Oral Liquid Paracetamol from the Republic of Ireland

Final Report

Dumping and Countervailing Duties Act 1988

Dumping Investigation

Trade Remedies Group

Ministry of Economic Development

March 2005

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Abbreviations

The following abbreviations are used in this Report:

ACP	Alternative Commercial Proposal
Act	Dumping and Countervailing Duties Act 1988 (and its subsequent amendments)
AFT	AFT Pharmaceuticals Limited
Agreement	World Trade Organisation Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994
API	Australian Pharmaceutical Industries Pty Limited
Aztec	Aztec Information Systems Limited
BAF	Bunker adjustment fee
£	British Pounds Sterling
CIF	Cost, insurance and freight
Customs	New Zealand Customs Service
DHB	District Health Board
Douglas	Douglas Pharmaceuticals Limited
EBIT	Earnings Before Interest and Tax
EC	European Commission
EFC	Essential Facts and Conclusions
€	Euros
FOB	Free on Board
GMP	Good Manufacturing Practice
GSK	GlaxoSmithKline NZ Limited
IMM	Interchangeable multi-source medicines
Ireland	The Republic of Ireland
MedSafe	New Zealand Medicines and Medical Devices Safety Authority
Minister	Minister of Commerce of New Zealand
Ministry	Ministry of Economic Development of New Zealand
mg	Milligram
ml	Millilitre

NV(VFDE)	Normal Value (Value for Duty Equivalent)
NZD	New Zealand Dollars
OANDA	www.oanda.com
OLP	Oral liquid paracetamol
OTC	Over the counter
PBL	PharmacyBrands Limited
Pfizer	Pfizer New Zealand Limited
PHARMAC	New Zealand's Pharmaceutical Management Agency
PIC	Convention for the Mutual Recognition of Inspection in Respect of the Manufacture of Pharmaceutical Products
Pinewood	Pinewood Laboratories Limited (trading as Pinewood Healthcare)
POI	Period of investigation, being the year ended 31 August 2004
PSM	PSM Healthcare Limited (trading as Healthcare Manufacturing Group New Zealand)
Softwood Lumber	World Trade Organisation Dispute Settlement Panel *United States – Investigation of the International Trade Commission in Softwood Lumber from Canada* (WT/DS277/R)
[redacted]	Confidential information

1. Executive Summary

Introduction

1. On 27 May 2004, the Ministry of Economic Development (the Ministry) accepted an application from PSM Healthcare Limited (PSM) for a dumping investigation into oral liquid paracetamol (OLP) from the Republic of Ireland (Ireland) as being properly documented.

2. On 1 October 2004 the Ministry initiated a dumping investigation into OLP from Ireland, being satisfied that the application provided sufficient evidence that the imports were being dumped and causing material injury to PSM, the sole New Zealand producer of OLP.

3. PSM requested in its application that provisional anti-dumping duties be considered, which are only considered when requested by the applicant and may be applied under section 16 of the Dumping and Countervailing Duties Act 1988 (the Act) at any time after 60 days of investigation, when necessary to prevent material injury being caused during the investigation. The Minister of Commerce (Minister) declined to impose provisional measures on 21 February 2005 being satisfied, on a provisional basis, that the imports were dumped and by reason thereof causing material injury to the New Zealand industry but was not satisfied that provisional anti-dumping duties were necessary to prevent injury during the remainder of the investigation.

4. On 23 February 2005 the Ministry released in accordance with section 10A of the Act the essential facts and conclusions (EFC) report for interested parties to comment upon. All interested parties provided submissions based on the EFC report and these have been incorporated into this final report.

Goods Subject to the Investigation

5. The goods subject to the investigation are:

> *Oral liquid paracetamol in various strengths and pack sizes excluding: elixirs and paracetamol in other forms.*

Dumping

6. The Ministry has received information from the Irish manufacturer and the sole New Zealand importer, and has used this information to establish whether the subject goods were dumped during the period of investigation (POI).

7. Ninety-one percent of the goods imported from Ireland during the POI were dumped, with dumping margins ranging from –18 (not dumped) to 15 percent when expressed as a percentage of the export price.

8. The Ministry notes that the Irish manufacturer disagrees with the way the cost of credit and freight elements of some of the normal values were calculated and therefore disagrees with the dumping margins calculated using those normal values.

9. Several parties to the investigation have stated that the investigation should be terminated because the overall weighted-average dumping margin is below 2 percent, or de minimis. As the Ministry uses a transaction-to-transaction methodology for assessing dumping it does not believe that a weighted-average dumping margin calculated from the transaction-to-transaction dumping margin figures constitutes a de minimis weighted-average dumping margin and therefore the investigation does not need to be terminated. In addition the Ministry notes that alternative calculations are permissible under the Agreement, which would result in dumping margins that are greater than 2 percent.

Injury

10. Information from PSM, the Pharmaceutical Management Agency of New Zealand (PHARMAC), the Irish manufacturer and the sole New Zealand importer was received and used in relation to the Ministry's analysis of injury. This information illustrated that import volumes of the subject goods have increased significantly.

11. PSM's prices have been undercut, depressed and suppressed by these imports, which combined with the significant loss of volume resulting from PHARMAC sole and hospital supply agreements being awarded to the dumped goods, has resulted in significant declines in sales volume and revenue, market share, profit, productivity, return on investments, capacity utilisation and cash flow.

12. The award of the PHARMAC tender and the corresponding loss of the largest volume market segment caused material injury to PSM.

Causal Link and Other Causes of Injury

13. The Ministry has concluded that the level of savings available to PHARMAC based on a non-dumped tender bid for the supply of OLP to the subsidised community pharmacy part of the market has broken the causal link between the dumped OLP from Ireland and the material injury suffered by PSM. This is because the savings that PHARMAC could have achieved by accepting un-dumped prices from the importer of the Irish OLP, compared to PSM's multi-supplier market prices would have been sufficient, due to the volumes involved, for PHARMAC to have awarded the tender to un-dumped prices.

14. The causal link finding has changed since the EFC report and the Ministry now finds that there is not a causal link between the dumped goods and the material injury suffered by PSM. This change is the result of further information that was submitted by several interested parties and additional analysis that was able to be conducted by the Ministry as a result. If the information that the Ministry now has before it was available at the time of the EFC report, the Ministry would have found there was not a causal link between the current dumping and the material injury.

Threat of Material Injury

15. The Ministry has assessed the threat of material injury and considers that the Irish OLP is dumped and is threatening to cause material injury and that a clear and imminent threat of material injury from dumped imports exists, given PHARMAC is currently assessing tender bids for the invitation to tender that closed recently. PSM

has confirmed that it entered the tender, the Irish manufacturer has stated that it wishes to continue to sell OLP to New Zealand and given the nature of the tender process it is likely that the bids that PHARMAC is currently assessing are lower than the current subsidy level and therefore the likelihood of continued or even greater dumping is high.

Duties

16. The Ministry has recommended that duties be imposed. Several parties to the investigation have raised the issue of the extent of the Minister's discretion under the Act to impose duties.

17. Due to the finding that the material injury currently suffered by PSM was not caused by the dumping but by the level of savings available to PHARMAC based on a non-dumped tender bid for the supply of OLP to the subsidised community pharmacy part of the market and a threat of material injury has been found, the Ministry is recommending that the Minister defer making a decision on the imposition of duties on the 1000millilitre (ml) OLP presentations until PHARMAC has announced the results of the current tender round or another event occurs that changes the dispensary market supply situation. To impose duties now would target the current injury to PSM, which has been caused by the quantum of savings that PHARMAC would have achieved even at an un-dumped price, not the threat of material injury from the dumped goods. The threat of material injury for the dispensary market only becomes operative at the point that a change to the current Pharmaceutical Schedule listings occurs and to impose any duties prior to this would only serve to be punitive. A review or reassessment, whichever is appropriate in the circumstances, may also need to be undertaken after PHARMAC has announced the outcome of its assessment of the tender bids that are currently before it, or any other change that affects access to the subsidised portion of the dispensary market if the prices have changed from the levels found during the investigation.

18. The Ministry is proposing not to impose duties on the 100ml as any duties imposed would not be effective in remedying the threat of material injury. The Ministry is recommending not placing any duties on the 200ml, as only one transaction was dumped and it had a de minimis dumping margin. No duties are recommended to be placed on the 500ml OLP as it was not dumped.

Conclusion

19. The Ministry has concluded that:

- The subject goods are being dumped.
- Dumped goods from Ireland are not the cause of material injury to the New Zealand industry, as an un-dumped tender bid from AFT would have still offered PHARMAC savings of a level that the tender bid would be accepted.
- There is a clearly foreseen and imminent threat of material injury caused by the dumped goods to the New Zealand industry in the form of a new competitive tender process, which if won at dumped prices would be a cause of material injury to PSM.

- The imposition of duties is recommended to be deferred until the results of the new PHARMAC tender is announced, or another event occurs that changes the supply situation in the dispensary market segment. A reassessment or review may also need to be carried out at this time.

2. Proceedings

20. On 27 May 2004, the Chief Executive of the Ministry of Economic Development (Ministry) accepted a properly documented application from PSM Healthcare Limited (PSM), trading as Healthcare Manufacturing Group, alleging that oral liquid paracetamol (OLP) from the Republic of Ireland (Ireland) was being dumped and by reason thereof causing and threatening to cause material injury to the New Zealand industry.

21. On 1 October 2004, the Chief Executive of the Ministry formally initiated an investigation pursuant to section 10 of the Dumping and Countervailing Duties Act 1988 (Act) being satisfied that sufficient evidence had been provided that:

- the goods imported into New Zealand were being dumped; and
- by reason thereof material injury to the industry has been or is being caused.

22. In accordance with section 10 of the Act, the Ministry's investigation was to determine both the existence and effect of the alleged dumping of OLP from Ireland.

23. On 21 February 2005, the New Zealand Minister of Commerce (Minister) declined to impose provisional measures that were requested by PSM in its application, being satisfied, on a provisional basis, that the imports were dumped and by reason thereof causing injury to the New Zealand injury but was not satisfied that provisional anti-dumping duties were necessary to prevent injury during the remainder of the investigation. This decision took into account the level of stock of the Irish OLP already in New Zealand and that Pharmaceutical Management Agency of New Zealand (PHARMAC) supply agreements would mean that any provisional measures imposed would be ineffective in remedying a large part of the injury that was due to PSM's exclusion from the subsidised portion of the dispensary market.

24. On 23 February 2005 the Ministry released a draft final report of the essential facts and conclusions (EFC) report. The EFC report provided interested parties with written advice of the essential facts and conclusions that would likely form the basis for any final determination to be made under section 13 of the Act, within 150 days after the initiation of the investigation, as to whether or not the goods are being dumped and by reason thereof material injury to an industry has been or is being caused or is threatened, in accordance with section 10A of the Act.

25. Interested parties had until 9 March 2005 to make submissions upon the EFC report in order for the submissions to be taken into account in the final report and in the recommendations made to the Minister. All submissions received up to 22 March 2005 were taken into account in this report. The Ministry did not receive any submissions after this date. Key aspects of the submissions received are briefly summarised below.

26. The Ministry received submissions from all interested parties on the EFC report. The submission from AFT Pharmaceuticals Limited (AFT), the New Zealand importer of Irish OLP, centred on the calculation of duty amounts, freight, cost of credit and PSM's failure to enter the tender. The submissions received from the Irish manufacturer, Pinewood Laboratories Limited (Pinewood), have been ongoing since

its verification report and relate largely to the calculation of the dumping margins and the method of calculation and extent of some of the adjustments made to the base prices for the normal values. The submission from PSM agreed with the approach taken by the Ministry in relation to treating like goods as a whole and responded to PHARMAC's comments on PSM's past failures to supply OLP. The European Commission (EC) made a submission stating that despite the Ministry's use of the transaction-to-transaction methodology the investigation should be terminated as the weighted-average dumping margin is below 2 percent and therefore de minimis. PHARMAC provided two submissions. PHARMAC stated that it thought the investigation process was biased and predetermined to find that dumping was causing injury. It also largely addressed the issue of causality and PSM's failure to enter into its competitive process. It also provided a report by LECG, an economics consulting group, suggesting that the dumping margins should be assessed for the margin of error and that dumping should only be remedied if it breached the concepts of "fair competition" and "competitive equality". It also questioned the extent of the Minister's discretion under the Act. Details of all the issues raised by interested parties are discussed in the relevant areas of the report.

27. For the purpose of clarity the Ministry would like to note that throughout this report statements made by various parties are recorded as "PSM stated…", "Pinewood believes…" or "AFT told the Ministry..." Any such statements are the recording of arguments presented by interested parties to the investigation and the inclusion of such statements in the report does not mean that the Ministry accepts these statements as being valid. The Ministry's analysis takes all statements made by interested parties into account and then comes to its own conclusions having regard to all the information that is relevant in accordance with the Act.

2.1 Grounds for the Application

28. PSM stated in its application that the material injury resulting from the importation of allegedly dumped OLP commenced in January 2003, and sales of the Irish imports in New Zealand first appeared in August 2003.

29. PSM stated that as a result of the alleged dumping, material injury was resulting from:

- an increased volume of the allegedly dumped imports
- price depression, price suppression and price undercutting

resulting in a:

- decline in output and sales;
- decline in market share;
- decline in profits;
- decline in productivity;
- decline in return on investments;

- decline in utilisation of production capacity; and in
- adverse effects on employment, growth and ability to raise capital and investments.

30. PSM did not make any claims in respect of cash flow, inventories or wages in its application.

2.2 Interested Parties

New Zealand Industry

31. The application was submitted by PSM, the sole New Zealand manufacturer of OLP. The Chief Executive of the Ministry was satisfied that the application was made by or on behalf of the New Zealand industry producing like goods, and had the amount of support required by section 10(3) of the Act.

32. The Ministry did discover sales by another New Zealand manufacturer, Douglas Pharmaceuticals Limited (Douglas) in the market. However, Douglas confirmed that it no longer manufactures OLP in New Zealand and that any sales in the market place are of existing stocks.

Importers and Exporters

33. PSM identified the following exporting manufacturer and importer of the subject goods:

Manufacturer	**Importer**
Pinewood Laboratories Limited, trading as Pinewood Healthcare (Pinewood)	AFT Pharmaceuticals Limited (AFT)
Ballymacarbry	Takapuna
Clonmel	Auckland
County Tipperary	New Zealand
Ireland	

34. The Ministry has not discovered any other parties known to have manufactured or exported OLP from Ireland that was exported to New Zealand, or any other party who has imported OLP from Ireland, over the period of investigation (POI).

PHARMAC

35. PHARMAC has also been involved in the investigation due to its central role in the New Zealand subsidised pharmaceutical market. PHARMAC was given the same opportunities to participate in the investigation process as the other interested parties.

36. PSM stated that PHARMAC is very much a "sideline observer" in the investigation and its status as an interested party is debateable. The Ministry rejects any notion that PHARMAC is not an interested party to this investigation. First and foremost, it is the negotiator for the New Zealand government, the single largest purchaser of pharmaceuticals in the market. Second, it was involved in the award of the sole and hospital supply arrangements under which most of the imported OLP is supplied. Third, it has shown an active interest in the investigation, has supplied relevant information and has a vested interest in the outcome of the investigation and is therefore legitimately, an interested party to the investigation.

37. Article 6.11 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (Agreement) states that interested parties shall include known manufacturers, exporters, importers and any associations that are largely comprised of these types of businesses but also that this list should not preclude authorities from allowing domestic or foreign parties other than those mentioned to be included as interested parties. The Ministry has a practice of treating any party that presents an interest in an investigation as an interested party and the extent to which the Ministry seeks information from or imparts it to the interested party will depend on the circumstances of each investigation.

2.3 Imported Goods

38. The goods which were the subject of the application, hereinafter referred to as OLP, or "subject goods", were:

> *Oral liquid paracetamol in various strengths and pack sizes, excluding paracetamol in other forms.*

39. Following information received, the Ministry proposed in the EFC report, for reasons discussed following paragraph 139, narrowing the description of the goods subject to the investigation as follows:

> *Oral liquid paracetamol in various strengths and pack sizes, excluding: elixirs and paracetamol in other forms.*

40. No submissions were received on this point and the recommendations of this report relate only to the narrowed description of subject goods.

41. The New Zealand Customs Service (Customs) has advised that OLP should enter New Zealand under the following tariff classifications (text in italics is included only for comprehension of the tariff items that follow):

30.03			**Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale:**
3003.10			*- Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives:*
3003.10.01	*00B*	*..*	*- - For veterinary medicine*
3003.10.09	*00C*	*..*	*- - Other*
3003.20			*- Containing other antibiotics:*

3003.20.01	*00F*	*..*	*- - For veterinary medicine*
3003.20.09	*00G*	*..*	*- - Other*
			- Containing hormones or other products of heading 29.37 but not containing antibiotics:
3003.31.00	*00H*	*..*	*- - Containing insulin*
3003.39			*- - Other:*
3003.39.01	*00L*	*..*	*- - - For veterinary medicine*
3003.39.09	*00A*	*..*	*- - - Other*
3003.40			*- Containing alkaloids or derivatives thereof but not containing hormones or other products of heading 29.37 or antibiotics:*
3003.40.01	*00C*	*..*	*- - For veterinary medicine*
3003.40.09	*00D*	*..*	*- - Other*
3003.90			- Other:
3003.90.01	*00A*	*..*	*- - For veterinary medicine*
3003.90.09	10K	..	- - Other
30.04	**Medicaments (excluding goods of headings 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale:**		
3004.10			*- Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives:*
3004.10.01	*00L*	*..*	*- - For veterinary medicine*
3004.10.09	*00A*	*..*	*- - Other*
3004.20		*..*	*- Containing other antibiotics:*
3004.20.01	*00D*	*..*	*- - For veterinary medicine*
3004.20.09	*00E*	*..*	*- - Other*
		..	*- Containing hormones or other products of heading 29.37 but not containing antibiotics:*
3004.31.00	*00F*	*..*	*- - Containing insulin*
3004.32			*- - Containing corticosteroid hormones, their derivatives and structural analogues:*
3004.32.01	*00G*	*..*	*- - - For veterinary medicine*
3004.32.09	*00H*	*..*	*- - - Other*
3004.39		*..*	*- - Other:*
3004.39.01	*00J*	*..*	*- - - For veterinary medicine*
3004.39.09	*00K*	*..*	*- - - Other*
3004.40			*- Containing alkaloids or derivatives thereof but not containing hormones, other products of heading 29.37 or antibiotics:*
3004.40.01	*00A*	*..*	*- - For veterinary medicine*
3004.40.09	*00B*	*..*	*- - Other*
3004.50			*- Other medicaments containing vitamins or other products of heading 29.36:*
3004.50.01	*00E*	*..*	*- - For veterinary medicine*
3004.50.09	*00F*	*..*	*- - Other*
3004.90			- Other:

3004.90.01	*00K*	*..*	*- - For veterinary medicine*
			- - Other
3004.90.11	*00E*	*..*	*- - - Organo-therapeutic glands and other goods of heading 30.01 put up in measured doses or in forms or in packings of a kind sold by retail*
3004.90.19			- - - Other
			. . . . In aerosol containers:
	02B	*No*	*. . . . . Containing chlorofluorocarbons*
	08A	*No*	*. . . . . Other*
	19G	..	. . . . . Other

42. OLP from all sources enters duty free.

43. The OLP under investigation was exported directly from Ireland to New Zealand. Therefore section 3(6) and section 5(5) of the Act, which relate to goods passing through a transit country, do not apply.

2.4 Investigation Details

44. In this report, unless otherwise stated, years are calendar years. Amounts in the dumping section are, unless otherwise stated, expressed in Euros (€) and amounts in the injury section are in New Zealand Dollars (NZD). All OLP strengths are expressed in milligrams (mg) and amounts in millilitres (ml) and volumes in tables are in litres.

45. In tables, column totals may differ from individual figures due to rounding.

46. The POI for dumping is the year ended 31 August 2004, while the investigation of injury involves evaluation of data for the calendar years 2002 to 2004.

2.5 Exchange Rates

47. Article 2.4.1 of the Agreement states:

> When the comparison under paragraph 4 requires a conversion of currencies, such conversion should be made using the rate of exchange on the date of sale[8], provided that when a sale of foreign currency on forward markets is directly linked to the export sale involved, the rate of exchange in the forward sale shall be used. Fluctuations in exchange rates shall be ignored and in an investigation the authorities shall allow exporters at least 60 days to have adjusted their export prices to reflect sustained movements in exchange rates during the period of investigation.
>
> [8] Normally, the date of sale would be the date of contract, purchase order, order confirmation, or invoice, whichever establishes the material terms of sale.

48. In this report British Pounds Sterling (£) have been converted from € using the interbank bank exchange rate found at www.oanda.com (OANDA). Any conversions from € to NZD have been made using OANDA.

2.6 Information Disclosure and Gathering

49. The Ministry makes all non-confidential information relating to the investigation available to any interested party through its public file system, which was explained to all interested parties to the investigation. The interested parties that did not request information from the public file were the EC and AFT. However, both of these parties were sent public file documents following the EFC report, along with all the other interested parties.

50. A copy of the Act and the Agreement is available at :

- www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes; and
- www.wto.org/english/docs_e/legal_e/19-adp.pdf or www.wto.org/english/docs_e/legal_e/19-adp.doc

51. Article 6.7 of the Agreement provides as follows:

> In order to verify information provided or to obtain further details, the authorities may carry out investigations in the territory of other Members as required, provided they obtain the agreement of the firms concerned and notify the representatives of the government of the Member in question, and unless that Member objects to the investigation. The procedures described in Annex I shall apply to investigations carried out in the territory of other Members. Subject to the requirement to protect confidential information, the authorities shall make the results of any such investigations available, or shall provide disclosure thereof pursuant to paragraph 9, to the firms to which they pertain and may make such results available to the applicants.

52. Verification visits were conducted with PSM and Pinewood and meetings were held with AFT and PHARMAC. Copies of verification reports and copies of file notes regarding the meetings were provided to the parties involved and non-confidential versions were placed on the public file.

53. Article 6.8 of the Agreement provides as follows:

> In cases in which any interested party refuses access to, or otherwise does not provide, necessary information within a reasonable period or significantly impedes the investigation, preliminary and final determinations, affirmative or negative, may be made on the basis of the facts available. The provisions of Annex II shall be observed in the application of this paragraph.

54. Section 6 of the Act states:

> Where the [Chief Executive] is satisfied that sufficient information has not been furnished or is not available to enable the export price of goods to be ascertained under section 4 of this Act, or the normal value of goods to be ascertained under section 5 of this Act, the normal value or export price, as the case may be, shall be such amount as is determined by the [Chief Executive] having regard to all available information
>
> For the purpose of subsection (1) of this section, the [Chief Executive] may disregard any information that the [Chief Executive] considers to be unreliable.

55. While there is a similar wording in subsection 8(3) that relates to material injury, (subsection 8(3) largely repeats subsection 6(2)), the inclusion of best information available wording reflects the content of Article 6.8 of the Agreement. Article 6.8

allows an investigating authority to make preliminary and final determinations on the basis of the facts available when an interested party refuses access to, or otherwise does not provide, necessary information.

56. Information was requested, but was not received in full from Pinewood and PHARMAC. In the absence of full information, decisions relating to these parties are based upon the best information available. PHARMAC commented in its submission on the EFC report that "[I]n the absence of fact the Ministry has relied on a number of assertions made by PSM and has made a number of assumptions in relation to crucial parts of its reasoning." The Ministry notes that, in the absence of information in relation to any part of the investigation, it has relied on the best information available. The Ministry also notes that PHARMAC was given several opportunities to provide further information on its operations and processes and was in fact asked several specific questions that it did not respond to. The Ministry notes that as anti-dumping investigations, involve a single product or product line, of a business' entire operations, this frequently results in businesses being unable to identify product specific information and the Ministry has imperfect information to work from.

57. In response to the EFC report PHARMAC stated "PHARMAC considers it impossible for the Ministry to make these assumptions without PHARMAC's assistance, which it has not sought." The Ministry considers that through its asking of questions that were related to PHARMAC's procedures it was seeking PHARMAC's help in understanding this area and that prior to the EFC report PHARMAC had chosen not to respond to most of the questions. However, given PHARMAC's comments in response to the EFC report the Ministry gave PHARMAC further opportunity to answer the previously posed questions. PHARMAC provided some but not all of the information requested and stated that "PHARMAC notes that the questions that it has not answered mainly relate to the reasons PSM has provided for not entering a tender bid, which are not relevant to the dumping investigation," The Ministry notes that the questions relate to the operation of PHARMAC's competitive processes and were designed to help assess PSM's decision not to enter the tender in addition to assessing the threat of material injury. However, in the absence of a full response the Ministry must make a decision with less than full information, as permitted under the Act and the Agreement.

3. New Zealand Industry

58. Section 3A provides the definition of “industry”:

> **3A. Meaning of “industry”—**For the purposes of this Act, the term "industry", in relation to any goods, means—
>
> (a) The New Zealand producers of like goods; or
>
> (b) Such New Zealand producers of like goods whose collective output constitutes a major proportion of the New Zealand production of like goods.

59. “Like goods” is defined in section 3 of the Act as:

> “Like goods”, in relation to any goods, means—
>
> (a) Other goods that are like those goods in all respects; or
>
> (b) In the absence of goods referred to in paragraph (a) of this definition, goods which have characteristics closely resembling those goods:

3.1 Like Goods

60. In order to establish the existence and extent of the New Zealand industry for the purposes of an investigation into injury, and having identified the subject goods, it is necessary to determine whether there are New Zealand producers of goods which are like those goods in all respects, and if not, whether there are New Zealand producers of other goods which have characteristics closely resembling the subject goods.

61. The subject goods are defined at paragraph 38. PSM produces the following three stem formulations of OLP:

- Double strength orange;
- Junior strawberry; and
- Colour-free strawberry.

62. In identifying which goods produced in New Zealand are like goods to the subject goods the Ministry considers physical characteristics, function and usage, pricing structures, marketing and any other relevant considerations (with no one issue being necessarily decisive).

63. The Ministry has firstly compared the Irish OLP, Parapaed, with the domestically produced equivalent in the like goods consideration. The Ministry has also assessed whether other forms of paracetamol products manufactured by PSM are like goods to the Irish OLP.

Physical Characteristics

64. Assessing the physical characteristics involves looking at the appearance, size and dimensions, composition of the product and the production methods and technology utilised to manufacture the product.

65. PSM stated that the imported Parapaed OLP has a slightly different composition to that which it manufactures, however it considers the differences as cosmetic in nature.

Parapaed

66. Pinewood stated that Parapaed OLP is manufactured according to the good manufacturing process (GMP) as it is implemented in Ireland by the Irish Medicines Board. Pinewood stated that GMP is based on the Convention for the Mutual Recognition of Inspection in Respect of the Manufacture of Pharmaceutical Products (PIC). Pinewood manufactures Parapaed using a batch manufacture process.

67. Pinewood confirmed that Parapaed OLP is a suspension product. Junior Parapaed has a cherry flavouring and the Six-Plus Parapaed has an orange flavouring. Both the Junior Parapaed and Six-Plus Parapaed contain [redacted] alcohol.

68. PSM stated that the subject goods have been imported in strengths of 120mg and 250mg, in both plastic and glass bottles and in 100ml, 200ml, 500ml and 1,000ml sizes.

PSM Paracare

69. PSM stated that its OLP is also manufactured to GMP and that the New Zealand standards are based upon the PIC. PSM also uses a batch manufacture process to produce its OLP.

70. PSM's OLP is also a suspension product. PSM's Adult Paracare, like the Six-Plus Parapaed, has an orange flavour. Junior Paracare has a strawberry flavour, which PSM stated is more accepted by children than other flavours. All Paracare OLP is alcohol free, which PSM stated is more accepted by consumers over other brands of OLP that contain alcohol. PSM also produces a colour-free variation of its Junior OLP product.

71. PSM's OLP package sizes are 100ml and 200ml for the "over the counter" (OTC) market and 500ml and 1000ml for the dispensary market.

Oral Liquid Paracetamol

72. The active ingredient, paracetamol, is presented in a liquid suspension. According to the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) composition report for Paracare OLP it contains eight to ten other excipients depending upon the strength of the product. The excipients are necessary for the active ingredient to be dissolved and distributed evenly but have no active pharmaceutical role.

73. A special grade of paracetamol powder is required in order for an adequate suspension to be achieved and to ensure that the paracetamol is dissolved. OLP is a specialised formulation and is the only Paracare paracetamol product to be manufactured with a flavour.

74. The manufacturing process for OLP is quite distinct to that used to manufacture other forms of paracetamol products, as liquids are used. The physical presentation of the finished product is a liquid in a plastic bottle. The packaging for OLP can vary depending on whether it is destined for the dispensary or OTC market.

75. OLP is the only Paracare product that is available in the lower strength of 120mg per 5ml, which is designed as an infant strength.

Tablets

76. According to the MedSafe composition report Paracare tablets have only four added excipients, which are both distinct from and fewer in number than those that compose OLP. Each tablet contains 250mg of paracetamol.

77. The manufacture of tablets is achieved by pressing the paracetamol powder into a solid form. The physical presentation of the finished product is tablet form presented in a 20 tablet blister pack. The blister packs are then packaged in a cardboard box for sale or dispensing.

Capsules

78. Capsules, like the tablets, are stated as containing only four added excipients in the MedSafe composition report. Each capsule contains 250mg of paracetamol.

79. The manufacture of capsules is achieved by pressing the paracetamol powder into a solid form, similar to that used to manufacture tablets, except capsules are encased in a gelatine shell at the end of the process. The physical presentation of the finished product is in capsule form presented in a 20 capsule blister pack. The blister packs are then packaged in a cardboard box for sale or dispensing.

Suppository

80. Suppositories are stated as containing only one added excipient in the MedSafe composition report. Each suppository contains 250mg of paracetamol.

81. The manufacture of suppositories is achieved by moulding the paracetamol powder with the excipient to form a moulded jelly. The physical presentation of the finished product is a suppository form presented in a 20 suppository blister pack. The blister packs are then packaged in a cardboard box for sale or dispensing.

Physical Characteristics Conclusion

82. The OLP products manufactured by Pinewood and PSM are both in liquid suspension form, the active ingredient is paracetamol and contains several other excipients. Parapaed OLP is packaged in glass or plastic bottles, while Paracare OLP is packaged only in plastic bottles.

83. PSM's other Paracare paracetamol products do not appear to have like physical characteristics to the OLP it produces. Other forms of Paracare are manufactured via a different method of production than that used for OLP and the end product is presented in blister packs, rather than a bottle presentation.

