BIOTECanada

July 28, 2011

Ms. Leanne Jardine
Executive Director
Pharmaceutical Services
Department of Health
PO Box 5100
520 King Street, 6th Floor
Fredericton, NB E3B 5G8

Dear Ms. Jardine,

When the Government of New Brunswick launched the generic drug pricing policy on June 1, 2011 through Bill 39, An Act to Amend the *Prescription Drug Payment Act*, it began an important discussion on the future of healthcare in New Brunswick. BIOTECanada commends the New Brunswick Prescription Drug Program (NBPDP) on the open and inclusive nature of the consultations to date. Our members appreciated the opportunity to participate in discussions around this initiative on July 26, 2011 and we are pleased to provide additional comments on the "Fair Drug Prices for New Brunswickers" consultation document.

BIOTECanada approached this process as an opportunity to advance the health of New Brunswickers as we are committed to delivering innovation and value to patients through the introduction of advanced biopharmaceutical therapies. We offer the following comments in a spirit of collaboration to ensure changes to the system continue to enable the development of new therapies and ultimately, patient access to these innovations.

Patients at the Centre of Decision-Making Processes. Ensuring patients' timely access to safe and effective treatments to live and enjoy a healthier and better quality of life remains our members' primary focus. As such, BIOTECanada supports competitive agreements that apply only to multi-source products to protect patient outcomes and the sustainability of the innovation system. The province must ensure that "ability to supply" is considered when tendering in a multi-source environment. We do not support the use of financial incentives to initiate substitution within, or across, therapeutic classes based on mandated cost management practices. Furthermore, we caution the province from adapting prescribing practices based on cost alone since it seldom leads to the best health outcomes for patients.

Adoption of Innovative Therapies. The research and development cycle for new biotherapeutic products is time-intensive and expensive; successes are the result of countless incremental scientific discoveries, trials, and failures. As our members work to shape the cutting edge of science to bring biomedical therapies to prevent and alleviate the burden of today's most dreaded and complex challenges – Cancers, Alzheimer's disease, Metabolic Disorders, Tissue Regeneration and many more – there must be a market that recognizes the value of these innovations.

As the Government of New Brunswick works to establish maximum reimbursement levels for generic drugs as a percentage of innovative drug prices, the resulting cost savings provide an important opportunity for the province to improve patient care through the enhanced adoption of innovative products and also to support expanded roles for pharmacists in providing patients improved access to, and increased collaboration between, health care professionals. Without the adoption of new innovative medicines, especially first-in-class medicines, the innovate biopharmaceutical industry will not be able to continue to make the significant advances that have led to robust treatments for HIV, Rheumatoid Arthritis, and Lymphoma for instance.

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Impact on Specialty Pharmacies and Distributors. Biologic therapies are distinct from traditional pharmaceuticals. As highly complex molecules that often have different modalities of action, biologics require extensive supply chain management due diligence including shipment and storage under cold-chain conditions. Biologics also generally require enhanced patient interaction and monitoring. Changes to New Brunswick's pharmacy system need to account for these specialized differences.

Regulatory amendments could have a significant negative impact on the wholesalers and pharmacists who specialize in biologic therapies, especially provisions capping product markups and requirements for minimum stock. These types of provisions could serve to limit the ability of local and specialty pharmacies to carry these complex products. To ensure patients' access to biologics we recommend that any amendments account for an appropriate fee structure to ensure that pharmacists and distributors of specialized biologics are able to participate in NBPDP programs. BIOTECanada also supports additional targeted compensation for pharmacists providing services to patients, such as chronic disease management and appropriate utilization education.

Appropriate Use of Subsequent-Entry Biologics (SEBs). BIOTECanada supports the development of a transparent, predictable regulatory framework for the approval of SEB products that rigorously ensures patient safety and preserves incentives for the continued introduction of innovative biologics. We support Health Canada's position on SEBs, which clearly states that SEBs are not 'generic' biologics. Health Canada does not support automatic substitution of a SEB for its reference biologic drug and recommends that physicians make only well-informed decisions regarding therapeutic interchange. We encourage New Brunswick to follow to the lead of other provinces in stating that the approval of a SEB is not a declaration of pharmaceutical or therapeutic equivalence to the reference biologic drug.

In conclusion, BIOTECanada recommends that Government of New Brunswick consider the generic drug pricing policies of other provinces (i.e. Ontario, Alberta, and Nova Scotia) before finalizing/implementing its own strategy. Since it is one of the last provinces to address the issue of generic cost, it may be worthwhile to progress more rapidly towards harmonization with provinces that have already implemented a similar policy. There exist real opportunities to reinvest savings into innovative therapies and vaccines, in particular, enabling patient access to therapies for rare disorders and unmet medical needs. Finally, we encourage New Brunswick to move quickly to adopt a catastrophic drug coverage policy (with reasonable deductible and co-pay), especially in the absence of a policy for patients under 65 who need innovative therapies but are faced with high prescription drug costs and have limited or no public and private access.

Implementing concrete policies that reward innovation in health care such as time to listing performance targets and the maintenance of a predictable multi-criteria decision making policy environment for innovative product listings will demonstrate an explicit recognition of the correlation between timely patient access to new therapies, improving health outcomes, a productive population and a robust commercial marketplace.

Our members look forward to working with you as the process moves forward.

Sincerely,

Peter Brenders
President and CEO

cc: The Honourable Madeleine Dubé, Minister of Health