**LEO Pharma** **research based, people driven**

March 3, 2008 **VIA EMAIL**

Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

Dear Ms. Dupont:

**Re: LEO Pharma Response to January 31, 2008 Board Discussion Paper**

LEO Pharma appreciates the opportunity to provide the following comments to the Board on the issues raised in the Discussion Paper dated January 31, 2008. LEO Pharma, of course, has a particular interest in the matters raised in the Discussion Paper given the focus on the March 21, 2007 decision of the Federal Court in the Dovobet® matter in *LEO Pharma v. Attorney General of Canada*. LEO Pharma looks forward to continuing to engage with the Board as this process continues, specifically with regard to the impact of the Federal Court of Canada's decision, and also more generally on the question of how pricing is to be considered and treated under the Board's Guidelines.

Our comments in response to the Board's Discussion Paper are divided into three main sections as follows:

1. The impact of the Federal Court's *LEO Pharma* decision.
2. Specific response to the Board's proposed options responding to the *LEO Pharma* decision.
3. "Any Market" Price Review & Re-setting the MNE Price.

In brief summary, LEO Pharma believes that the policy with regard to free goods and other benefits as set out under the Guidelines and the April 2000 NEWSletter reflects an approach consistent with the objectives of the *Patent Act* and the *Regulations*, so long as there is no attempt to impose an intent requirement upon the provision of such benefits. LEO Pharma also believes, as further discussed below, that the Federal Court's decision in the Dovobet® matter does not interfere with such an approach.

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## 1. IMPACT OF THE FEDERAL COURT'S DECISION IN *LEO PHARMA*

### 1.1 Introduction

LEO Pharma, as the applicant before the Federal Court in the *LEO Pharma* matter, is intimately familiar with the facts and the positions taken by the parties both in the hearing before the Board and in the subsequent judicial review before the Federal Court.

LEO Pharma provides the following comment on the discussion of the Federal Court's decision in *LEO Pharma* so as to give its perspective on the intent and meaning of that decision. LEO Pharma feels this is necessary since it appears that the Board has adopted an unnecessarily broad – and in LEO Pharma's view, incorrect – interpretation of that decision. Specifically, in being told by the Court that it cannot consider the purpose of a compassionate use program, the Board has concluded that this must necessarily require other wholesale changes to the Board's approach to reporting and price calculation.

While the Board must of course take its own counsel on these legal issues, LEO Pharma considers it important that significant changes to the *Regulations* not be undertaken on the basis of adoption of a single view of the impact of the Court's reasons. The following discussion regarding the background to and nature of the decision is therefore set out for consideration of both the Board and other stakeholders.

### 1.2 Factual Background and the Board's Decision in Dovobet®

In 2004, approximately two years after the introduction of Dovobet®, LEO Pharma instituted a "compassionate use program" for the distribution of free Dovobet®. Under the terms of this program, 120 g tubes of Dovobet® were distributed, upon request, to doctors in the same dosage form and packages as that distributed to pharmacies. The program allowed doctors to provide these packages free of charge to patients who could not afford the product and/or did not have access to insurance to cover the cost. This also reduced inconveniences arising from "call-backs" from pharmacies and promoted adoption of the product by patients.

At issue in the hearing before the Board was the question of whether this distribution of free or promotional goods under the Dovobet® compassionate use program could be taken into account in determining the average transaction price of Dovobet®. The Board refused to consider the quantities of Dovobet® distributed under the program, on the basis of the Board's finding that the program was introduced to reduce the average transaction price, and for reasons such as reducing "time-wasting 'call-backs' from pharmacists". The Board concluded that LEO Pharma's program was "not a compassionate use program in the sense that the Board applies when considering the average transaction price of a medicine", and refused to consider the

distribution of such product in calculating the average transaction price of Dovobet®.

### 1.3 Issues before the Federal Court

On judicial review of the Board's decision, LEO Pharma argued that since the reporting requirements of the *Patented Medicines Regulations, 1994* make no reference to the "purpose" for which free goods are distributed, there was no basis for the Board to exclude the amounts distributed under LEO Pharma's compassionate use program on the basis that it was not a "genuine" compassionate use program.

