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Dr. Brien Benoit
Chairperson, Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West
Suite 1400, Ottawa, Ontario
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Dear Dr. Benoit:

On behalf of Janssen-Ortho Inc., I am pleased to provide our submission to the Patented Medicine Prices Review Board in response to the draft revised Excessive Price Guidelines issued for Notice and Comment on August 20, 2008. Attached to this letter is a more detailed appendix, which sets out specific comments on a number of the elements in the consultation package.

We have appreciated the opportunity to take part in these consultations since the process was launched in May 2006. We are pleased to see a number of positive developments in the proposals, but unfortunately we have serious concerns with the package as a whole. It represents to us a sharp shift away from the Board's mandate of ensuring that prices for patented medicines are not excessive towards an unprecedented degree of price control and regulation.

From Janssen-Ortho's perspective, the proposal to establish four levels of therapeutic improvement, and to distinguish "moderate improvement" from "slight or no improvement" drugs, represents an important step forward from the current categories used by the PMPRB. It is positive in recognizing the value of incremental pharmaceutical innovation and providing incentives for research and development. While we believe this proposal represents an improvement, we remain disappointed that the Board did not give more consideration to the proposal made by Rx&D and supported by many patentees to simplify the process with an appropriate excessive price test that could apply to all drugs and remove the need for categorizing new medicines in the first place.

One of the areas that needs to be addressed is the CPI adjustment methodology and the impact of reporting of benefits. We have supported the de-linking concept that would tie future price changes to a maximum non-excessive (MNE) price as opposed to tying it to an average transaction price (ATP) net of all discounts, rebates and other benefits. The latter system creates real disincentives to the offering of benefits, including compassionate use programs, that serve to promote competition and to benefit patients. The Board's proposal to implement part of the recommendations of the Working Group on Price Tests represents an improvement over what the situation would be with an inflexible application of the CPI methodology. However, it does not address what the Working Group called the "gap" issue and it introduces additional rigidity and regulatory burden.

Among other things, the proposed system will establish disincentives for patentees to offer programs, including services, discounts, rebates, compassionate use and co-pay programs, during the immediate post launch period. This is typically an important time because these programs help to ensure access to drugs during the time that national and provincial reimbursement bodies conduct their reviews and make decisions on reimbursement.

Many of the proposed changes, along with the requirement for full reporting of discounts and benefits announced in the August 18 Communiqué, will interact and the impact of these interactions is not entirely clear. The package of changes does not accomplish the stated goal of simplicity and transparency but will serve to make the system considerably more complicated and unwieldy. We are concerned that it may lead to many unintended consequences, including the potential reduction or even cancellation of existing programs that benefit Canadian patients. Rather than facilitating compliance, the resulting uncertainty may lead to an increase in disagreements between PMPRB and patentees and more hearings. Hearings are an expensive and lengthy process, which should only be a last resort. In one of the cases in which we were involved, the proceedings took two years and we incurred costs of close to $1 million. In our view, it would be preferable to apply more flexible policies to allow PMPRB to reach solutions without lengthy hearings as it did in the past.

Finally we have serious concerns about the timing of potential changes. From April 2007 when PMPRB first signaled that mandatory reporting was an issue, until the August 18, 2008 Communiqué, patentees believed there was a good possibility the Board would not take this step. There had been ongoing discussions and legal opinions that full mandatory reporting is not required. All in all, there were reasonable grounds to believe that the eventual outcome of the matter was uncertain and we proceeded on the basis of business as usual. To adjust the affected programs now requires a considerable lead time. A 12 month notice (or 12 month transition period) is needed in order to respond to such significant changes in PMPRB policy. Similarly with the proposed changes to the Guidelines, longer advance notice of changes will be needed.

We respectfully recommend that plans to implement the proposed Guidelines and requirement for reporting of benefits be suspended pending meaningful bilateral discussions between PMPRB and patentees to allow a better understanding of the Board's rationale in making changes to the Guidelines and to develop workable solutions. Furthermore we suggest that the most productive approach to such discussions would be to engage a facilitator to help develop consensus on the way ahead.

