July 25, 2007

The Honourable Maxime Bernier
Minister of Industry
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The Honourable Tony Clement
Minister of Health
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Dear Ministers,

Re: Canada's Access to Medicines Regime:
highlights from an international expert consultation

We write with regard to the government's review of Canada's Access to Medicines Regime (CAMR), currently underway, and to share you with some highlights of findings from a recent international consultation our organizations co-hosted to examine CAMR and related issues.

As you know, both the North-South Institute and the Canadian HIV/AIDS Legal Network have been actively engaged in consultations with government and discussions with parliamentarians over several years in the drafting, enactment and review of the 2004 legislation that created CAMR. You may be aware that, during the drafting of that legislation, it was recognized that the perspective of developing countries was not adequately represented in the policy-making process. This was recognized again more recently during hearings in April of this year by the House of Commons Standing Committee on Industry, Science and Technology into the experience to date with CAMR. While several Canadian civil society groups active in providing input to the Government of Canada in 2003/04 brought to those discussions their many years of experience working in developing countries to provide humanitarian aid, this was an imperfect substitute.

In light of this, and in order to contribute to the review of CAMR, on April 19-21, our organizations co-hosted in Ottawa an ***International Expert Consultation on Canada's Access to***

Medicines Regime, Global Developments, and New Strategies for Access to Medicines, an initiative aimed at ensuring that CAMR and related issues could benefit from analysis by an expert group that specifically included the perspectives of developing country representatives.

This pertinent meeting was attended a wide range of participants, including numerous representatives from developing countries such as Kenya, Ghana, Zambia, South Africa, Thailand, India, Morocco, Costa Rica and Brazil. A number of the participants work in the area of pharmaceutical procurement and related policy issues for government agencies or for private care providers (e.g., Kenya Medical Supplies Agency, Mission for Essential Drugs and Supplies, Centre for Infectious Diseases Research Zambia, Health Consumer Protection Project at Thailand's Chulalongkorn University), as did a number of participants working for international organizations (e.g. International Dispensary Association, the Global Fund to Fight AIDS, Tuberculosis & Malaria) or projects engaged in scaling up access to AIDS treatment (e.g., Columbia University's International Center for AIDS Care and Treatment Programs). Other meeting participants included some of the world's leading policy experts in the area of intellectual property and pharmaceuticals from civil society (including from developing countries), academia and international organizations (e.g., the World Trade Organization). Finally, the meeting enjoyed the participation of officials from Health Canada, Industry Canada, Foreign Affairs and the Canadian International Development Agency. The event was organized with partial financial support from CIDA and Health Canada, and with the support and advice of the other departments.

In total, some 60 participants attended two and a half days of intensive discussion that not only examined CAMR in detail but also explored related global developments regarding intellectual property policy and access to medicines, as well as new strategies that could be pursued to advance both research into global public goods for health such as medicines and access to those goods particularly for the developing world. The motivation of the Expert Consultation was founded in the desire to contribute effectively to the internationally-agreed objective of universal access to HIV/AIDS treatment by 2010 (e.g., G8 2005 Summit Communiqué, UN General Assembly's 2006 Political Declaration on AIDS). The overall intent and result of the debates in the Expert Consultation was to facilitate and simplify the process of licensing, procurement and sale under the Canadian legislation.

The full report of the Expert Consultation will follow in due course, but we wish to share with you highlights of the consultation, as a way of further informing and contributing to the government's review of CAMR.

The objective of responding to urgent health needs, and to the requirements of purchasing governments or agencies, must be the predominant objective. As one expert commented, at present CAMR seeks to make importing countries fit the mechanism, rather than making the mechanism or procedure fit the needs of the prospective importers and their patients. It was also noted that the current legislation does not adequately take into account the practical considerations facing generic drug manufacturers who are the intended suppliers of lower-cost medicines to these prospective purchasers.

For example, it was noted that *the current legislation is incongruent with standard international procurement practice*. If Canada wishes to facilitate generic manufacturers issuing a bid for an international tender, CAMR must serve rather than restrict the ability of a generic company to make such a bid and be ready to undertake a contract. In other words, such a

company must have a license permitting manufacture for export already in hand, authorizing supply to any of the countries eligible under CAMR to benefit as importers of Canadian-made generics, and without restriction on the quantity of the product permissibly exported. The Canadian licensing process should be made as automatic as possible.

To achieve this, participants considered the requirement of a *Health Canada approval* for the product for export, and its relationship to the WHO's Prequalification Programme. Health Canada approval does not guarantee automatic WHO approval, although it is encouraging that Health Canada and WHO have taken steps to streamline WHO prequalification following Health Canada approval. It should be borne in mind that national regulatory agencies of importing countries must further make the effective decision of whether or not to register the product. In doing so, the WHO Prequalification Programme is the most common reference standard for those products to which WHO's programme applies, including antiretroviral for treatment people living with HIV. There was some expert support for a continuation of Health Canada approval, and it may well be that Canadian generic manufacturers in some instances will prefer to pursue this route, but increased expertise on and sensitivity to the circumstances and requirements of product use in developing country contexts was advised. It was also suggested by some participants that Canada create alternative streams for product approval, allowing WHO prequalification to suffice as an alternative to Health Canada approval should a generic manufacturer and an importing country determine this suits them better.