To support this argument, LEO Pharma referred the Court to the *Patent Act*, the *Regulations* and the existing Guidelines, including in particular Section 5.4, referring to the Board's April 2000 NEWSletter, which reaffirms that one of the goals of this approach is not to discourage the offering of incentive programs:

> In summary, it is the Board's intention in these circumstances that its policies and procedures not discourage a patentee from offering an incentive program or entering into an agreement which would benefit patients.

### 1.4 The Federal Court's Decision and Reasons

The Federal Court agreed with LEO Pharma's submissions. In his reasons, Justice Blais considered the relevant statutory and regulatory language outlined above. After reviewing this language, he stated:

> It should be noted that no reference is made in either the Act or the Regulations to the establishment of compassionate use programs. Rather, the Regulations speak of the 'reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature', with no mention of the intent behind such distribution. [emphasis added]

It is clear that the Court's focus was on the "intent" requirement adopted by the Board to exclude consideration of LEO Pharma's compassionate use program. Justice Blais' conclusions with regard to this intent requirement can be found in their entirety in paragraphs 55-57 of his reasons. Importantly, Justice Blais' primary conclusion with respect to this issue was that the *Regulations* state that free goods "can" be included in calculating the average price of a medicine without any reference to the intent of the patentee. Permissive, rather than mandatory, language is used:

> That being said, I find that I cannot reconcile the general requirement that free goods be distributed for 'compassionate' reasons in order to be considered in the calculation, with the statement in the Regulations that free goods can be included in calculating the average price of a medicine, without any reference to the intent of the patentee in distributing such free goods. [emphasis added]

It is very important to note that the Federal Court, having quoted the *Regulations* and the Board's own Guidelines regarding inclusion of free goods and compassionate use programs, focused on Parliament's intent being to encourage Canadians' access to medicine. Again, the Court used permissive language in describing the inclusion of such free goods in the average transaction price, using the word "allowing":

> Furthermore, the fact that the distribution of free goods may benefit the patentee should not make such a distribution any less valuable to the patients who receive the free medicine. In fact, it seems much more reasonable to assume that Parliament, through section 4 of the Regulations, sought to increase access to patented medicines for Canadians, many of whom do not have extensive drug insurance coverage. To achieve this objective, the Regulations were drafted so as to provide incentives for patentees to distribute free medicine, by allowing them to include these goods in the average price calculation under section 80, and by extension section 85, regardless of their actual 'intent' in distributing such free goods. [emphasis added]

## 1.5 Meaning and Impact of the Federal Court's Decision and Reasons

As set out above, the Court's focus was on encouraging and increasing access to patented medicines to Canadians in need, and the Court's deliberate use of permissive language – "can" and "allowing", rather than "must" and "requiring". As a result, the Federal Court would no doubt be extremely surprised by an interpretation of its decision that (a) imports mandatory language rather than permissive language; and (b) provides disincentives rather than incentives for the distribution of free medicines, by making inclusion mandatory even if disadvantageous to the patentee. Such an interpretation appears to run contrary to both the spirit and the language of the Federal Court.

In LEO Pharma's view, therefore, there is nothing in the Court's reasons that can be taken to justify the Board's position that it requires that "all benefits ... must now be included in the calculation of an Average Price of a patented medicine". The Federal Court's decision does not, as the Discussion Paper claims, supersede the direction provided by the Board in the April 2000 NEWSletter.

The Court ordered that the Board's particular directive to Board Staff and LEO Pharma with respect to the drafting of an order regarding the MNE of Dovobet® include the stipulation that "the determination of the average price per package of medicine for each period must take into account any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature". This order from the Court, however, applied specifically to the Board's consideration of an MNE price for Dovobet® so as to compel the Board's consideration of LEO Pharma's compassionate use program, *given that LEO Pharma had elected to have it included.* It does not create any obligation upon the Board to insert such language in all instances. To the contrary, when considering the general case, as noted above, the Court deliberately used permissive rather than mandatory language.