Function/Usage

84. The use of medicines within New Zealand has to be approved by MedSafe of the Ministry of Health, which has responsibility for the regulation of therapeutic products in New Zealand. This approval, combined with listing on New Zealand's Pharmaceutical Schedule, largely determines the function and usage that a pharmaceutical product will have, especially for medicines that are only dispensed and are not available OTC.

85. PHARMAC manages the Pharmaceutical Schedule on behalf of the Crown. PHARMAC makes decisions on listings in the schedule, subsidy levels, and prescribing guidelines and conditions. As a result, PHARMAC is often the single largest customer (or at least makes the decisions affecting the largest purchasers of product), that a pharmaceutical company can obtain in New Zealand.

86. Listings in the Pharmaceutical Schedule are based on the anatomical therapeutic chemical system, with therapeutic sub-headings. All products within a sub-category of the schedule are used to treat similar conditions as other pharmaceuticals within the sub-category.

87. All forms of paracetamol come within the nervous system section of the schedule. Paracetamol is listed under analgesics, specifically antipyretics and non-opioid analgesics, and is designed to be used for pain relief.

88. The administration of paracetamol to control pain is used in both the dispensary and OTC market segments. The dispensary market segment is made up of OLP dispensed in District Health Board (DHB) hospitals and in community pharmacies. PSM stated that paracetamol is also used as the active ingredient in other medicines such as those used to remedy coughs, colds, sinus congestion and period pain but that the presence of paracetamol, and in some cases the similarity in presentation, does not make them like goods to the subject goods.

Parapaed

89. Parapaed OLP was granted MedSafe approval in August 2003. Parapaed OLP currently has sole supply status for paracetamol in oral liquid form for the community pharmacy market segment and hospital supply status for the DHB hospital market segment in the Pharmaceutical Schedule, under the analgesics, antipyretics and non-opioid analgesics sub-category. Parapaed OLP is used both in the OTC and dispensary market segments.

PSM Paracare

90. Paracare OLP was granted MedSafe approval for its current formulations in 1999 and in 2003 for its colour-free versions. PSM stated that it has been manufacturing OLP in New Zealand for twenty-five years. Paracare is not currently listed on the

Pharmaceutical Schedule in Section B, relating to the community pharmacy market segment, as a subsidised product, but had previously enjoyed preferred supplier status for OLP in Section B, and is listed in the same category as the Parapaed OLP in Section H of the schedule, relating to the DHB hospital portion of the dispensary market segment. Paracare OLP is used both in the OTC and dispensary market segments.

OLP

91. As OLP is in a liquid form, the dosage to be administered needs to be measured. OLP is used for patients, particularly infants, children and the elderly, who are unable to take paracetamol in other forms, specifically being unable to swallow tablets or capsules.

Tablet

92. Tablets provide a pre-measured dosage and therefore no additional preparation is required in administering the pharmaceutical. PSM stated that paracetamol in tablet form is designed for dispensing paracetamol in "uncontrolled" environments, that is when consumers may purchase it in the OTC market, or when it is prescribed for use in a non-supervised environment.

93. Tablets are used by adults as an adequate form of pain relief, which does not require consideration of other special circumstances that alternate forms of paracetamol can require.

Capsule

94. Capsules, like tablets, provide a pre-measured dosage and there is no additional preparation required in administering the required amount for a patient. The capsule's gelatine coating is intended to make the product easier to swallow for those patients that have difficulty with tablets. Its intended use is similar to that of a tablet.

95. Capsules are used by adults as an adequate form of pain relief, which does not require consideration of other special circumstances that alternate forms of paracetamol can require.

Suppository

96. Suppositories are also a solid pre-measured dose and require no additional preparation. Administration of paracetamol in this form is usually recommended by health professionals and is used when other paracetamol forms are not suitable.

97. Suppository use is generally not considered by adults when looking for a simple form of pain relief, as other considerations need to be taken into account when using this form of paracetamol. Suppositories are primarily used when a patient is unable to take paracetamol orally.

Function/Usage Conclusion

98. While there may be a preference for one product over another, due to its flavouring and absence of alcohol, there is no fundamental difference in the function

and usage between PSM's Paracare and the imported Parapaed OLP. This is illustrated by both products being considered to be in the same sub-category of the Pharmaceutical Schedule.

99. There are other medicines that contain paracetamol as the active ingredient, such as cough syrup, however this is not sufficient to make them a like good to the subject goods, as their intended functions extend beyond simple pain relief and usually address several other symptoms as well.

100. There are no differences in the perceived function of other forms of paracetamol manufactured by PSM being tablets, capsules and suppositories as they are all designed for pain relief. However there are significant differences in the usages of the other forms of the product, in particular the suppositories, which distinguish them from the usage of the OLP. This difference in intended use is likely to be most pronounced in the OTC market segment, where customer preferences and the circumstances in which the pain relief is to be administered are more varied.

Pricing structures

Parapaed

101. Pinewood supplied its cost build-ups for Parapaed OLP and explained how it sets prices for the New Zealand market. Parapaed is available to the dispensary market segment at the subsidised prices published in the Pharmaceutical Schedule that are listed in Table 3.1.

Table 3.1 Subsidised Parapaed Prices

Product	Subsidised Price per 1000ml (NZD)
Parapaed OLP 120mg	7.29
Parapaed OLP 250mg	7.70

102. Pinewood has provided a breakdown of its direct costs to manufacture each presentation. Pinewood's cost to manufacture its 1000ml 120mg product is equivalent to NZD[redacted] and its 1000ml 250mg product is equivalent to NZD[redacted].

103. AFT confirmed that its Parapaed prices, as they appeared in the March 2004 "Over the Counter" Health Support Limited promotional leaflet sent to pharmacies were its correct list prices. These prices appear in Table 3.2.

Table 3.2 Parapaed OLP OTC Prices as at March 2004

	Product	Price to Pharmacies (NZD)
100ml	120mg	6.05
	250mg	6.11

200ml	120mg	8.14
	250mg	8.20

PSM Paracare

104. PSM provided a detailed breakdown of its cost structure. PSM provided a breakdown of its cost to manufacture and sell 1000ml Paracare OLP, giving an average cost of NZD[redacted] for the 120mg product and NZD[redacted] for the 250mg product. Paracare was listed in 2003 in the Pharmaceutical Schedule at a fully subsidised rate as shown in Table 3.3.

Table 3.3 Paracare 2003 Subsidised Prices

Product Strength	Ex-subsidised Price per 1000ml
120mg	8.10
250mg	8.75

105. PSM provided the Ministry with a copy of its OTC Paracare price list valid between 26 January 2004 and 31 July 2004, which displayed the prices in Table 3.4.

Table 3.4 Paracare OLP Prices to Pharmacies

Product		Price to Pharmacies
100ml	120mg	9.95
	250mg	9.95
200ml	120mg	13.94
	200mg	13.94

106. Comparing the cost to manufacture Parapaed and Paracare OLP the [redacted] percent difference in the price of the 120mg strength and the [redacted] percent difference for the 250mg is largely accounted for by the inclusion of indirect costs in the Paracare prices given to the Ministry, which are not included in the Parapaed direct cost of manufacture.

OLP

107. PSM provided information on the pricing structures underlying the different types of paracetamol it manufactures for comparative doses. The comparative amount is based upon a 1000mg dose, being a common dose for adult pain relief.

108. OLP is expensive to manufacture compared to other products whose sole active ingredient is paracetamol. PSM's OLP price to the OTC market segment is NZD[redacted] for a 1000mg dose.

Tablet

109. PSM's price to the OTC market for a 1000mg dose (two tablets) is NZD[redacted]. This price represents only [redacted] percent of the price of Paracare OLP for the OTC market segment.

Capsule

110. PSM's price to the OTC market segment for a 1000mg dose (two capsules) is NZD[redacted]. This represents only [redacted] percent of the price of Paracare OLP to the same group of consumers.

Suppository

111. PSM's price to the OTC market segment for a 1000mg dose (two suppositories) is NZD[redacted]. This price represents [redacted] percent of the price of OLP to the same market segment.

Pricing Structures Conclusion

112. From the information provided, the pricing structures underlying the prices offered to the OTC market for the Parapaed and Paracare OLP products are similar.

113. Both Paracare and Parapaed have distinct pricing structures for the OTC and dispensary market segments, which is due to the differing market pressures in each market segment. The Parapaed price to the dispensary market for 1000ml of the 120mg strength at NZD7.29 represents only 12 percent of the price of Parapaed to pharmacies (for the OTC market segment) being NZD6.05 for 100ml of the 120mg strength (i.e. NZD60.50 for 1000mls). Similar comparisons for Paracare show the price to the dispensary market to be approximately 8 percent of the OTC prices for the equivalent product.

114. The pricing and costing structures that apply to other forms of Paracare paracetamol are distinct enough to preclude their comparison. Other forms of paracetamol that PSM manufactures are at least [redacted] percentage points different from the OLP price, with suppositories being the closest in price to OLP.

Marketing

115. Marketing considerations include the distribution channels used, customers (both actual and targeted), branding and advertising.

Parapaed

116. AFT's OLP carries the brand name Parapaed. Parapaed 120mg strength is branded 'Junior Parapaed' and the 250mg strength is called 'Six Plus Parapaed'. The Junior Parapaed comes in a cherry flavour and the Six-Plus product comes in an orange flavour.

117. Parapaed OTC presentations display the phrase “Sugar Free” on the packaging presented to the OTC market, as a marketing tool to reassure the consumer.

118. AFT’s deals sheet (a marketing device used commonly in the pharmaceutical industry) that was valid until 12 September 2003, and the “Over the Counter” Health Support Limited March 2004 leaflet, which featured Parapaed advertising, displayed prices to pharmacies for Parapaed OLP. Both the leaflet and the deals sheet offered the same bulk-buy specials, where an increasing percentage was deducted from the price as the number of units purchased increased.

119. AFT stated that [redacted] of its promotion of Parapaed OLP is carried out through such publications, with discounts offered relating to volume.

120. PHARMAC agreements, such as that under which Parapaed is made available to the dispensary market, usually contain an advertising clause. The clause states that no advertising must be entered into that “is aimed at consumers of pharmaceuticals” which breaches the relevant advertising guidelines and certain statutes.

121. AFT stated that as a non-manufacturing supplier it is more like a wholesaler, for the distribution purposes and that all of its OLP sales are made directly to a pharmacy or DHB hospital. This supply chain applies for both the OTC and dispensary market segments.

PSM Paracare

122. PSM’s OLP product carries the brand name Paracare, which it uses to market its own paracetamol product range. Paracare 120mg strength is branded ‘Junior Paracare’ and the 250mg strength is called ‘Adult Paracare’. PSM promotes its product on the basis that it does not contain alcohol and also provides a colour-free version of Junior Paracare to alleviate concerns that parents may have about the effect of colouring and alcohol in the medicine upon their children.

123. PSM also provides a ‘Paracare Passport’ as an additional marketing tool to attract parents to using Paracare OLP, over other brands of OLP that are available. PSM’s website states that the Paracare passports are designed to help track paracetamol dosage by a child's weight and it makes the passports available to customers through selected pharmacy chains.

124. PSM also contract manufactures OLP for two pharmacy chains, Amcal and Unichem, that sell OLP in the New Zealand market under the pharmacy chain’s own brand name.

125. PSM provided a copy of its Winter Product Order Form 2004 that is similar to AFT’s deals sheet, which shows prices for its Paracare products including OLP. Unlike the deals sheet provided including Parapaed products, there was no discount that increased as the units being purchased increased and the PSM sheet offered a single cost to pharmacy price. There was a space for a discount rate to be entered on the order form. PSM stated that discounts are based on [redacted] but that its sales representatives [redacted] discounts so the [redacted] discounts [redacted] apply [redacted]. PHARMAC stated

in its response to the EFC that "PSM still has a mechanism for discounting, it is just less transparent than AFT's." The Ministry has indicated above that PSM grants discounts and has not stated, as PHARMAC appears to have understood, that PSM does not have a mechanism for awarding discounts. The fact that PSM's discounts appear to be variable, by means of a blank space rather than a set amount, indicates that they may be less consistent than those offered by AFT.

126. PSM stated that wholesalers are not involved in the dispensary market supply chain as manufacturers and suppliers, such as AFT, sell directly to DHB hospitals and pharmacies, however, that distribution of OLP is generally from a supplier to a wholesaler and then onto a pharmacy. PHARMAC stated in response to the EFC report that the statement that wholesalers are not involved in the dispensary market distribution chain is incorrect and that wholesalers "…will inevitably supply some customers." The Ministry notes that PHARMAC's use of the word "some" indicates that it is not the majority, or all of, the customers in the dispensary market that are supplied by wholesalers. Also as the distribution of OLP for the OTC market segment is carried out through wholesalers, this matter is not determinative in considering whether the dispensary product is a like good to the OTC product.

OLP

127. OLP is a pharmacy only medicine (if 10 grams or under and if over this amount it is a prescription medicine), which means that it cannot be sold in supermarkets or other non-pharmacy outlets. When a medicine is a pharmacy only medicine a prescription is not required in order to purchase the product, but it can only be purchased from a pharmacy and is sometimes stored behind the counter in a pharmacy to reflect the nature of the pharmaceutical.

128. Pharmacists should advise consumers of the correct dosage of OLP to be administered, stressing that OLP should be carefully dispensed and shaken before use to ensure that the correct dose is administered.

Tablet

129. Paracetamol in tablet form is not a pharmacy only medicine (if packs contain 10 grams or less of paracetamol and 500 milligrams or less of paracetamol per unit) and can be purchased from a range of fast-moving consumer goods outlets, such as supermarkets, in addition to pharmacies, without requiring specialist advice. (Tablets containing more than 500 milligrams of paracetamol per unit are prescription medicines. Tablets in packs with more than 10 grams of paracetamol are pharmacy only medicines.)

130. Generally distribution is from a manufacturer or supplier to a wholesaler and then to the retailer.

Capsule

131. Paracetamol in capsule form is not a pharmacy only medicine (if packs contain 10 grams or less of paracetamol and 500 milligrams or less of paracetamol per unit) and can be purchased from a range of fast-moving consumer goods outlets, such as supermarkets, in addition to pharmacies, without requiring specialist advice. (Tablets

containing more than 500 milligrams of paracetamol per unit are prescription medicines. Tablets in packs with more than 10 grams of paracetamol are pharmacy only medicines.)

132. Generally distribution is from a manufacturer or supplier to a wholesaler and then to the retailer.

Suppository

133. Paracetamol in suppository form is a pharmacy only medicine. This form is usually purchased under the direction of a healthcare professional.

134. Generally distribution is from a manufacturer or supplier to a wholesaler and then to the pharmacy.

Marketing Conclusion

135. Parapaed and Paracare OLP seem to be marketed in a very similar manner. Both products use separate packaging for the OTC and dispensary markets. Both products use similar chains of distribution to reach the end-user, although as AFT is not a manufacturer its product is sent directly to its customers, rather than sending any product through a wholesaler.

136. Due to OLP being a pharmacy only medicine it is marketed in different ways to other forms of paracetamol (tablets and capsules) that are usually sold as general sale medicines.

Other

137. This category allows consideration of any other matter that is relevant in determining whether the goods produced in New Zealand are like goods to the allegedly dumped goods. This can include tariff classification or any other matters which could be applicable in the circumstances.

138. PSM provided the Ministry with the tariff items and statistical keys that it considers its goods would enter under if they were imported into New Zealand, and also those it thought that the Parapaed product should be entering under. The tariff items and statistical keys that were identified by PSM were 3003.90.09.10K and 3004.90.19.19G. These tariff items were confirmed by Customs as the tariff items and statistical keys that fitted the description of the subject goods. From the Customs data the Ministry found that the imports made by AFT did enter under these tariff items, however, the tariff items and statistical keys are broad and contain many items that are not like goods.

Elixirs

139. During the investigation the Ministry discovered that the subject goods description as it appears at paragraph 38 included elixirs, which are not sold by PSM in the New Zealand market, or imported from Ireland.

140. PSM's manufacture of OLP began about 25 years ago with an elixir that contained both sugar and alcohol and was sold primarily in a 2 litre presentation to

the dispensary market segment. PSM stated that elixirs were then the predominant method of distributing paracetamol in an oral form, but this has since given way to the use of suspensions. PSM previously manufactured a paracetamol paediatric elixir that it stated was quite distinct from its current OLP suspension products and it has not made the elixir since 1999.

141. Pinewood also stated that elixirs were the original method of producing a paracetamol oral medicine, but that these have been largely replaced by suspension products. Pinewood however does still manufacture a [redacted]ml oral liquid paracetamol in an elixir form. Pinewood stated that elixirs are [redacted] form of medicine and that it only [redacted] its paracetamol elixir to [redacted], where it is used by pharmacists primarily to achieve cost savings. Pinewood stated that it does not anticipate exporting its paracetamol elixir to New Zealand.

142. The Ministry discussed the characteristics of the elixir with both Pinewood and PSM. Both manufacturers stated that elixirs are a distinct product from a suspension product due to: the viscous nature of elixirs; elixirs reliance on sugar and alcohol to distribute the active ingredient; pricing of the finished product; and its inability to meet modern market demands.

143. The Ministry sought comment on whether elixirs should be excluded from the subject goods description in the EFC report. No submissions were received on this point and as a result the Ministry has changed the subject goods description to specifically exclude elixirs as set out following paragraph 39.

144. There were no other matters that were presented to the Ministry in relation to the consideration of like goods.

Conclusions Relating to Like Goods

Paracare OLP Manufactured by PSM

145. The imported Parapaed OLP is not identical in every way to the Paracare (and other brands of) OLP produced by PSM but the function and end-use, two defining characteristics of any pharmaceutical, are identical. The small differences in other points of comparison, that relate largely to flavour and colour, are not significant enough to preclude their close resemblance to each other.

146. Therefore the Ministry considers the imported Parapaed OLP, the subject goods, and the domestically produced OLP manufactured by PSM are considered to be like goods.

Other Forms of Paracetamol Manufactured by PSM

147. PSM stated that a product should not be deemed to be a like good merely due to the fact that it contains paracetamol, as many other forms of pain relief contain paracetamol as an active ingredient. Consideration of whether other forms of paracetamol constitute a like good was limited to products whose sole active ingredient was paracetamol.

148. The other non-OLP paracetamol products manufactured by PSM fall within the same sub-therapeutic category of the PHARMAC schedule as OLP and have the same function and similar end use as the subject goods.

149. However there are sufficient distinguishing characteristics to exclude other forms of paracetamol from the definition of the like goods. In particular, the methods of distribution and manufacture, price, and physical composition, exclude other forms of paracetamol from the like goods description.

3.2 New Zealand Industry

150. An investigation may not be initiated unless the Chief Executive is satisfied that the requirements of section 10(3) of the Act are met. These requirements are that the collective output of those New Zealand producers who have, in writing, expressed support for the application constitutes:

a. Twenty-five percent or more of the total New Zealand production of like goods produced for domestic consumption (assessed during the most recent representative period, being not less than six months); and

b. More than 50 percent of the total production of like goods produced for domestic consumption (as so assessed) by those New Zealand producers who have, in writing, expressed support for or opposition to the application.

151. PSM stated in its application is the sole manufacturer of OLP in New Zealand. However, the Ministry discovered sales in the New Zealand market by another New Zealand manufacturer Douglas. Douglas confirmed to the Ministry that it no longer manufactures OLP and that its sales in the New Zealand market are of stock manufactured prior to the POI.

152. PSM is the sole manufacturer in New Zealand and the Ministry is therefore satisfied that the application met the domestic industry standing requirements of section 10(3) of the Act.

3.3 New Zealand Market

153. PSM was unable to obtain volume import data for the relevant tariff items that contain OLP, as the information is not available from Statistics New Zealand. This is because OLP is not able to be separately identified from other products in Customs data, and quantities are not collected because the products covered by the tariff items enter in different forms and units. PSM, therefore, provided point of sale data from Aztec Information Systems Ltd (Aztec).

154. Aztec collects and collates market sales information by recording the sales of brands of individual pharmaceutical products in New Zealand. The data is collected by scanning products at the point of sale in pharmacies and is available on a daily basis. Aztec records sales from a sample of representative pharmacies across New Zealand and then extrapolates these to provide figures to approximate the New Zealand market over a particular period. These figures include all sales through pharmacies, both OTC and dispensary, but do not include dispensary sales to DHB hospitals.

155. Aztec collects data from all PharmacyBrands Limited (PBL) pharmacies, which use the Unichem and Amcal banner names. PSM said that PBL use the Aztec data to forecast sales and analyse its own performance and PBL pharmacies now constitute over half of the total pharmacies from which Aztec collects data.

156. Aztec designs its sample by splitting New Zealand into 9 regions, in which it then calculates the number of PBL and independent pharmacies that should be in the sample for each region. Aztec then assigns each pharmacy within the region a small, medium or large indicator and extrapolates the sales of the total pharmacies within the region based on the average sales earned by the pharmacies within the size bracket in the sample.

157. PSM monitors the New Zealand market for OLP, and its share, using data from Aztec. PSM said that Aztec has supplied grocery and oil company trade data in Australasia for several years and has been supplying pharmacy data in New Zealand since 1998. Aztec data is collected at the point of sale and therefore captures sales directly to pharmacies that are not captured in the IMS Health Australia Pty Ltd data, which is collected on an ex-wholesaler basis. PSM stated that GlaxoSmithKline NZ Limited (GSK) and Pfizer New Zealand Limited (Pfizer) also purchase Aztec data for market monitoring. Given the manufacturers' use of Aztec for market monitoring, the Ministry considers it a suitable estimate of market activity. PSM stated that the Aztec data has become a more accurate measure over time as the sample size and integrity of the data has increased.

158. Aztec effectively provides PSM with access to its data stores and PSM then selects the parameters by which it wishes to extract data.

159. PSM stated that there is fierce competition in the OTC market both within OLP products and between OLP and ibuprofen liquid. PSM believes that the New Zealand OLP market has the [redacted], estimating the dispensary market segment is [redacted] percent per annum and the OTC market at about [redacted] percent per annum. PSM believes that the OTC market segment may become [redacted] market segment as this is where most of the [redacted] will occur. This [redacted] is based upon a [redacted], and the effect of increasing consumer [redacted]. PSM also believes that this [redacted] market will [redacted].

Market Segmentation

160. PHARMAC considers that there are four distinct parts of the New Zealand market for OLP, which are: the subsidised community pharmacy market; the DHB hospital market; the OTC market; and the unsubsidised prescription market. The Ministry recognises that the differences in the four sub-markets that PHARMAC has identified relate primarily to the availability of subsidies and access to the market.

161. For the purposes of this report the Ministry views the market as being in two major segments, the dispensary market segment (which has two parts, community pharmacies and DHB hospitals) and the OTC market segment.

162. The dispensary market covers OLP dispensed in DHB hospitals and through pharmacies for a prescription from a registered physician (as well as residual amount of dispensing by pharmacists to customers without prescriptions and to private hospitals and rest homes). The dispensary market is based on 500ml and 1000ml presentations. PHARMAC estimates that DHB hospitals account for 8 to 10 percent of the dispensary market by volume, with the rest being prescriptions issued by community pharmacies. The dispensary market accounts for approximately 75 percent of the total New Zealand market by volume and 24 percent by value. The dispensary market includes OLP that is dispensed, with or without a prescription, that is not subsidised.

163. Any other OLP sales that occur are considered to be OTC sales where a customer may purchase OLP over the counter in a pharmacy without a prescription. The OTC market covers 100ml and 200ml OLP presentations. The OTC market accounts for approximately 25 percent of the total New Zealand market by volume and 76 percent by value.

164. Table 3.5 below shows the estimated New Zealand market volume. The Ministry has used Aztec data to estimate the entire market, which does not include any sales to the DHB hospital portion of the dispensary market segment that account for approximately 5 percent of the total New Zealand OLP market. The amounts for 2002 are annualised based on data for October to December 2002, but as OLP is a seasonal product with strong demand in winter this may be an underestimate. The New Zealand industry amounts include sales by PSM and by Douglas as well.

Table 3.5: New Zealand Market Volume (Litres)

	2002	2003	2004
Imports from Ireland	0	19,139	200,020
Other Imports	35,835	33,206	15,315
Total Imports	35,835	52,345	215,335
New Zealand Industry	191,576	157,826	26,284
New Zealand Market	227,411	210,171	241,619

Government Participation

165. In New Zealand the sale of medicines is regulated in two separate ways by two bodies. The first is MedSafe, whose role is to analyse medicines for their safety and permit them to be registered as suitable to be sold in New Zealand, subject to any restrictions that it may recommend. MedSafe affects both the OTC and dispensary parts of the OLP market.

166. In New Zealand, OLP is classed as a pharmacy only medicine which means that it may not be sold in any non-pharmacy retail environment, such as a supermarket, although it can be sold by a retail assistant in a pharmacy and does not need to be purchased from a registered pharmacist. The pharmacy is obliged to ensure that the

medicine is correct for the customer's intended use and that the customer fully understands the pharmaceutical's effects, including any interaction it may have with other pharmaceuticals that the customer is taking.

167. The second body is PHARMAC, a crown entity established pursuant to the Health and Disability Act 2000. Its primary function is to "secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided [by the Government]."

168. PHARMAC plays the role of pharmaceutical negotiator for the New Zealand Government. PHARMAC enters into negotiations of various sorts with pharmaceutical companies for the supply of certain pharmaceuticals to ensure that the money the New Zealand Government spends on pharmaceuticals is used as effectively as possible. PHARMAC operates the New Zealand Pharmaceutical Schedule, which lists the subsidy or DHB purchase price for certain pharmaceuticals. This means that New Zealanders will have some pharmaceuticals fully subsidised by the Government, others only partially so and are required to pay a co-payment, and some pharmaceuticals customers are required to pay for in full. The subsidised prices determined by PHARMAC only affect the dispensary part of the market, both for community pharmacies prescription and DHB hospital sales.

169. As part of the way that the Section B of the Pharmaceutical Schedule is operated, some pharmaceuticals are only subsidised for certain listed manufacturers/suppliers who have been granted a sole supply status, which means community pharmacies must purchase the listed brand of pharmaceutical if they wish to claim the subsidy for dispensing the product. Not all pharmaceuticals listed in the Pharmaceutical Schedule have a sole supply status attached to them. PHARMAC noted in its response to the EFC report that "[p]harmacists are likely to make a much larger margin [for] non-subsidised [product], as the mark-up on subsidised products in pharmacy contracts is relatively small."

170. Section H of the Pharmaceutical Schedule lists the purchase prices that will apply for sales to DHB hospitals and has hospital supply status for some pharmaceuticals, which is similar to sole supply status that applies in Section B, except that it can specify an allowance for a discretionary variance spending amount. The discretionary variance only applies to sales to DHB hospitals and means that pharmaceuticals up to the specified amount can be purchased from suppliers other than the supplier who has hospital supply status. Discretionary variances vary and some pharmaceuticals have no discretionary variance, meaning that only the brand with hospital supply status may be purchased.

171. Parapaed OLP currently has sole and hospital supply status in the Pharmaceutical Schedule, with a 20 percent discretionary variance amount allowed for DHB hospital purchases of OLP. Effectively this means that the hospital supply status applies to only 80 percent of purchases and DHB hospitals have the discretion to purchase the remaining 20 percent of their OLP needs from any of the listed suppliers. Currently Paracare Junior Suspension, PSM paracetamol elixir paediatric, Paracare Double Strength Suspension, Douglas, Pamol and Parapaed are all listed in Section H as brands that may be purchased in the discretionary variances.

4. Dumping Investigation

172. Section 3(1) of the Act states:

> "Dumping", in relation to goods, means the situation where the export price of goods imported into New Zealand or intended to be imported into New Zealand is less than the normal value of the goods as determined in accordance with the provisions of this Act, and "dumped" has a corresponding meaning:

173. Article 2.1 of the Agreement states:

> For the purpose of the Agreement, a product is considered as being dumped, i.e. introduced into the commerce of another country at less than its normal value, if the export price of the product exported from one country to another is less than the comparable price, in the ordinary course of trade, for the like product when destined for consumption in the exporting country.

4.1 Methodology for Calculation of Dumping Margins

174. The Ministry uses a transaction-to-transaction methodology for calculating dumping margins, as allowed under sub-paragraph 4.2 of Article 2 of the Agreement. The transaction-to-transaction methodology involves matching export prices and normal values for transactions made as nearly as possible at the same time, to customers at the same level of trade. Adjustments are made where relevant to ensure a fair comparison is made between the export prices and the normal values.

4.2 Export Prices

Introduction

175. Export prices are determined in accordance with section 4 of the Act:

> (1) Subject to this section, for the purposes of this Act, the export price of any goods imported or intended to be imported into New Zealand which have been purchased by the importer from the exporter shall be-
>
> (a) Where the purchase of the goods by the importer was an arm's length transaction, the price paid or payable for the goods by the importer other than any part of that price that represents-
>
> (i) Costs, charges, and expenses incurred in preparing the goods for shipment to New Zealand that are additional to those costs, charges, and expenses generally incurred on sales for home consumption; and
>
> (ii) Any other costs, charges, and expenses resulting from the exportation of the goods, or arising after their shipment from the country of export.

176. FT's purchase prices, and the adjustments made to them, are detailed in the following paragraphs.

Export Sales Distribution

177. Pinewood explained that it did not have another OLP customer, either export or domestic, like AFT. AFT offers a secure market situation where AFT has [redacted] supply Pinewood's OLP brand, Parapaed, to the New Zealand dispensary market for a set period of time. The [redacted] provides guaranteed sales volumes (although these are approximate), as well as additional sales in the OTC market. Pinewood advised that there was no relationship other than a business relationship between itself and AFT.

178. Normally AFT provides Pinewood with a [redacted] forecast, updated [redacted] with forward orders and forecasts. Confirmed orders are given [redacted] in advance.

179. Pinewood issues invoices to AFT on the date that the goods leave Ballymacarbry and it is from this date that any credit extended is calculated.

Date of Sale

180. Pursuant to Footnote 8 to Paragraph 4.1 of Article 2 of the Agreement, the date of sale of exported goods is determined by the date when the material term(s) of the contract to buy and sell the goods are fixed and an obligation is accepted by both the buyer and the seller of the goods.

> [8] Normally, the date of sale would be the date of contract, purchase order, order confirmation, or invoice, whichever establishes the material terms of sale.

181. The selection of a date of sale impacts upon any currency conversions undertaken, which are based on the date of sale, and also in determining the length of credit extended.

182. The Ministry asked Pinewood when it considered that a sale was finalised and at what point AFT would be obliged to pay for the goods ordered. Pinewood stated that if AFT wanted to [redacted] export of any order [redacted] confirmed it would "[redacted]" to do so and would [redacted] the order (and invoicing the customer) [redacted]. Order cancellation is [redacted] in Pinewood's agreement with AFT for OLP exported to New Zealand.