Yours very truly,

Chris Halyk

CC: Barbara Ouellett, PMPRB Executive Director
Mary Catherine Lindberg, PMPRB Vice Chairperson
Tim Armstrong, PMPRB Board Member
Anthony Boardman, PMPRB Board Member
Anne Warner La Forest, PMPRB Board Member

Encl: attachments

Appendix

Submission by Janssen-Ortho Inc.

Janssen Ortho Inc. (JOI) is pleased to have an opportunity to make submissions on PMPRB's consultation package released on August 20, 2008. We are a member of *Canada's Research-based Pharmaceutical Companies*, Rx&D, and share in and endorse the submissions made by Rx&D. Ortho Biotech, a division of JOI, is a member of BIOTECanada and we also endorse the submissions made by that association.

This appendix provides additional comments and recommendations, from the perspective of JOI's experience, on the issues and proposals in PMPRB's Notice and Comment document and the draft revised Excessive Price Guidelines (draft Guidelines).

1. Issue - Underlying Principles

The Board proposes to add the following language to the description of the Board's regulatory mandate in Section I of the Compendium: "... thereby protecting consumers and contributing to Canadian healthcare." This language does not appear in the *Patent Act* and it may lead to a misinterpretation of the Board's role by some stakeholders.

While PMPRB was established as the "consumer protection pillar" of the reforms that led to the pharmaceutical provisions of the 1987 *Patent Act* amendments, it was one of five pillars. The main pillars, which provided the impetus for the amendments, were to improve pharmaceutical patent protection and to encourage innovation in the sector. The PMPRB was established to maintain an appropriate balance between the incentives for pharmaceutical research and development and protection against excessive prices.

Recommendation:

We recommend the following language: "... thereby maintaining an appropriate balance between the incentives for research and development and protection against excessive prices" instead of the language proposed by the Board.

2. Issue - Levels of Therapeutic Improvement

Given the Board's position that an assessment of therapeutic improvement is central to PMPRB's role, the establishment of four levels of therapeutic improvement, and a new test for medicines that provide a moderate improvement over existing therapies, is an important step forward in appropriately recognizing the value of incremental pharmaceutical innovation.

However, JOI also supports the position put forth by Rx&D, that there is no need for PMPRB to distinguish levels of therapeutic improvement for purposes of applying the pricing provisions of the *Patent Act* and their proposal that there be a single test of excessive price.

JOI also supports the consensus recommendations of the Working Group on Therapeutic Improvement (WG-TI) on the criteria to be taken into account by the Human Drug Advisory Panel (HDAP). We are concerned the Board did not accept all of the Working Group's recommendations. Specifically, we are concerned by the exclusion of demonstrated economic benefit as a factor in determining the level of therapeutic improvement. PMPRB has included economic benefit as a criterion in assessing "substantial improvement" in the past and no one had proposed removing that factor in the consultations. As an economic regulatory body, it would be inappropriate for PMPRB to ignore economic benefit.

We are concerned by the proposed caveat that improved compliance will only be a secondary benefit if it leads to improved therapeutic efficacy. Compliance improvements should be considered an important factor, regardless of whether evidence of improved efficacy has been generated. Efficacy improvements from compliance are often very difficult to demonstrate, but it is inherently logical that if patients are more likely to take medicines, they are more likely to benefit from them.

We are also concerned by the large number of changes to the language in the draft Guidelines governing the assessment of therapeutic improvement by HDAP. Many of these changes were not the subject of previous notice or consultation and the rationale for the changes is not clear. Introducing these changes without explanation gives HDAP little guidance in interpreting the language and adds to uncertainty for patentees.

We note that HDAP has expressed concerns about the language for identifying "drug products that are either superior or inferior in treating the approved indication or use." HDAP states that they have looked at several drugs reviewed in 2007 to demonstrate that they can identify inferior drugs, but not superior ones. We suggest that PMPRB make that information available to all stakeholders so we can see how HDAP proposes to interpret this provision.

Recommendations:

We recommend that PMPRB revisit the necessity of assessing therapeutic improvement from the perspective of fulfilling its excessive price mandate.

In the interim, we recommend proceeding with the proposal to establish a "moderate improvement" category for price review purposes provided that the price test provides greater flexibility than currently exists for such drugs.

