



January 24, 2007

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Brigitte Zirger
Director – Therapeutic Product Directorate
Health Canada
1600 Scott Street
Ottawa, ON
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Dear Ms. Zirger:

RE: Review of Canada's Access to Medicines Regime

In reference to the government's review of Canada's Access to Medicines Regime (CAMR), Bayer Inc. is pleased to offer the following comments.

As a member of Canada's Research-Based Pharmaceutical Companies (Rx&D), Bayer Inc. endorses our association's submission regarding the consultation paper.

We would also like to comment on some aspects of this legislative review based on our own experience with CAMR.

Schedule I and the Expert Advisory Committee

During the drafting of this legislation, Bayer Inc. learned that our antibiotic product, Avelox[®] (moxifloxacin), was included in Schedule I as a treatment for Tuberculosis (TB). This decision was made at Committee stage of the review without any prior consultation with Bayer Inc. or medical experts. Bayer Inc. was concerned about the recommendation to include Avelox[®] in Schedule I since the TB indication was not approved by Health Canada and the decision seemed to be made by elected officials rather than medical experts.

As such, we believe it is critical for CAMR to maintain an evidence-based paradigm in making decisions regarding the inclusion of pharmaceutical products within CAMR. Products that are included on the list should be made on the basis of global need and medical

evidence which we believe reflects the original intent of the legislation. Any proposals to weaken the review process for the drugs to be included in Schedule A would be problematic.

Health Canada's Drug Review

As noted in the submission by Rx&D, it is good policy for Canada to ensure that the products exported are safe and efficacious, particularly given that many of the importing countries will not have the capacity to review and approve pharmaceutical products. Bayer Inc. fully supports this principle in that it ensures that we do not have a double standard for the use of pharmaceutical products – one for developed countries and another for under-developed/developing countries.

Bayer Inc.'s Commitment to Make Medicines Affordable and Accessible

As part of our commitment to make medicines affordable and available, on October 18th 2005 Bayer AG (our parent company) launched a historic global clinical trial program with the Global Alliance for TB Drug Development to study the potential of Avelox (moxifloxacin), to shorten the standard 6-month treatment of TB. If the trials are successful, the partnership aims to register moxifloxacin for a TB indication and is committed to making it affordable and accessible in developing countries where patients need it most. The trials will take place in Brazil, Canada, South Africa, Spain, Tanzania, Uganda, the United States and Zambia.

Bayer Inc. believes that this research program, which includes collaboration with many international agencies, will ensure the best clinical evidence is generated for moxifloxacin and that those in need have the hope of a better treatment for TB, supported by strong clinical evidence.

Thank you for the opportunity to comment on the consultation paper.

Best regards,

A handwritten signature in black ink, appearing to read 'Doug Grant', with a long horizontal line extending to the left.

Doug Grant
Vice-President, Corporate Affairs
Bayer Inc.