183. Pinewood does [redacted] based on specific OLP orders from AFT and [redacted] is first [redacted] by the [redacted] that customer in the relevant market. Pinewood receives confirmed orders from AFT [redacted] prior to the intended delivery date and at that point it seems that a contract has been entered into in which Pinewood is obliged to supply the product to AFT and AFT is bound to pay for it. Pinewood, due to its [redacted] the estimated export dates for orders placed by AFT.

184. [redacted] Pinewood's comments indicate that it does not see the date [redacted] as the date of sale, as

two of the material elements of the sale are not fixed; the date of [redacted] and the date of [redacted].

185. Pinewood stated that it sets an internal "exchange rate" for all foreign exchange conversions, which it uses for twelve months. Over the POI this internal conversion rate was €1: £[redacted] and Pinewood said that if the Ministry used this rate for foreign currency conversion it means that the method for selecting the date of sale will have no impact. (The actual exchange rates used by the Ministry in calculating dumping margins are discussed at paragraph 191.)

186. After consideration of the issues outlined above, the date of sale has been determined (in accordance with Footnote 8 to Paragraph 4.1 of Article 2 of the Agreement) as being the date that Pinewood issues an invoice for the OLP exported to AFT (also the date of dispatch). This is the date that best determines the material terms of sale, as when Pinewood [redacted] by either Pinewood or AFT and therefore the [redacted] and [redacted] dates are [redacted].

Base Prices

187. Pinewood provided, in its response to the Ministry's questionnaire, a schedule of the OLP exported to New Zealand over the POI, and details of the presentation sizes in each shipment, supported by copies of invoices for each shipment showing the [redacted] prices.

188. Base prices used for export prices are the [redacted] per unit costs for sales to AFT, as invoiced in £ by Pinewood. These have remained the same, with the [redacted], over the POI.

189. Pinewood stated that it set prices for export to New Zealand by looking at the volume forecasts given to it by AFT for the guaranteed quantity over the period of the contract. It took into account that it [redacted] and [redacted] and the [redacted] that it would [redacted] and then [redacted] price it [redacted] AFT [redacted] to PHARMAC's requests for supplier bids. Pinewood has entered several tenders and when deciding a price to submit in a tender it looks at the [redacted] what price they will enter. Pinewood also has an average margin of [redacted] percent that it [redacted] across all products, and an average margin it [redacted] exports. Pinewood is achieving approximately a [redacted] percent margin on the OTC products and a [redacted] percent margin on the dispensary products exported to New Zealand. Pinewood stated that it would [redacted] on the [redacted] whether it is worth the [redacted].

190. There are no discounts or [redacted] paid to AFT for any of the OLP exported to New Zealand and the base prices have been taken as the actual invoiced prices, which have not changed over the POI.

Exchange Rates

191. The Ministry discussed exchange rates with Pinewood. As outlined in paragraph 185, Pinewood bases its foreign exchange conversions for its purchases on €1: £[redacted], but this [redacted] a sale foreign currency on forward markets, as referred to in Article 2.4.1 of the Agreement, it is merely an internal estimate. Pinewood stated that this exchange rate is based upon its previous experience and current market conditions. (The Ministry notes that the actual average rate over the period was €1: £[redacted]). Pinewood stated that it has [redacted] £ therefore its foreign exchange exposure is minimised by this.

192. The Ministry stated that it normally uses the interbank exchange rate, as obtained from OANDA, for the date of sale pursuant to Article 2.4.1 of the Agreement. Pinewood originally stated that it believed either its conversion rate or the OANDA rate would be suitable to use, as actual conversion rates were very close to the conversion rate that it used over the POI. Pinewood has subsequently argued that the Ministry should use Pinewood's internal conversion rate as the exchange rates used for the date of sale, taken from OANDA, are considerably [redacted] than Pinewood's internal conversion rate. PHARMAC stated in its submission on the EFC report "…that a proxy exchange rate should not be used when an actual figure is available" and refers to the use of best information available. The Ministry notes that Pinewood's internal conversion rate is a [redacted] that it [redacted] all its [redacted] the year and therefore it would not be appropriate to use this rate when actual figures as at the date of sale are available from OANDA.

193. Given Pinewood's initial comments that the actual rates from the date of sale could be used and the fact that the Ministry uses a transaction-to-transaction methodology to calculate dumping, the Ministry has used the interbank exchange rate from OANDA on the date of the sale (the invoice date).

Adjustments

194. The Ministry has made the following adjustments from the invoiced price to calculate the export price at the ex-factory level.

Export Packaging Costs

195. The OLP exported to New Zealand, is packaged into a shipping case that is additional to the packaging used for the Irish domestic market. Pinewood stated that a shipping case would also be necessary for the 500ml and 1000ml products if these were sold on the Irish domestic market, due to their size, so no adjustment has been made for these larger sizes. The adjustment has only been made to 100ml and 200ml sizes.

196. An adjustment for the shipping case has been made, on a per litre basis, using costs from Pinewood's bill of materials for each size of presentation as shown in Table 4.1.

Table 4.1: Export Price Packaging Adjustments (€ per litre)

	100ml	200ml
120mg/5ml	[redacted]	[redacted]
250mg/5ml	[redacted]	[redacted]

Export Labelling

197. There was an additional label used for export sales, but no adjustment was made for the label because the cost per unit was below €0.00.

Other Export Costs

Export Freight Costs

198. Pinewood loads the OLP onto [redacted] and into the [redacted] foot containers used for export to New Zealand at the factory, where the containers are [redacted] to New Zealand.

199. Pinewood provided copies of the freight invoices covering the majority of shipments to New Zealand over the POI and a schedule matching each export container with its invoices to AFT. The freight costs for export to New Zealand are [redacted]. The exceptions are separate [redacted] due to the [redacted]. [redacted] of the extra cost of [redacted] Pinewood. The cost [redacted] AFT. These extra costs have been included in the ocean freight cost adjustment and have been averaged across all the shipments.

200. All products exported to AFT are packed [redacted]. The freight schedule listed the total number of [redacted] in each container, detailing the OLP strength and size presentation [redacted] and the number of bottles [redacted] of OLP.

201. The costs of [redacted] were able to be allocated to each presentation by dividing the number of [redacted] OLP by the total number of [redacted] in the container, to calculate a ratio, which was then applied to the total costs of [redacted] that container. These costs were then further allocated on the same proportionate basis to the individual presentation sizes in each [redacted].

202. Because information was provided for a large proportion, but not all, of the exports of OLP during the POI an adjustment was made based on the weighted-average per litre cost for each presentation.

Inland Freight (Cartage)

203. Based on the above the following adjustments for inland freight have been made:

Size (ml)	€ per litre
100	[redacted]
200	[redacted]
500	[redacted]
1000	[redacted]

Ocean Freight

204. Based on the above the following adjustments for ocean freight have been made:

Size (ml)	€ per litre
100	[redacted]
200	[redacted]
500	[redacted]
1000	[redacted]

Bill of Lading

205. Based on the above the following adjustments for the bill of lading have been made:

Size (ml)	€ per litre
100	[redacted]
200	[redacted]
500	[redacted]
1000	[redacted]

Bunker Adjustment Fee

206. Based on the above the following adjustments for a bunker adjustment fee (BAF) have been made:

Size (ml)	€ per litre
100	[redacted]
200	[redacted]
500	[redacted]
1000	[redacted]

Other Freight Charges

207. Customs and documentation fees and overseas insurance are included in the costs charged by [redacted] but are not itemised separately, therefore amounts for these items are included in the adjustments covering inland freight, ocean freight, bill of lading and bunker adjustment fee.

Duty Drawback

208. There is no duty paid on any of the OLP inputs, therefore no duty drawback is received.

Cost of Export Credit

209. A cost of credit adjustment is made to ensure that normal values and export prices are compared at the ex-factory level. The cost of credit is calculated from the date of sale to the date of payment.

210. Pinewood provided a schedule of some of AFT's payments and the invoices each payment related to. The cost of credit for export was calculated using Pinewood's overdraft rate of [redacted] percent per annum and the average number of days credit extended to AFT from the date of sale, which was determined as discussed from paragraph 180.

211. Cost of credit adjustments ranged from €[redacted] to €[redacted] per litre.

212. Pinewood has made continuing submissions since its verification report that it believes the Ministry's calculation of cost of credit is incorrect and does not believe that a cost of credit adjustment should be made. The Ministry notes that to not make an allowance for the cost of credit would incorporate a cost after the ex-factory level into the dumping margin and may, in fact, be to Pinewood's disadvantage.

213. Pinewood suggests that if an adjustment for the cost of credit is made that its standard credit terms should be used to calculate the cost of credit, or alternatively that it should be calculated as the cost of working capital from the date of manufacture to the last date of sale for any particular batch of OLP. AFT also stated that to compare the credit terms Pinewood extends to the Irish market ([redacted]) to the credit it extends to AFT ([redacted]) is unfair, due largely to transit time.

214. Pinewood participated in a full discussion on the date of sale and the implications that the choice of a date of sale had during the verification visit and agreed with the approach proposed by the Ministry. However, since then Pinewood's submissions on the cost of credit adjustment have focussed on the standard credit terms that Pinewood offers to its customers and transit time for both export and domestic sales rather than the actual cost of credit incurred for each individual sale. Pinewood queried what the situation would be if it altered the credit terms it offered to AFT, to match the credit terms extended in Ireland. The Ministry pointed out that first, the standard credit terms Pinewood offers are not relevant but rather the actual amount of credit for each sale is, i.e. the number of days it takes the customer to pay from the date of sale. Second, if Pinewood changed its current credit terms to AFT this would not alter the cost of the actual length of credit extended during the POI, which is relevant in determining dumping margins.

215. For both domestic and export sales the Ministry has taken the date of sale, as defined by footnote 8 of the Agreement, as being the date of invoice. Pinewood has not argued that the date of invoice is not the date that the material terms of the sale are set. However, Pinewood has argued that as the date of invoice for export sales is also the date that the OLP leaves its Ballymacarbry factory that the date of dispatch from Ballymacarbry to Dublin should be used for calculating the cost of credit for domestic sales. The Ministry notes that Pinewood manufactures stock for its Dublin warehouse and that when the product leaves Ballymacarbry there is no identified purchaser, no sale or internal price transfer occurs, and the material terms of sale are not yet set. At the point in time that the OLP is sent to Dublin there are no obligations or rights held by Pinewood as the seller and likewise for the purchaser, who has not yet even been identified. The Ministry does not normally make cost of credit adjustments based on holding stock or inputs as, while this impacts upon Pinewood's working capital, it is a cost related to a business decision but cannot legitimately be linked to the decision to sell a specific amount of OLP, to a specific customer, at a specific point in time, for a specific price. To take the date of dispatch from Ballymacarbry to Dublin would be the equivalent of treating Pinewood's Dublin distribution centre as a customer, which is inconsistent with the information provided by Pinewood. The Ministry gave Pinewood the opportunity to provide further information on this point, but it did not do so. The Ministry has taken an equal approach to the treatment of cost of credit by using the date of invoice as when the obligations and rights of buyer and seller, being the material terms of sale, are established.

216. The Ministry has explained the cost of credit adjustment in detail to Pinewood and that the purpose of the cost of credit adjustment is to calculate the actual cost of credit extended, not the standard credit terms.

217. The cost of credit was calculated for both the normal values and export prices from the date of invoice to the customer. The cost of credit has been calculated by taking the weighted-average cost of credit for the selected domestic customer, being the number of days from the invoice to payment for the transactions that were able to be matched.

4.3 Normal Values

Irish Pharmaceutical Market

218. The Irish pharmaceutical market has no dispensing of non-ethical pharmaceuticals (those that are able to be sold OTC), as the New Zealand market does. This means that there is no dispensing of prescriptions for pharmaceuticals that are no longer on patent and classified as ethical pharmaceuticals, they are only sold as OTC products. The only dispensing that occurs is within hospital pharmacies.

219. Pinewood stated that there is very little wholesaling in the Irish domestic market and most sales are made directly to pharmacies by the manufacturers.

220. Pinewood, as a generic pharmaceutical manufacturer, primarily manufactures pharmaceuticals once they come off patent and then lobbies the general medical practitioners to prescribe their cheaper generic version of the innovator

pharmaceutical and gain market share. Pinewood stated that the first generic manufacturer to release a generic version will generally price it at [redacted] percent of the price of the innovator pharmaceutical. Pinewood stated that there can be up to [redacted] generic companies in competition with the innovator in the Irish market and the lowest that one of their prices would be reduced to is [redacted] percent of the innovator's price.

221. In [redacted] market share [redacted] manufacturers [redacted] to offer discounts, [redacted] to pharmacists. In this environment all brands are heavily discounted, [redacted] manufacturers are [redacted]. Pinewood grants [redacted] on the basis [redacted] products.

222. The OLP brand leader in Ireland is Calpol, manufactured by Pfizer Ireland Pharmaceuticals, and Pinewood estimates Calpol has about [redacted] percent of the market. Calpol has been on the market for approximately 30 years and [redacted] and its dominance affects the way that the Irish OLP market operates. Pinewood estimates that it has [redacted] percent of the Irish OLP market, but it is not certain, as there is no sales data available that includes sales to pharmacies.

223. Parapaed was first launched [redacted] percent of the Calpol price and it now sits at about [redacted] percent of the Calpol price. There is also competition in the Irish market from another generic brand, Paralink.

224. There is no body in Ireland, equivalent to PHARMAC, but there is a medical card system that provides discounted, or free, pharmaceuticals to those eligible for a card. However with an Irish medical card any brand of a pharmaceutical, at any cost will be reimbursed, as opposed to the set price, set brand system, which operates in New Zealand.

Distribution in the Irish Market

225. The OLP is stacked on [redacted] sent to the Pinewood Dublin distribution centre. Once the OLP reaches the Dublin warehouse it is [redacted] packed with other products in boxes to meet the requirements of each individual pharmacy's order, for example one box may contain OLP, [redacted] and a [redacted] all in a single dispatch box. However, [redacted] medicines [redacted] if the liquid [redacted] during transit. The boxes are couriered directly to customers and invoices are raised when the goods [redacted]. There is [redacted] minimum order size for pharmacies and orders are generally dispatched [redacted] placed.

226. Pinewood operates two separate cost centres for the domestic market and another for [redacted] and [redacted] of the Dublin distribution centre and while all the costs associated with sales in the Irish market are grouped into these cost centres, it is difficult to extract OLP specific costs.

227. Annual [redacted] are made for OLP for the Irish market with the Dublin distribution centre requesting [redacted] in advance. Pinewood stated that its [redacted] OLP [redacted] are [redacted] to [redacted] percent [redacted]. Pinewood monitors [redacted] and aims to have at least [redacted] stock of OLP on hand in Dublin. Pinewood stated that, due to the small quantities of OLP it sells on the Irish domestic market, it has [redacted] of OLP for sale in Ireland.

228. OLP [redacted] for the Irish domestic market for the year ended 30 June 2004 were; [redacted] bottles 70ml 120mg, [redacted] bottles 140ml 120mg and [redacted] bottles of the 70ml 250mg presentation, giving a total of [redacted] units for the year for sales on the Irish domestic market.

Base Prices

229. Normal values are determined in accordance with section 5 of the Act, being the price paid for like goods sold in the ordinary course of trade for domestic consumption in the country of export, in sales that are arm's length transactions by the exporter or, if like goods are not sold by the exporter, by other sellers of like goods and making adjustments to those prices to ensure that the price comparisons between the export price and normal value are fair.

230. The volume of exports to New Zealand was not able to be matched with the volume of sales to any individual customer in the Irish domestic market and was in fact in excess of the total sales on the Irish domestic market. There were also no sales of the 500ml and 1000ml presentations on the Irish domestic market.

231. Small volumes of sales on the domestic market of the exporting country are dealt with in Paragraph 2 of Article 2 of the Agreement, which states (emphasis added):

> When there are no sales of the like product in the ordinary course of trade in the domestic market of the exporting country or when, because of the particular market situation or the low volume of the sales in the domestic market of the exporting country[2], such sales do not permit a proper comparison, the margin of dumping shall be determined by comparison with a comparable price of the like product when exported to an appropriate third country, provided that this price is representative, or with the cost of production in the country of origin plus a reasonable amount for administrative, selling and general costs and for profits.
>
> [2] Sales of the like product destined for consumption in the domestic market of the exporting country shall **normally** be considered a sufficient quantity for the determination of the normal value if such sales constitute 5 per cent or more of the sales of the product under consideration to the importing Member, provided that a lower ratio should be acceptable where the evidence demonstrates that domestic sales at such lower ratio are nonetheless of sufficient magnitude to provide for a proper comparison.

232. When comparing the total volume of OLP sales in the Irish domestic market with export sales to New Zealand the volume sold in Ireland represents [redacted] percent of the total export sales to New Zealand on a per unit basis and [redacted] percent on a per litre basis. Pinewood considers that comparison on a per unit basis is a more

appropriate measure, as units, rather than the exact amount used, are indicative of the customer's volume and size.

233. If the exported OTC sizes are compared directly with the OTC sizes sold in the Irish market (all Irish sales are OTC sizes), the domestic sales represent [redacted] percent of the OTC presentations of OLP exported to New Zealand (and [redacted] percent by volume). The Ministry notes that the two different groups of presentations (OTC and dispensary) exported to New Zealand have different market situations surrounding them that make them dissimilar in a number of respects. In addition, the costs of preparing OTC presentations for the domestic and export markets are similar, but they are not similar to the costs of preparing dispensary presentations for export to New Zealand.

234. The Ministry considers that because the relative sales volumes of the OTC sales are comparable on a per unit basis, it is reasonable to consider the OTC presentations, 70ml and 140ml, and dispensary presentations, 500ml and 1000ml, separately for the purposes of establishing normal values in the Irish market and that on this basis normal values would provide for a proper comparison for the OTC presentations exported to New Zealand.

235. The Ministry considers that for the OTC presentations, while these volumes are below 5 percent, they are sufficient in quantity to determine normal values when compared with similar sized presentations exported to New Zealand, representing [redacted] percent of similar sized exports to New Zealand. The Ministry is not aware of any other indicators that rebut the preference expressed in footnote 2 to Article 2 of the Agreement that a lower ratio should be accepted when the facts illustrate that the sales are of a magnitude that allows for a proper comparison.

Over the Counter Sizes

236. Pinewood provided information on its sales of OLP in Ireland giving a breakdown by customer for each OLP presentation, detailing the invoice quantity and value for a thirteen month period that was only one month different from the POI.

237. Pinewood stated that its Irish OTC OLP prices are set following a standard costing formula of [redacted] and [redacted] plus [redacted] (bearing in mind the [redacted] percent).

238. The Ministry selected Pinewood's largest OLP customer [redacted] Hospital Pharmacy. Total sales to this customer represented [redacted] percent of the OTC OLP sales made to AFT over the POI. While the selected customer is a hospital pharmacy and Pinewood also sells to community pharmacies, both the Ministry and Pinewood considered that a hospital pharmacy was a more appropriate customer to select. Pinewood stated that there are no [redacted] to hospital pharmacies that are [redacted] community pharmacies in Ireland and the net invoiced amounts are reflective of the true price paid, [redacted] market.

239. The Ministry has used the invoiced OLP sales to [redacted] Hospital Pharmacy over the POI to establish base prices for the OTC normal values.

Base prices for the 70ml presentation were € and € for the 140ml presentation. There was the 120mg and 250mg strength products.

Dispensary Product

240. All interested parties to the investigation stated that there is no cost or sales price relationship between the OTC and dispensary presentations. The Ministry considers that despite the existence of prices in the domestic market for sales in the ordinary course of trade for the OTC presentations, to use these prices as base prices for the dispensary presentations would not be effecting a fair comparison, especially given the comments made regarding the disparity between the pricing structures in the two parts of the market. Therefore as no relevant prices exist for the dispensary sized product in Ireland the Ministry must construct a normal value under one of the methods permitted in the Act and Agreement.

241. Section 5 of the Act appears below:

> 5 (1) Subject to this section, for the purposes of the Act, the normal value of any goods imported or intended to be imported into New Zealand shall be the price paid for like goods sold in the ordinary course of trade for home consumption in the country of export in sales that are arm's length transactions by the exporter or, if like goods are not so sold by the exporter, by other sellers of like goods.
>
> (2) Where the [Chief Executive] is satisfied that the normal value of goods imported…into New Zealand cannot be determined under subsection (1) of this section because-
>
> (a) There is an absence of sales that would be relevant for the purpose of determining a price under that subsection; or
>
> …
>
> the [Chief Executive] may determine that the normal value, for the purposes of this Act, shall be either-
>
> (d) The sum of-
>
> (i) Such amount as is determined by the [Chief Executive] to be the cost of production or manufacture of the goods in the country of export; and
>
> (ii) On the assumption that the goods, instead of being exported, had been sold for home consumption in the ordinary course of trade in the country of export,-
>
> (A) Such amounts as the [Chief Executive] determines would be reasonable amounts for administrative and selling costs, delivery charges and other charges incurred in the sale; and
>
> (B) An amount calculated in accordance with such rate as the [Chief Executive] determines would be the rate of profit on that sale having regard to the rate of profit normally realised on sales of goods (where such sales exist) of the same general category in the domestic market of the country of export of the goods; or
>
> (e) The price that is representative of the price paid for similar quantities of like goods sold at arm's length in the ordinary course of trade in the country of

export for export to a third country.

Constructed Values

242. The Ministry has constructed base prices for normal values of the dispensary presentations using Pinewood's standard cost of production for the 500ml and 1000ml product it exports to New Zealand.

Profit Margins

243. When constructing prices the Ministry considered what the correct allowance to make for profit was and several possibilities were advanced and considered for possible profit margins.

244. Pinewood does not have a fully attributed cost system and it calculates the contribution margin of each product as the selling price less the direct manufacturing costs, as shown in its bill of materials. Overheads are treated as an expense that are subtracted from the total contribution that all products generate. Therefore, the Ministry will apply the profit margin it determines on the same basis as Pinewood does, that is, add the contribution margin to the direct cost of manufacture.

245. Pinewood provided the Ministry with examples of the contribution margins it makes on its large volume contract manufacture for Irish customers for sales within Ireland and [redacted] based customers for sale on the Irish domestic market. Pinewood provided invoiced prices for a range of the contract manufactured products (listed below) and the associated bill of materials showing the cost of manufacture. In calculating the contribution of each product Pinewood [redacted] to provide ex-factory comparisons. Pinewood selected these products as being similar in terms of volume and contractual terms as the OLP supplied to AFT and the Ministry has accepted its selection. Similar products used include; [redacted] units of [redacted], [redacted] units of [redacted], [redacted] units of [redacted], [redacted] units of [redacted], [redacted] units of [redacted] and [redacted] units of [redacted]. The contribution margins for these products ranged from [redacted] percent to [redacted] percent, with an average ex-factory contribution margin of [redacted] percent, expressed as a percentage of the selling price. Pinewood considered that these margins were the most appropriate for the Ministry to use when constructing a normal value.

246. The Ministry also considered using the margins that Pinewood achieved on its sales of [redacted]ml OLP suspension to [redacted]. However, as Pinewood is the only licensee in the market it is more similar to a period of patent protection than a PHARMAC type situation, where intensive competitive pressure to win sole supply status drives prices down, and it would therefore be inappropriate to use these margins.

247. Pinewood outlined the profitability of the 1000ml OLP it exports to New Zealand. Pinewood explained that its export sales division has an [redacted] contribution margin of [redacted] percent and stated that the average [redacted] percent that it achieves on its sales to New Zealand ([redacted] percent on OTC products and [redacted] percent on dispensary products) is well within this range. Pinewood stated that it would not want to go much below a [redacted] percent contribution margin and [redacted] percent as the lowest contribution it achieves indicating a floor in the contribution levels it is [redacted] on a single product, albeit if its profitability is not linked to any other product. Pinewood stressed that the way it operates does not focus on the [redacted] of individual products, but that the [redacted] each product makes is more important. It does not feel that it is looking for a low price in its exports to New Zealand and wants to maintain the margin that it is currently achieving on sales of OLP to New Zealand as any drop below a [redacted] percent contribution margin leaves the [redacted].

248. Pinewood stated that to allow for a contribution margin on the normal values for the dispensary OLP that is greater than the one it is currently achieving on its Irish OTC product would be unrealistic, due to the disparity between the prices and margins in the two market segments. Pinewood currently achieves margins ranging from [redacted] to [redacted] percent on its OTC presentations of OLP in Ireland, with an average contribution margin of approximately [redacted] percent. Pinewood also raised the complicating factor of the price in Ireland being set by the long time market leader Calpol, which has very high market penetration. Pinewood claims that whatever [redacted] market the Calpol brand dominance means that it is [redacted], therefore the pricing of all OLP in Ireland, including any constructed pricing for a dispensary market, is [redacted] by the price that Calpol determines for its OLP and [redacted] price their OLP [redacted] market share. The Ministry has taken the market dominance of another brand into account in deciding which profit margin to use.

249. A further approach considered for calculating the contribution margin was to look at the margins that are being achieved on the OTC and dispensary product that is being exported to New Zealand and apply the difference in contribution margins between the two market segments to the Irish OTC margins to determine a contribution margin for the dispensary product. The exported OTC product is achieving a margin of [redacted] percent compared with a margin of [redacted] percent on the dispensary product, giving a difference of [redacted] percent. Applying this percentage difference to the Irish OTC margin of [redacted] percent would suggest a contribution margin of [redacted] percent is an appropriate figure. The weakness of this method is that it is based on dumped prices.

250. Given all of the above methods the Ministry considers it is reasonable to use the contribution margins Pinewood achieves for other similar products sold in similar volumes in Ireland, or sold to Irish customers but destined for export markets, of [redacted] percent.

251. PHARMAC submitted in its response to the EFC report “that the Ministry should have made further allowance to reflect the certainty of sole supply to a particular

market for a period of time." The Ministry notes that the use of a profit margin that was based upon contract sales of a similar nature to sales made to AFT, with certainty of volume and supply, provides an appropriate base and that in these circumstances no further allowance for the nature of the PHARMAC supply agreements needs to be made.

252. The LECG submission also stated that "...the nature of the competitive conditions in the N[ew] Z[ealand] dispensary market compared to Ireland may ultimately explain any measured dumping margin." The Ministry notes its comments in the previous paragraphs and while there is no equivalent body to PHARMAC in Ireland that another brand, Calpol, is extremely dominant in the Irish market and there is limited market share available to other brands meaning Pinewood has limited ability to "set" the price of its OLP because of this. The LECG submission argues that because there is no equivalent body to PHARMAC in Ireland that the dispensary market prices would function differently, but it has overlooked the fact that there is actually no dispensary market in Ireland. It also discusses subsidies awarded in Ireland as if they were global, as in New Zealand, when in fact only limited medical cost reimbursements are given. The submission also presumes a higher degree of market differentiation in Ireland than in New Zealand. From the information given it appears that there are only three main brands in Ireland, including Parapaed, with Calpol accounting for almost the entire market. This can be contrasted to New Zealand where there are at least seven different brands of OLP available in the OTC market.

253. The Ministry notes that Pinewood has not disputed the calculation for the constructed values, apart from the cost of credit adjustment that applies to all normal values.

Constructed Values Calculations

254. The base price for the 120mg 500ml product has been calculated as the cost to manufacture the same size presentation destined for export to New Zealand of €[redacted]. A contribution margin of [redacted] percent, or €[redacted] was then added, which, as Pinewood does not have a fully burdened cost system, is required to cover all other costs incurred in the manufacture and sale of OLP in the Irish domestic market. The constructed normal value for the 120mg 500ml product is €[redacted].

255. The base price for the 120mg 1000ml product has been calculated as the cost to manufacture the same size presentation destined for export to New Zealand of €[redacted]. A contribution margin of [redacted] percent, or €[redacted] was then added to give a constructed normal value of €[redacted].

256. The base price for the 250mg 500ml product has been calculated as the cost to manufacture the same size presentation destined for export to New Zealand of €[redacted]. A contribution margin of [redacted] percent, or €[redacted] was then added to give a constructed normal value of €[redacted]

257. The base price for the 250mg 1000ml product has been calculated as the cost to manufacture the same size presentation destined for export to New Zealand of

€[redacted]. A contribution margin of [redacted] percent, or €[redacted] was then added to give a constructed normal value of €[redacted].

Adjustments

258. Section 5(3) of the Act provides:

> Where the normal value of goods imported or intended to be imported into New Zealand is the price paid for like goods, in order to effect a fair comparison for the purposes of this Act, the normal value and the export price shall be compared by the [Chief Executive]-
>
> (a) At the same level of trade; and
>
> (b) In respect of sales made at as nearly as possible the same time; and
>
> (c) With due allowances made as appropriate for any differences in terms and conditions of sales, levels of trade, taxation, quantities, and physical characteristics, and any other differences that affect price comparability.

259. As some of the base prices were constructed, the following adjustments do not necessarily apply to both the dispensary and OTC presentations. Each adjustment specifies the presentations to which it applies.

Quantities

260. The sizes of OTC presentations of OLP sold in the Irish market differ from those that Pinewood exports to New Zealand, therefore an adjustment has been made for the differing volumes of the presentations. These adjustments have only been made to the OTC presentations.

70ml to 100ml

261. The Ministry has made adjustments using the 120mg 100ml standard cost for the bottles of €[redacted] and the bulk formulation at €[redacted] to give a quantity adjustment of -€[redacted].

262. The Ministry has made adjustments to use the 250mg 100ml standard cost for the bottles of €[redacted] and the bulk formulation at €[redacted] to give a quantity adjustment of -€[redacted].

263. Pinewood only uses the 70ml bottle for its OLP and the adjustment made for the volume increases reflects the economies of scale that would be achieved from using one of its standard sized bottles.

140ml to 200ml

264. The Ministry has made adjustments using the 120mg 200ml standard cost for the bottles of €[redacted] and the bulk formulation at €[redacted] to give a quantity adjustment of €[redacted].

Strength

265. Due to Irish regulations there are no sales of a presentation equivalent to the 250mg 200ml presentation that Pinewood exports to New Zealand. The Ministry has therefore made both strength and volume adjustments to the base price of the 120mg 140ml presentation to obtain a price for an equivalent 250mg 200ml presentation in the Irish market.

266. The Ministry has made adjustments to approximate a 200ml 250mg presentation using the 200ml standard cost for the bottles of €[redacted] and the bulk formulation at €[redacted] to the standard costs of the 120mg 140ml presentation to give a strength and quantity adjustment of €[redacted].