LEO Pharma therefore respectfully submits that the Court's decision must be taken to stand for – and only stand for - exactly what it says: the *Regulations* allow patentees to include free medicine in the average price calculation under s. 80, "regardless of their actual 'intent' in distributing such free goods". No change to either the *Regulations* nor the Guidelines is necessary based on the decision. All that is necessary is that in applying those Guidelines, the Board refrain from entering into an inquiry about the "intent" of the patentee.

## 2. BOARD'S OPTIONS TO ADDRESS THE FEDERAL COURT DECISION

As noted, LEO Pharma takes the position that the Federal Court's decision in the Dovobet®matter does not require any amendment to the Regulations or the Board's Guidelines. The decision does not affect the continuing application of the Board's policy as set out in the April 2000 NEWSletter other than to confirm that any "intent requirement" imparted by the Board has no basis under the *Act* or the *Regulations*.

Given the opportunity, however, LEO Pharma would like to make some general comments with regard to the options presented by the Board in Part VI of the January 31, 2008 Discussion Paper.

### 2.1 Regulatory Options

#### *2.1.1 Option 1 – Maintain the current* Regulations

As set out above, LEO Pharma believes that this is the appropriate approach.

The Federal Court decision, however, does not compel any changes to the way in which the Board has historically dealt with free goods and other benefits.

### 2.1.2 *Option 2 – Amend the* Regulations *to exempt patentees from the requirement to report benefits provided to third-party payers*

Again, there is no need to amend subsections 4(4) and 4(5) of the *Regulations* to specifically exempt payments to third-party payers as they can continue to be treated as they have been in the past. However, to the extent that regulatory change is considered to be required, certain patentees may wish to exclude payments to third-party payers from the calculation of the Average Price.

### 2.1.3 *Option 3 – Amend the* Regulations *with respect to free goods*

*2.1.3.1 Amend the Regulations to exclude all free goods from the calculation of the Average Price*

The Discussion Paper admits in considering this option that the exclusion of free goods "might even cause the Average Price to become excessive under the existing Guidelines" for some patentees. It is difficult to see how such an approach, which potentially discourages the use of free goods, meshes with the Federal Court's determination in *LEO Pharma* that Parliament, through section 4 of the *Regulations*, "sought to increase access to patented medicines for Canadians, many of whom do not have extensive drug insurance coverage" and that the *Regulations* were drafted "so as to provide incentives for patentees to distribute free medicine".

The current approach, which again is not affected by the Federal Court's decision in the Dovobet® matter, allows those patentees who may be concerned about the MNE price being constrained by a decreased Average Price due to the inclusion of benefits to act accordingly, while allowing those patentees who do wish to calculate their Average Price with reference to the provision of benefits to do so long as any such reporting is consistent.

*2.1.3.2. Amend the Regulations to exclude free goods from the calculation of the Average Price when only free goods are provided to a particular customer class*

Such an approach runs directly contrary to any Parliamentary intent to increase access to patented medicines for Canadians who do not have drug insurance coverage. Indeed, given Board Staff's previous indication that it views those receiving free goods as a separate "class",[1] by definition free goods would be all but excluded under this approach. The effective removal of any consideration of compassionate use programs would be contrary to Parliamentary intent and to the

[1] See, by way of example, Submissions of Board Staff Respecting the Order in Decision: PMPRB-04-D2-DOVOBET® dated August 31, 2006 in which Board Staff took the position that those receiving goods pursuant to a compassionate use program would be a separate class from "paying customers" (at paragraph 25).

desire previously expressed by both the Board and the Federal Court to encourage such programs.

Board Staff, both with reference to the Discussion Paper at hand and in its broader approach, appears to have developed specific concern with regard to any differentiation in pricing between groups of customers or classes. However, this approach does not reflect the intent of the *Patent Act* or the *Regulations*.

The *Act* refers in sections 83 and 85 to the Board's assessment of pricing being done on a "market" basis. There is, importantly, no stipulation in the *Act* that the examination is to be taken on an individual person or even class by class basis. Had Parliament intended that no individual pay more than an excessive price, it could easily have drafted the legislation accordingly. It did not do so. Likewise, the *Regulations* require that "average price" or "net revenue" be provided, and the Board's Guidelines recognize and confirm the average price as the basis of the required approach.

