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

AND IN THE MATTER OF Schering Canada Inc. ("Schering") and the medicine "Remicade"

JOINT SUBMISSION

A. Purpose of this Joint Submission

1. The purpose of this Joint Submission is to provide the Board with the rationale behind the attached proposed VCU and its terms and provisions.

B. Grounds for Approving the draft VCU

2. Board Staff and Schering recommend 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 Remicade to be within the Guidelines effective immediately.

   b. It protects Canadian consumers by ensuring that Schering will immediately lower the price of Remicade by about 20%.

   c. It respects the policies of the Board by ensuring that excess revenues received by Schering to date will be offset by a payment to Her Majesty the Queen in Right of Canada in the amount of $7,792,650.8926.

   d. The proposed maximum non-excessive (MNE) price in the VCU is based on the median international price and the proposed list price for Remicade is based on the therapeutic class comparison.

   e. It establishes a relationship between the price of Remicade and Enbrel that is within the range of relationships prevailing in the countries listed in the Regulations.

   f. It reflects a VCU based on meaningful and constructive consultation and discussion between Board Staff and Schering.

C. Background details of proposed VCU

3. Schering will lower the list price of Remicade from $1150.00 to $940.00 per vial.

4. The MNE price for Remicade for 2003 will be $909.5094 per vial.

   This price is calculated using the median international price established for the introductory period July to December 2001, and applying the CPI factors for 2002 and 2003.

July to Dec. 2001	$875.3700
2002	$895.5035
2003	$909.5094

   The above result occurs in the course of the application of the Guidelines. The maximum non-excessive price in the introductory period establishes the benchmark price. Following this period, a patentee's average transaction price would be presumed to be excessive if it exceeds the benchmark price adjusted for changes in the Consumer Price Index.

5. The proposed $940.00 list price is calculated based on a Therapeutic Class Comparison (TCC) using Enbrel as the comparator. For the purposes of the negotiated solution, both parties have agreed on the following:

   a. that the average person weighs 70 kg;
   b. that there could be a number of ways to calculate a therapeutic class comparison;
   c. that the starting dose set out in the product monograph is 3 mg/kg and that there is now anecdotal evidence that approximately 50% of individuals may require a modification to the starting dose (either in terms of increased dosing, increased frequency or both);
   d. that the use of the maintenance dose for comparison purposes as per paragraph 10.2 of the Compendium of Guidelines, Policies and Procedures is appropriate;
   e. that the number of vials used per treatment depends on a number of factors (e.g. weight, response). Board Staff had been of the view that on average 3 vials per treatment were used. Schering was of the view that on average 2 vials per treatment were used. Based on current information available regarding starting dose, the following was agreed upon as an appropriate TCC:

	number of vials per treatment	distribution	number of vials for maintenance per year
3 mg/kg	2.1 vials	50%	13.65
5 mg/kg	3.5 vials	50%	22.75
		Average number of vials per year	18.2
		Average number of vials per treatment	2.8*

*The maintenance dose is calculated as requiring on average 6.5 treatments over the period of a year. The average number of vials per treatment, 2.8, is calculated by dividing the average number of vials per year (18.2) by the average number of treatments per year (6.5).

Based on the above and the comparable dosing of Enbrel (25 mg twice a week), following is the cost of therapy using the proposed list price for Remicade:

REMICADE	
	2.8 vials x 6.5 treatments/yr x $940.00 = $17,108 ($46.87 per day)
ENBREL	
	50 mg x 52 weeks x $165.00 = $17,160 ($47.02 per day)

6. This VCU reflects a negotiated solution based on open dialogue and frank discussion on behalf of both parties and incorporates elements that are fundamental to their positions:

   - The maximum non-excessive (MNE) price has been established based on the median international price at the time of introduction of Remicade, as advocated by Board Staff.
   - The proposed list price has been established based on the Therapeutic Class Comparison for the use of Remicade in RA as advocated by Schering.

7. In light of all the above, and without prejudice to the positions of Board Staff and Schering with respect to the application of the Guidelines, both parties consider that it is appropriate to apply the method described above for calculating the MNE price for Remicade.

8. The above approach ensures that the ratio of the prices of Remicade and Enbrel in Canada is within the range of the ratios of the prices for these drug products in the comparator countries.

9. Schering will offset excess revenues it may have received from the sale of Remicade by making a payment in the amount of $7,792,650.8926.

10. The VCU is consistent with the Guidelines and with the provisions of the Patent Act. The parties submit that it is in the public interest for the Board to approve this VCU.

Dated this 18th day of March, 2003

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