We also recommend listing "compliance improvements" as a secondary factor under section 6.1 of Chapter 1, and deleting the words "leading to improved therapeutic efficacy."

3. Issue - International Therapeutic Class Comparison (ITCC) Test

We agree that the ITCC should not normally be used as a price test for a new patented medicine but should be used in dispute resolution. We understand this was PMPRB's informal practice in the past.

The draft Guidelines do not exclude generic medicines from the ITCC, as was recommended by the Working Group on ITCC, and do not specify what the price test will be. As a result, these provisions will continue to create uncertainty for patentees. Since PMPRB's mandate is to ensure a price is not excessive, the MNE price under the ITCC should be established as the "top" of the ITCC.

Recommendation:

The Board should amend the proposed Schedule 7 to exclude generic drugs from the ITCC, and add a statement that the MNE will be established at the top of the ITCC, when the test is used in dispute resolutions.

4. Issue - Introductory Price Tests

We are extremely concerned by proposed changes to the Reasonable Relationship (RR) test and the TCC test. The Board did not consult on these changes and the introduction to the Notice and Comment document does not refer to these changes or provide any rationale for them.

The Notice and Comment states that the RR test for line extensions will be maintained where no therapeutic improvement is proposed. However, the draft Guidelines proposed significant changes to this test, as outlined below:

- In Test 3: Different Strength Test, the existing provisions for a new DIN of a lower strength have been omitted. They provide that the price of the new DIN cannot exceed the price of the existing higher strength DIN. This test makes sense and is consistent with the other provisions of the RR test. Through omission, the draft Guidelines would introduce a new and unreasonable standard for a new DIN of a lower strength requiring the price to be directly proportional on a price/kg or price/mg basis to the existing DIN.

- The draft Guidelines have deleted an existing provision that provides an alternative when the RR test is not appropriate; this provision should be reinstated to provide greater clarity:

  8.3 .... When the above methodology is not considered adequate or appropriate, Board Staff may conduct a Therapeutic Class Comparison Test (Schedule 2) to determine if the introductory price of the new DIN is excessive. This could be relevant if, for example, the new DIN has a therapeutic use or dosage regimen that differs materially from the other DINs of the same or comparable dosage forms of the medicine.

The draft Guidelines have also omitted a key provision that provides an alternative when the Therapeutic Class Comparison Test is not appropriate:

> *8.6 When it is inappropriate or impossible to conduct a Therapeutic Class Comparison Test, Board Staff will give primary weight to the median of the international prices identified in an International Price Comparison Test (Schedule 3) to determine if the introductory price of the new DIN is excessive.*

There will be many instances when the RR test or TCC test will not be appropriate or possible, and the draft Guidelines, as written, give no guidance for these situations. Both of these provisions should be reinstated.

The draft Guidelines also omit language related to modified release formulations. The current Guidelines provide that it may be appropriate to apply the TCC test for certain modified release drugs. That provision was included to deal with cases of modified release drugs where the price per treatment is more relevant and appropriate than the price per kilogram. No rationale is given for this omission.

Measuring the Price in a TCC: The proposed Guidelines state that Board Staff will use an "appropriate public source for the prices of comparable products" to be determined on a case-by-case basis. This proposal is too vague and introduces too much uncertainty for patentees attempting to establish their prices within the Guidelines. A more appropriate standard would be the highest publicly-available price for the comparable products. This concept would provide greater certainty to patentees and the Board Staff; it is consistent with the excessive price standard of the Act, and it is consistent with the recent decision of the Board in the *Adderall XR* case.

Finally, we ask that the Board reconsider the need for multiple tests based on levels of therapeutic improvement and rather adopt a single test that would only consider prices excessive if they exceed the prices in all other PMPRB reference countries and the CPI-adjusted prices of all other drugs in the therapeutic class. This test will allow the Board the opportunity to fulfill its mandate under the Act without resorting to the added complexity and uncertainty that would be generated by the proposed revisions.

Recommendations:

We recommend that the Board amend the draft Guidelines to re-incorporate these provisions from the existing Guidelines:

- RR: the existing different strength test,
- RR: the existing alternate test (TCC) where appropriate,
- TCC: the existing alternate test (IPC) where appropriate,
- Language related to modified release formulations.