Despite this clearly delineated reliance upon an average transaction price, Board Staff appears to be moving further away from the Board's original mandate as established by Parliament. The Federal Court is of the opinion that Parliament wanted to provide incentives for patentees to distribute free medicine. Rather than focusing upon the need of Canadians who would benefit from these free goods, however, Board Staff (both here and in other issues relevant to the proposed revisions to the *Regulations* and on several of the issues in the ongoing consultations on the Guidelines) seems focused upon removing any price differentials between groups of customers or classes. LEO Pharma believes it is well worth remembering, as the Federal Court noted, that there are other interests at stake.

There is, therefore, no reason to exclude free goods from the Average Price calculation when only free goods are provided to a particular class. Again, the current approach allows patentees to act accordingly.

*2.1.3.3 Amend the Regulations to exclude free goods in "non-saleable" or "sample" package sizes*

Regardless of one's interpretation of the impact of the Federal Court decision, such an amendment to subsections 4(4) and 4(5) the *Regulations* is unnecessary. Section 4(1)(e), of course, refers to "the average price per package or the net revenue from sales of each dosage form, strength and package size in which the medicine <u>was sold</u> in final dosage form" [emphasis added]. Section 4(1)(e) therefore only requires the reporting of information with regard to the package sizes "in which the medicine was sold" (regardless of the inclusion or exclusion of benefits provided for such packages sizes under sections 4(4) and 4(5)).

Non-saleable or sample package sizes different from those sold are therefore not reportable under section 4(1)(e) as they are not a "package size in which the

medicine was sold", and their specific exclusion from "free goods" under sections 4(4) and 4(5) would be irrelevant and redundant.

### 2.1.4 *Option 4 – Amend the* Regulations *to change "free services" to "services (free or partially subsidized)"*

Section 4(4) and 4(5) of the current *Regulations* expressly refer both to "discounts" and to "any other benefits of a like nature", either of which would presumably capture any instance of goods or services that were offered on a basis other than entirely free. Regulatory change therefore does not appear to be required to address the concern raised in the Discussion Paper. That said, to the extent that any regulatory change is considered to be required, this clarification may be of value. However, LEO Pharma suggests that the term "free or discounted services" be used rather than the term "free or partially subsidized" given the potential limitations and/or confusion that may be caused by the use of the word "subsidized".

### 2.1.5 *Option 5 – Amend the* Regulations *to exclude "gifts"*

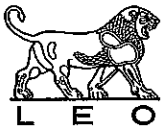
Similar to Option 2 above, there is no need to amend subsections 4(4) and 4(5) of the *Regulations* to specifically exempt gifts as they can continue to be treated as they have been in the past. LEO Pharma agrees, however, that this is largely an irrelevant question as "gifts" as they are commonly understood should not be offered by patentees under the Rx&D code of conduct.

### 2.1.6 *Option 6 – Amend the* Regulations *to permit the Board to disallow any or all benefits which it determines, pursuant to a public hearing, were implemented by a patentee for the purpose of reducing its liability in regard to excessive pricing in terms of the calculation of excess revenues.*

LEO Pharma considers that this suggestion presents considerable difficulties, both legal and practical, and strongly opposes its adoption.

First, the Board's discussion of this proposal mischaracterizes the Federal Court's findings in the Dovobet® matter. Justice Blais did not state, as the Discussion Paper claims, that "the language of the Regulations gave him no choice but to require their [the Dovobet® compassionate use program's] inclusion in the calculation of the average price". Rather, as noted above, Justice Blais' examination of the *Act* and the *Regulations* led him to conclude that "the Regulations were drafted so as to provide incentives for patentees to distribute free medicine, by allowing them to include these goods in the average price calculation ... regardless of their actual 'intent' in distributing such free goods".

Rather than having "no option" but to include the Dovobet® compassionate use program in the average price transaction, Justice Blais felt that in allowing patentees to include such benefits, the *Regulations* provided incentives for patentees to distribute free medicines. This, he believed, was the intent of Parliament.




