**IN THE MATTER OF the Patent Act, R.S.C. 1985, c. P-4, as amended**

**AND IN THE MATTER OF Sanofi-Synthélabo Canada Inc., (the "Respondent") and the medicine "Fasturtec"**

# SUBMISSION OF SANOFI-SYNTHÉLABO CANADA INC.

## A. Purpose of this Submission

1. The purpose of this Submission is to provide the Board with the rationale behind the attached proposed Voluntary Compliance Undertaking (VCU) and its terms and provisions.

## B. Background

2. Fasturtec (rasburicase) is a medicine indicated for the treatment and prophylaxis of hyperuricemia in paediatric and adult cancer patients, and is administered intravenously in a hospital setting.

3. Between May 2002 and June 2004, Fasturtec was sold to 28 hospitals in Canada. In Canada, Sanofi sells Fasturtec to hospitals only.

## C. Grounds for Approving the draft VCU

4. Sanofi recommends that it is appropriate for the Board to approve the VCU for the following reasons:

    a. It provides for a reduction in the price of Fasturtec to be within the Guidelines effective immediately.
    b. It protects the Canadian health care system by ensuring that all Canadian hospitals purchasing Fasturtec pay no more than allowed by the PMPRB Guidelines.
    c. It respects the policies of the Board by ensuring that excess revenues received by Sanofi to date are returned to the hospitals that purchased Fasturtec
    d. The proposed maximum non-excessive (MNE) price in the VCU is based on the median international price adjusted for CPI.
    e. It reflects a VCU based on meaningful and constructive consultation and discussion between Board Staff and Sanofi.

## D. Background details of proposed VCU

5. For purposes of the Guidelines, the MNE price of Fasturtec in 2002 at the time of its introduction in Canada was $119.1838 per vial and the MNE price in 2004 is $124.7854 per vial.

6. The price of Fasturtec will be reduced within 30 days of acceptance of this VCU, so that the average transaction price for 2004 does not exceed the MNE price of $124.7854 per vial.

7. Excess revenues received by Sanofi from May 21, 2002 to December 31, 2003 shall be offset by making payments to each of the customers that purchased Fasturtec over this period. Each payment shall be calculated by taking the difference between the actual price paid and the MNE price at the time of purchase times the number of vials purchased over the period. All payments shall be made within 30 days of acceptance of this VCU.

8. Sanofi shall advise each of the 28 hospitals that purchased Fasturtec between May 2002 and acceptance of this VCU, of the price reduction and the repayment specific to their hospital and to further advise that these actions are the result of an undertaking to the PMPRB and to provide a reference to the PMPRB website for the complete text of the VCU. Sanofi shall provide the PMPRB with copies these notifications.

9. Sanofi shall provide, within 30 days of making the payments, copies to the PMPRB of the cheques made to each of the customers that purchased Fasturtec and the documentation to support the calculation of the said payments.

10. Sanofi shall provide, in addition to the price and sales data to be filed pursuant to the *Patented Medicines Regulations* by January 30, 2005, the PMPRB with customer specific price and sales information.

11. Sanofi shall ensure that the average transaction price of Fasturtec remains within the Guidelines in all future periods in which it remains under the Board's jurisdiction, and that no customer in Canada shall pay a price higher than the MNE price.

## E. Recommendation

12. The VCU is consistent with the Guidelines and with the provisions of the *Patent Act*. Sanofi respectfully submits that it is in the public interest for the Board to approve this VCU.

Dated this 25th day of June 2004
Sanofi-Synthélabo Canada Inc.