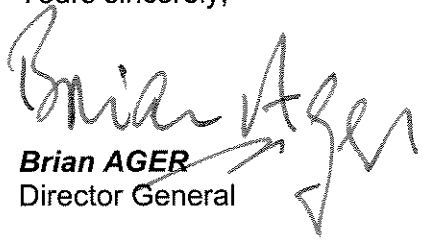
3. Policy makers have failed to address the economic realities of the developing world

The commitment of these emerging economy suppliers is far from clear, even when there are immense problems of access in their home markets. We detect little evidence that such companies are focusing on improving access locally, as much as on more conventional commercial strategies directed towards developed world markets. As recently as last week, a leading Indian company reported that its major priority was to expand by acquisition in Europe, confirming the overall trend[1]. While this is entirely logical from the business perspective, it highlights both the continued progress to be gained from alternative access-to-medicines strategies, such as providing incentives for local and regional voluntary licensing and other forms of partnership with innovators, and the need for governments and local industries in affected countries to show commitment to a needs-based approach to supply.

Conclusion

Compulsory Licensing has its place as a policy option, but if its place is rather limited, that should not be taken as evidence of policy failure. It is likely that a more developed and specific sense of its utility will emerge over time. In the meantime, experience to date suggests that progress in improving access to medicines will continue through more appropriate means.

Yours sincerely,



Brian AGER
Director General

[1] International Business Strategies Newsletter, March 2006 "Bhavin Chheda, an analyst at Pioneer Intermediaries, a brokerage firm based in Mumbai, expects almost all major drug companies to make an acquisition over the next 12 to 14 months. "It is the best way to ensure long term survival," Mr. Chheda said. Over the past year, Indian companies struck 26 deals. Some 15 were acquisitions, the rest were joint ventures. An estimated 30% of the purchases were in Europe, including the UK, while 50% of joint ventures and alliances were in the U.S., both regulated markets where Indian companies sell generic drugs after the patents on the products expire……Matrix Laboratories Ltd., with makes generic drugs and pharmaceutical ingredients, bought Docpharma NV of Belgium for $259 million in June, gaining access to what Matrix's chief executive N. Prasad described as the "underrepresented, high-growth generic markets of Belgium and southern Europe." Dr. Reddy's Laboratories, Ltd., among the top five companies in the industry by revenue, bought F. Hoffmann-La Roche Ltd.'s drug-making plant in Mexico last year for $59 million, adding 18 products, including steroids, to its portfolio……Late last year, Ranbaxxy Laboratories Ltd., the largest pharmaceutical company in India by revenue, set aside $1 billion for acquisitions and said it is targeting a marketing company in the U.S. and Europe and a manufacturing company in India. Recently, the company said it plans to establish a subsidiary in Japan, the world's second largest pharmaceutical market with drug sales of $65 billion, which is opening up to generic drugs to save on health care costs.