Physical Characteristics

Packaging

267. Pinewood's OLP manufactured for the Irish domestic market has a leaflet in the carton of the OTC presentations that does not feature in its exports to New Zealand. There is also a difference in the form and cost of packing that applies to the exported goods from those sold in Ireland.

70ml

268. The Ministry has made adjustments to the 70ml 120mg presentation for the leaflet of €[redacted] and packing of €[redacted] to give a total adjustment of -€[redacted].

269. The Ministry has made adjustments to the 70ml 250mg presentation for the leaflet of €[redacted] and packing of €[redacted] to give a total adjustment of -€[redacted].

140ml

270. The Ministry has made adjustments to the 140ml 120mg presentation for the leaflet of €[redacted] and packing of €[redacted] to give a total adjustment of -€[redacted].

271. The Ministry has made adjustments to the 140ml 250mg base price for the leaflet of €[redacted] and packing of €[redacted] based on the 140ml 250mg cost build-up, to give a total adjustment of -€[redacted].

Cost of Credit

272. An adjustment has been made for the cost of credit extended to Pinewood's customers on the domestic market for both the OTC and dispensary presentations using the weighted-average length of credit extended to the selected domestic customer, which was [redacted] days. PHARMAC in its response to the EFC stated that it considered that this approach was only suitable if "…a large proportion of sales were made to those 'selected' customers." The Ministry notes, as outlined in paragraph 238, that the selected customer is Pinewood's largest OLP customer in Ireland.

273. A cost of credit adjustment was made for [redacted] days at Pinewood's overdraft interest rate of [redacted] percent per annum to the net sales value. All of the credit adjustments were less than €[redacted].

274. Pinewood's comments on the calculation of the cost of credit adjustment are outlined from paragraph 209 above.

Levels of Trade

275. Pinewood sells its products through three sales divisions: export, home market and hospital market. Pinewood stated all sales of OLP in Ireland are made through its home market division.

276. Pinewood discussed with the Ministry the type of customer AFT was and decided that it is most similar to a wholesaler in the Irish domestic market, as AFT purchases large volumes of OLP and distributes it on to retailers. Pinewood noted though that the volume of sales it makes to AFT is much larger than any of its sales to domestic wholesalers and that it does not sell any OLP through wholesalers. Pinewood also stated that in Ireland if sales are made to a wholesaler then it is still liable for discounts [redacted] and due to this actually receives a [redacted] margin on product sold to wholesalers, than on the product it markets directly to pharmacies. Pinewood later decided that perhaps AFT was more similar to its Dublin distribution centre. The Ministry notes that Pinewood invoices AFT when it sends product to it and the [redacted] is set from this point in time. However, when Pinewood sends OLP to its Dublin distribution centre it does not know when payment will be due as it invoices individual customers when the goods leave the Dublin distribution centre. Therefore the Dublin distribution centre is really an internal warehouse, rather than a customer.

277. Discounts are normally given by way of a [redacted] each month. Hospital pharmacies do [redacted] have discounts and a [redacted] price as they are more focused on [redacted]. Supply to all pharmacies is on [redacted] basis, with no minimum purchases and [redacted] governing the purchasing relationship. As most pharmacies are independent they [redacted] place an order [redacted]

278. Pinewood stated that AFT is responsible for [redacted] activities in New Zealand and therefore AFT differs in nature from the wholesalers Pinewood sells to in the Irish market.

279. The Ministry considers that a level of trade adjustment should be made, as the base prices for the OTC product are those to the selected domestic customer, for which Pinewood incurs selling and administration activities beyond those incurred in the manufacture of OLP for export to New Zealand. Pinewood stated that it does not have [redacted] sales and administration costs associated with its exports, beyond that of manufacture, preparing the product for export and shipment, as opposed to the full range of marketing and sales activities it undertakes in the domestic market.

280. An adjustment for level of trade has been made based on the selling and administration costs in Ireland. As prices for the dispensary presentations were constructed (and the contribution margins were based on contract manufacture which are at the same level of trade as sales to AFT, which have a similar level of selling and administration expenses for Pinewood) a level of trade adjustment is required only for the OTC presentations.

281. Pinewood does not have a fully burdened cost system, meaning that all overheads are not attributed to the products to which they relate, as it [redacted], provided that [redacted] contribution. The [redacted] contribution is calculated on both a per [redacted] and per [redacted] basis, so some form of allocation of overheads is taken into account. Three cost centres of the total cost centres applicable to OLP were identified as applying only to sales on the domestic market: administration, distribution, and home pharmacy ([redacted]). All overhead percentages are calculated as a percentage of total revenue.

282. Additional information and clarification provided by Pinewood subsequent to the EFC report indicated that freight charges were not included in the three cost centres the Ministry had based the level of trade adjustment upon, and that the domestic delivery charges should also be included in the level of trade adjustment. The Ministry analysed the information provided by Pinewood and agreed that the fourth cost centre should be included in the level of trade adjustment.

283. Distribution overheads cover the Dublin distribution centre. In 2004 the distribution overheads were [redacted] percent of total overhead costs. Home pharmacy covers selling costs and was [redacted] percent in 2004 of total overheads. [redacted] cost centre, although Pinewood questioned the equivalence in its response to the EFC report. In 2004 the administration overhead was [redacted] percent of total overheads. Domestic delivery charges are reported separately from the rest of the overheads and represented [redacted] percent of total domestic sales revenue in 2004.

284. The Ministry calculated the percentage of net domestic sales revenue that the administration, distribution, domestic delivery charges and home pharmacy costs for 2004 were, being [redacted] percent, and made an adjustment based on this amount.

285. AFT also stated that "[i]n constructing the weighted-average normal value price, the M[inistry] has not attributed the costs from the Irish marketing company." First, the Ministry notes that the OTC prices referred to are not weighted-average prices. They are actual market prices from the selected Irish customer, adjusted back to the ex-factory level, for the transaction best able to be matched to the export transactions to New Zealand. Second, the Ministry notes that it has taken Pinewood's Dublin distribution centre and domestic costs centres relating to the marketing of sales in Ireland into account and the inclusion of these cost centres in the level of trade adjustment has never been in dispute. However, since the EFC report the Ministry has responded to further information provided by Pinewood and altered the level of trade adjustment as a result, but this was not related to the inclusion or exclusion of any Irish selling costs.

Freight

286. Following Pinewood's provision of further information on its overheads the basis on which the freight adjustment was calculated has changed since the EFC report and an amount for freight is now included within the level of trade adjustment.

287. Pinewood submitted that a further freight adjustment should be made for OLP as it is a more bulky product than other products it sends from Dublin. The Ministry had rejected this claim, as Pinewood is a specialist liquids manufacturer and most of its products would be of similar bulkiness to OLP. PHARMAC stated in response to the EFC report that the Ministry's presumption that most of the products sent from Dublin are liquids was an example of "…the Ministry making assumptions where it would be relatively easy to establish the facts." The Ministry notes that Pinewood had difficulty in finding OLP relevant freight information. The Ministry discussed the provision of relative freight information (in relation to the other products and the volume thereof Pinewood dispatches from Dublin) with Pinewood during the verification visit and that this information was not able to be provided. Hence the information that PHARMAC stated would be "relatively easy to establish" is not readily available and in the absence of specific information the Ministry must have regard to all other information it has on hand, namely that Pinewood is a specialist liquids manufacturer. The Ministry also notes that PSM also had difficulty in isolating freight information specific to OLP and Pinewood's inability to supply this information does not seem unreasonable given the similar difficulty experienced by PSM.

288. The Ministry outlined to Pinewood, following the EFC report, the exact information required to make an adjustment for OLP based on actual costs, which would then reflect any higher than average costs. Pinewood had already provided this information in relation to one invoice, which did suggest, if representative, that the cost of freight for OLP could be higher than the average. Pinewood did not provide this additional information therefore the Ministry has used the best information available, being the average freight costs.

Taxation

289. Ireland's value-added tax does not apply to any oral medicines and therefore no adjustment has been made for taxation.

Other Differences Affecting Price Comparability

290. The Ministry does not consider that there are any other adjustments, further to those made above that need to be made in order to undertake a fair price comparison.

4.4 Comparison of Export Price and Normal Value

291. A summary of the dumping margins appears in Table 4.2. Dumping margins are calculated by subtracting the export price from the normal value, and then expressing that amount as a percentage of the export price. A negative dumping margin means that the goods are not dumped.

Table 4.2: Dumping Margins

Presentation and Strength		Normal Value (€)	Export Price (€)	Dumping Margin (€)	Transaction-to-transaction Dumping Margin as % of Export Price	Weighted-Average Dumping Margin as % of Export Price
100ml	120mg	[redacted]	[redacted] - [redacted]	[redacted] to [redacted]	[redacted] to [redacted] %	[redacted]%
	250mg	[redacted]	[redacted] - [redacted]	[redacted] to [redacted]	[redacted] to [redacted] %	[redacted]%
200ml	120mg	[redacted]	[redacted] - [redacted]	[redacted] to [redacted]	[redacted] to [redacted] %	[redacted]%
	250mg	[redacted]	[redacted] - [redacted]	[redacted] to -[redacted]	Not Dumped	[redacted]%
500ml	120mg	[redacted]	[redacted] - [redacted]	-[redacted] to -[redacted]	Not Dumped	[redacted]%
	250mg	[redacted]	[redacted] - [redacted]	-[redacted] to -[redacted]	Not Dumped	[redacted]%
1000ml	120mg	[redacted]	[redacted] - [redacted]	[redacted] to [redacted]	[redacted] to [redacted] %	[redacted]%
	250mg	[redacted]	[redacted] - [redacted]	[redacted] to [redacted]	[redacted] to [redacted] %	[redacted]%

*Note: Some of these figures differ due to rounding to those quoted elsewhere in this report.

Evidence of Dumping

292. Section 11(1) of the Act provides that where the Minister is satisfied in respect of some or all of the goods under investigation, that there is insufficient evidence of dumping, or injury, to justify proceeding with the investigation then it shall be terminated. Section 11(2) of the Act provides that evidence of dumping shall be regarded as insufficient if either: the dumping margin is less than 2 percent, when expressed as a percentage of the export price; or the volume of dumped imports, expressed as a percentage of total imports of like goods into New Zealand, is negligible, having regard to New Zealand's obligations as a party to the Agreement.

293. The Agreement deals with the negligibility of dumped imports under Article 5.8 as follows:

> An application under paragraph 1 shall be rejected and an investigation shall be terminated promptly as soon as the authorities concerned are satisfied that there is not sufficient evidence of either dumping or of injury to justify proceeding with the case. There shall be immediate termination in cases where the authorities determine that the margin of dumping is *de minimis*, or that the volume of dumped imports, actual or potential, or the injury, is negligible. The margin of dumping shall be considered to be *de minimis* if this margin is less than 2 per cent, expressed as a percentage of the export price. The volume of dumped imports shall normally be regarded as negligible if the volume of dumped imports from a particular country is found to account for less than 3 per cent of imports of the like product in the importing Member, unless countries which individually account for less than 3 per cent of the imports of the like product in the importing Member collectively account for more than 7 per cent of imports of the like product in the importing Member.

294. In respect of the dumping margin the Ministry has calculated individual dumping margins using the transaction-to-transaction methodology (rather than the weighted-average to weighted-average methodology). The Ministry considers that this is consistent with the Act and the Agreement. Using the individual transaction-to-transaction dumping margins the 100ml and 1000ml presentations are dumped. The 500ml presentations are not dumped. The 200ml presentations have been treated as un-dumped, as they are mostly un-dumped, with one transaction recording a de minimis dumping margin, below 2 percent.

295. In respect of volume the following table uses the Aztec data to estimate total imports for the POI and includes the non-dumped Irish imports in other imports. Aztec data does not incorporate sales to DHB hospitals and therefore underestimates the total market but it is considered representative and is the only market information source that covers sales by all market participants. The Ministry has applied the percentage of goods that were found to be dumped, being 91 percent of imports from Ireland, to the total Aztec figures for Parapaed over the POI.

Table 4.3: Import Volumes of OLP into New Zealand (Litres)

	Year Ended August 2004	Percentage of Total Imports
Dumped Imports	130,492	81%
Other Imports	29,694	19%
Total Imports	160,186	100%

296. On the basis of this information, imports of the dumped goods from Ireland are not negligible.

Transaction-to-Transaction Methodology and *De Minimis* Dumping Margins

297. In using a transaction-to-transaction methodology to calculate dumping margins the Ministry can determine which transactions are dumped and which are not. This methodology is therefore intended to be quite specific in targeting dumped goods that are causing or threatening to cause material injury to the New Zealand industry. In response to the EFC report (and based on further information received from Pinewood), Pinewood, the EC, AFT and PHARMAC have made submissions stating that the weighted-average dumping margin is *de minimis* and therefore the investigation should be terminated.

298. The Ministry considers that if it had used a weighted-average to weighted-average methodology to calculate dumping margins, that is, if the weighted-average of all of Pinewood's export sales to New Zealand and the weighted-average of all Pinewood's domestic sales in Ireland (at the appropriate level of trade) were used to calculate the margin of dumping, then the Ministry would agree that if the overall weighted-average dumping margin was *de minimis*, it should terminate the investigation. The Ministry, however, did not use a weighted-average to weighted-average methodology.

299. The EC raised the issue of *de minimis* dumping margins and the requirement under Article 5.8 of the Agreement to terminate an investigation where the margin of dumping is de minimis. The 500ml presentations are all un-dumped and only one line of the 200ml imports is dumped and this is at a level that is *de minimis*. The EC stated that using the transaction-to-transaction methodology "…does not entitle the Ministry to disregard un-dumped imports" and that "[b]y considering imposition of anti-dumping measures for selected presentations of OLP or all imports of OLP originating in [Ireland], the Ministry appears to circumvent the underlying principle of the [Agreement] which was confirmed by the W[orld] T[rade] O[rganisation] Appellate Body rulings on bed linen, namely that non-dumped imports can be used to offset dumping on other imports…In conclusion, since the overall weighted-average margin of dumping is *de minimis*, this investigation should be terminated."

300. The use of a transaction-to-transaction methodology allows the Ministry to consider whether margins on a transaction-to-transaction basis are *de minimis*. The accuracy of a weighted-average margin that is calculated using values from the transaction-to-transaction methodology is limited by the fact that all available normal values are not present in the data set. An overall weighted-average that can be calculated is indicative only. There are at least three methods of calculating an overall weighted-average margin under the Agreement when using the transaction-to-transaction methodology: to include all transactions; to include only the dumped transactions; and to include all the transactions, but for those that are not dumped set the dumping margin to zero.

301. The Ministry considers that the wording of Article 5.8 of the Agreement, which refers to the "margin of dumping", when using the transaction-to-transaction methodology cannot be interpreted as being any amount other than the individually computed transaction-to-transaction dumping margins, and the Ministry only calculates an overall weighted-average dumping margin, using the dumping margins for each transaction, for reporting purposes. In using a transaction-to-transaction methodology the Ministry is satisfied that the dumped goods causing the material injury are more accurately targeted and each model has a duty applied to it only to the extent necessary to remedy the material injury. Therefore the Ministry has not disregarded the un-dumped imports over the POI.

302. The investigation has found that 91 percent of the volume of Irish imports are dumped and of these ▒ percent have *de minimis* dumping margins, therefore ▒ percent of the dumped goods have dumping margins greater than 2 percent. While dumping margins ranged between -18 (not dumped) and 15 percent, when expressed as a percentage of the export price, most of the dumping margins are above the *de minimis* level.

303. In the transaction-to-transaction methodology of calculating dumping margins used by the Ministry, an overall weighted-average margin of dumping based on actual transactions is limited in its use and is different from a weighted-average margin of dumping that would be calculated using the weighted-average to weighted-average methodology, which would include all available normal values, rather than just those few normal values matched with export prices. While the Ministry has calculated an overall weighted-average margin of dumping of ▒ percent, this includes both negative and positive margins of dumping. The Ministry is also able under the Agreement to calculate a weighted-average margin of dumping using only

positive margins, which would be [redacted] percent, that is greater than *de minimis*. Despite either of these approaches, the Ministry considers when using the transaction-to-transaction methodology that in assessing *de minimis* the individual transactions are relevant. In this case most of the export transactions are dumped at levels above 2 percent, and clearly there is sufficient information on balance to conclude that dumping margins in this case are not *de minimis* and that the investigation should not be terminated on those grounds.

Transaction-to-Transaction Results

304. There were [redacted] lines of imports of OLP by AFT over the POI. Of these [redacted] lines were dumped, [redacted] lines were un-dumped and [redacted] lines had dumping margins that were de minimis, or less than 2 percent.

1000ml

305. There were [redacted] lines of imports of 1000ml OLP by AFT over the POI all of these were dumped. [redacted] lines had dumping margins that were de minimis, or less than 2 percent.

500ml

306. There were [redacted] lines of imports of 500ml OLP by AFT over the POI all of these were un-dumped.

200ml

307. There were [redacted] lines of imports of 200ml OLP by AFT over the POI. Of these [redacted] lines were un-dumped and [redacted] line had a dumping margin that was de minimis, or less than 2 percent.

100ml

308. There were [redacted] lines of imports of 100ml OLP by AFT over the POI, all of which were dumped with dumping margins that were greater than 2 percent or de minimis.

309. The Ministry selected Pinewood's largest domestic OLP customer as it was most comparable to AFT and had a sufficient volume of sales of OTC products to compare with each OTC export transaction. In assessing this, the Ministry looked for sales of the nearest volume and at the closest possible time and at the correct level of trade. For sizes that were not sold in Ireland and were not comparable with those that were, the normal value was constructed.

310. The Ministry has calculated a weighted-average dumping margin for each strength and size of presentation for reporting purposes, however, it is the transaction-to-transaction dumping calculations that assess if there is dumping and for which products. These indicative, rather than determinative, overall weighted-average calculations have taken account of both the dumped and un-dumped transactions (the Ministry has incorporated un-dumped transactions since 2002, but prior to that had not included them in the weighted-average figure and still believes that to exclude them is a valid method of calculating an overall weighted-average). The Ministry only uses the overall weighted-average margin for reporting purposes.

An overall weighted-average dumping margin calculated from individual transaction-to-transaction dumping margins gives an average of the specific calculations of the sale-to-sale comparison and is not representative of all of the relevant sales (of the subject goods on the domestic market at that level of trade) that would be included if a weighted-average to weighted-average methodology was used. By using all sales it is likely that incorporating smaller volume sales at higher prices would raise the normal values and therefore increase any dumping margins that may exist.

311. The LECG submission made on the EFC report stated that "[i]t is easy to envisage that as a result of the materiality of the assumptions made that the dumping margin calculations may be subject to large magnitudes of error. Given significant scope for error the estimated dumping margins for the dispensary products would need to be very large to be worth relying on. If they are small then there is a greater scope for them to be swamped by the potentially large errors. As such we believe the assumptions made in the Ministry's calculations need to be verified and substantiated, and a sensitivity analysis undertaken to assess the scope for confidence in the results."

312. The Ministry considers that the process of a dumping investigation provides checks to ensure that the calculations and adjustments made are available to all interested parties, in method at least, through the non-confidential version of Pinewood's verification visit report. This report details how and why the selected domestic customer was chosen, the basis for the adjustments and the financial information upon which they are based. All interested parties have the opportunity to request the report from the public file and assess the accuracy, suitability or any other basis of the Ministry's calculations. Several interested parties to the current investigation specifically requested a copy of the non-confidential version of Pinewood's verification report, which contained the methods used to calculate the dumping margins. Pinewood was also sent a confidential version of the report and was asked to comment, clarify and correct before the report was finalised. Pinewood did comment on the report and continued in dialogue with the Ministry even after the release of the EFC report on the basis and method for the calculations, even providing additional information. Pinewood, as the owner of the confidential information within the report, is able to share the calculations with whomever it pleases. In this case the Ministry is aware that Pinewood discussed the report, in detail, with the EC and AFT.

313. In this sense the dumping margins calculations are checked by those most affected by them. However, the Ministry notes that there is no requirement either in the Act, or the Agreement, that a certain minimal margin of error be achieved, as suggested by LECG, and that any dumping margins that are above *de minimis* can be remedied and in fact allowances exist for imperfect information to be used, if it is the best information available.

4.5 Dumping Conclusion

314. The investigation has established that [redacted] litres of OLP from Ireland have been dumped during the POI, (this figure differs from that in Table 4.3 as it is the actual amount of dumped imports and Table 4.3 is an estimated figure based on Aztec data, which was used for the purpose of comparability to determine if the dumped imports were negligible).

315. Transaction-to-transaction dumping margins per presentation range from -18 percent (not dumped) to 15 percent. Overall margins of dumping for the subject goods can be calculated using the limited data normal value data set that the transaction-to-transaction methodology offers.

5. Injury

316. Section 8(1) of the Act outlines the basis for considering material injury.

> (1) In determining for the purposes of this Act whether or not any material injury to an industry has been or is being caused or is threatened or whether or not the establishment of an industry has been or is being materially retarded by means of the dumping … of goods imported or intended to be imported into New Zealand from another country, the [Chief Executive] shall examine—
>
> (a) The volume of imports of the dumped or subsidised goods; and
>
> (b) The effect of the dumped or subsidised goods on prices in New Zealand for like goods; and
>
> (c) The consequent impact of the dumped or subsidised goods on the relevant New Zealand industry.

317. The Ministry interprets this to mean that injury is to be considered in the context of the impact on the industry arising from the volume of the dumped goods and their effect on prices. This is consistent with Article 3 of the Agreement.

318. Section 8(2) of the Act sets out a number of factors and indices which the Chief Executive shall have regard to, although not exhaustive, these include:

- the extent to which there has been or is likely to be a significant increase in the volume of dumped goods, either in absolute terms, or relative to production or consumption in New Zealand.
- the extent to which the prices of dumped goods represent significant price undercutting in relation to prices in New Zealand of the New Zealand producers at the relevant level of trade.
- the extent to which the effect of the dumped goods is, or is likely significantly, to depress prices for like goods of New Zealand producers or significantly to prevent price increases for those goods that otherwise would have occurred.
- the economic impact of the dumped goods on the industry, including actual or potential decline in output, sales, market share, profits, productivity, return on investments, and utilisation of production capacity; factors affecting domestic prices; the magnitude of margin of dumping and actual and potential effects on cash flow, inventories, employment, wages, growth, ability to raise capital, and investments.

319. In addition, the Chief Executive must have regard to factors other than dumping which may be injuring the industry, as it must be demonstrated that the dumped imports are, through the effects of dumping, causing material injury. Article 3 of the Agreement requires that authorities shall examine any known factors, other than the dumped imports, which at the same time are injuring the domestic industry, and must not attribute the injury caused by these other factors to the dumped imports. Other factors which may be relevant include the volumes and prices of non-dumped

imports, contraction in demand or changes in the patterns of consumption, trade restrictive practices of and competition between the foreign and domestic producers, developments in technology and the export performance and productivity of the domestic industry.

320. Section 11(1) of the Act provides for the termination of an investigation where the Minister is satisfied in respect of some, or all, of the goods under investigation, that there is insufficient evidence that material injury to the New Zealand industry has been, or is being caused, or is threatened, by means of the dumping of the goods.

321. PHARMAC submitted in its response to the EFC report "…that the Ministry has demonstrated bias in favour of PSM by, without cause, favouring the arguments advanced and unsubstantiated assertions made by PSM and disregarding arguments raised and points made by other parties." The Ministry is able, as outlined at paragraph 56, to rely upon best information available and has had to rely on information supplied by PSM in some circumstances, in the absence of information provided by other interested parties.

322. PHARMAC stated in response to the EFC report that the Ministry had stated "…that the injury commenced in 2003. However, it is unclear from the report where that date was found." The Ministry notes that in its application PSM stated that the injury commenced in 2003 and this was reported at paragraph 15 of the initiation report for this investigation. The Ministry does not consider that this statement is incorrect and PHARMAC has been aware of PSM's belief that injury commenced in 2003 since its application, and further, as stated below, sales of the Irish imports did first occur in 2003.

5.1 Import Volumes

323. Section 8(2)(a) of the Act provides that the Chief Executive shall have regard to the extent to which there has been or is likely to be a significant increase in the volume of imports of dumped goods either in absolute terms or in relation to production or consumption in New Zealand.

324. Customs could not provide statistical unit data (as explained in paragraph 153). Import volumes have therefore been compiled from Aztec data, which does not include sales to DHB hospitals. PSM has stated that, while its sales are slightly than the figures shown in the Aztec data, it believes Aztec data provides a reasonable estimate of the market.

325. Aztec data was provided by PSM for the entire New Zealand market from October 2002 to December 2004 in weekly periods. The 2002 data has been annualised to give an estimate for that year. The volume of dumped imports has been estimated by applying the percentage of actual dumped goods from the POI to the Aztec figures for Parapaed. Non-dumped goods from Ireland have been added to the imports from other sources in the un-dumped import figures. Table 5.1 shows the volumes of OLP sold in the New Zealand market.

Table 5.1: OLP Import Volumes (Litres)

	2002	2003	2004
Dumped Imports	0	17,417	182,019
Un-dumped Imports	35,835	34,928	33,317
Total Imports	35,835	52,345	215,335
NZ Industry Sales	191,576	157,826	26,284
NZ Market	227,411	210,171	241,619
Change on Previous Year:			
Dumped Imports		17,417	164,602
Un-dumped Imports		-906	-1,612
Total Imports		16,510	162,990
NZ Industry Sales		-33,751	-131,542
NZ Market		-17,241	31,448
Percentage Change:			
Dumped Imports			945%
Un-dumped Imports		-3%	-5%
Total Imports		46%	311%
NZ Industry Sales		-18%	-83%
NZ Market		-8%	15%
Dumped Imports as a percentage of:			
NZ Industry Sales		11%	693%
NZ Market		8%	75%

326. Sales of the Irish imports in the New Zealand market were first recorded in August 2003. Since then, import volumes from Ireland have increased significantly in absolute terms and relative to New Zealand production and consumption.

327. Relative to New Zealand production the Irish imports increased from nil in 2002 to 11 percent in 2003 to 693 percent in 2004 and relative to consumption increased from 8 percent in 2003 to 75 percent in 2004.

328. The import volumes shown in Table 5.1 are expected to continue if AFT is awarded sole supply and hospital supply status by PHARMAC in the current tender.

Conclusion

329. The Ministry concludes that import volumes of the subject goods have increased significantly in absolute terms and relative to the estimated New Zealand production and total consumption in New Zealand. PHARMAC stated in response to the EFC report that the Ministry had erred in not linking this increase in the volume of dumped goods to PHARMAC supply agreements "…and that these volumes do not represent a saturation of the market with product, but rather the replacement of one brand with another following the outcome of a PHARMAC process." The Ministry agrees that there are underlying drivers of why the volumes of the Irish imports have increased but that the analysis of the import volumes is a simple analysis of the change in the level of the imports and any other drivers in the reason for the change in these volumes is analysed in the relevant part of the injury section below.

5.2 Price Effects

330. In calculating any price effects the Ministry has used PSM's prices for its Paracare OLP and has not incorporated the prices of the Amcal and Unichem OLP that it contract manufactures. The reason for excluding the Amcal and Unichem OLP is that the prices of these products are determined by a contract, fixed at a point in time and are less reflective of market pressures upon price. PSM also stated that it has not undertaken any contract manufacture since the dumped goods have entered the market, although later stated that it had manufactured one of the products since the Irish goods entered the market.

Price Undercutting

331. Section 8(2)(b) of the Act provides that the Chief Executive shall have regard to the extent to which the prices of the dumped goods represent significant price undercutting, in relation to prices in New Zealand (at the relevant level of trade) for like goods of New Zealand producers.

332. Price undercutting occurs when the imported goods are presented for sale in the New Zealand market at a price lower than the domestically produced goods, therefore undercutting the price that the New Zealand manufacturer can obtain for the like goods.

333. In considering price undercutting, the Ministry will normally seek to compare prices at the level of ex-factory and ex-importer's store, to ensure that any differences in distribution costs and margins do not confuse the impact of dumping. However, the correct point at which to assess price undercutting must be considered in each investigation. In order to determine the level of trade at which to make a price undercutting comparison, it is necessary to establish the point at which the imported goods first compete with the domestically manufactured product, or put another way, ask at what level of trade has the importer the choice of buying from the New Zealand manufacturer or the Irish manufacturer.

334. PSM stated that to determine if any price undercutting existed, the Ministry should consider the OTC and dispensary markets separately. PSM stated that for the dispensary segment of the market all ex-store prices are basically set at the subsidy level, but may include some delivery costs. PHARMAC responded to the

EFC stating that the preceding statement was incorrect. However, the Ministry notes that AFT also gave a statement to this effect stating "the PHARMAC agreement stipulates that the supplier must sell at a certain price (the subsidy level) to the party it is contracted to supply under the contract, for OLP, that is, to wholesalers" and is a reasonable representation of how suppliers perceive the subsidies operating. The Ministry notes PHARMAC's comment that it does not perceive that it sets prices but rather subsidy levels and for some pharmaceuticals these two amounts are not the same. PSM stated it would sell both dispensary and OTC products to AFT. PSM has not previously sold to AFT, although it did approach AFT after PHARMAC had awarded AFT sole supply for the community pharmacy market segment, at which time PSM offered to supply AFT with OLP to fill the contract. (The awarding of sole and hospital supply status to AFT by PHARMAC is discussed from paragraph 443 onwards.)

335. AFT stated that tender bids need to name the brand that would be supplied if the bid is successful and therefore all bids are entered with the manufacturer's supply already agreed. PSM said that it would not have entered a tender bid with AFT, as being a manufacturer in the New Zealand market it would have meant that it would have to sell the product to AFT at a lower price than if it entered a tender bid itself. The Ministry considers that AFT did not have the choice of buying OLP from PSM at ex-factory level at the time of submitting its alternative commercial proposal (ACP) and tender bid. AFT therefore had the choice of buying from a foreign manufacturer or from PSM at the ex-warehouse level, the level at which PSM makes all its sales direct to customers and to wholesalers. Comparisons have been made between PSM's ex-warehouse price and AFT's ex-store price to determine if there is any evidence of price undercutting.

336. PHARMAC's response to the EFC report stated that under its supply agreements a supplier is required "to 'maintain all consents' that includes registration with MedSafe as the Sponsor in New Zealand." Therefore this would mean in order for AFT to enter a tender bid using Paracare "PSM would have to transfer sponsorship of the brand to AFT." PHARMAC stated that it considered it unlikely that PSM would do this. The Ministry agrees. However, PSM did indicate by approaching AFT after the tender had been awarded that it would be prepared to supply OLP to AFT and given PHARMAC's comments on the requirement for the supplier to hold all consents it is likely that this could only happen if PSM contract manufactured dispensary OLP presentations for AFT, as it has previously done for OTC presentations for Amcal and Unichem. PHARMAC stated that it believes "that AFT did not have the choice to purchase from PSM at any point" the Ministry believes that this is consistent with the statements in paragraph 335 and the level at which the comparison has been made.