In essence, therefore, Option 6 as put forward could subvert this intent and remove or limit the incentive described by Justice Blais.

In addition, Parliament has made clear in s. 85(1) of the *Act* that the Board's determination on whether a medicine is excessively priced is to be based on objective pricing factors. The *Act* sets out a separate section in which the conduct of the patentee is to be considered, namely s. 83(4) which deals with whether there has been a policy of excessive pricing, after a determination of excessive price has been made. To introduce an "intent" element into the excessive pricing determination would therefore be contrary to the scheme and spirit of the *Act*, which is to make excessive pricing determinations on the basis of objective price information and not subjective assessments of the motivation behind any particular pricing element.

As a practical matter, the suggestion of incorporating an "intent" requirement will have five other significant adverse consequences:

I. it will re-focus the issue of the impact of the distribution of free goods not on the Canadian patient consumer, but on the intent of the patentee, contrary to the Court and Parliament's intent;

II. it would ignore the practical reality that the distribution of free goods may have benefits for both patient and patentee – one ought not to be taken to preclude the other;

III. it would result in the curious situation that patentees are somehow taken to be acting improperly if they act with an intention to lower the average transaction price, which is precisely the goal of the Guidelines;

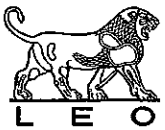
IV. it would import an unnecessary and unsupported distinction between those who introduce a benefit before Board Staff has advised as to its position and those who introduce the same benefit after Board Staff's communication, regardless of the impact or nature of the benefit; and

V. it will lead to a greater number of costly hearings before the Board for the sole purpose of attempting to determine the "intent" of the patentee in introducing a program, when such intent may be multi-faceted, and should in any event be irrelevant.

## 2.2 Guidelines Options

The Board offers two further options which would seek to amend the CPI adjustment methodology as currently found in the Guidelines without actually amending the *Act* or the *Regulations*.

The first option suggests that if the actual Average Price declines from the previous year due to a new or increased reported benefit, the MNE price would be calculated




with reference to the highest previous non-excessive Average Price. The new lower actual Average Price would be ignored for the purposes of calculating an MNE until it equaled or surpassed the previous highest Average Price.

The second option adds one refinement to the option set out above: the MNE price would be the higher of the introductory MNE price based on the introductory price test and the price resulting from the CPI-adjustment methodology. A lower actual Average Price resulting from the reporting of new or increased benefits would still be ignored.

LEO Pharma has no objection to the Board's maintenance of a higher MNE price in the face of a dropping Average Price, should the patentee so desire. This is essentially the result of the current policy with regard to free goods and other benefits.

However, the *Patent Act* requires the Board to consider the consumer price index as a factor in assessing whether a medicine is excessively priced, a clear indication that Parliament recognized the need to consider the impact of inflation on what constitutes an "excessive price". Both of the options presented by the Board effectively reduce the MNE price compared to where it would otherwise be with an unfettered application of the cost of living adjustment (although less so than the Board's current guidelines). This necessarily creates a disincentive to the introduction of price-reducing benefits, whether in the form of discounts, compassionate use programs or otherwise, contrary to the intent of Parliament as described by the Federal Court.

As a result, the most sensible change to the CPI methodology would seem to be to consider the MNE price on a basis that is completely separate from what the actual ATP was in a previous year. A MNE price should be established at the introduction of a drug product, and then be allowed to increase according to a cost of living factor, irrespective of any ATP. This would more accurately reflect Parliament's intent in requiring the Board to consider the ongoing impact of inflation.

While not specifically addressed in the Discussion Paper, LEO Pharma would like to take this opportunity to make one further comment on the effect of international currency fluctuations on the Board's use of the CPI to adjust the MNE. According to s. 2.8 of Schedule 4 of the Guidelines, the CPI-adjusted price for a given year is determined by multiplying the price in a "benchmark year" by the CPI-adjustment factor. The "benchmark year" is the year three years prior to the year for which prices are being set. In certain situations, exchange rate fluctuations can (and have) caused the highest international price in a given year to fall below a CPI-adjusted therapeutic class comparison price.