The Board should also amend the proposed Schedule 4, "Measuring the Price", to read: "For comparison purposes, Board Staff will use the highest publicly available prices for the comparable products."

5. Issue - Modified Guidelines for Certain Patented Generic Drug Products

This is a new issue for Janssen-Ortho, and we have not been consulted on it prior to publication of the Notice and Comment.

In principle, we object to special treatment by PMPRB for the generic drug industry in these consultations. The generic industry had a separate, bi-lateral Working Group with no representation from stakeholders other than PMPRB and generic manufacturers. There has been insufficient public consultation on the changes related to generic medicines. If exceptions to the Guidelines are to be made for patented generic medicines, then the same exceptions should be made for all patented medicines facing generic competition. Specifically, all patented medicines facing generic competition should be exempt from the highest international price rule.

Recommendations:

We recommend that the Board amend the draft Guidelines to exempt all patented medicines facing generic competition from the requirement to comply with the maximum international price rule.

6. Issue: Impact of Reporting Benefits (De-linking of the ATP from the MNE Price)

As part of its submissions during the consultations, Rx&D has encouraged the Board to consider an alternative model of price review that would involve de-linking the MNE price from the ATP. Janssen-Ortho is supportive of Rx&D's position in this regard.

It is positive that the draft Guidelines address some of the recommendations of the Working Group on Price Tests, namely the "dip" methodology. However, the methodology as proposed is ill-defined, impossibly complex and will lead to many unintended negative consequences. The examples provided by Board Staff, appended to this submission, demonstrate some of the problems. The sheer number of examples required highlights the degree of complexity these changes would introduce. Also, it is interesting to note that in many examples, the price deemed to be "excessive" is the lowest price offered to a class of customer. This is inherently inconsistent with the concept of "excessive price."

Many of the changes proposed to the Guidelines will create significant practical challenges and greatly increased workload for both patentees and Board Staff. True de-linking of ATP and MNE would eliminate much of this complexity and unnecessary workload. While the Board's rationale for many of the proposed changes is unclear, de-linking might, in fact, accomplish much that the Board would value. We support Rx&D's submission that the Board replace its current CPI-adjusted methodology with a true de-linked price review model, i.e. a model whereby the Board reviews prices with reference to the MNE price adjusted for changes in CPI, as opposed to the current model whereby the Board reviews prices against a previous net ATP adjusted for CPI. True de-linking would be consistent with the *Patent Act*, simple for both patentees and Board Staff, and transparent.

Recommendation:

We recommend further, urgent, bilateral discussions on the issue of de-linking the MNE price and the ATP, with the objective of implementing true de-linking of MNE and ATP.

7. Issue - Any Market Price Reviews

It is not clear why the PMPRB wishes to expand its regulatory activities to review prices "in any market." The current practice of Board Staff is to conduct an "any market" review on a case-by-case basis, and this approach has been overwhelmingly supported by a broad range of stakeholders. The proposed application of "any market" review is vague and overly complex. The "any market" examples shown in the Board Staff examples also highlight the fact that this approach could lead to allegations of excessive pricing in markets which actually experience the lowest prices. In our view, this is illogical.

Implementation of the proposed Guidelines on "any market" review will have the unintended consequence of making it far less likely that patentees will offer discounts to specific customers. There is no evidence to suggest that these provisions are warranted and in fact they will result in unfounded allegations of excessive pricing.

The proposed expansion of PMPRB activities in "any market" reviews will result in a major increase in workload for PMPRB and patentees. From a burden of regulation perspective, this very much is in contrast with the explicit objectives of the current Federal Government.

Recommendations:

The issue of "any market" price review requires much additional thought and analysis. The Board should clarify its rationale for wishing to implement "any market" price review, and consider alternative approaches to achieving those objectives. Janssen-Ortho submits that a true de-linking of ATP and MNE, including provisions that no individual customer pays a price above the CPI-adjusted MNE would make "any market" price reviews irrelevant, and would achieve the Board's goals in a simple, streamlined way.

In the event the Board applies "any market" review and finds a price is excessive, it should base the calculation of excess revenues on the national average transaction price.