337. All of PSM's prices are inclusive of delivery. PSM was unable to separately identify, from its total freight and warehousing costs, the cost of freight from the Healthcare Logistics warehouse to its customers. The Ministry has calculated an ex-warehouse price for PSM by deducting an amount for freight from PSM's selling prices based on AFT's costs of distribution to customers. The Ministry believes, from information gathered during the investigation, that AFT's distribution costs are a reasonable estimate of PSM's delivery costs. Table 5.2 compares AFT's ex-store prices and PSM's ex-warehouse prices for each presentation. PHARMAC stated in its submission on the EFC report that it "finds it unusual PSM does not have a price

(ex-warehouse) at which it sells product to wholesalers." The Ministry notes that PSM, AFT and Pinewood all sell product at a delivered price and all stated that industry standard is to price inclusive of delivery. PHARMAC requested that the Ministry revise its methodology for determining price undercutting. The Ministry has used AFT's freight costs as a proxy for those that PSM would incur and considers that this is reasonable. Given the information gathered during its verification visit with PSM, the Ministry is satisfied that PSM is unable to extract the freight costs that relate solely to OLP and therefore calculate an ex-warehouse price.

338. PSM stated in its application that the prices used in determining price undercutting should be those that it was attempting to achieve during the mediation with PHARMAC prior to 1 July 2003. PSM claimed that the amount by which the price could be increased in this mediation was effectively suppressed by the presence of the dumped goods in the New Zealand market and the tender bid based upon dumped prices. The Ministry considers that only actual prices that have been achieved in the market, or non-injurious prices (usually those in a period prior to the dumping) can be used in a price undercutting analysis. The Ministry does not consider that the prices PSM was attempting to achieve constitute non-injurious prices.

Table 5.2 Price Undercutting

Presentation and Strength	PSM's ex-Warehouse Price	AFT's Ex-Store Price	Price Undercutting (NZD)	Undercutting as a Percentage of PSM's Price
100ml				
120mg	[redacted]	[redacted]	[redacted]	[redacted]%
250mg	[redacted]	[redacted]	[redacted]	[redacted]%
200ml				
120mg	[redacted]	[redacted]	[redacted]	[redacted]%
250mg	[redacted]	[redacted]	[redacted]	[redacted]%
500ml				
120mg	[redacted]	[redacted]	[redacted]	No undercutting
250mg	[redacted]	[redacted]	[redacted]	No undercutting
1000ml				
120mg	[redacted]	[redacted]	[redacted]	No undercutting
250mg	[redacted]	[redacted]	[redacted]	No undercutting

339. The price undercutting analysis shows that there is price undercutting, at the ex-store level of trade, for the 100ml and 200ml presentations but no price undercutting for the 500ml and 1000ml dispensary market segment presentations. The finding of

no price undercutting for the dispensary presentations is consistent with the fact that PSM has dropped its prices for the dispensary sized presentations in order to maximise its sales in the available part of the dispensary market segment.

340. PSM said that price undercutting would be visible further down the distribution chain and AFT's access to pharmacies is ensured, as every pharmacy must stock Parapaed OLP for dispensing when wishing to claim the subsidies. PSM stated having sole supply status in the community pharmacy part of the market places AFT in a better position to launch its brand to the OTC market segment, as sole supply status in the dispensary market increases access to pharmacists and the ability to push the OTC demand. PSM believes that as AFT has sole supply status, price competition and price undercutting for OTC sales to pharmacies will increase. In response to the EFC report PHARMAC stated that it "does not accept that having sole supply status in the community market increases demand for the brand to the OTC market. Patients who have access to subsidised paracetamol are much less likely to buy it for themselves. The Ministry provides no evidence to back up PSM's assertion that this is the case." The Ministry notes that both AFT and PSM stated PHARMAC processes were the best way of introducing a new product to the market. AFT stated that its OTC sales of OLP have been relatively minor to this point given its [redacted] pharmacies within [redacted] that [redacted] pharmacies. The Ministry believes the [redacted] imports of OLP for the OTC market made by AFT, without any substantial marketing to assist these sales, also indicates AFT believed that sole supply in the dispensary market would drive demand in the OTC portion of the market. PHARMAC stated "[t]he main advantage of the dispensary market in furthering an OTC market is the ability to access the pharmacist rather than the patient." PHARMAC also stated that AFT's ability to compete in the OTC market is restricted by its failure to gain access to the PBL banner group that operates the Unichem and Amcal pharmacy chains and that PBL has common ownership with PSM. PSM's parent company Australian Pharmaceutical Industries Pty Limited (API) has a 48 percent shareholding in PBL (the remainder of the shares appear to be held by the proprietary pharmacists).

341. The Ministry notes that there is significant price undercutting by AFT at the ex-store level in the OTC market segment, which is consistent with the large discounts AFT has advertised for sales of the 100ml and 200ml presentations to pharmacies, although substantial discounting of sales to pharmacies appears to be the industry standard for generic pharmaceutical products. However, the further away a price undercutting comparison is carried out from the entry of the goods into New Zealand, the more likely it is for the undercutting to be related to market considerations other than dumping. AFT's current sales volume in the OTC market segment is small, although these sales are significantly undercutting PSM's prices.

Price Undercutting Conclusion

342. There is price undercutting of the OTC 100ml and 200ml presentations at the ex-store level of trade.

343. There is no price undercutting of the dispensary presentations at the ex-store level of trade, which is consistent with PSM's lowering the prices of these presentations in order to maximise its sales volume.

Price Depression

344. Section 8(2)(c) of the Act provides that the Chief Executive shall have regard to the extent to which the effect of the dumped goods is or is likely significantly to depress prices for like goods of New Zealand producers.

345. Price depression occurs when prices are lower than those in a market unaffected by dumping, which usually are prices from a pre-injury period.

346. PSM stated that the price depression for OLP began when PHARMAC removed the 500ml subsidy from the community pharmacy market segment and prices decreased for PSM's sales made to private hospitals, rest homes and pharmacies for dispensing without a subsidy. There was also a limited number of sales of Paracare to the community pharmacy market segment between 1 November 2003 and 1 February 2004 (the transition period to sole supply) at the lower subsidy rate, but after 1 February 2004 sales of Paracare to the community pharmacy market segment for dispensing under a subsidy were not permitted. The figures in Table 5.3 are PSM's actual net selling prices and therefore differ from the New Zealand industry sales volumes in the tables based on the Aztec data, which also include sales made by Douglas.

Table 5.3: Average Price Depression per Litre

	2002	2003	2004
Sales Revenue			
Litres Sold			
Sales Revenue (per Litre)			
Percentage Change		%	%

347. Table 5.3 shows PSM's invoiced revenue has dropped dramatically, as has its litres sold. However, the revenue per litre has increased significantly. This is the result of a larger proportion of 2004 sales being of the low volume, high value OTC presentations than in 2003, when greater amounts of the low value, high volume dispensary presentations were sold.

348. Table 5.4 illustrates the price depression that PSM has incurred for each presentation using the average selling prices per unit for 2003 and 2004. The price used for the 200ml 120mg strength presentation is the average of the Paracare Junior Strawberry and Junior Colour-Free Strawberry products of that size and strength. No price depression analysis had been undertaken for any of the 100ml presentations, as they only entered the market in September 2004.

Table 5.4: PSM's Price Depression per Presentation

Presentation and Strength	2003	2004	Price Depression (NZD)	Price Depression as Percentage of 2003 Price
200ml				
120mg	[redacted]	[redacted]	[redacted]	No price depression
250mg	[redacted]	[redacted]	[redacted]	No price depression
500ml				
120mg	[redacted]	[redacted]	-[redacted]	[redacted]%
250mg	[redacted]	[redacted]	-[redacted]	[redacted]%
1000ml				
120mg	[redacted]	[redacted]	-[redacted]	[redacted]%
250mg	[redacted]	[redacted]	-[redacted]	[redacted]%

349. The 500ml and 1000ml presentations are illustrating price depression ranging from [redacted] to [redacted] percent of PSM's 2003 prices. There is no price depression for the 200ml presentation.

Conclusion on Price Depression

350. Prices of the 500ml and 1000ml presentations have been depressed. This is consistent with PSM's lowering of 500ml and 1000ml prices to maximise its sales in an environment where Parapaed has both sole and hospital supply status. The 200ml prices have not been depressed and no comparison has been undertaken of the 100ml presentation sizes as they were not in the market in 2003.

351. The average selling price per litre has not been depressed and has in fact increased since 2003. This is a result of PSM's 2004 sales being predominantly of the 100ml and 200ml presentations that have a higher per litre price than the 500ml and 1000ml presentations.

Price Suppression

352. Section 8(2)(c) of the Act also provides that the Chief Executive shall have regard to the extent to which the effect of the dumped or subsidised goods is or is likely significantly to prevent price increases for those goods that otherwise would have been likely to have occurred.

353. The Ministry generally bases its assessment of price suppression on positive evidence, in particular, the extent to which cost increases have not been recovered in prices. Cost increases not recovered in prices will be reflected in declines in gross profit and earnings before interest and taxation (EBIT) and increases in costs, when

expressed as a percentage of revenue. Where costs savings have been made, the lack of any price increase will not normally be regarded as price suppression. While the inability to recover cost increases in prices is the main indicator of price suppression, the Ministry will consider any other factors presented as positive evidence of price suppression.

354. PSM stated that it believes price suppression may have been evident in early 2003 when it was negotiating with PHARMAC for increases in the 1000ml presentations subsidy levels. PSM stated that dispensary prices have been suppressed as a result of the Parapaed product having sole and hospital supply status and that the small amount of non-Parapaed OLP that is able to be sold under the discretionary variance allowance in the DHB hospital market segment has forced price competition depressing prices further.

355. PSM stated that there have been increases in the cost of some of its packaging materials and one of the excipients it uses in the manufacture of OLP due to the smaller volumes it is now purchasing having higher per unit prices. PHARMAC stated in its response to the EFC report that exchange rate movements in recent years would mean any internationally sourced inputs would be cheaper. The Ministry is satisfied that (as discussed at paragraph 187 of PSM's verification report) the invoices provided by PSM show increases in the cost of OLP labels and [redacted] an excipient used in the manufacture of OLP. These costs have increased from 2003 levels. The Ministry also notes that most of PSM's inputs are purchased in New Zealand and therefore the effects of any exchange rate movements, while reflected, are likely to be less marked than when purchasing in foreign currency.

356. Table 5.6 shows the price suppression analysis.

Table 5.6: Price Suppression

	2002	2003	2004
Total OLP Revenue	[redacted]	[redacted]	[redacted]
Cost of Production	[redacted]	[redacted]	[redacted]
S & A Expenses	[redacted]	[redacted]	[redacted]
Total Costs	[redacted]	[redacted]	[redacted]
As a % of Revenue			
- Cost of Production	[redacted]%	[redacted]%	[redacted]%
- S & A Expenses	[redacted]%	[redacted]%	[redacted]%
- Total Costs	[redacted]%	[redacted]%	[redacted]%

357. Total costs expressed as a percentage of revenue decreased in 2003, but rose [redacted] percentage points from 2003 to 2004, indicating that prices have been suppressed. Table 5.7 shows PSM's cost of production for each OLP presentation. The 100ml presentations are not included as they were first produced in 2004. The cost of

production figures are taken from September cost sheets in each year (as these best represent the increased costs as a result of the lost volume of OLP being the most recent period) and compared against average annual selling prices. (The average annual selling prices were the simple average of the September and March cost sheets.) Figures are per presentation.

Table 5.7: Price Suppression per Presentation

	2003	2004	Change from 2003 to 2004
200ml			
120mg			
Cost of production			
Average selling price			
Costs as % of revenue	%	%	-%
Colour-free 120mg			
Cost of production			
Average selling price			
Costs as % of revenue	%	%	-%
250mg			
Cost of production			
Average selling price			
Costs as % of revenue	%	%	-%
500ml			
120mg			
Cost of production			
Average selling price			
Costs as % of revenue	%	%	%
250mg			
Cost of production			
Average selling price			
Costs as % of revenue	%	%	%
1000ml			

120mg			
Cost of production	[redacted]	[redacted]	[redacted]
Average selling price	[redacted]	[redacted]	[redacted]
Costs as % of revenue	[redacted]%	[redacted]%	[redacted]%
250mg			
Cost of production	[redacted]	[redacted]	[redacted]
Average selling price	[redacted]	[redacted]	[redacted]
Costs as % of revenue	[redacted]%	[redacted]%	[redacted]%

358. There is no evidence of price suppression for the 200ml presentations, because cost of production increases have been recovered in price increases.

359. There has been significant price suppression for the 500ml and 1000ml presentations due to increased costs of manufacture combined with decreases in the average selling price. PHARMAC stated that "a result of the loss in volume…there would be certain fixed costs that would not decrease proportionally with the reduced volume" and price suppression cannot be considered separately. The Ministry notes that price and volume effects are usually intertwined when an industry is suffering injury and that the injury conclusion draws all the indicators together to give an overall picture. As Table 5.7 illustrates the price suppression suffered by PSM is a combination of increased costs of production and decreases in selling price.

360. PSM stated that over time it believes [redacted] caused by the presence of Parapaed in the New Zealand market [redacted] Panadol and Pamol are much higher in price than Paracare.

Conclusions on Price Suppression

361. There is evidence that total costs as a percentage of revenue have increased by [redacted] percentage points in 2004 when compared with 2003 levels indicating that prices have been suppressed. On a presentation by presentation basis prices range from displaying no suppression when the cost of production is expressed as a percentage of revenue (for the 200ml presentations) to showing price suppression through an increase of up to [redacted] percentage points from the 2003 levels (500ml and 1000ml presentations).

Other Price Effects

362. PSM has not claimed any other price effects, nor has any evidence of any other price effects been discovered during the investigation.

Conclusion on Price Effects

363. There is evidence of price undercutting of OTC size presentations, but not on the dispensary size presentations.

364. On a per litre basis there is no evidence of price depression. This can be attributed to a change in the ratio of presentations sold. There is evidence of price depression for the 500ml and 1000ml presentations.

365. There is evidence of price suppression, with an increase in the cost of production, when expressed as a percentage of revenue, of [redacted] percentage points. There is no evidence of price suppression of the 200ml presentations but there is significant price suppression of the 500ml and 1000ml presentations. No price suppression analysis was able to be undertaken for the 100ml presentations as these were only introduced into the market in 2004.

5.3 Economic Impact

366. Section 8(2)(d) of the Act provides that the Chief Executive shall have regard to the economic impact of the dumped or subsidised goods on the industry, including—actual and potential declines in output, sales, market share, profits, productivity, return on investments, utilisation of production capacity, effects on cash flow, inventories, employment, wages, growth, ability to raise capital investments, factors affecting domestic prices, and the magnitude of the margin of dumping.

367. The Ministry outlined at paragraph 330 that it had based price effects analysis only upon PSM's Paracare prices and had excluded the Amcal and Unichem product it manufactures. For analysing economic effects the Ministry has included the Amcal and Unichem products. The Ministry notes that the volumes of product involved are small and the effect of including or excluding these figures is minimal.

Output and Sales

368. PSM stated that, as it uses a batch method of manufacture, its output levels of OLP are very close to its sales volumes and that it actively manages its inventory levels. PSM stated that it has been injured by a decline in output as it has lost significant sales in the New Zealand market due to the dumped goods from Ireland. PSM also stated that it has manufactured Amcal OLP in addition to its Paracare OLP in the last year.

369. Table 5.8 shows PSM's OLP output using actual sales volume as an estimate for output. The figures are taken from PSM's financial records.

Table: 5.8 Output of OLP (Litres)

	2002	2003	2004
Production	[redacted]	[redacted]	[redacted]
Increase/decrease		[redacted]	[redacted]

Percentage Change	-[redacted]%	-[redacted]%

370. The 2004 decline in output was significant and output in 2004 represents only [redacted] percent of output in 2002. PSM stated that the decline in volume in 2004 directly reflects the entrance of Parapaed into the subsidised portion of dispensary market segment in which it has sole and hospital supply status. Table 5.9 below shows output by presentation. There are no comparisons for the 100ml presentations as PSM only commenced manufacture of the 100ml presentations in 2004.

Table 5.9: Output by Presentation

	2003	2004	Change	2004 as % of 2003 Output
200ml				
120mg	[redacted]	[redacted]	[redacted]	[redacted]%
Colour-free 120mg	[redacted]	[redacted]	[redacted]	[redacted]%
250mg	[redacted]	[redacted]	-[redacted]	[redacted]%
Unichem 120mg	[redacted]	[redacted]	-[redacted]	[redacted]%
Amcal 120mg	[redacted]	[redacted]	-[redacted]	[redacted]%
500ml				
120mg	[redacted]	[redacted]	-[redacted]	[redacted]%
250mg	[redacted]	[redacted]	-[redacted]	[redacted]%
1000ml				
120mg	[redacted]	[redacted]	-[redacted]	[redacted]%
250mg	[redacted]	[redacted]	-[redacted]	[redacted]%

371. PSM's 2004 output levels for both the 120mg 200ml OLP presentations increased from the 2003 levels, however the output of all other presentations decreased from the 2003 levels.

372. PSM stated that it will produce OLP (and other pharmaceuticals) in its pharmaceutical plant as long as it is still marginally profitable to do so and that if the plant as a whole was unable to achieve marginal profitability then it would be closed. However, the Ministry notes that PSM [redacted]

[redacted] by the [redacted] and the [redacted] it undertakes.

Revenue

373. Movements in sales revenue reflect changes in the volumes and prices of goods sold. Dumped imports can affect both of these factors through increased supply of goods to the market and through price competition.

374. PSM sets its prices [redacted] and for the [redacted]. Therefore the existence of dumped goods in the New Zealand market and any price effects that they have, are incorporated into PSM's pricing model. In response to the dumped goods PSM has been [redacted] and has priced its dispensary presentations at [redacted] share of the DHB hospital and non-subsidised dispensary market segments.

375. PSM stated that AFT is currently dramatically reducing the price of Parapaed OTC products to try to make sales, which it stated indicates that AFT has large stock levels of these presentations. (The Ministry notes that AFT [redacted].)

376. Table 5.10 shows the changes in PSM's sales revenue.

Table 5.10: PSM's Sales Revenue

	2002	2003	2004
Sales Revenue	[redacted]	[redacted]	[redacted]
Change		[redacted]	[redacted]
Percentage Change		[redacted]%	-[redacted]%
Litres Sold	[redacted]	[redacted]	[redacted]
Revenue per litre	[redacted]	[redacted]	[redacted]
Change		[redacted]	[redacted]
Percentage Change		[redacted]%	[redacted]%

377. PSM's OLP generated revenue dropped by [redacted] percent from its 2003 level, representing only [redacted] percent of 2002 revenue. Revenue per litre increased in both 2003 and 2004 and is now at [redacted] percent of its 2002 level. Total sales revenue in 2004 declined significantly and this was accompanied by an increase in the sales revenue per litre. Both trends are the result of the loss of volume sales in the dispensary market segment and an increase in OTC market segment sales.

Conclusion

378. There is evidence of a significant decline in both output and revenue.

Market Share

379. The analysis of market share must take account of changes in the growth of the market as a whole. A decline in the market share held by the New Zealand industry in a situation where the market as a whole is growing will not necessarily indicate that injury is being caused, particularly if the domestic industry's sales are also growing. The New Zealand industry does not have an entitlement to a particular market share.

380. The Ministry asked PSM to comment on its strategy taken to counter the effects of the imported Parapaed in New Zealand. PSM stated that it dropped its price from NZD8.75 to NZD[redacted] in the transition period to get rid of stock and retain as much of the market for as long as possible. PSM altered its long term forecasts as soon as it found out that AFT had won the tender. During the transition period PSM [redacted] and PSM stated its sales representatives [redacted]. Since the sole and hospital supply status has come into effect, PSM has dropped the prices of the dispensary sized presentations in order to maximise sales.

381. Table 5.11 shows the New Zealand OLP market figures taken from Aztec data by the method outlined in paragraph 325.

Table 5.11 New Zealand Market Share (Litres)

	2002	2003	2004
Dumped Imports	0	17,417	182,019
Un-dumped Imports	35,835	34,928	33,317
New Zealand Industry Sales	191,576	157,826	26,284
New Zealand Market	227,411	210,171	241,619
As a percentage of the New Zealand Market			
Dumped Imports	0%	8%	75%
Un-dumped Imports	16%	17%	14%
New Zealand Industry Sales	84%	75%	11%

382. The New Zealand industry's market share, which includes sales made by Douglas, was 84 percent in 2002 and had dropped to 11 percent in 2004. The dumped imports were not sold in New Zealand until 2003 and started from a zero base in 2002, achieving 8 percent market share in 2003 and climbing to 75 percent in 2004.

383. Market share held by the non-dumped imports (including non-dumped imports from Ireland) was fairly stable at 16 percent in 2002 and 17 percent in 2003 and dropped to 14 percent of the New Zealand market in 2004.

384. The Ministry has also assessed market share trends by the individual parts of the market in the tables below.

385. PHARMAC stated PSM cannot claim to be injured in the OTC market segment as Parapaed accounts for less than [redacted] percent of that market segment. As Table 5.12 shows below in 2004 Parapaed had 3 percent of the New Zealand market for the 100ml and 200ml presentations.

Table 5.12: Sales Volumes of 100ml and 200ml OLP (litres)

	2002	**2003**	**2004**
Dumped Imports	0	247	1,019
Un-dumped Imports	19,271	14,169	15,026
New Zealand Industry Sales	10,316	19,143	17,430
New Zealand Market	29,587	33,559	33,475
As a % of NZ market			
Dumped Imports	0%	1%	3%
Un-dumped Imports	65%	42%	45%
New Zealand Industry Sales	35%	57%	52%

386. Sales of the dumped 100ml and 200ml presentations have increased from zero to 247 litres in 2003, to 1,019 litres in 2004. The un-dumped imports were dominant in this market segment in 2002 occupying 65 percent of the market segment, this decreased in 2003 to 42 percent and rose slightly to 45 percent in 2004. The portion of the market held by the New Zealand industry increased from 35 percent in 2002 to 57 percent in 2003 and decreased by 5 percentage points in 2004, 2 percentage points of which have been replaced by the dumped goods and the remaining 3 have been occupied by non-dumped imports.

387. The dumped import volumes of the 100ml and 200ml presentations of OLP have increased from a zero base in 2002, but do not illustrate the marked increase that is evident in the total import volumes.

Table 5.13: Sales Volumes of 500ml OLP (Litres)

	2002	**2003**	**2004**
Dumped Imports	0	0	0
Un-dumped Imports	5,116	2,733	11

New Zealand Industry Sales	43,124	28,094	3,442
New Zealand Market	48,240	30,827	3,453
As a % of NZ market			
Dumped Imports	0%	0%	0%
Un-dumped Imports	11%	9%	0%
New Zealand Industry Sales	89%	91%	100%

388. There are no sales of the dumped imports recorded in Table 5.13 as the figures are based upon Aztec data, which excludes sales to DHB hospitals. This does indicate, however, that AFT is not selling any 500ml Parapaed into the unsubsidised portion of the community pharmacy market segment. PSM stated that it believes that it has ▒▒▒▒ of the discretionary variance in the DHB hospital market segment due to the exit of the Pamol and Panadol brands from this part of the market. Table 5.13 shows that the market share for 500ml held by the un-dumped imports has decreased from 11 percent in 2002 to zero in 2004 and that the New Zealand industry's market share has increased by the same amount, which supports PSM's statement that Pamol and Panadol are withdrawing from the dispensary portion of the New Zealand market.

Table 5.14: Sales Volumes for 1000ml (Litres)

	2002	**2003**	**2004**
Dumped Imports	0	17,170	181,000
Un-dumped Imports	11,448	18,026	18,280
New Zealand Industry Sales	138,136	110,589	5,412
New Zealand Market	149,584	145,785	204,692
As a % of NZ market			
Dumped Imports	0%	12%	88%
Un-dumped Imports	8%	12%	9%
New Zealand Industry Sales	92%	76%	3%

389. Table 5.14 illustrates that the market share for the 1000ml presentations held by the dumped goods started from a zero base in 2002, increased to 12 percent in 2003 and in 2004 has 88 percent of the New Zealand market for this size presentation.

390. The market share held by un-dumped imports has fluctuated, in 2002 it was 8 percent, which then increased to 12 percent in 2003 and decreased again in 2004 to

9 percent. This may be due to a withdrawal of the Pamol and Panadol brands from the dispensary market segment as suggested by PSM.

Table 5.15: New Zealand Market Share by Value (NZD)

	2002	2003	2004
Dumped Imports	0	82,038	846,448
Un-dumped Imports	1,989,369	1,600,338	1,733,642
New Zealand Industry Sales	1,169,556	1,603,631	1,242,751
New Zealand Market	3,158,925	3,286,006	3,822,841
As a percentage of the New Zealand Market			
Dumped Imports	0%	2%	22%
Un-dumped Imports	63%	49%	45%
New Zealand Industry Sales	37%	49%	33%

391. The dumped goods were not sold in the New Zealand market in 2002 and represented 22 percent of the value of total market sales in 2004. Un-dumped imports suffered a decline of 18 percentage points over the same period. The New Zealand industry increased the proportion of the value of the total New Zealand market it occupied in 2003 and in 2004 lost 16 percentage points to the dumped goods.

392. PHARMAC stated in response to the EFC report that Table 5.15 "shows large fluctuation in the market share from year to year", which does not establish any effect and "requests that the Ministry either disregard this analysis or undertake a more detailed analysis". The Ministry notes that market share is a matter that must be examined under section 8(2)(a) of the Act and that a more detailed analysis by market segment appears below. It is the relationship between the changes in the market share held by the New Zealand industry and the dumped imports that is relevant, not the absolute market values that are held. As with all analysis that is undertaken in a dumping investigation the Ministry is only able to use the information that is presented to it and that it is able to find from other sources, including those that are publicly available. The Ministry has used Aztec data to analyse market share and considers that it is a reasonable base for such analysis. Conclusions are drawn from the figures that appear below and emphasise the relationship between the changes in the market share held by PSM and the dumped imports as the decisive trend, rather than absolute figures.

Table 5.16: OTC 100ml and 200ml Market Share by Value (NZD)

	2002	2003	2004
Dumped Imports	0	21,084	85,470

Un-dumped Imports	1,728,801	1,399,583	1,650,372
New Zealand Industry Sales	439,151	1,040,980	1,146,877
New Zealand Market	2,167,952	2,461,646	2,882,719
As a % of NZ market			
Dumped Imports	0%	1%	3%
Un-dumped Imports	80%	57%	57%
New Zealand Industry Sales	20%	42%	40%

393. The dumped goods rose from a zero base in 2002 to 3 percent of the value of the New Zealand OTC market segment in 2004. Un-dumped imports dominated the OTC market in 2002 accounting for 80 percent of its sales, which had dropped to 57 percent in 2004.

394. The New Zealand industry has doubled the proportion of sales value of the OTC market segment it occupies from 20 percent in 2002 to 40 percent in 2004. PHARMAC stated in its response to the EFC report that "PSM has not lost market position in the OTC market regardless of the dumping…" The Ministry notes that Table 5.16 records a drop of 2 percent in 2004 from 2003, when the dumped goods entered the market and that the value of the market held by un-dumped goods has remained static over the same period, while the percentage held by the dumped goods increased by 2 percent. Therefore the loss of market value held by PSM appears to have been replaced by the dumped goods but this has occurred in a growing market and PSM, as the New Zealand manufacturer, is not entitled to any particular market share. PHARMAC went on to state that this "reinforces PHARMAC's position that the loss of sales suffered by PSM is due to its failure to enter the tender…" The Ministry notes that PSM's loss of sales has primarily occurred in the dispensary market segment and the reasons for this and the cause of the injury suffered by PSM are discussed later in this section and in section 6.

Table 5.17: 500ml Market Share by Value (NZD)

	2002	**2003**	**2004**
Dumped Imports	0	0	0
Un-dumped Imports	124,945	56,618	533
New Zealand Industry Sales	182,014	183,059	74,477
New Zealand Market	306,959	239,676	75,010
As a % of NZ market			
Dumped Imports	0%	0%	0%
Un-dumped Imports	41%	24%	1%

New Zealand Industry Sales	59%	76%	99%

395. Table 5.17 does not show any sales of dumped 500ml presentations, as sales to DHB hospitals are not included in the Aztec data. The table does illustrate that the Pamol and Panadol brands appear to have withdrawn from the New Zealand market for the 500ml presentations, although they may be sold in the limited portion of the DHB hospital market that is available under the discretionary variance amount.

396. The Ministry notes that the Aztec data in Tables 5.13 and 5.17 shows that the pharmacy point-of-sale per unit prices for the 500ml presentation vary considerably and are very high compared to the net price PSM achieves as shown in Table 5.4. The unit prices recorded for the other size presentations in the Aztec data are more consistent and are also closer to the net prices that PSM achieves. The Ministry queried this with PSM. PSM stated that this is because the sales of the 500ml presentation are mainly sold into the private healthcare market; private hospitals and rest-homes, and the average prices reflect the retail prices that pharmacists can achieve at any given point in time. PSM stated that as its OLP is currently the only 500ml product supplied to this part of the market there are no other prices against which sales need to compete and pharmacists tend to maximise revenue where possible.

Table 5.18: 1000ml Market Share by Value (NZD)

	2002	**2003**	**2004**
Dumped Imports	0	60,954	760,978
Un-dumped Imports	135,623	144,137	82,737
New Zealand Industry Sales	548,392	379,593	21,396
New Zealand Market	684,014	584,684	865,111
As a % of NZ market			
Dumped Imports	0%	10%	88%
Un-dumped Imports	20%	25%	10%
New Zealand Industry Sales	80%	65%	2%

397. The dumped imports held 88 percent of the total market value in 2004. The portion held by un-dumped imports fell 15 percentage points to 10 percent in 2004 and the portion held by the New Zealand industry fell 63 percentage points to occupy only 2 percent of the value of the community pharmacy market segment in 2004.

Conclusion

398. The dumped imports were not sold in the New Zealand market in 2002 but in 2004 they occupied 75 percent of the market by volume and 22 percent by value.

The dumped imports have had the most impact on the community pharmacy market segment with the 1000ml presentations.

399. Non-dumped imports occupied 16 percent of the market by volume and 63 percent by value in 2002, which had decreased to 14 percent by volume and 45 percent by value in 2004.

400. The New Zealand industry held 84 percent of the market share by volume and 37 percent by value 2002 but in 2004 they occupied only 11 percent of the market by volume but only suffered a drop of 4 percentage points by value, accounting for 33 percent of the market by value.

