Canadian HIV/AIDS Legal Network | Réseau juridique canadien VIH/sida

July 26, 2006

Ms. Susan Bincoletto
Director General
Marketplace Framework Policy Branch
Industry Canada
10th Floor, East Tower
235 Queen Street
Ottawa, Ontario
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Dear Ms. Bincoletto:

Re: Addition of oseltamivir phosphate to Schedule 1 to the *Patent Act*

On July 1, 2006 the Departments of Industry and Health published, in Part I of the *Canada Gazette*, the proposed text of an order to amend Schedule 1 to the *Patent Act* to add "oseltamivir phosphate", in both capsule form as well as in powder for oral suspension, to the list of patented pharmaceutical products eligible to be exported under compulsory license. The Canadian HIV/AIDS Legal Network wishes to register its support for the proposed amendment, and to encourage the Governor in Council to make the proposed order without further delay.

We have a keen interest in the outcome of this request. We were one of the non-governmental organizations heavily involved in the drafting and enacting of the *Jean Chrétien Pledge to Africa Act* (then Bill C-9) in 2004, amending the *Patent Act* and the *Food and Drugs Act* to allow for compulsory licensing in Canada of patented pharmaceutical products for the purposes of exporting them to eligible countries in need of lower-cost medicines to address public health problems. The bill was supported unanimously by all Members of Parliament and all Senators as an important Canadian initiative to respond to the pressing public health needs of the developing world. However, since the legislation was proclaimed into force in May 2005, it has not yet been used to produce and export a single medicine to developing countries. Amending Schedule 1 to the *Patent Act* as proposed would create an opportunity for using this legislation to supply a product that could respond to a significant public health threat.

As you know, oseltamivir phosphate is an anti-viral medicine used, for both treatment and prophylaxis, of influenza (including the H5N1 variant) and is of considerable and growing interest given its possible beneficial use in the event of outbreaks of what is commonly referred to as "avian flu". There is considerable concern that a future strain of avian flu may be transmitted from person to person. Leading public health authorities say

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there is a risk of a global pandemic of avian flu, and that in some scenarios would lead to the death and suffering of millions. The World Health Organization (WHO) has already released a report "Responding to the avian influenza pandemic threat - Recommended Strategic Actions"[1] and the Canadian Government has recognized the threat on different occasions[2].

Very few developing countries have stockpiled oseltamivir phosphate in anything remotely resembling the quantities recommended. As a consequence, they lack one of the tools for treatment or prevention of pandemic influenza, should such a pandemic occur. One major barrier to building up adequate stockpiles is cost; another is scarcity. In 1996, the multinational pharmaceutical company Hoffmann-La Roche, Inc. (Roche) acquired worldwide licenses to certain patents on oseltamivir phosphate from Gilead Sciences, Inc. (Gilead). Roche and firms licensed by Roche or Gilead are unable to meet the current demand for oseltamivir phosphate, having cut off commercial sales of Tamiflu in many countries, and having rationed and delayed delivery of government stockpiles in many countries. The high prices for Tamiflu are also a significant barrier for developing countries to build needed stockpiles of this medicine.

It would, therefore, be important to enable the use of Canada's legislation on compulsory licensing for export to address this growing public health concern, a matter of particular urgency as the virus continues to spread in the developing world. We note that recently, the first cases of avian flu have been reported on the African continent, which region would be particularly hard hit by pandemic influenza given the existing numbers of people living with immune systems already compromised by HIV and other infections such as tuberculosis. It seems particularly fitting that the *Jean Chrétien Pledge to Africa Act* be amended to enable the supply of a medicine that could be of great benefit to the people and countries of that continent facing yet another serious public health threat.

However, the current list of pharmaceutical products eligible for export, set out in Schedule 1 to the *Patent Act*, does not include oseltamivir phosphate. As we understand it, Biolyse Pharma, a Canadian pharmaceutical company, has developed a generic formulation of this medicine that is manufactured from needles of coniferous trees rather than the limited Chinese supply of star anise. Biolyse has indicated to us that, should the necessary legislative amendment proceed, it intends to apply for a non-exclusive compulsory license to produce and export oseltamivir phosphate to developing countries at a reduced cost. On February 13, 2006, Biolyse formally requested the Ministers of Health and Industry to initiate the necessary amendment.

We are pleased to see this process is now underway with the publication of the proposed order in the *Canada Gazette*, and we trust that the Governor in Council will move quickly with bringing this amendment into force. We are concerned, however, that it has taken over four months to even publish, for public comment, a proposed amendment adding

[1] Report available at http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_05_8-EN.pdf

[2] Information and press releases available on the Health Canada Website: http://www.hc-sc.gc.ca/dc-ma/avia/index_e.html

oseltamivir phosphate to Schedule 1 of the Act. We recall that both the *Jean Chrétien Pledge to Africa Act* and the 2003 WTO General Council Decision which it implements were intended to support a rapid, flexible response to the public health needs of developing countries. Indeed, during the process of drafting and passing the *Jean Chrétien Pledge to Africa Act*, stakeholders were repeatedly assured that it would be a simple, rapid process for Governor in Council to add products to Schedule 1. We note that this particular request concerns a response to a potential public health emergency, and there is an urgent need for countries to prepare for a possible pandemic. We hope that future amendments to add other pharmaceutical products to the schedule will move more quickly.

In this instance, we have a Canadian company that is ready and willing to make use of the law to respond to an emerging public health need of developing countries. This is an opportunity for the Government of Canada to follow through on Parliament's stated commitment to improving access to medicines and to demonstrate the usefulness of this precedent-setting legislation. We trust that the Government will move quickly with finalizing this amendment and bringing it into force.

Please do not hesitate to contact us if you would like any additional information or to discuss this matter further.

Sincerely,

Joanne Csete
Executive Director