8. Issue - Re-setting the MNE Price

We have no issue with maintaining Guideline provisions for re-setting the benchmark price when the median international price test is the relevant price test, and the medicine is sold in fewer than five countries at launch.

However, we disagree with the omission of the existing provisions for re-setting the MNE price in the case of a drug being sold under the Special Access Programme (SAP).

Our position is that patentees should always have the option of re-setting their price upon issuance of the Notice of Compliance if SAP sales have occurred prior to approval. There are many reasons a manufacturer might want to offer SAP medicines at below market prices, including providing patients access to an important life saving drug that Health Canada has not yet approved. SAP programs are not considered commercial activity and prices applicable to these programs are not reflective as such. The lack of flexibility in re-setting the price at approval makes it impossible to do continue offering these programs

Recommendation:

The existing provisions on re-setting the MNE prices of drugs sold under SAP should be reinstated in the Guidelines and manufacturers should be afforded full flexibility in applying those provisions, subject to the other provisions of the Guidelines.

9. Issue - Exchange Rates

The draft Guidelines include provisions, (Schedule 6, paragraph 5.1, p. 31) to require patentees to lower prices in the event of unusual factors in foreign markets:

- changes in exchange rates;
- price reductions due to a foreign regulator; and
- removal of a drug from the market in another country.

These provisions did not exist in the Guidelines in the past, and they have not been the subject of these consultations. Because of the dramatic changes in exchange rates in recent years, this question has become more significant than it was in the past. The proposals are not reasonable for several reasons:

- The restrictions on the introductory prices of medicines, as they relate to the prices in PMPRB reference countries, provide Canadians with adequate protection from excessive pricing;

- The rise in Canadian prices of drugs over time is already adequately restrained by the PMPRB's CPI Guidelines and usually to an even greater extent by provincial policies;

- In a period of fluctuating exchange rates, there will be greater uncertainty for pricing and marketing purposes. Patentees cannot predict or control this factor;

- Finally, it is unreasonable to hold a Canadian manufacturer accountable for a decision to remove a product from the market in another country.

Recommendation:

We recommend that the Board amend these provisions and provide that the patentee will not be required to lower a price in Canada due to these specified circumstances.

10. Conclusions

Although the proposed changes to the Guidelines include some improvements over the manner in which the current Guidelines are being applied, there are too many difficulties with the proposals as a whole and it would not be appropriate to implement them as of the end of the year as the Board has proposed.

In addition to the specific concerns with many of the proposals announced by the Board, we have identified a large number of additional changes that appear in the draft Guidelines that have not been the subject of consultation until now. In light of the broad scope of the changes and their complexity, we are concerned

that there may be additional matters that we, and perhaps the Board, have not yet identified.

We strongly recommend that the Board suspend its plans to implement the proposed Guidelines and undertake meaningful bilateral, facilitated discussions with patentees to seek a greater measure of consensus on the issues and solutions. We will be pleased to take part in such discussions.

Attachment: *Sample Explanations by Board Staff on Application of De-Linking methodology (Dip) and "Any Market"*

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SAMPLE EXPLANATIONS BY BOARD STAFF ON APPLICATION OF DE-LINKING METHODOLOGY (DIP)

Assumptions for all examples - HIPC $15.00 and TCC $12.00, therefore intro MNE price $12.00, constant yearly CPI of 2%

(1) De-linking - example one - a benefit in one market - no excessive pricing

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10.00	$10.00		$10.00	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10.00	$6.00		$8.00	$10.20	N-ATP less than N-MNE, no review at the level of any market
year 3	$10.00	$6.00		$8.00	$8.16	N-ATP less than N-MNE, no review at the level of any market
year 4	$10.20	$10.00		$10.10	$8.16	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence to meet de-linking conditions in Pharmacy class Previous highest ATP for Pharmacy is $10.00 ATP in Pharmacy class in year 4 not excessive Review at the level of any market Price in Wholesaler class rose by no more than CPI, no excessive pricing
year 5	$10.40	$10.00		$10.20	$10.30	N-ATP less than N-MNE, no review at the level of any market