401. There is evidence showing that the New Zealand industry's share of the total market has declined significantly in relation to volume and that it has also suffered a small decrease in the proportion of the value of total market sales that it holds.

Profits

402. Changes in net profit reflect changes in prices, sales volumes or costs and dumped imports can impact on any or all of these. Normally, the extent of any decline in profit will be measured against the level achieved in the period immediately preceding the alleged commencement of dumping.

403. PSM stated that the decline in its profits is directly related to the effect of dumped OLP in the New Zealand market. PSM stated that because dumped prices secured supply for most of the dispensary market segment, it can only produce minimal quantities for this market segment.

404. PSM also stated that, because of the overhead under-recovery that it is suffering due to the decline in OLP volume, its price would need to be at least NZD[redacted] per 1000ml to maintain its previous profit levels. Table 5.19 shows the profitability of PSM's OLP operations.

Table 5.19: PSM's OLP Earnings Before Interest and Tax

	2002	2003	2004
Sales Revenue	[redacted]	[redacted]	[redacted]
Litres Sold	[redacted]	[redacted]	[redacted]
EBIT	[redacted]	[redacted]	[redacted]
EBIT Change		[redacted]	- [redacted]
% EBIT Change		[redacted]%	-[redacted]%
Per Litre EBIT	[redacted]	[redacted]	[redacted]
Per Litre Change		[redacted]	-[redacted]
% Per Litre Change		[redacted]%	-[redacted]%

EBIT as % of Revenue	[redacted]%	[redacted]%	[redacted]%

405. Table 5.19 shows that PSM enjoyed an increase in its OLP profitability in 2003 but suffered a major drop in profit levels in 2004. PHARMAC stated in its response to the EFC report that "PSM has made no mention of efforts to seek alternative contract manufacturing in order to mitigate its costs through lost volume, of which a significant portion appears to be attributed to down time of its factory." The Ministry notes that while it is a prudent business decision to attempt to mitigate any losses that are incurred, the Act and the Agreement do not impose any obligation upon a domestic industry to do so. Although PSM did attempt to mitigate the losses suffered as a result of the decreased volumes of OLP, as reported at paragraph 177 of its verification report, by introducing new products to the market, but these other products have not be as successful as PSM had anticipated.

406. PSM stated in its application that it is suffering continuing losses and would face potential write-offs. However, PSM confirmed that the losses are reductions in profit rather than losses and that it does not plan any write-offs at this stage. The Ministry notes that PSM's parent company API has closed one of its Australian manufacturing plants and is relocating the production to PSM in New Zealand which is likely to improve PSM's overhead under-recovery, which is the main driver of decreased profitability relative to revenue.

Conclusion

407. There is evidence of a significant decline in profits.

Productivity

408. Productivity is the relationship between the output of goods and the inputs of resources used to produce them. Changes in productivity are affected by output levels and by the level of capacity utilisation.

409. Productivity has been adversely affected by the loss of volume of OLP primarily due to the GMP cleaning requirements and the cleaning and set up times associated with smaller, more infrequent runs. PSM stated that in 2003 OLP batches were being produced "back-to-back" so less cleaning was required between batches of the same product. PSM stated the amount of cleaning time for each batch of OLP produced has increased due to the time limit for having the manufacturing facility empty before it requires cleaning again prior to the next production run is constantly being exceeded.

Table 5.20: Productivity

Size and Strength Presentations	Hours per 1000ml Year Ended 2002	Hours per 1000ml Year Ended 2004	Change in Hours	Percentage Change
120mg 100ml and 200ml	[redacted]	[redacted]	[redacted]	[redacted]%

250mg 100ml and 200ml	[redacted]	[redacted]	[redacted]	[redacted]%
500ml and 1000ml (120mg and 250mg)	[redacted]	[redacted]	[redacted]	[redacted]%

410. Table 5.20 shows that the time taken to produce all presentations of OLP has increased significantly and there is therefore evidence of an adverse impact upon productivity.

Return on Investments

411. A decline in return on investments will result from a decline in returns with, or without, a relative increase in the investment factor being used. Movements in the return on investments can affect the ability to retain and attract investment.

412. PSM did not comment on the effect of any injury on its return on investments specifically, but provided the Ministry with its ex-factory margin as a percentage of net funds employed for OLP.

Table 5.21: Return on Investments (Year to October)

	2002	2003	2004
Ex-Factory Margin	[redacted]	[redacted]	[redacted]
Net funds employed	[redacted]	[redacted]	[redacted]
Return of Investments	[redacted]%	[redacted]%	[redacted]%

413. The decrease in net funds employed in 2004 [redacted] net book value of the pharmaceutical plant, a [redacted] in indirect overheads and a [redacted] in debtors and creditors.

414. PSM's ex-factory margin as a percentage of its net funds employed decreased by [redacted] percentage points in 2004 from its 2003 level and therefore is evidence of an adverse impact on return on investments.

Utilisation of Production Capacity

415. The utilisation of production capacity usually reflects changes in the level of production, although in some cases it will arise from an increase or decrease in capacity. In either case, a decline in the utilisation of production capacity will lead to an increase in the unit cost of production, and a consequent loss of profit.

416. PSM has a maximum production capacity of [redacted] 3,000 litre and [redacted] 1,500 litre batches of OLP per week, that is a combined [redacted] litres per week. This

excludes the manufacture of other products that are also manufactured in the same suites. PSM stated that this incorporates both batch run and cleaning times which vary by batch size and product.

417. Table 5.22 below compares PSM's average OLP capacity utilisation for the 15 months to November 2003 and for the 11 months to October 2004. The table shows that PSM's production capacity declined significantly for the 1,500 litre manufacturing suite but only slightly for the 3,000 litre manufacturing suite.

Table 5.22 Utilisation of Production Capacity

	August 2002 to November 2003	December 2003 to October 2004
1500 litre		
Total batch capacity	[redacted]	[redacted]
OLP produced	[redacted]	[redacted]
OLP % of total capacity	[redacted]%	[redacted]%
3000 litre		
Total batch capacity	[redacted]	[redacted]
OLP produced	[redacted]	[redacted]
OLP % of total capacity	[redacted]%	[redacted]%

418. PSM stated that due to AFT's sole and hospital supply status for OLP that it would not expect the volumes that it is currently producing to increase. The decline in PSM's production has resulted in a decline in the utilisation of its production capacity.

419. The Ministry concludes that there is a significant decline in the utilisation of production capacity.

Factors Affecting Domestic Prices

420. PHARMAC has a major role in setting subsidies and entering contracts from which market prices flow, its role in the market is discussed in relation to OLP from paragraph 443. The Ministry is not aware of any other factors affecting domestic prices that have had an adverse economic impact upon PSM, other than the dumped imports of OLP from Ireland.

Magnitude of the Margin of Dumping

421. The magnitude of the dumping margin can be a useful indicator of the extent to which injury can be attributed to dumping, particularly when it is compared with the level of price undercutting.

422. The weighted-average dumping margins for the Irish OTC products range from [redacted] to [redacted] percent of the export prices. For the dispensary products the [redacted]. The weighted-average dumping margin for the 1000ml product is [redacted] percent of the export prices.

Other Adverse Effects

423. In addressing other adverse effects, the Ministry considers actual and potential effects on cash flow, inventory, employment, wages, growth, ability to raise capital, and investments.

Cash Flow

424. The effects of the OLP business on PSM's cash flow are largely the same as the profit effects shown above. PSM stated that it was unaware of any specific cash flow effects associated with [redacted] used in the manufacture of OLP.

425. Table 5.23 illustrates the net cash flow (from operating activities) as it related to OLP, which illustrates that cash flow declined by [redacted] percent in 2004 from its 2003 levels.

Table 5.23: PSM OLP Net Cash Flow Effect

	2002	2003	2004
Net Cash Flow	[redacted]	[redacted]	[redacted]
Change		[redacted]	- [redacted]
Percentage Change		[redacted]%	- [redacted]%

426. There is evidence to show that there has been a significant decline in cash flow.

Inventories

427. PSM did not make any claims in respect of inventories but provided the information on its inventory levels as at the end of April and December for 2000 to 2004. PSM indicated that seasonal variations in OLP meant that there is a higher demand in winter and therefore the December inventory levels should be less affected by seasonal stock requirements. Table 5.24 shows PSM's inventory level in litres as at 31 December for 2002 and 2004 and as at 31 April for 2003, as no December 2003 figures were available.

Table 5.24 PSM Inventory (Litres)

	31 December 2002	31 April 2003	31 December 2004
Inventory	[redacted]	[redacted]	[redacted]

Change	[redacted]	-[redacted]
Percentage Change	[redacted]%	-[redacted]%

428. The figures do not show any build-up in inventory, as stocks are managed by batch manufacturing. However, as output closely matches sales, the decrease in inventory levels reflects the lower volumes produced and sold.

429. PHARMAC stated in its response to the EFC report that "the statement that a reduction in inventory reflects a reduction in sales is not logical." The Ministry agrees that of itself a reduction in inventory cannot be automatically linked to a reduction in sales and in some cases will be the result of an increase in sales. However, given that PSM's output closely reflects its sales, due to a managed batch manufacture process, lower inventory closely reflects the level of sales PSM intends to make.

430. There is no evidence of an adverse effect on inventories.

Employment and Wages

431. PSM stated that it had to [redacted], with only [redacted] key staff [redacted] employees [redacted] to [redacted] with those awarded in its parent company, API. PSM stated that it is busy for the next six months in its consumer division [redacted] there is [redacted] that [redacted] to [redacted] that is required for [redacted] pharmaceutical plant, [redacted] produce pharmaceuticals including OLP.

432. PSM stated that there has been no change in the numbers employed as a result of the decline in OLP production.

433. The Ministry notes that API is closing one of its Australian manufacturing plants and shifting the manufacturing to PSM's Auckland plant. The impact on the up-take of production time and therefore employment in the liquid manufacturing suites in the pharmaceutical plant is not known by the Ministry, however, it would be reasonable to assume that there will be some positive impact on employment. An article in the Manukau Courier, dated 25 January 2005, estimated that the additional manufacture from API will create 50 more jobs at PSM.

Growth

434. PSM provided the Ministry with its key performance indicators, which it stated commented on its ability to grow. PSM stated that the lack of profit generated by sales of OLP will mean that it is unable to maintain and upgrade the pharmaceutical plant.

435. PSM's total sales are forecast to drop in 2005 from just above NZD[redacted] million in 2004 to just below that amount; a similar small drop is expected in the forecast 2005 gross margin from its 2004 level of NZD[redacted] million. Both of these indicators had shown improvement in 2004 from their 2003 levels. The gross margin affects flow from record low sales. A lower gross margin means that PSM will have less money to invest in maintenance and extensions; both restricting its ability to grow. However, operating profit had a 2003 level of just above NZD[redacted] million, which fell below NZD[redacted] million in 2004 and is forecast to drop further to approximately NZD[redacted] million in 2005. PSM stated that this decrease is directly attributable to the loss of OLP volume.

436. PHARMAC stated that "two points are not a trend" in response to the growth analysis in the EFC report and that "to attribute the total effect on these values to OLP shows a lack of analysis" and "requested that the Ministry carry out a more detailed analysis into the causes of PSM's decreased sales." The Ministry notes that the above comparison involves three years, although one is based upon forecast figures. However, the use of these three years is the best information available and the Ministry has no other information upon which to base any growth analysis. To have more suitable data for a longer period would be ideal, but this has not been provided and would only serve to assist in identifying long-term trends. The Ministry has not attributed these changes either wholly or partially to OLP but has simply recorded the movements. The Ministry notes that it is often difficult for an industry to identify the impact of a single product on growth and that information of this level of detail is not unusual. However, given the broad nature of the information, the conclusions reached using it are always framed in a much less authoritative manner than those based upon detailed product specific information.

437. PSM also provided figures relating to its return on investment that illustrated a decrease of [redacted] percent in 2003 from the previous year and a further [redacted] percent decrease is forecast for 2005. The return on investment is a good indicator of growth as investors are, in most circumstances, unlikely to continue to invest in an entity that is offering declining returns, unless absolute profits are at such a high level that the declining returns are at a level that is still attractive. However, the forecast return on investment is likely to be affected by the transfer of the additional production to PSM from API that has been discussed in paragraph 433.

438. PSM stated that it sees [redacted] OLP [redacted] percent per annum, [redacted] of increasing the [redacted] customers [redacted] OLP.

439. The Ministry concludes that the loss of volume of sales of OLP has resulted in a loss of profits for PSM and has likely had a negative effect on growth, although PSM forecasts [redacted] in the medium term and the transfer of API's Australian business to PSM is also likely to help mitigate any negative impacts upon growth, as the increase in production will reduce the overhead under-recovery PSM is currently experiencing due to the loss of OLP. However, the analysis of injury is an analysis of the effects of changes in OLP and any mitigation of losses or injury at the company level is not relevant in assessing the impact of the loss of OLP volume.

440. PHARMAC stated in its response to the EFC report that PSM's statements in paragraph 434 that it is unable to upgrade and maintain its plant is inconsistent with the fact that API is transferring manufacturing activity to PSM as stated in paragraph 433, which has been "reported as involving equipment upgrades and increase in manufacture…" The Ministry is aware that these two statements are somewhat conflicting. However, the comments on growth were made at the time of the verification visit and the announcement of API's transfer of production to PSM was made some time after that. PSM has commented on the effect of the business from API only orally and very briefly and no written evidence was presented to the Ministry by PSM, therefore the verbal information cannot be relied upon in the Ministry reaching its conclusions. These comments included a statement that some of the OLP lost volume would be replaced but that the pharmaceutical plant still needed the OLP business. In the EFC the Ministry stated that there were no negative impacts upon growth at this stage but it was likely that the loss of OLP has negatively impacted on growth. The Ministry recognises that the extent of that likelihood of future negative impacts on growth caused by the loss of the OLP business, is severely impacted upon by the transfer of the API manufacture to PSM.

Ability to Raise Capital and Investments

441. In assessing investment decisions PSM stated that it does not have any set criteria but that it looks at the following factors; the stage of the lifecycle of the market that the product would be entering and the corresponding potential for market growth; the gross margin contribution that the product would make; the manufacturing fit of the product within both the physical facilities and PSM's core competencies; the capital recovery (payback) period; whether the item has been budgeted for; and the rate of return it would provide and the effect on the share price. PSM stated that all capital expenditure requests must be approved by API.

442. PSM provided figures relating to its return on investment that illustrated a decrease of ▒ percentage points in 2004 compared with 2003. The Ministry considers that this is likely to have a negative effect on PSM's ability to raise capital.

Other Market Factors

443. There are a number of factors, other than the dumping, that need to be considered when discussing whether the injury incurred by PSM can be attributed to the dumping.

444. The most important of these market factors relates to PSM's failure to enter a PHARMAC tender process for the community pharmacy market segment. AFT, Pinewood and PHARMAC have stated that the failure of PSM to enter the tender process under which the sole supply status was awarded is the cause of injury and not the dumped goods. PHARMAC submitted that the Ministry was incorrect in addressing the issue of the PHARMAC tender separately from the other injury matters considered above. The Ministry notes that the injury indicators listed above are rightly analysed separately and then all the injury indicators, including other market factors, are brought together to present an overall view of the injury situation that is faced. The analysis of injury indicators separately, such as import volumes, does not preclude finding that the changes in those indicators are due to changes in other market factors.

445. PHARMAC also submitted that "the event that caused the injury to PSM, namely failing to submit a bid in the tender, occurred prior to [the Irish] OLP being imported into New Zealand or to any alleged dumping…" and "the cause arose even before the alleged dumping." The Ministry rejects such an analysis as it means that a failure to enter a tender would always result in injury to PSM, and as discussed below, there is evidence, some of which has been presented by PHARMAC, to suggest that this is not the case and that in certain circumstances a failure to enter a tender could result in a finding of injury caused by dumped goods.

446. PSM stated that AFT would not have won the tender which gave it sole supply status for the community pharmacy part of the market if its prices were not based on dumped goods. PSM also stated that dumped prices enabled AFT to make a bundled offer in its ACP that would not have been possible without the dumped goods. PHARMAC stated in response to the EFC report that the Ministry should disregard PSM's preceding statements on the basis that they are "…conjecture and have no basis in fact." The Ministry notes that PSM's comments have only been reported as PSM's comments and have not been relied on. PHARMAC also stated that as "AFT's price was higher than the existing [OLP] price so the bundle progressed despite, not because of the price of the 500ml OLP." The Ministry notes that AFT's prices were in fact higher than the existing prices in the market, but to say that the bundle advanced despite this is inconsistent with the nature of a bundled offer. In a bundling situation the group of products are offered at the given prices, which are contingent upon the other prices in the bundle being accepted. This means that PHARMAC is likely to assess the bundle as a whole and the overall price savings it offers, amongst its other decision criteria, rather than individual products.

PHARMAC

447. PHARMAC plays a central role in the New Zealand pharmaceutical market. PHARMAC is responsible for the operation and development of the Pharmaceutical Schedule in which it publishes set subsidy rates (that are paid from government funds) and DHB purchase prices for some pharmaceuticals. In order for a pharmaceutical to be listed in the Pharmaceutical Schedule, a supplier must deal with PHARMAC.

448. Under PHARMAC's crown funding agreement, tendering is one of the methods PHARMAC can use to facilitate the supply of subsidised pharmaceuticals to the New Zealand market. Another method is awarding ACPs which are contracts for supply that are an alternative to a product being tendered.

449. Below is a summary of recent events in the New Zealand OLP market, particularly as it relates to interaction between PSM and PHARMAC, which outlines how the current OLP pharmaceutical listings occurred. PHARMAC stated in response to the EFC report that the timeline "appears to give consideration to a number of irrelevant proceedings and discussions between PSM and PHARMAC." The Ministry notes that the timeline is included in the report as a background tool to allow the reader to comprehend the market activity that is detailed later in the report. Any part of the timeline that is relied upon in reaching the conclusions of this report is discussed in the following paragraphs. PHARMAC commented upon the timeline in its submission dated 24 December 2004.

1997

Pamol was the leading OLP brand in the New Zealand market with a listed subsidy price of around NZD14.00. PSM's Pharmacare was listed at about NZD10.00.

1 June 1998

PSM, through its Pharmacare OLP, was listed in the Pharmaceutical Schedule as preferred supplier for 2 years until 1 June 2000, but the subsidy was able to be claimed for purchases of any of the listed brands.

1 June 1999

Paracare was listed on the Pharmaceutical Schedule as PSM's new OLP brand.

Prior to 9 December 1999

Several brands were listed in the Pharmaceutical Schedule for OLP, including PSM's Paracare, at NZD9.15 for 1000ml. Paracare dominated the dispensary market segment.

9 December 1999

PHARMAC entered into in a "terms of listing" agreement with PSM for a tender protection period for OLP until June 2002 . The listed subsidy price dropped to NZD8.10 per 1000ml which was effective from 1 June 2000. The preferred supplier agreement was ended by the signing of this new agreement.

14 June 2000

Fax from PSM to PHARMAC requesting preferred supplier status for OLP be restored.

14 July 2000

PSM resend fax of 14 June 2000 to PHARMAC in the absence of a response.

14 August 2000

Letter to PHARMAC from PSM draws attention to the unanswered fax of 14 June 2000.

22 August 2000

PHARMAC refuses to grant PSM preferred supplier status for OLP unless PSM relinquishes the tender protection period granted in the 9 December 1999 agreement.

9 October 2001

PHARMAC issues a consultation on tender of certain pharmaceuticals, including OLP, and requests for proposals, with a deadline of 29 October 2001 for receiving any ACPs. PSM believed that OLP was mistakenly included in the consultation given its tender protection period until June 2002. PSM did not check with PHARMAC if OLP's inclusion was a mistake.

20 December 2001

An invitation to tender was issued by PHARMAC for a wide range of products, one of which was OLP. PSM did not enter this tender. PSM did enter this tender for other products.

4 March 2002

The 20 December 2001 tender closed.

June 2002

PHARMAC issues a request for ACPs for the DHB hospital market. This is the first time PHARMAC has run a competitive process for the DHB hospital market, as previously its activities only covered community pharmacies.

30 June 2002

Tender protection period given to PSM by PHARMAC in the 9 December 1999 agreement ends.

July 2002

June 2002 request for ACPs for the DHB hospital market closes.

7 August 2002

PSM increases price of 500ml Paracare OLP from NZD4.05 to NZD5.00 due to increased costs of manufacture effective from 12 August 2002. PSM also advises PHARMAC that price increases may be necessary in the 1000ml presentations as well.

5 November 2002

PSM informs PHARMAC of increased prices to be effective from 12 January 2003 for the 1000ml presentations from NZD8.10 to NZD9.15 for the 120mg strength and to NZD9.35 for the 250mg strength.

November 2002

PHARMAC consults on the provisionally accepted ACP for the DHB hospital market segment from AFT. It is a bundled offer which includes OLP.

7 November 2002

PSM responds to PHARMAC's consultation on AFT's ACP to supply 500ml OLP to the DHB hospital dispensary market segment for NZD5.50 for 120mg strength OLP and NZD5.60 for 250mg strength, stating that the prices offered by AFT are more expensive than PSM's current subsidy level of NZD5.00 for both 500ml strengths.

End November 2002

PHARMAC Board approve AFT's provisionally accepted ACP subject to MedSafe registration.

19 December 2002

PSM sends fax confirming Paracare price increases for 1000ml OLP notified on 5 November 2002 will take effect from 12 January 2003.

20 December 2002

AFT was confirmed as supplier to the DHB hospital market segment (Section H of the Pharmaceutical Schedule) through PHARMAC's notification of its acceptance of the ACP from AFT. Parapaed's listing was still subject to MedSafe approval with the new listing in the Pharmaceutical Schedule and corresponding decrease in subsidy price taking effect from a date to be notified upon Parapaed's registration and the hospital supply status would come into effect three months after Parapaed's listing in Section H of the Pharmaceutical Schedule.

17 January 2003

PHARMAC writes to PSM over the intended price increases for the 1000ml OLP stating that the notified price increases are in breach of its contract and that PHARMAC will take action accordingly.

3 February 2003

PSM sends a fax to PHARMAC in response to its letter of 17 January 2003 and restates that the price increases will take effect.

11 February 2003

PHARMAC writes to PSM rejecting the price increases for the 1000ml product.

17 February 2003

Russell McVeagh writes to PHARMAC on PSM's behalf.

30 April 2003

Mediation occurs between PHARMAC and PSM.

1 May 2003

Terms of listing of OLP, a listing contract, is given to PSM with price increases on 1000ml presentations from NZD8.10 to NZD8.75 for 120mg strength and from NZD8.10 to NZD8.90 for 250mg strength to take effect from 1 July 2003. This includes a prohibition on any price increase for OLP until 1 October 2003 after which point six months notice must be given. The terms of listing replace the 9 December 1999 agreement between PSM and PHARMAC.

5 May 2003

PSM signs the terms of listing offered by PHARMAC of 1 May 2003.

12 June 2003

Price increases for the 1000ml need to be effective in the market from this date in order for the increased subsidy to take effect 1 July 2003.

1 July 2003

Price increases on 1000ml presentations from NZD8.10 to NZD8.75 for 120mg strength and from NZD8.10 to NZD8.90 for 250mg strength take effect.

31 July 2003

Notification of results from the invitation to tender dated 20 December 2001 include naming Parapaed with sole supply status for OLP for community pharmacies. Listing is to occur on 1 September 2003, subsidy price changes to take effect 1 November 2003 and sole supply status to commence 1 February 2004. OLP subsidy levels for the 1000ml presentations reduce from NZD8.75 to NZD7.29 for 120mg and from NZD8.90 to NZD7.70 for 250mg.

1 September 2003

Listing of Parapaed OLP in the Pharmaceutical Schedule to occur.

1 November 2003

Listed subsidy levels prices in the Pharmaceutical Schedule were changed to NZD7.29 for 120mg and NZD7.70 for 250mg 1000ml presentations for community pharmacies.

1 February 2004

Sole supply for the OLP dispensary market commenced with Paracare only able to be sold subject to discretionary variance purchases in the DHB hospital market segment and the private market i.e. non-subsidised sales to the community pharmacy segment.

23 September 2004

Consultation on proposed tender issued by PHARMAC, which includes OLP with an estimated date of late December 2004 for the invitation to tender to be released and 15 October 2004 as a closing date for ACPs. Schedule 3 of the consultation lists products that currently have hospital supply status in section H of the Pharmaceutical Schedule, which includes OLP, that PHARMAC is considering offering an additional 12 months hospital supply status. Responses in regard to Schedule 3 of the consultation were due by the end of September 2004 with notification of decisions to occur in December 2004.

23 December 2004

PHARMAC invitation to tender issued. OLP was included in the products for tender, for both the DHB hospital and community pharmacy markets, meaning that OLP is not included in any ACP PHARMAC has accepted. This is the first time that both the DHB hospital and community pharmacy portions of the dispensary market have been tendered at the same time. The invitation to tender indicates that sole supply and hospital supply may be awarded. The proposed discretionary variance for the DHB hospital portion of the market has reduced from 20 percent to 1 percent. Tender bids must be submitted by 28 February 2005.

28 February 2005

Tender bids for the invitation to tender dated 23 December 2004 closed. Winning tender bids are expected to be announced from April 2005 onwards.

Current OLP Market

450. PHARMAC issued a tender for the sole supply of OLP to the community pharmacy segment in December 2001. The tender was won by AFT with imported OLP. This means AFT's OLP brand is subsidised when on prescription to the customer with only (the prescription charge, and any manufacturer's surcharge, after hours service fee or special packaging fee, collectively referred to as) the co-payment, being paid by the patient and pharmacies cannot claim the subsidy when dispensing any other OLP brand. PSM did not enter the tender. All interested parties to the investigation, other than PSM, argue that this failure to enter a tender bid and not any dumping of the Irish OLP is the cause of injury to PSM.

451. In June 2002, PHARMAC called for ACPs for pharmaceuticals to be supplied to the DHB hospital segment. An ACP allows suppliers to bundle pharmaceuticals offering a combined price for two or more products. PHARMAC negotiated prices for sales of OLP to DHB hospitals by entering into an agreement with AFT, effectively allocating AFT 80 percent of the DHB hospital segment. This means DHB hospitals may only purchase 20 percent of their OLP requirements from other listed suppliers.

452. PSM responded to PHARMAC's consultation of the proposed acceptance of the ACP from AFT by pointing out that PSM's price was lower than the prices PHARMAC was proposing to accept. PSM stated that it did not receive a response from PHARMAC and noted that the ACP probably provided overall cost savings, in addition to making new pharmaceuticals available to PHARMAC.

453. The Irish OLP was not sold in the New Zealand market prior to the tender being awarded and required MedSafe registration prior to being listed in the Pharmaceutical Schedule and being sold in New Zealand. The Irish OLP gained MedSafe registration in May 2003 and was first sold in the New Zealand market in August 2003.

454. It is possible for a prescription for OLP to be filled with a non-subsidised product, that is a non-Parapaed brand, however the patient will then bear the full cost of the product, and as a result this is not a common practice.

455. Under PHARMAC agreements a pharmacist can still dispense Paracare, or any other brand of OLP, if the customer is prepared to pay full price for it and the pharmacist does not claim the subsidy for filling that prescription. PSM stated that because the flavour of its 120mg OLP and that its OLP does not contain alcohol some private hospitals and rest homes are still purchasing Paracare, despite Parapaed being subsidised.

456. Several parties to the investigation stated that [redacted] Paracare OLP [redacted].

457. The expiry date for the current listings for OLP in PHARMAC's Pharmaceutical Schedule is 30 June 2005 and tender bids for the invitation to tender currently in the market closed on 28 February 2005. This invitation to tender includes sole supply in both the community pharmacy and DHB hospital segments, so it covers the entire

dispensary portion of the market, with a proposed one percent remaining available to all suppliers under the DHB hospitals discretionary variance.

458. All brands are able to be sold into the OTC segment of the market, which includes sales to private hospitals and rest homes.

PSM's Decision Not to Enter the Tender

459. PSM gave a number of reasons why it did not enter the 2001 tender for the community pharmacy segment tender, which have been summarised below.

460. PSM, in consultation with PHARMAC, had improved its OLP product for the New Zealand market. PSM was mindful of the struggle that it had been through with market acceptance of its OLP flavour and thought that any alternative formulation not currently registered would need to go through the same process in order for PHARMAC to accept it. PHARMAC stated in its response to the EFC report that "[t]hese assumptions made by PSM have no basis and are not supported by any PHARMAC correspondence or documents." The Ministry accepts that PHARMAC does not believe it had assisted PSM in this manner, but also that PSM stated it believed it had consulted with PHARMAC over improvements in its formula and that the Ministry is only noting PSM's comments.

461. PSM had previously held PHARMAC "preferred supplier" status for a two years prior to 2000. PSM claims its OLP was highly accepted, although it was not the leading brand.

462. PSM's OLP was competitive at NZD8.10 for 1000ml, which was well below the prices of the only two other competitors at that time, Pamol at NZD14.80 and Panadol at NZD18.95 for the same volume. PSM stated that it looked at what its competitors were doing in the Australian market and their prices to PHARMAC and thought it was unlikely that either of these brands would be prepared to drop their prices below that of Paracare. PSM did not believe that sole supply status would be awarded for OLP, as its price was already very competitive, and that it could continue to supply OLP to the dispensary market without being subject to the onerous conditions of a sole supply contract. PHARMAC stated in response to the EFC report that price is only one of the reasons that it may award sole supply and that "the other main reason is to secure supply of the product."

463. The Ministry has asked PHARMAC if tender bids were submitted for OLP involving the Pamol and Panadol brands in response to the 2001 invitation to tender. PHARMAC has not responded to this question, amongst other questions, or indicated if any other tender bids (other than AFT's) were submitted for OLP stating as an overall reason that the compilation of answers to the Ministry's questions would have taken a substantive amount of time and that as they relate to PSM's decision not to enter the tender that PHARMAC does not see the answers as matters that are relevant to the investigation. PHARMAC also has since stated that it considers information on the number of tender bids it receives is commercially sensitive and is unable to be provided to the Ministry, despite the Ministry assuring PHARMAC that such information would be treated as confidential. The reasons for requesting this information are detailed later at paragraph 582.

