Stakeholder Comments on the Discussion Paper:
"Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines"

Submitted by:

Pharmaceutical Services
Nova Scotia Department of Health
Joseph Howe Building
1690 Hollis Street
PO Box 488
Halifax, B3J 2R8
Attention: Dr. Steve Graham
grahamsd@gov.ns.ca

In response to the discussion paper we would like to submit the following comments:

1. With respect to the determination of the Average Price of medicines and the inclusion of "benefits" in the calculation of the Average Price.

Throughout the document references to "benefits" such as; compassionate use programs, trial prescription programs and expenditure limitation agreements, and the proposed inclusion of such "benefits" in the determination of Average Price have been made. We do not support the inclusion of "benefits" in the calculation of the Average Price for three reasons;

- The inclusion of benefits such as expenditure limitation agreements could lead to the economic favouring of larger jurisdictions where limitation agreements would serve a larger market at the expense of smaller jurisdictions with smaller market share. The imbalance in market share among third party public payers is stated on page 12 of the document, "In 2006, Ontario and Quebec's drug benefit programs accounted for 40.8% and 36.1% respectively of total provincial drug expenditures." If limitation agreements are arranged with the larger jurisdictions thereby lowering the Average Price the difference could be made up through higher prices being paid by smaller jurisdictions.
- In a number of places throughout the document reference is made to PMPRB's mandate as being, "responsible for regulating the prices that patentees charge – the factory-gate price – for prescription and non-prescription patented drugs sold in Canada…" (page 18) We believe that the inclusion of "benefits" in the determination of Average Price is beyond PMPRB's mandate as stated on page 18.
- The actual value of "benefits" described in the document has not been quantified. We believe that it would be ill-advised to incorporate

changes into the Regulations without a firm understanding of those products and services which fall under “benefits”, the costs of such “benefits” and the current distribution of “benefits” across jurisdictions.

2. With respect to the setting of the “interim” MNE Price when the Median of the International Price Comparison is the pivotal test and the medicine is sold in too few countries at introduction (page 6).

We believe that the setting of the “interim” NME based on the median price in 3 countries is inappropriate (page 7). The assertion that the current threshold of 3 years or at least 5 countries is arbitrary does not seem to hold for the minimum number of countries.

If the patented medicine prices are unregulated in at least 2 countries then the median price using the proposed 3 country rule would lead to the median price possibly being equal to that of an unregulated country (assuming prices are higher in countries with unregulated prices). If the price setting rule is left at 5 countries then the number of unregulated countries needed to have an unregulated price (the median of 5 countries) used as the Canadian price is 3 (assuming higher prices in unregulated countries).

We are more comfortable with the use of 5 countries in the determination of the “interim” NME due to the decreased possibility of the “interim” price being set at the same level as the price in a country without price regulation.