Board Staff has taken the position that this renders the benchmark price in such a year to be lower than the year before. As a result, and owing entirely to currency fluctuations in one year, the MNE price of a patented medicine could go through a cycle in which the MNE price would drop every three years throughout the life of the patent.

LEO Pharma submits that this is not a rational approach to the calculation of the MNE price for a patented medicine. Rather than applying the CPI-adjustment factor to a "highest international price" MNE price, it would be more appropriate to derive a CPI-adjusted benchmark price established through a therapeutic class comparison which would, of course, not be subject to currency fluctuations and their unintended effects on an MNE price.

## 3. "ANY MARKET" PRICE REVIEW & RE-SETTING THE MNE PRICE

### 3.1 "Any Market" Price Review

LEO Pharma also wishes to take this opportunity to respond briefly to the various situations in which the Board proposes it would be appropriate to conduct a price review "at the level of any market".

As the Board states, section 83 of the Act provides the PMPRB with the authority to determine that a price of a patented medicine sold in Canada is excessive and make an order in respect of the price at which a patented medicine is being sold in "any market" in Canada. However, at page 5 of the Discussion Paper, the Board appears to take the position that the term "market" as used in the Act can be melded with "class of customer". Again, the Board appears to be concerned with a situation in which one class of customer pays a price below the MNE price, while another class of customer pays a price above the MNE price.

LEO Pharma does not believe that the Act or the Regulations are drafted so as to conflate "market" and "class of customer" in this manner. The term "market", of course, is not defined in the Act. It appears that a defined and consistently applied definition would be valuable to the Board and to the Board's stakeholders. As a starting point, it must be noted that "market" is juxtaposed in the Act with a comparison to foreign jurisdictions. This suggests that "market" is intended simply to refer to geographic markets. Even if a broader definition of markets were intended, a wholesale assumption that every class of customer is in a different market is overly facile and is unwarranted, and economic evidence would have to be presented to establish the scope of each "market" in the appropriate case.

The Board's approach as set out in the Discussion Paper further appears to assume that it would be possible to compare the price in "any market" as defined by the Board to a single (presumably cross-Canada, but perhaps also international?) MNE price, as opposed to having to undertake a separate MNE analysis for each relevant market. This does not accord with the language of the Act, which uses the phrase "in the relevant market" in s. 85(1)(a) and (b). As such, even if a "class-based" approach to markets were used, if the Board wished to review, for example, the

non-formulary price of a patented medicine and compare this price to an MNE price determined through a therapeutic class comparison, the non-formulary prices of the other medicines used in the therapeutic class comparison would also necessarily have to be used.

### 3.2 Re-Setting the MNE Price

LEO Pharma agrees with Rx&D in that the current criteria and practice for re-setting the MNE price when warranted on a case-by-case basis continues to be appropriate.

However, LEO Pharma also has specific further concern with the Board's suggestion of a re-setting of the MNE price when the MNE is established on the basis of an international price comparison test done when the drug is sold in less than five countries. While there is concern in setting an MNE without sufficient comparative information, the appropriate measure in such a situation is not the re-setting of the MNE but rather recognition that the International Price Comparison test should not be applied with a rigid "golden rule".

Indeed, applying a rigid "golden rule" when one country – the United States – generally has significantly higher prices than the other international comparables can lead to a number of difficulties. Drug manufacturers would have a specific incentive to delay the introduction of a patented medicine in Canada until after the establishment of a U.S. price – a situation that is known to have occurred. LEO Pharma does not believe that the Act or the Regulations were drafted so as to encourage such an outcome.

## 4. CONCLUSION

LEO Pharma welcomes the opportunity to engage in dialogue with the Board in an effort to develop policies consistent with the objectives of the *Patent Act* and the *Regulations*. LEO Pharma believes that the policy with regard to free goods and other benefits as set out under the Guidelines and the April 2000 NEWSletter reflected such an approach, so long as there was no attempt to impose an intent requirement upon the provision of such benefits. LEO Pharma also believes, as set out above, that the Federal Court's decision in the Dovobet® matter does not interfere with such an approach.

Yours truly,

Paul Kidson

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LEO Pharma Inc.