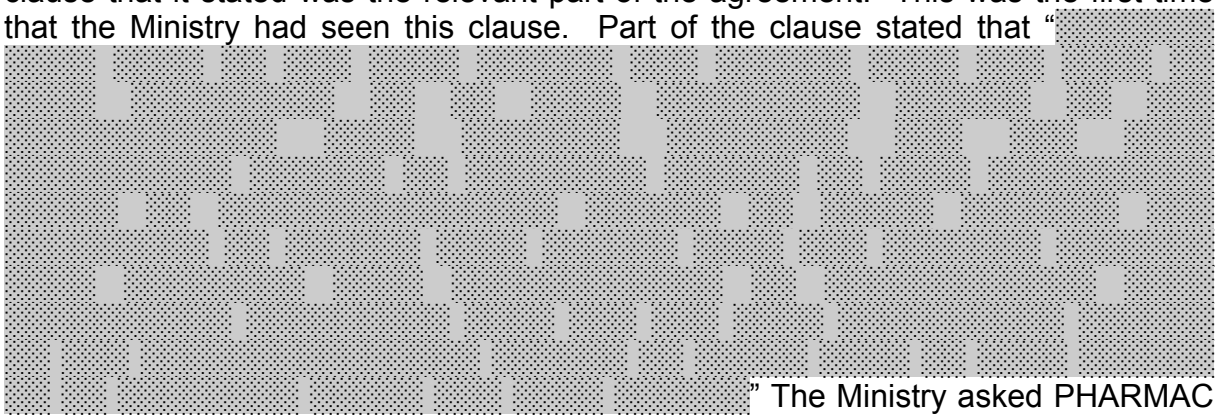
464. The Ministry considered in the EFC from information available at the time, that it was unlikely either of these other brands entered a tender bid for OLP. PHARMAC stated in its response to the EFC report that it was unreasonable that the Ministry make an assumption that no other brands would have entered a tender bid and that "[t]he Ministry has no way of knowing, without approaching these parties, who bid in the tender."

465. The Ministry is cautious in the circumstances in which it seeks information that is not publicly available from parties outside of an investigation, as it has the potential to upset market behaviour and can create commercial problems for some or all of the interested parties to an investigation. However, in this case given the importance of this matter and PHARMAC's refusal or inability to supply any information on other tender bids for OLP, the Ministry approached Pfizer and GSK, the two other known OLP suppliers at the time of the 2001 tender, asking whether they entered a tender bid for the 2001 tender. The Ministry received a response from Pfizer New Zealand that stated it [redacted]. The Ministry did not receive any response from GlaxoSmithKline New Zealand. The Ministry is aware that there is a possibility that another non-registered supplier entered a tender bid for OLP in the 2001 tender, but in the absence of information from PHARMAC, can only use the resources publicly available to it, such as MedSafe registration, to say that the risk of an unregistered supplier submitting a tender bid was unlikely to have been an obvious one.

466. The Ministry notes its comments in paragraph 56 on using the best information available. PHARMAC stated in response to the EFC report "PHARMAC has a strict policy of not releasing information on the identity of tender participants or the extent of bidding for specific items included in a tender." The Ministry notes that this answers why some of the questions cannot be answered but not all of them. Regardless of the reasons why PHARMAC was unable to fully respond, the Ministry is in a situation where it must draw conclusions from limited information. PHARMAC also stated that the Ministry failed to indicate the reasons that it was asking these questions of PHARMAC. Documents numbered 370 and 376 on the public file for this investigation specifically indicate that the questions relate to the assessment of other causes of injury and PSM's decision not to enter a tender bid. This is in addition to explanations of why the information was required during conversations with PHARMAC. The Ministry also gave PHARMAC the additional opportunity to provide responses to its questions after receiving PHARMAC's submission on the EFC report.

467. PSM's volume of sales of OLP was increasing, particularly for its junior OLP after it developed a strawberry flavour. PSM stated its OTC market share increased [redacted] percent in 2003, in support of its statement that its OLP had good market acceptance.

468. PSM believed that its tender protection agreement with PHARMAC guaranteed that PHARMAC would not tender OLP until after June 2002 and considered the inclusion of OLP in the tender documentation in December 2001 was a mistake. PSM also thought that, under the tender protection agreement and PHARMAC's operating policies and procedures, PHARMAC would consult with PSM before making any decision relating to OLP that would materially affect PSM's listing on the Pharmaceutical Schedule. PSM seems to have understood this to be individual consultation. PHARMAC stated that PSM had no basis for considering that any consultation would be individual. PHARMAC stated in response to the EFC report that its agreement with PSM explicitly stated that it could "enter into sole supply arrangements with other suppliers, provided that supply does not commence until after 30 June 2002." The Ministry notes that PHARMAC's statement that PSM was aware PHARMAC was able to enter into or negotiate arrangements for sole supply with other suppliers provided that supply commenced after 30 June 2002 is inconsistent with a statement made by PHARMAC in a letter dated 22 August 2000 to PSM. The letter states "…PHARMAC has agreed not to tender paracetamol suspensions before 1 July 2002." The Ministry considers that the language used in PHARMAC's letter seems to indicate that OLP would not be tendered, rather than any alternative supply arrangements entered into. However, the letter must be read in conjunction with the relevant contractual term.

469. PHARMAC, in its response to the EFC report supplied the Ministry with the clause that it stated was the relevant part of the agreement. This was the first time that the Ministry had seen this clause. Part of the clause stated that "  " The Ministry asked PHARMAC for a full copy of the agreement from which the clause came and understood that the 9 December 1999 agreement (of which the Ministry only had pages two to eleven) was the establishing agreement for the tender protection period (as indicated in the timeline following paragraph 449). PSM confirmed that the clause was part of the Agreement and provided the Ministry with a full copy of the agreement.

470. The 2001 invitation to tender was the first time that OLP had been included in a tender. PSM considered that a tender would not be awarded by PHARMAC as it considered PHARMAC does not award tenders most of the time and its price of OLP was already very competitive. PHARMAC has confirmed that on average it only awards supply for 20 to 25 percent of products tendered. PHARMAC stated in response to the EFC report that the above statement was misleading as "this figure does not account for the large number of products PHARMAC tenders and does not receive a bid for. PSM stated that PHARMAC does not award tenders most of the time, which is consistent with the figures provided by PHARMAC. The Ministry is not aware of whether PSM considered that other tender bids would have been received but not accepted, or that no other tender bids would have been received. PHARMAC

further submitted that "[l]arger markets with a number of manufacturers internationally are more attractive to suppliers and therefore more likely to attract tender bids. OLP is a market that fits this description…" PHARMAC did not provide the Ministry with any information on the relative size of the global OLP market or any other information to support this statement. The Ministry notes that paracetamol is a well known pain killer and is supplied by many manufacturers but that information received from several parties in the investigation indicates that globally there is greater supply of hard medicines such as tablets, rather than liquid medicines such as OLP. The Ministry requested information from PHARMAC following the EFC on the average number of pharmaceuticals that bids are received for but no sole supply awarded. PHARMAC did not respond to this request. As PHARMAC has a policy of not stating whether any tenders were received or not, or the number that were received, the Ministry considers that the important percentage from a supplier's point of view is the number that are not awarded as suppliers do not know if any bids were received (other than any they may have entered).

471. PSM considered that the conditions of PHARMAC's agreements were onerous. PSM gave the example that there is no protection for the supplier from *force majeure*, which PSM had suffered from in the past with its Paradex listing in 2001, when an earthquake affected its raw material supplier in India. PSM stated that it did find an alternative supplier but that it was at a higher cost and PHARMAC would not make any allowance for this. PSM felt that the interaction it had with PHARMAC over Paradex with PHARMAC's reluctance to accept force majeure exceptions, cost contributions, or advance notice illustrated that it did not want to work with manufacturers, even when they were acting in good faith.

472. PSM also considered the penalties for out-of-stock situations in PHARMAC agreements were onerous especially for a seasonal product like OLP. PSM stated that if any one participant in the distribution chain ran out of stock, even for a few days and even if stock was available elsewhere, this was still considered to be an out-of-stock situation, where PHARMAC may impose penalties. PSM stated that in order to be consistent with this clause every participant at every level of the market needs to have, or have access to, stock. PSM believes this is unrealistic and goes well beyond ensuring customers or patients have access to the pharmaceutical. PHARMAC in its response to the EFC stated that it had made "significant comment" on the tender agreement and was "disappointed that this comment has been entirely neglected in the [r]eport." The Ministry notes that the above comments from PSM relate to reasons it gave for why it did not enter the tender and are not advanced as statements of fact. The Ministry notes that it is clear from PHARMAC agreements that the amounts it can recover for out-of-stock situations are related to cost recovery, although defined broadly, and does not carry any punitive amount specifically stating "the amounts referred to as liquidated damages are not intended to include any penalty element…" PSM's above comment relates to the amounts that are able to be recovered under the out-of-stock provisions in PHARMAC's agreements that PSM perceives as penalties.

473. Another factor that PSM considered onerous was the clause relating to advertising, stating that with sole supply status you cannot actively promote the product in the dispensary market. PSM feels that it must promote its products as PHARMAC, presumably, has no inclination to grow the market. PHARMAC stated in response to the EFC report that PSM's view is based upon a misinterpretation of the

contractual terms. (The Ministry noted at paragraph 111 of PSM's verification report that this appeared to be a misinterpretation of the contract.)

474. PSM stated that the litigation support clause could also prove to be costly as PHARMAC could be the initiator of proceedings and still impose huge costs upon the contract partner. PSM stated that it feels PHARMAC is not hesitant in commencing litigation and that the risk of the cost of litigation support being placed on a contracting party by PHARMAC is not low. PHARMAC stated in response to the EFC report that it felt the Ministry could have easily checked the above statement by looking at the wording of the clause. The Ministry notes that the above statement is merely recording PSM's views and as stated in paragraph 27 it is the view of PSM not the Ministry. The clause does only relate to proceedings which are issued against PHARMAC or to which PHARMAC is made third party and the Ministry notes that PSM's interpretation is incorrect.

475. PSM stated there was also a general "uncertainty" in PHARMAC contracts, such as PHARMAC, *inter alia,* being able to change guidelines or restrictions, change reference pricing and therefore subsidy levels immediately, de-list pharmaceuticals and part or all of therapeutic groups and sub-groups, and amend the basis on which pharmaceuticals are classified unilaterally, although PHARMAC could consult prior to making changes if it wished. PHARMAC stated that it "has to reserve some ability to make changes because pharmaceuticals carry some risks for people's health". The Ministry realises that there are very real reasons that PHARMAC needs to maintain flexibility in its agreements, but that PSM views it as creating an environment of uncertainty. PHARMAC stated that the degree of uncertainty is mitigated by the limited circumstances in which PHARMAC can invoke the clauses that PSM claims cause this uncertainty, which largely relate to public health concerns. PHARMAC also stated that it meets its public law obligations in using these clauses.

476. PHARMAC indicated in response to the EFC that PSM has also submitted a tender for aqueous cream in response to the December 2001 invitation to tender. PSM had not indicated specifically that it entered a tender bid for aqueous cream in the 2001 tender but had commented on losing the aqueous cream. PSM subsequently stated that it placed a tender bid for aqueous cream in the 2001 tender (in which it did not enter a bid for OLP), as it had lost aqueous cream to Multichem in the previous tender. PSM stated that it was "reluctant to tender for aqueous cream for the same reasons surrounding the OLP tender. However, having lost business in 1999 and knowing that it was a bone fide tender, PSM reluctantly put forward a price." PSM also stated that the market for aqueous cream is quite distinct from OLP in that the product is relatively straight forward to manufacture and is not characterised by a heavy consumer need for taste and alcohol free formulations. PSM's reasoning seems to rely on: its belief that OLP was mistakenly included in the tender document; that PSM at the time had most of the dispensary market segment business; and it believed market acceptance of a new formulation was a reasonable barrier to entry.

477. There were no new entrant suppliers of OLP registered in the New Zealand market (or any going through the MedSafe registration process), other than those already listed in the Pharmaceutical Schedule with whom PSM was competing prior to the tender for OLP. PHARMAC noted in response to the EFC report that tender bids may be submitted in relation to unregistered pharmaceuticals.

478. PSM stated that when they made the decision not to enter a tender bid it did [redacted] and [redacted] OLP [redacted] its [redacted] Since the listing of Parapaed as sole supplier PSM has undertaken an analysis of the overhead under-recovery caused by the loss of the OLP volumes.

479. The Ministry emphasises that the 2001 tender relates only to the community pharmacy portion of the dispensary market and does not relate to the OTC or DHB hospital portions of the market.

480. The Ministry agrees with PHARMAC's statements that PSM's misinterpretation of PHARMAC contracts is part of the basis for its decision not to enter the tender and noted in the PSM verification report at paragraph 100 that this was the case. However, the Ministry notes that AFT also stated that some of the terms in the PHARMAC contracts could be perceived as onerous, particularly the lack of a force majeure provision. PHARMAC stated in response to the EFC report that an example of the bias illustrated towards PSM by the Ministry was the Ministry's acceptance of PSM's belief that the contract terms were onerous. However, as indicated at paragraph 27 the Ministry merely reported PSM's statements in this regard and does not necessarily agree with them. LECG submitted that "...clearly [PSM's] assessment [of the contractual terms] affected their willingness to supply OLP to PHARMAC."

481. PHARMAC stated in its submission to the EFC report that because some of the above reasons given by PSM were based on misunderstandings of its contractual terms that the "Ministry's assumption that PSM had "substantive reasons" for not participating in the tender or ACP is shown…to be baseless." The Ministry notes that not all of the above statements are covered by incorrect interpretation of the contract clauses, namely: that there were not other registered OLP products in the market, other than PSM's two existing competitors; PSM's product was priced well below the other two competitors; that only 20 to 25 percent of all lines tendered are awarded sole supply status; and the lack of a force majeure clause in the contract. The Ministry considers that these reasons alone are substantive reasons for not entering a tender and combined with the other genuinely if mistakenly held beliefs of PSM at the time were the reason that PSM did not enter the tender. The Ministry wishes to make it clear that in stating PSM had substantive reasons for not entering the tender it is not justifying or promoting its business decision not to enter the tender as the correct one, merely coming to a conclusion that it had a substantive basis for making such a decision.

482. The LECG submission on the EFC report posed that PSM's decision not to enter the tender "…may have been strategically motivated. It may have decided not to participate and rather take a dumping action" this was offered as a means of raising the price PSM could achieve in future tenders. The Ministry considers that, while the decision not to tender was obviously a business decision, it is highly unlikely that any business would make a decision not to enter a tender for the reason of making a dumping investigation application. The reasons that this is unlikely include the costs and time involved in preparing an application and participating in the investigation process. Also there is the uncertainty of the outcome as there is no guarantee that an investigation will be initiated or that dumping, injury and/or causal

link will be found and duties imposed. The fact that PSM was unaware of the Irish OLP entering the New Zealand market means that a decision to make a dumping application is improbable. LECG submits that "[t]o award dumping duties for alleged harm despite PSM's failure to participate…reward such behaviour. It may also open floodgates to other marginal participants in the industry taking dumping action." The Ministry considers for the reasons of uncertainty surrounding the commencement and success of a dumping investigation discussed above that this is an unlikely probability. This likelihood of the "floodgates" being opening is also constrained by the small amount of pharmaceutical manufacture in New Zealand.

PSM's Decision Not to Enter an ACP

483. PSM did not submit an ACP in response to PHARMAC's consultation to tender dated 9 October 2001, involving the DHB hospital segment. PSM stated that its decision not to enter an ACP for the DHB hospital segment consultation was for many of the same reasons that existed for not submitting a tender bid but also involved other considerations.

484. Pinewood and AFT referred to PSM's failure to enter a tender bid and have not commented on PSM's decision not to enter an ACP. PHARMAC did provide a comment that PSM's decision not to enter an ACP did constitute a failure on PSM's behalf but did not focus on this to the same extent as the tender. In the EFC report the Ministry stated that this indicates that the decision not to enter an ACP is not seen as at the same level as failing to enter a tender bid and noted comments made by several interested parties to the investigation that ACPs are primarily used for the introduction of new brands or products to the Pharmaceutical Schedule. PHARMAC responded to this comment stating that the decision not to enter an ACP "was a poor commercial decision, but had nothing to do with dumping" and that "the extent to which PHARMAC focused on PSM's failure to enter an ACP does not indicate that PHARMAC sees the failure on any different 'level' as PSM's failure to enter a tender bid."

485. PSM stated that it did not respond to PHARMAC based on its past experience both with Paradex (see paragraph 471) and the general lack of response to correspondence. PSM stated that most suppliers do not respond to consultation to tender documents put out by PHARMAC and most responses are likely to be submitted by community pharmacies, which PHARMAC will consider, as pharmacies appear to have less of a vested interest in the success of any particular pharmaceutical and are more likely to comment only on clinical effects in the tender process. PSM also stated that PHARMAC tends to only respond to submissions on consultations that benefit it and the rest are ignored. PHARMAC stated in its response to the EFC report that it "does not respond to consultation as a matter of course" and that it "can only be aware of issues that are raised".

486. PSM stated that ACPs are reasonably common and once they are provisionally accepted they are usually finally accepted. PSM feels that suppliers and manufacturers are limited in their ability to submit an ACP to new pharmaceuticals because if PHARMAC proposes a three year sole supply period for an existing pharmaceutical it is not seeking anything else. PSM has stated that it has submitted an ACP for another product but it was not accepted.

487. PHARMAC has said that "the number of ACP … varies from year to year, however PHARMAC normally receives more than one, and has received more than 10 in some years", but did not indicate how many are normally accepted. This means that based upon there being approximately 45 suppliers in the New Zealand market that only between 2 and 24 percent of suppliers enter an ACP for any given consultation. PHARMAC responded to the EFC report by stating that it "was not asked how many ACP[s] are normally accepted." The Ministry notes that PHARMAC is correct that it was asked about how many ACPs were received, not accepted, as it is the decision not to enter an ACP that is under assessment, not the award of an ACP. PHARMAC stated that it was unsure why the second sentence of this paragraph was included in the report. The statement in question goes to illustrating that the majority of suppliers do not enter an ACP in response to each request for ACPs that PHARMAC issues, which goes towards assessing PSM's failure to enter an ACP.

488. PSM responded to PHARMAC's consultation on its intention to accept the ACP from AFT, stating that its price in the DHB hospital segment was NZD5.00 for both strengths of OLP and PHARMAC was proposing to accept a higher price from AFT at NZD5.50 and NZD5.60 for the two differing strengths. PSM stated that PHARMAC did not respond to this correspondence.

PHARMAC'S Comments

489. PHARMAC stated that PSM has not been injured by the dumped goods but was in fact injured by its failure to participate in a competitive tender process. PHARMAC further submitted in response to the EFC report "while PSM's prices may have been low [prior to the tender] in comparison to the existing market prices, there was nothing stopping other suppliers in the New Zealand market lowering their prices to seek to obtain sole supply status or new suppliers entering the market to take advantage of the opportunity."

490. PHARMAC stated that its processes, including those for its competitive tender and ACPs, are fair and transparent where all suppliers have the opportunity to compete for supply. PHARMAC believes that its publicly available operating policies and procedures are "well known and understood by suppliers" and that its use of a standard invitation to tender each year, with minor improvements evolving over time, furthers the predictability and comprehension of the process. PSM has also stated that PHARMAC is clear, consistent and transparent in the way that it operates, although that PHARMAC often does not respond to correspondence but it believes this is a resource issue. PHARMAC responded to the EFC report stating that it "does not accept its contracts are 'onerous'". PHARMAC reasons that as most suppliers have entered into tender contracts with it that its contracts being onerous is untenable. The Ministry notes as outlined at paragraph 480 that AFT has agreed some of the contractual terms could be described as onerous. In addition the Ministry notes that PHARMAC is a monopsony and suppliers do not have any equal alternative to entering into contracts other than with PHARMAC. The Ministry is not stating that PHARMAC's contracts are onerous or questioning the wisdom of the terms and the certainty they provide to patients and PHARMAC, but rather that some of the contracts contents are viewed as onerous by suppliers and given PHARMAC's role in the market that suppliers do not have any real alternatives, of the same level, to entering PHARMAC tenders.

491. PHARMAC included a comment on the EFC report that "PHARMAC also considers that its tender contracts offer significant benefit to suppliers, as it secures access to significant and predictable sales for a period of three years. It also reduces a supplier's need to market its product to gain market share." The Ministry is not disputing the fact that benefits accrue to suppliers from the sole and hospital supply status, although the extent of the benefit from these contracts will vary from supplier to supplier depending upon their market perceptions and situation at the time.

492. PHARMAC stated that while price is a determinative factor in assessing a tender bid there are also other matters taken into consideration. In deciding whether to award a tender, PHARMAC's tender evaluation committee has sole discretion to take into account a number of criteria which include, *inter alia,* the supplier's: financial resources; management and technical skills; existing supply commitments; previous supply performance; proposed supply and distribution arrangements; pack size; price; the continued availability of the product throughout the transitional and sole supply period; amount and timing of savings; and market approval of the brand, or likelihood of gaining all necessary consents.

493. PHARMAC stated in its submission that "[e]ven in the event PSM had placed a bid in the tender process or submitted a proposal in the ACP process, and had offered a price below that offered by AFT, [redacted]… [as] PHARMAC would have taken into account a number of areas of concern it had with PSM at the time as part of its assessment of PSM's bid or proposal." Further PHARMAC has stated that "PSM on a number of occasions failed to supply products under contract, and had a history of breaching agreements with PHARMAC". PHARMAC stated that it had experienced "significant difficulty with PSM's supply of OLP." PSM responded to this by stating that "[i]t is important to note that PSM has never been out of stock for OLP."

494. The Ministry asked PHARMAC to provide it with details of PSM's OLP supply failures. PHARMAC responded that PSM had breached several of its contracts with PHARMAC by attempting to achieve price increases for OLP, aspirin, methadone oral liquids, codeine phosphate, pholcodine and fluoride tablets between 2001 and 2003.

495. The supply failures specific to OLP that PHARMAC outlined were that PSM breached its agreement with PHARMAC by increasing its prices for 1000ml presentation from 1 January 2003. The attempted price increase was 13 percent for the 120mg strength and 15 percent for the 250mg strength. PHARMAC stated that PSM had about 90 percent of the subsidised community pharmacy market and that the price increases would have cost around NZD200,000 per annum. (Ultimately, after mediation with PHARMAC, price increases of 8 percent for the 120mg strength and 10 percent for the 250mg strength were achieved.) PHARMAC stated that this attempt by PSM to increase prices "…resulted in patients paying a surcharge on prescriptions of OLP for up to 5 months while the dispute continued. The cost to patients is higher than the difference between the subsidy and the price, due to pharmacy mark-ups patients typically pay 1.5 to 2 times the difference between the subsidy and the ex-manufacturer price in addition to the usual co-payment."

496. PHARMAC stated "[g]iven PSM's track record for non-supply, and lack of regard for the terms set out in agreements, PHARMAC would be very reluctant to enter into future agreements where a viable alternative existed, especially, but not exclusively, where the alternative was more competitively priced. PHARMAC considers that contracting with PSM involves an additional risk to contracting with most other suppliers, being that the contract has a reasonable likelihood of being breached." The Ministry considers that it is not the possibility of PSM's failure to supply that is really the concern for PHARMAC but rather the propensity of PSM to seek price increases for products which it has agreements for with PHARMAC. The possibility of price increases is definitely a relevant consideration that would be taken into account when assessing price and other benefits as outlined in (c) and (i) in PHARMAC's matters for evaluation set out below.

497. The December 2001 invitation to tender issued by PHARMAC listed the following as the matters that would be taken into account in evaluating tender bids.

> **5.2 Matters for evaluation**
>
> The matters to be taken into account by the Evaluation Committee, the weight to be attached to them, and the basis on which it will evaluate Tender Bids, are all to be determined by the Evaluation Committee in its sole discretion. The matters taken into account by the Evaluation Committee will, however, include:
>
> (a) your ability to ensure continued availability of the Tender Item throughout the Sole Supply Period and/or Hospital Supply Status Period and each of the Transition Periods, as applicable, taking into account each of the following separate points:
>
> (i) your financial resources;
>
> (ii) your management and technical skills;
>
> (iii) your, or your supplier's, existing supply commitments;
>
> (iv) your, or your supplier's, previous supply performance;
>
> (v) your quality assurance processes, where applicable;
>
> (vi) the site of manufacture and packaging of the Pharmaceutical, and site of manufacture of the active ingredient;
>
> (vii) your proposed distribution and supply arrangements for the Tender Item; and
>
> (viii) your approximate lead times for both initial and ongoing supply;
>
> (b) the pack size of the Tender Item and the type of packaging;
>
> (c) the price of the Tender Item (including the price in a Permitted Currency if a Foreign Exchange Bid is submitted);
>
> (d) the amount and timing of savings, including non-pharmaceutical savings accruing to the Funder or PHARMAC during the Hospital Supply Status Period and/or the Second Transition Period and the Sole Supply Period, as applicable;
>
> (e) either:
>
> (i) evidence that you have obtained, and still have, market approval for your brand of

the Tender Item, and all necessary Consents; or

(ii) evidence that will enable the Evaluation Committee to form a view on the likelihood and timing of your brand of the Tender Item gaining all necessary Consents;

(f) whether your brand of the Tender Item has [Interchangeable multi-source medicines] IMM status, or is likely to gain IMM status;

(g) the name and location of the manufacturer of the finished product and active ingredients of the Tender Item;

(h) for a Hospital Tender Bid, your drug and interaction support services; and

(i) any other benefits to the Funder of selecting you as the supplier of the Tender Item.

498. The Ministry notes that PHARMAC has since awarded sole supply, under a tender, to PSM for paracetamol suppositories and therefore does not believe that PHARMAC's concerns would have necessarily prevented PSM from being awarded sole supply. In response to the EFC report AFT stated that the Ministry has come to an illogical conclusion because suppositories are a special case in that they are difficult to transport and melt easily when exposed to heat and do not suit transport from another country, so makes the example of PHARMAC being prepared to award a tender to PSM based on suppositories illogical. PHARMAC responded to the EFC report by stating that the situation for suppositories and OLP cannot be compared as the markets are significantly different. PHARMAC stated that "[t]he suppository market is a significantly smaller market than the OLP market, and the risks associated with non-supply are significantly lower because it affects fewer patients and there are more alternatives. Therefore, there is reasonable cause to believe that there would be a difference in the weighting of the tender evaluation criteria for the two markets." Volume information provided in PHARMAC's tender documentation supports its statement that the market size for suppositories is much smaller than that for OLP.

499. However, as PHARMAC has not provided any information on how it applies the decision criteria the Ministry is not in a position to assess the above statement and notes that (a)(iv) of the decision criteria appears to refer to a supplier's entire supply history, although this of course would be considered in relation to the relevant pharmaceutical. The Ministry agrees that the total market volume for paracetamol suppositories is much smaller than that for OLP. However, paracetamol suppositories are primarily used when patients are unable to take paracetamol orally, as paracetamol cannot be administered intravenously and is generally seen as the last resort form of administering paracetamol. Any risk of running out of product would affect less people but there would be no alternative form of administering paracetamol and an alternative pain killer would need to be administered. As PHARMAC's details of PSM's supply failures mainly relate to price increases the impact of any price increases would be more limited with paracetamol suppositories smaller volumes, than for OLP with larger volumes.

500. PHARMAC has also stated that regard must be had to the below cost prohibition in its agreements and the ability of PSM to supply OLP below the AFT

price without breaching the below cost clause in the agreement. PHARMAC explained to the Ministry that the below cost prohibition does not allow any amount for profit. The Ministry notes that any comparison that occurs regarding the ability of PSM to compete with AFT's prices without breaching the below cost warranty needs to be a comparison with AFT's non-dumped prices.

501. The Ministry notes, however that PHARMAC has awarded sole supply status to PSM for at least one other product in subsequent tenders and does not believe that any previous supply problems would have necessarily prevented PSM being awarded sole supply status in respect of OLP. PHARMAC stated in response to the EFC that the Ministry was incorrect in assuming this and that it was another example of the bias illustrated by the Ministry. The Ministry notes that it did not reject the argument put forward by PHARMAC but that the award of a sole supply tender to PSM after the award of the OLP tender, indicates that PHARMAC is willing to provide PSM with sole supply status in some circumstances. PHARMAC stated that the Ministry "is not in a situation to be able to assess this" and later provided additional information on the supply failures as outlined in paragraph 494. The Ministry notes that with one exception that is unrelated to OLP, all of the supply failures PHARMAC detailed were not evidence of failure to supply stock, but rather the breach of agreements and attempts to increase prices.

502. PSM responded to PHARMAC's submission on the EFC report stating that the supply failures were incorrectly represented and that it had never been out of stock of OLP. PSM also pointed to the sole supply status it has since been awarded for paracetamol suppositories and codeine phosphate tablets. PSM also submitted that PHARMAC would have supplied the same decision criteria to the decision to award sole supply for paracetamol suppositories and codeine phosphate tablets as it would have considered for any OLP tender bid that it may have submitted. PSM responded to the allegations made by Pinewood and AFT that suppositories cannot be compared with OLP as there are certain shipping requirements regarding temperature, as they melt easily that make the likelihood of import more remote. PSM stated that MedSafe approval was granted to Baxter Healthcare in 1999 to sell paracetamol suppositories from Rice Steele & Co Ltd, Tallaght, Dublin, Ireland. This illustrates that it is possible for paracetamol suppositories to be shipped the same distance as OLP. In addition all the other paracetamol suppositories listed in the Pharmaceutical Schedule are imported from Australia. PHARMAC has awarded both Panadol and Pacimol brands of suppositories sole supply status, which indicates that PSM is likely to have competition in the suppository market, although from the MedSafe notifications of newly approved medicines since 1999 it appears that PSM may be the only approved supplier of the strength suppository for which it has sole supply.

Precedent Investigation

503. The Ministry previously conducted a dumping investigation into Tamoxifen from the United Kingdom that also involved a PHARMAC tender. Tamoxifen (a cancer treatment) was tendered by PHARMAC for sole supply and there was no OTC or residual non-subsidised dispensary market segment for this pharmaceutical. In that case the New Zealand industry entered a tender bid and lost the tender to a dumped product. The investigation found that, even at an un-dumped price, the imported

goods would still have won the tender, as the un-dumped price was [redacted] lower than the New Zealand industry's bid.

504. In the current investigation there are two distinct market segments, one of which PSM still has full access to (OTC segment). The second is the dispensary market segment, in which PSM has access to 20 percent of the DHB hospital portion of the segment, and is excluded, through PHARMAC granting sole supply as the result of a tender process, from the community pharmacy part of the segment.

505. PHARMAC stated that the effects recorded in the injury indicators above "would have occurred in this manner had a tender been awarded in the absence of any alleged dumping." The Ministry considers that this is true as PSM would still have lost access to the community pharmacy market. The Ministry has considered this issue and in the following analysis seeks to illustrate the effect that an un-dumped tender bid from AFT would have had upon PSM.

