

October 30, 2009

VIA FAX: 416-326-1571

The Honorable Deb Matthews
Minister of Health and Long Term Care
Hepburn Block, 10th Floor
80 Grosvenor Street
Toronto, ON M7A 2C4

Dear Minister Matthews:

Re: Drug System Review

The Biotechnology Initiative (TBI), the voice of bioscience in Ontario, is pleased to have been invited to participate in the ongoing consultation process with respect to the drug system in Canada. Ontario is a major North American bioscience hub that employs more than 50,000 Ontarians at more than 800 companies and generates more than \$11 billion in revenues annually. The sector includes drug manufacturers, firms developing biopharmaceutical products, firms undertaking research or manufacturing on a contract basis, agricultural biotech organizations, clean tech entities and firms that offer consulting services to the sector, including lawyers, accountants, engineering firms, IT firms and health consultants. Universities, hospitals and research centres across Ontario also play a pivotal role in the research and development activities of this sector.

TBI, the largest and most successful community based bioscience organization in Canada, has a membership base that is drawn from each of the above elements of the bioscience community in Ontario and, as a result, has a unique perspective of the importance of the sector to Ontario.

Preliminary Observations

TBI congratulates the Government and, in particular, the Ministry of Health and Long Term Care for having constructed such an open and inclusive consultation process. While there are never any certainties when complex and inter-related changes are being proposed to significant areas of public policy, it is generally the case that an open and inclusive consultation processes where the



objectives of government are understood by stakeholders will result in a higher quality of input and outcome, that is better targeted to the actual challenges that are to be addressed.

In the consultation process, TBI has been seated at the brand name table and has participated alongside representatives of Rx&D and BIOTECanada. TBI agrees with the views expressed by the representatives of each of these organizations.

Key Comments

The Need To Consider Drug Expenditures as Investments

Dr. Henry Friesen, one of the most distinguished members of the Canadian life sciences community has observed on many occasions, including in speeches to members of TBI, that the health-care system should not be viewed simply as a provider of health care for Canadians, but also as a generator of wealth for Canada.

There has never been a more important time for the Government to re-evaluate expenditures within the mandate of MOHLTC as investments in the future health of Ontario, both the health of its citizens and the Ontario economy. The traditional focus of the Government on the automotive sector, we recognize, has proven to be costly. Other Ontario sectors, notably natural resources and the forestry sector have also experienced dramatic difficulties as the economy has softened. While emerging bioscience companies have suffered from a punishing lack of venture and development capital, ironically, in part, contributed as a result of regrettable policies of the Government of Ontario, we believe, the drug manufacturers are much better positioned to help contribute to the economic prospects and growth of Ontario than many other sectors. This fact alone should give policy makers with economic development responsibilities reason to be rethinking their interest in the sector as an engine of economic growth and a significant contributor to the future economic prosperity of Ontario.

The Importance of a Biopharmaceutical Strategy with a Drug System Policy

Historically, Ontario has not considered the implications for its bio-pharmaceutical industry, when it has considered changes to its drug system policies. This observation was readily apparent at the time of the introduction of Bill 102 (the Transparent Drug) in 2006. At the very time that the Minister of Health and Long Term Care was rising to introduce the Bill in the Provincial Legislature, the Premier was accompanying a number of leading members of the bio-pharmaceutical community to the U.S. Bio meetings who were unaware of the changes being proposed by Bill 102, some of which were not consistent with the message of the Premier about the open and welcoming environment for the bio-pharmaceutical industry in Ontario.



Following the adoption of Bill 102, the Government did reach out to the bio-pharmaceutical community through such initiatives as the Biopharmaceutical Investment Program. This has been an important collaborative effort. However, it must be noted, what is missing is the level of recognition that it is important to link health and industrial policy to ensure that the government acts coherently in these fields.

In this regard, we in Ontario have much to learn from our friends in Quebec. The Government of Quebec has publicly linked the drug and bio-pharmaceutical policy since its consultation paper of drug policy in 2004. Most recently, earlier this month, the Government of Quebec published a new policy paper entitled ***Bio-pharmaceutical - Maintain Excellence by Creating Wealth in Quebec***. In relevant sections the Government of Quebec notes that the paper and the strategy represents an additional step towards excellence and it is complementary to the Quebec Research and Innovation Strategy and the Quebec Drug Policy.

We in Ontario need the same linkage and commitment to a coherent and coordinated strategy for innovation; “A Bio-pharmaceutical sector and Drug Policy” program. TBI has copied the Minister of Research and Innovation with this letter in the hope that he will see the importance of the issue we are raising and ensure that his Ministry is an active participant in any proposed reforms.

A Comprehensive Approach

Without getting into the details of the difficulties with the current rules, it seems clear that at least part of the problem is with the fragmented nature of the legislation regime. There are multitude of potentially relevant statutes, including the Ontario Drug Benefit Act, the Drug Interchangeability and Dispensing Fee Act, the Drug and Pharmacies Act, the Pharmacies Act and, potentially, the Health Insurance Act. The 2006 reforms were largely additive, rather than based on a comprehensive and coordinated plan to update the legislative environment to ensure clarity and comprehensiveness. For example, some believe that the current difficulties faced in interpreting and applying the professional allowance rules reflects the incremental approach taken to drafting the 2006 reforms. Said another way, it would be prudent for the legislation to reflect the two very different business models applicable to brand name and generic drugs in Ontario, rather than attempt to craft one set of rules of general application that does not appear to work well for either sector.

We believe, the 2010 reforms should start with a clear statement of Government policy, to be followed by draft legislation and regulations on which interested stakeholders can comment.

The Need For Transparency



While the 2006 reforms were an important step towards a greater level of transparency in respect of the drug system in Ontario, it would perhaps be a benefit for all stakeholders if the Executive Officer were to provide a clear statement as to the form and content of agreements that she is prepared to enter into with manufacturers with respect to new listings, existing drugs, including agreements that relate to such matters as diseases management. This approach may address, to some extent, the concerns by some stakeholders with respect to confidentiality of agreement with the Executive Officer.

Going Forward

We look forward to working with your staff and the Ministry in achieving a successful reform of Ontario's drug system in the best interests of all stakeholders. We are ready and willing to provide technical comments and input on any legislative or regulatory proposals that are forthcoming and ensure you that our contribution will reflect the wide experience of our diverse and very committed membership.

Yours truly,

THE BIOTECHNOLOGY INITIATIVE



Lorne Meikle
Chair and President

Copy: Ani Koulian, Office of Minister Deb Matthews
The Honourable John Milloy
TBI Board of Directors