Further, the *voluntary licensing requirements* have proven complicating, delaying and limited in terms of product, firm and contract. There was considerable support for waiving the voluntary license procedure, and creating instead a more automatic and direct compulsory licensing process. The current legislation leaves too many doors open for delay and complication. Should such a procedure remain in CAMR, a strict time limit of 30 days should be applied.

The current *time-limit of two years on the compulsory license*, and the *limit of any given licence to a specific, pre-determined quantity* of the product, were viewed as negative features of CAMR, economically unattractive and difficult given producers' needs to schedule production well in advance, confirm market demand, and reduce uncertainty. Furthermore, given the long-term aspect of the need for sustained treatment, the limit adds an additional unpredictability for importing countries, and limits flexibility in adjusting and extending purchase quantities over time.

The CAMR *list of eligible products (Schedule 1 of the Patent Act)* has proven an additional cause for delay, and an opportunity for patentees to lobby, successfully in some instances, against the addition of new products that address developing countries' public health needs. No such list is required under the 2003 WTO decision that CAMR implements, and indeed it runs counter to the spirit of the WTO negotiations, during which proposals to restrict the scope of the WTO decision to specific products or diseases were ultimately rejected in the text adopted by consensus. There was considerable support for removing the list completely.

The current requirement that potential *NGO purchasers* seek approval of the importing country should also be removed, as this is an additional feature of CAMR that is unnecessary under the WTO decision and creates additional barriers for humanitarian organizations in seeking to deliver treatment.

The *list of eligible importing countries (Schedule 3 of the Patent Act)* was a matter of significant debate, including its relationship to the 2003 WTO decision and the requirements under CAMR to satisfy additional requirements in order to be included, such as declaring a "national emergency" or situation of "extreme urgency", etc. The declaration of a "national emergency" has negative constitutional and other negative consequences, and is not required of importing developing countries that are WTO Members. A number of experts felt these requirements, and other provisions which could be considered "TRIPS-plus", should be avoided.

A further observation was the need for *incentives* for potential manufacturers that would encourage them to participate in the regime. A number of the simplifications recommended above can contribute to this end.

Participants in the Expert Consultation also considered policies and approaches which could facilitate production of needed pharmaceuticals and their availability at more affordable prices, including a number of proposals that Canada should explore further as Chair of the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. These included:

- the development of patent pools, on both a voluntary and non-voluntary basis, with a view to maximizing access to technologies for both further research and development and for treatment of patients;
- advance market commitments (AMCs) to encourage research into, and eventual access to, products needed for public health — both positive and negative aspects of AMCs were noted;
- prize funds leading to the development of pharmaceutical products addressing public health needs (rather than profit-driven priorities);
- merit-based, public investment by governments in research and development based on public health needs;
- various not-for-profit alliances between private and public sector actors with clear rules governing licensing of any products developed and accessible prices for developing countries (e.g., the Drugs for Neglected Diseases Initiative); and
- adoption by universities and/or through legislation of public-interest policies regarding the use of university-held patents.

Cost factors impeding the provision of universal access to HIV/AIDS treatment were in mind throughout the Consultation, although financing the scale-up of the AIDS response was not its focus. The importance of generic production and competition, the strategic usefulness of compulsory licenses and the urgency of action in the light of the international pandemic were all recurrent themes.

One of the additional benefits of the consultation was the opportunity for generic manufacturers – and in particular the only Canadian company that has yet developed a product for potential export under CAMR – to meet with colleagues involved in drug purchasing from a number of countries, particularly in Africa. A number of conversations occurred at the meeting, and subsequently, regarding possible use of CAMR to secure the existing generic product, but many concerns remain about the feasibility of doing so.

In recent days, we have witnessed the historic step of Rwanda becoming the first country to notify the WTO of its intention to import the generic ARV drug from a Canadian manufacturer, setting the stage for what may prove to be the first use of CAMR to export lower-cost medicines to a country in need. We are very pleased at this news, but we caution that a number of steps are still required of both Rwanda and the Canadian manufacturer, under both the strictures of the 2003 WTO decision and CAMR, and the benefits to patients have not yet been realized. Given the unanimous support in Parliament for CAMR when it was created, and the considerable support and interest of the Canadian public that has been demonstrated over the years in seeing the pledge of affordable medicines fulfilled, we trust that in the coming weeks and months your government will take the necessary steps to ensure that this possible first use of CAMR comes to fruition.

We also stress that it has taken more than three years, and an extraordinary amount of time and work by NGOs and the Canadian manufacturer, to arrive at this stage. It is unrealistic to expect that such effort can or is likely to be repeated. Indeed, the sole Canadian manufacturer that has attempted to use CAMR has publicly indicated that it is not likely to undertake such an initiative again, given the hurdles experienced with the regime to date. A recurrent theme throughout the Expert Consultation was the need to amend Canada's regime to make it more straightforward and easier to use for potential beneficiary countries in the developing world and generic suppliers able to assist in addressing their public health needs. We look forward to the government's report on its review of CAMR, which we understand you expect to table in Parliament when it resumes in September of this year, as well as to ongoing engagement with your offices in making the necessary reforms to the regime that will encourage its use in future to benefit patients in the developing world.

Sincerely,

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