(2) De-linking - example two - a benefit in one market - excessive pricing

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$9.00	$10.00		$9.50	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$9.00	$10.00		$9.50	$9.69	N-ATP less than N-MNE, no review at level of any market
year 3	$8.00	$10.00		$9.00	$9.69	N-ATP less than N-MNE, no review at level of any market
year 4	$9.50	$10.00		$9.75	$9.18	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence to meet de-linking conditions in Wholesaler class Previous highest ATP for Wholesaler is $9.00 ATP of $9.50 in Wholesaler class excessive

(3) De-linking - example three - two benefits in the same market

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10.00	$10.00	$10.00	$10.00	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10.00	$10.00	$8.00	$9.33	$10.20	N-ATP less than N-MNE, no review at the level of any market
year 3	$10.20	$10.20	$7.50	$9.30	$9.52	N-ATP less than N-MNE, no review at the level of any market
year 4	$10.20	$10.40	$9.50	$10.03	$9.49	N-ATP exceeds N-MNE, triggers investigation criteria Two benefits were introduced, one in year 2 and one in year 3 Patentee provides evidence to meet de-linking conditions for year 2 benefit in Hospital - impact of loss of this benefit results in previous highest ATP of $9.50 in Hospital class - ATP in Hospital not excessive Review at the level of the any market Prices in Wholesaler and Pharmacy rose by no more than CPI, no excessive pricing
year 5	$10.20	$10.40	$9.50	$10.03	$10.23	N-ATP less than N-MNE, no review at the level of any market

(4) De-linking - example four - variable uptake of one benefit in one market

year 1	$10.00	$10.00	$10.00	$10.00	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10.00	$10.00	$9.00	$9.67	$10.20	N-ATP less than N-MNE, no review at the level of any market
year 3	$10.00	$10.00	$8.00	$9.33	$9.86	N-ATP less than N-MNE, no review at the level of any market
year 4	$10.00	$10.00	$7.00	$9.00	$9.52	N-ATP less than N-MNE, no review at the level of any market
year 5	$10.00	$10.00	$8.50	$9.50	$9.18	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence that fluctuation in Hospital class due variable uptake of a bulk offer Previous highest ATP in Hospital class is $10.00, no excessive pricing Review at the level of any market Prices in Wholesale and Pharmacy did not increase, no excessive pricing
year 6	$10.20	$10.20	$8.50	$9.63	$9.69	N-ATP less than N-MNE, no review at the level of any market

(5a) De-linking example five - a benefit in one customer class in introductory period

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10.00	$10.00	$7.00	$9.00	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10.00	$10.00	$10.00	$10.00	$9.18	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence that hospital knew that it was receiving a benefit Review of other non-discounted markets, previous highest ATP for Hospital would be $10.00 as this price in the two other markets was not excessive ATP in Hospital in year 2 is not excessive
year 3	$10.20	$10.20	$10.10	$10.17	$10.20	N-ATP less than N-MNE, no review at the level of any market

(5b) De-linking example five - a benefit in one customer class in introductory period

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$7.00			$7.00	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10.00			$10.00	$7.14	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence in terms of a contract that shows the price prior to the benefit and that the non-discounted price was $10.00 ATP in Wholesaler in year 2 is not excessive
year 3	$10.00			$10.00	$10.20	N-ATP less than N-MNE, no review at the level of any market

(5c) De-linking example five - a benefit in one customer class in introductory period

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$7.00			$7.00	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10.00			$10.00	$7.14	N-ATP exceeds N-MNE, triggers investigation criteria Patentee indicates that the price in year 1 included a benefit - a review of the patentee's first day of sale shows an ATP of $10.00 ATP in Wholesaler in year 2 is not excessive

(6) New customer class added post-intro - no benefits in that class

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10.00	$10.00		$10.00	$12.00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10.00	$10.00	$8.00	$9.33	$10.20	N-ATP is less than N-MNE, no review at the level of any market
year 3	$10.00	$10.00	$9.00	$9.67	$9.52	N-ATP exceeds N-MNE, triggers investigation criteria Review at the level of any market Prices in Wholesale and Pharmacy did not increase, no excessive pricing ATP in Hospital in year 3 excessive as price increase more than CPI