506. The Ministry has calculated un-dumped prices for the Irish OLP by converting the dumping margin in € to a NZD amount, using the exchange rate from OANDA at the date of sale and adding this amount to AFT's prices in the Pharmaceutical Schedule. The Ministry considers that this is the fairest method of calculating an un-dumped price as it does not incorporate the cost of any of the other components that make up AFT's prices, such as profit or delivery to customers.

Table 5.25: Comparison of PSM and Un-dumped 1000ml Prices

	PSM's Pre Tender Prices	AFT's Tender Prices	AFT's Un-Dumped Prices	AFT's Un-dumped Prices as % of PSM's Prices
June 03				
120mg	8.10	7.29	[redacted] to [redacted]	[redacted] to [redacted]%
250mg	8.10	7.70	[redacted] to [redacted]	[redacted] to [redacted]%
July 03				
120mg	8.75	7.29	[redacted] to [redacted]	[redacted] to [redacted]%
250mg	8.90	7.70	[redacted] to [redacted]	[redacted] to [redacted] %

507. Table 5.25 illustrates that AFT's un-dumped OLP prices represent between [redacted] and [redacted] percent of PSM's prices. It should be noted that PSM attempted to increase its prices for the 1000ml in November 2002 and after negotiation with PHARMAC raised them slightly in July 2003. The Ministry in making the above comparison has used both PSM's June and July 2003 prices. The reason for using the two sets of prices is that PSM's prices are not sole supply prices and normal commercial practice would indicate that a price submitted for a sole supply tender would be lower than that in a marketplace with other competitors. PHARMAC has also stated "…all of the tender participants will generally offer prices much lower than those prevailing in the market in normal multi-supplier conditions, precisely

because the tender will assure them of sole supply or majority supply to the relevant market…".

508. The Ministry is aware that PSM did not enter a tender and is not trying to estimate the price at which it would have entered a tender bid. However, the only AFT price available to compare to PSM's prices is one that applies in a sole supply situation. The un-dumped prices range from being [redacted] than PSM's June 2003 prices to [redacted] percent below PSM's July 2003 prices. The Ministry considers that the proximity of these prices is sufficient to indicate that PSM's prices were competitive, especially as the next closest price in the dispensary market at the time was NZD14.80, which is approximately 65 percent higher than PSM's July 2003 prices. PSM's cost to manufacture was compared with those of Pinewood in paragraphs 101 to 106 and they were found to be of a similar level that would indicate PSM has the ability to be competitive.

509. PSM's prices appear to be competitive and therefore the Tamoxifen investigation approach does not indicate that the investigation should fail on this point.

510. PHARMAC, in response to the EFC report stated that it disagrees with the Ministry reasoning in "discounting" the Tamoxifen investigation. The Ministry notes that the precedent value of the Tamoxifen investigation is limited to considering how competitive the New Zealand producer's goods could be with the imported goods at an un-dumped level. PHARMAC stated that the "only scenario where the Tamoxifen precedent would not apply is that in which PHARMAC would not have accepted any tender bids had AFT bid with un-dumped prices." The Ministry disagrees. The precedent value of the Tamoxifen case is limited to the competitiveness of the New Zealand manufactured product and is most useful in circumstances that compare two tender bids.

511. However in the present case the assessment of whether the un-dumped prices would have won the tender is not as simple as comparing an adjusted un-dumped tender bid with another tender bid. The question in this case is, in the absence of dumping would AFT still have won the tender, meaning that PSM's decision not to enter the tender may have been the cause of the injury it has suffered rather, than the dumping. This is the situation that PHARMAC was referring to in paragraph 510 above.

512. PHARMAC stated in its response to the EFC report that "AFT would likely have won the tender at a price that the Ministry does not consider to be dumped. PHARMAC considers that the latter is a very strong possibility. PHARMAC believed that the dumping margin for the 1000ml OLP was [redacted] percent (the Ministry notes that it is, in fact, [redacted] percent) and that "a price [redacted] percent higher bid by AFT would have produced very similar savings to PHARMAC and would have otherwise been identical to the bid that was accepted under PHARMAC's decision criteria at the time." PHARMAC stated that while it is difficult to reassess a past decision based on different parameters PHARMAC considers that a price increase of [redacted] percent would have made little difference as to whether or not a tender was awarded in that case. Also "that it considers that it is very unlikely that its decision would have been different had AFT bid a price that the Ministry considers under its own calculation is not dumped"

513. AFT also stated in a submission that "the tender is awarded to the lowest bid in the absence of any major confounding factors (for example a history of poor supply as may have been the case for PSM)". AFT considers it still would have been awarded the tender, even if the price had only been NZD0.01 less than PSM's market price as PHARMAC would save money and have a set price for a defined period of time. AFT considers that because PHARMAC is the major buyer, not bidding clearly causes the damage if the tender is won by another party. AFT says it would have won the tender as long as its price was lower than PSM's market price and "the damage is related to this point and not to any possible dumping."

514. The Ministry has calculated the savings that it estimates that PHARMAC made by accepting AFT's tender bid and the savings that it would have made had it accepted an un-dumped price. Table 5.26 shows the OLP subsidy per litre and the value that the market volume tendered in 2001 represents.

Table 5.26: Estimated Volume and Value from PHARMAC's 2001 Tender

Strength	Subsidy per litre	Volume (litres)	Total Market Value
120mg	8.10	106,265	$860,742.62
250mg	8.10	64,811	$524,966.27

515. Based on the volumes and values in Table 5.26 the following tables approximate the range of savings that PHARMAC could have achieved if it had been presented with an un-dumped tender bid from AFT for sole supply in the community pharmacy market.

516. The 2001 tender closed on 4 March 2002. The OLP results of the tender were not announced until 31 July 2003, sixteen months later. In the intervening period PHARMAC is likely to have been assessing many of the tender bids, including those for OLP. PSM attempted to raise its price in November 2002 and following mediation with PHARMAC achieved increased prices in May 2003. Therefore the Ministry has compared AFT's un-dumped prices with PSM's prices both before and after its price increases, as either, or both, of these sets of prices may have been taken into consideration by PHARMAC.

517. There is also a possibility that PHARMAC considered the potential savings that AFT's bid offered them against the price increases that PSM was attempting to achieve, which were in excess of those that it did achieve. However, given PHARMAC's reluctance to accept PSM's price increases for the 1000ml product, as it saw the increases as a breach of contract, contrasted with its acceptance of the notified price increases for the 500ml OLP, it is likely that PHARMAC considered it would not need to accept price increases of this magnitude, and ultimately did not. Therefore the Ministry has not used these prices as a comparison

518. The Ministry has compared the extreme points of AFT's un-dumped prices, that is, the highest and lowest prices. In comparing these, the Ministry has analysed the

highest price for both strengths together and the lowest price for both strengths together. In reality there are many combinations of savings that could have been presented to PHARMAC based on an un-dumped tender price, but all are within these minimum and maximum values.

Table 5.27: Comparison of PSM's June 2003 Prices with AFT's Un-Dumped Prices

	AFT's price	PSM's June 2003 prices	Difference	Percentage Change	Estimated Market (litres)	Savings
AFT's highest un-dumped price						
120mg	[redacted]	8.10	[redacted]	[redacted]	[redacted]	[redacted]
250mg	[redacted]	8.10	[redacted]	[redacted]	[redacted]	[redacted]
Total						[redacted]
AFT's lowest un-dumped price						
120mg	[redacted]	8.10	[redacted]	[redacted]	[redacted]	[redacted]
250mg	[redacted]	8.10	[redacted]	[redacted]	[redacted]	[redacted]
Total						[redacted]

519. Table 5.27 compares PSM's June 2003 prices with AFT's highest un-dumped price and illustrates total savings for both strengths at NZD[redacted]. Table 5.28 compares the June 2003 prices with AFT lowest un-dumped prices, which would have provided total savings of NZD[redacted].

Table 5.28: Comparison of PSM's July 2003 Prices with AFT's Un-Dumped Prices

	PSM's July 2003 prices	Difference	Percentage Change	Estimated Market (litres)	Savings
AFT's highest un-dumped price					
120mg	[redacted]	8.75	[redacted]	[redacted]	[redacted]
250mg	[redacted]	8.90	[redacted]	[redacted]	[redacted]
Total					[redacted]
AFT's lowest un-dumped price					
120mg	[redacted]	8.75	[redacted]	[redacted]	[redacted]

250mg	[redacted]	8.90	[redacted]	[redacted]	[redacted]	[redacted]
Total						[redacted]

520. The savings PHARMAC would have achieved prior to 30 June 2003 were significantly lower (NZD[redacted] to NZD[redacted]) than the savings after PSM increased its price in July 2003 (NZD[redacted] to NZD[redacted]). The Ministry has looked at the value that these savings would provide to PHARMAC in the context of the total market value for individual lines of the Pharmaceutical Schedule contained in the 2001 tender. Of the 859 lines that were included in the tender only [redacted] lines, or [redacted] percent, of the products included had a total market value in excess of the NZD[redacted] savings that would have been achieved by accepting the lowest un-dumped prices for OLP in the light of PSM's price rise. Only [redacted] lines of the 859 lines, or [redacted] percent, of the products included had a total market value in excess of the NZD[redacted] savings that would have been achieved by accepting AFT's highest un-dumped prices for OLP. While price is not the only factor that PHARMAC takes into account when assessing tender bids, given the scale of the savings in relation to the market volume for other pharmaceuticals that were being tendered at the time, the Ministry considers that the savings would probably be the decisive factor in this situation.

521. The answer to the question of whether PHARMAC would have accepted an un-dumped price from AFT, had it been offered, appears to be that it would be highly likely given PSM's prices in July 2003 (and the fact that PSM had been attempting to increase its prices beyond that level since November 2002 indicates that the Ministry should use this figure to assess any savings rather than PSM's market price when the tender bids closed). This conclusion is based on the above analysis of prospective savings that PHARMAC still would have achieved from un-dumped prices. While the savings on a per unit basis do not appear to be large, given the volume of OLP that is subsidised, the absolute savings are large. The savings that could have been made from accepting non-dumped prices based on AFT's bids, are larger than most of the total market value of the subsidy for most of the pharmaceuticals PHARMAC tendered in the 2001 tender.

522. The Ministry considers it is less likely that PHARMAC would have awarded a sole supply tender with savings of between NZD [redacted] to NZD [redacted] as would have occurred when considering PSM's June 2003 prices, unless those savings were towards the higher end of that range but for reasons discussed above PSM's July 2003 prices are the correct comparators.

Conclusion on Other Market Factors

523. The Ministry considers that there were a number of substantive reasons why PSM did not enter the community pharmacy segment tender or submit an ACP for the DHB hospital segment. The Ministry notes, however, that the OLP market situation has changed substantially since December 2001. Whether the failure to enter PHARMAC's tender and request for ACPs is a cause of PSM's injury is not clear cut. PHARMAC stated in response to the EFC report that the Ministry's statement that the preceding sentence shows that "the Ministry does not seem to be

confident in its finding of causation." The Ministry notes that this statement is made in the injury section of the report and merely reflects that the matter is a complex one that will be addressed more fully later in the report when assessing the causal link.

524. PSM has lost access to the majority of the dispensary market segment following the award of PHARMAC sole and hospital supply agreements to AFT, which is the major cause of injury to PSM. The product that has replaced PSM's volume in this market is the dumped OLP from Ireland. A further discussion of this issue occurs in the causal link in section 6.

525. PHARMAC stated in response to the EFC report that "[t]he Ministry has no grounds to consider that PSM's non-participation was reasonable." The Ministry considers that it is appropriate to consider PSM's reasoning based on the beliefs that PSM held at the time PSM made the decision not to enter the tender. In coming to a conclusion that PSM had substantive reasons the Ministry is not agreeing with or validating any of the reasons provided by PSM but rather stating that the reasoning it provided is not insignificant and seems reasonable based upon the facts and submissions the Ministry had before it at the time. This is despite some of PSM's beliefs being erroneously held.

5.4 Other Causes of Injury

526. Sub-section 8(2) of the Act, also outlines factors other than the dumped goods that the Chief Executive shall have regard to when assessing injury. These include:

- The volume and prices of goods that are not sold at dumped prices.
- Contraction in demand or changes in the patterns of consumption.
- Restrictive trade practices of, and competition between, overseas and New Zealand producers.
- Developments in technology.
- Export performance and productivity of the New Zealand producers; and the nature and extent of importations of dumped goods by New Zealand producers of like goods, including the value, quantity, frequency and purpose of any such importations.
- The nature and extent of importations of dumped or subsidised goods by New Zealand producers of like goods, including the value, quantity, frequency, and purpose of any such importations.

Non-Dumped Goods

527. Competition from non-dumped OLP imports in New Zealand is mainly from Pamol and Panadol that have high brand power, with associated high prices. A small amount of the Irish OLP was also found not to be dumped. PSM believes that Pamol may exit the New Zealand OLP market because it no longer has a 120mg strength OLP, has no tablet support for the brand, and as the large volumes from the community pharmacy market segment are now closed off to it. PSM stated that

Panadol is less likely to leave the New Zealand market due to the high acceptance of its paracetamol in tablet form in the market. PSM stated that the amounts of OLP imported from Australia are fairly consistent.

528. The Aztec data shows that the sales of non-dumped OLP, primarily from Australia, have decreased by 7 percent by volume from 2002 to 2004. This is against an overall increase in the market volume of 6 percent over the same period. The prices of the Australian imports are well above those of PSM's OLP and most of the sales of non-dumped imports are in the OTC market, in which PSM has not suffered any price depression. Therefore the Ministry concludes that the injury incurred by PSM cannot be attributed to non-dumped imports.

529. PSM stated that there is a risk of other imported OLP that is not currently in the market place entering the New Zealand market. However, PSM believes that it would take a long time for new OLP competition to occur, as it is time-consuming and difficult to construct a formula that is accepted by the market and gain registration.

Contraction in Demand or Changes in Patterns of Consumption

Ibuprofen

530. There may be a small (but growing) amount of replacement of the OLP market by ibuprofen liquid medicines. Several interested parties to the investigation made comments on the progression of the preferred analgesic relief from paracetamol to ibuprofen. It was characterised as a natural progression of the same nature as that which occurred from aspirin to paracetamol.

531. PSM stated that it believed it will be at least [redacted] before ibuprofen completely cannibalises OLP. Boots Healthcare Limited has an ibuprofen liquid in the New Zealand market called Nurofen and AFT also distributes one called Fenaped that is manufactured by Pinewood. Aztec data confirms sales of ibuprofen liquid medicines are slowly increasing and information provided in the investigation indicates that a clinical shift is occurring. It is likely that this will be having a small but increasing effect on the OLP market.

Shift in Market Segments

532. PSM stated that all brands of OLP were able to be sold in the dispensary market segment until 1 February 2004, after which AFT's sole supply status took effect. PSM stated that part of the dispensary market segment available to other brands (the DHB hospital discretionary variance) would remain constant. However, as a result of only a single brand being subsidised PSM believes that there is likely to have been a transfer of some volume from the community pharmacy market segment to the OTC market segment. The Aztec data confirms that there have been increases in the volumes of OLP that have been purchased in the OTC market segment but the Ministry is unable to determine the cause for the increase in the volume of the sales.

533. AFT stated that there has been an increase in the volume of [redacted] being dispensed recently, which it attributes to [redacted] having sole supply status and [redacted].

534. The Ministry accepts that there may have been some changes in the presentations of OLP that were consumed in New Zealand over the past three years but these are minor in nature and cannot be linked in any way to the injury incurred by PSM.

535. While there may be a gradual move to ibuprofen from OLP and a possible shift of OLP from the dispensary market segment to the OTC market segment, the Ministry considers that there have been no significant changes in demand or in the patterns of consumption, that have caused the injury PSM has suffered.

Restrictive Trade Practices of, and Competition between, Overseas and New Zealand Producers

536. PSM stated that in its view there are no restrictive trade practices of, and competition between, overseas and New Zealand producers in the market in terms of the Commerce Act 1986. PSM commented that the level of marketplace competition is so high, a by-product of the PHARMAC environment, that it does not believe there are any restrictive trade practices that occur and that there is also an industry board that discusses any issues that are identified.

537. PSM mentioned that some [redacted] occurs but it is not extensive. The Ministry notes that [redacted] the nature indicated by PSM does not seem to constitute a restrictive trade practice within the meaning of the Act.

538. There are few barriers to entry regarding the manufacture of OLP in New Zealand, apart from registration and compliance issues due to OLP being a medicine. The only barrier to selling OLP is MedSafe registration, although PHARMAC agreements may limit the amount of the market that any given supplier can achieve. PSM stated that any supplier needs to deliver a price that is attractive to PHARMAC, which will be a low one. The Ministry notes that a low price market, while perhaps not attractive to potential suppliers, is not a barrier to entry.

539. The investigation has not discovered any evidence of restrictive trade practices of, or competition between them that has an adverse effect on PSM.

Developments in Technology

540. The Ministry visited both Pinewood's and PSM's manufacturing facilities. Both manufacturers use a batch method of production and comply with GMP. The Ministry did not discover any developments in technology that have adversely affected PSM, nor were any raised by any of the other interested parties to the investigation.

Export Performance and Productivity of the New Zealand Producers

541. PSM stated that it does not export the OLP it manufactures in New Zealand and therefore cannot be injured by its export performance. API has two forms of OLP registered in Australia and following the transfer of some of its manufacture to New Zealand PSM possibly may begin to export OLP.

542. PSM has experienced a decline in productivity but this is associated with the loss of volume that commenced with the injury, rather than any other factors.

Imports by the Industry

543. PSM does not import any OLP.

Buy out by API

544. PSM was purchased by Sydney based API in October 2002. AFT noted that PSM seemed to be doing quite well and then put up the price of OLP, as well as some of its other products, including those it contract manufactures, about the time that it was purchased by API. AFT stated that these price increases seemed to be a single 10 percent increase across the board and that this resulted in a general shift away from PSM for contract manufacture by the multi-national pharmaceutical companies.

545. Apart from a drive for increased margins, AFT stated that there should be no other reason for increases in prices, as given the strength that the New Zealand dollar has enjoyed input costs should have decreased both in relative and absolute terms. AFT also stated that while there has been upward pressure on labour costs domestically it has not been very marked. AFT also stated that API announced in December 2004 that it was closing its Sydney Kingsgrove plant and shifting its manufacture to New Zealand at the PSM plant to gain the benefit of PSM's lower manufacturing costs. Therefore increased labour costs did not seem to be the reason for the price increases.

546. The injury AFT attributed to PSM being purchased by API is really a statement that in increasing its prices PSM has caused itself injury. The Ministry has commented on PSM's decision to increase its prices when comparing an un-dumped price for the Irish OLP with PSM's prices. The Ministry notes that PSM's price increases did not cause the loss of volume directly but the consideration of whether an AFT tender bid based on un-dumped prices would have succeeded, as discussed in section 6, has attempted to take this into consideration.

Subsidies

547. Pinewood provided information to the Ministry relating to the granting of a subsidy to Pinewood by Enterprise Ireland, the Irish economic development agency, for several years prior to and including the POI. Information provided indicated that a subsidy had been granted in respect to OLP.

548. Pinewood stated the grant was in the form of non-recourse preference shares, with no interest being paid on them prior to the redemption period. Pinewood stated that the preference shares were used to [redacted] and the proceeds [redacted] are credited against the area to which they relate and are subject to an audit process. Pinewood stated that because of [redacted] the Enterprise Ireland preference shares are seen as an attractive form of finance, as they do not impose the same restrictions upon its activities as a commercial loan would.

549. Pinewood stated that it had also received grants specifically for capital expenditure into "bricks and mortar" some years ago and that the available grants were now focused on product and human resources capabilities development, with tangible assets and market development no longer being explicitly subsidised.

550. The Ministry has sought further information relating to the subsidy from both Enterprise Ireland and Pinewood but has not received any further information. For the purpose of this report no allowance for the effect of any subsidy has been made but this does not preclude the Ministry from taking any future action based on further information on this matter.

551. The Ministry has pointed out to Pinewood, that pursuant to the intent of the Act and the Agreement, any anti-dumping duties that may be put in place can only remedy injury that has been caused to the domestic industry by dumped goods, and should not take other matters, including countervailable subsidisation (when able to be adequately identified) into account.

Other Economic Arguments

552. The submission on the EFC report from LECG erroneously relies on "fair competition" as equally free and competitive trade and that dumping investigations can only remedy breaches of these. The LECG submission quotes an excerpt from *New Zealand Cereal Foods Ltd v Minister of Customs* (High Court, Wellington, CP 193/87, 11 May 1987, Greig J) that the purpose of the Act "..and the imposition of the dumping duty is to restore the competitive equality to the New Zealand producer on the statutory arithmetical pricing basis." LECG states that "[t]hese judicial comments seem particularly well guided in relation to the principles by which dumping legislation is to be construed in the modern environment, which among other things, includes an overwhelming movement towards free trade based on concepts of 'competitive equality'". In making this leap LECG has neglected the second part of the quoted passage in that the restoration of competitive equality is to be effected on the "statutory arithmetical basis", that is the extent of the dumping.

553. The LECG submission then progresses from this incorrect starting point and asserts that competition can only be eliminated by predatory pricing, which would manifest itself in the Ministry's price undercutting analysis. This illustrates that this economic viewpoint has resulted in the misinterpretation of the purpose of the Act, which provides a mechanism for remedying price discrimination between markets that is injurious to a New Zealand industry, as a role that is more akin to the monitoring role undertaken by the Commerce Commission. Injurious dumping and predatory pricing are not necessarily linked and usually occur independent of the other in the New Zealand market. The LECG submission also addresses government subsidies for which countervailing action may be taken as the only other circumstance in which the "judicial concepts of 'fair competition' and 'competitive equality'" are breached.

Conclusion on Other Factors

554. There is no evidence that other factors are a cause of injury to PSM.

5.5 Conclusions Relating To Injury

Import Volumes

555. Dumped imports have increased both in absolute terms and in relation to New Zealand production and consumption.

Price Effects

556. There is evidence of price undercutting of all the 100ml and 200ml presentations, but the volume of the imported OTC sales is very small. There is no evidence of price undercutting for the 500ml and 1000ml presentations, the prices of which have been depressed and therefore a finding of no price undercutting does not mean that no injury has occurred.

557. The 500ml and 1000ml presentations are illustrating price depression with 2004 prices substantially lower than the 2003 ones, due to the downward price pressure of the dumped imports on the prices of 1000ml presentations sold for dispensing without subsidies. There is no evidence of price depression for the 200ml presentations.

558. The 500ml and 1000ml presentations are displaying price suppression with increased overheads not being recouped in the selling price. There is no evidence of price suppression of the 200ml presentations as price increases have been sufficient to fully recover increased costs.

559. The 100ml presentations were not considered in analysing price depression and suppression, as PSM only launched the 100ml presentations in 2004 and had no earlier previous prices with which to compare them.

Economic Impact

560. As a consequence of the volume and price effects, there is evidence of a significant decline in sales volume and revenue, market share, profits, productivity, return on investments, capacity utilisation and cash flow.

561. Inventories have declined due to active stock management. There is no evidence of any adverse effects on employment, wages, growth or ability to raise capital at this stage but negative effects on some of these factors in the near future is likely given the changes in production and sales volumes and profitability. The extent of any negative impact in these areas is likely to be mitigated by the transfer of API manufacture to PSM.

562. PSM has lost market share for the 1000ml community pharmacy market segment but has recorded market share increases in all other market segments. However, the Aztec data used to calculate market share does not cover sales to DHB hospitals, and it is likely that PSM has also lost market share in the DHB hospital market segment which only includes 500ml presentations. PHARMAC stated in response to the EFC report that the loss of volume in the dispensary market illustrates that "PSM has only been affected through its lack of participation in PHARMAC processes." The Ministry has acknowledged that it is the award of

PHARMAC supply agreements that has clearly caused the injury and the correct assessment to be made is whether dumping was the reason that these agreements were accepted, or whether PSM's decision not to enter the tender was, and therefore caused the injury it has suffered.

Injury Conclusion

OTC

563. Despite PSM not submitting a tender bid for the community pharmacy market segment or an ACP for DHB hospital segment, for the 1000ml and 500ml product, the question of whether injury has been caused in the OTC segment needs to be considered. There is significant price undercutting of between [redacted] and [redacted] percent in the OTC market for the 100ml and 200ml presentations. However, the volume of dumped imports sold has been very small, although the Ministry notes that AFT has [redacted].

564. PSM's OTC prices have not been depressed or suppressed as the price increases have been sufficient to recover the increase in cost of production. Output has increased for the 200ml and production of the 100ml presentations began in 2004.

565. The Ministry considers that the injury to the OTC market is not material when considered in isolation. However, the cross over effects of injury from other market segments is likely to affect this segment in future, with PSM's increased costs of production and the increased brand presence of Parapaed increasing the injury effects. PHARMAC stated in response to the EFC report that the "assumption that future damage is likely to the OTC market as a result of crossover effects is not justified." The Ministry disagrees as both AFT and PSM, suppliers of OLP to the market, have indicated that having their brand subsidised in the dispensary market is an advantage to growing OTC sales. This is because every pharmacy that chooses to dispense subsidised product, which is practically every pharmacy, must stock that brand. This means that orders must be placed and product paid for with that supplier and this buying and selling relationship provides the opportunity to sell further products. PHARMAC stated that it "considers cross over between the dispensary market and the OTC market is highly unlikely, as most dispensed paracetamol contains little or no branding due to repackaging." The Ministry is aware that dispensed OLP carries very little explicit branding in terms of labelling or packaging. However, another very important brand feature that differs between the Parapaed and Paracare 120mg OLP is the flavour and the smell, which are likely to be more enduring brand differentials than two very similar names. The 250mg strengths of Parapaed and Paracare are both orange flavoured, so this differential is not present. Another factor that supports the link between the dispensary and OTC segments of the market are the [redacted] product [redacted] AFT. AFT launched Parapaed into the New Zealand market in 2003. Apart from some advertising in brochures circulated to pharmacies the Ministry is not aware of any substantial advertising carried out by AFT, [redacted] that [redacted] in the dispensary market [redacted] sales in the OTC market. PHARMAC stated that "AFT has approximately 3 percent of the [OTC] market share and growth is minimal to flat" in support of dismissing the cross over effect between the dispensary and OTC market segments. PHARMAC

pointed out that "PharmacyBrands [Limited] is not willing to advertise Parapaed." The Ministry notes that AFT's current stock levels of 100ml and 200ml OLP respectively account for [redacted] and [redacted] percent of its sales in the year ending October 2004, being [redacted] stock. AFT's [redacted] the statement made by PHARMAC that PBL will not stock OTC Parapaed. However, the [redacted] AFT [redacted] advertising indicates that a cross over effect between these two markets [redacted] and while this [redacted] stage the potential for it to increase does exist. A more relevant consideration in the Ministry's view is not whether this will occur, but the timeframe over which it will occur, in particular, whether it is imminent.

566. PSM stated in response to PHARMAC's EFC submission that "PHARMAC is not in the business of selling pharmaceuticals and this would explain why PHARMAC does not understand that access to the dispensary market provides a convenient and obvious means to promote the OTC product."

567. PHARMAC stated the above comments should be removed, as Article 3.7 of the Agreement states that "A determination of threat of material injury shall be based on facts and not merely on allegation, conjecture or remote possibility." The Ministry notes that the above statements refer to actual material injury, not the threat thereof.

Dispensary

568. PSM's potential sales volume in the dispensary market is constrained by the award of sole and hospital supply status to the dumped goods. PSM has experienced a significant loss of volume from being excluded from 80 percent of the DHB hospital segment and the entire subsidised portion of the community pharmacy segment that has resulted in significant loss of sales revenue, market share, profits and productivity, return on investments, capacity utilisation and cash flow as referred to in paragraph 560.

569. The Ministry considers that the injury caused by dumped imports in the dispensary market segment is material. The EC responded to this point that the weighted-average dumping margin for this segment is *de minimis.* The Ministry, for the reasons discussed at paragraph 300, considers that when using the transaction-to-transaction methodology the weighted-average margin of all the transactions do not provide a meaningful figure on which to consider if the margin of dumping is of a level that could cause material injury.

Other

570. There are other factors affecting domestic prices in the dispensary market, the primary one being the operation of PHARMAC and its role in establishing subsidy levels for the community pharmacy market and purchase prices for DHB hospitals.

571. It should be noted that in order for the dumping to be remedied, the dumping must have caused material injury, but that the dumping does not have to be the only cause of material injury. PSM did not enter the tender for OLP supply to the

community pharmacy market, however the question of whether this caused the injury it has experienced is primarily an issue of causality and is discussed in section 6.

572. PHARMAC stated in response to the EFC report that the Ministry does not consider the impact of PHARMAC's award of supply agreements to AFT at the same time it considers injury "means that the Ministry is more likely to decide that there is injury to PSM." The Ministry notes that injury analysis is an assessment of the above listed indicators and injury is either found to be occurring or not. However, not all industries that are suffering injury will be suffering injury due to the dumped goods. For example a New Zealand ice cream manufacturer may be suffering lost sales and decreased profit levels and it has been established that the imported ice cream is being dumped but in fact the injury may be caused by the New Zealand manufacturer's choice to alter its most popular ice cream flavour and this altered version has been rejected by consumers. In such an example injury is clearly occurring but the cause of the injury can, at least in part be attributed to the redesign of its most popular ice cream flavour. This simple fictitious example illustrates that consideration of injury and causation separately does not predetermine a finding of injury caused by dumping.

6. Causal Link

573. Section 13 of the Act states:

> ... the Minister shall make a final determination as to whether or not, in relation to the importation or intended importation of goods into New Zealand,—
>
> (a) The goods are being dumped or subsidised; and
>
> (b) By reason thereof material injury to an industry has been or is being caused or is threatened or the establishment of an industry has been or is being materially retarded.

574. This means that the material injury must be caused by reason of the dumping of goods. Dumping does not need to be the only cause of material injury or even the major cause of the injury, but must be a cause of material injury.

575. The question of whether there is a causal link between the injury suffered by PSM and the dumping of OLP is a complex matter.

576. The EC, Pinewood, AFT and PHARMAC all stated at various stages throughout the investigation that they failed to see how the Ministry could find a causal link between the dumping and the injury when PSM had not entered the tender and the loss of access to the tender volumes was the cause of all of the injury.

577. The Ministry, in examining causality first considers whether the imports are dumped and whether material injury has been caused as a result of the dumped imports by applying section 8 of the Act, which establishes an inference that material injury is caused by dumping. Secondly an examination is made of any known factors apart from the dumped goods which are also injuring the industry. If there are other factors then it must be established whether the injury caused by other factors breaks the inferred causal link.

578. PHARMAC, in its response to the EFC report, stated that the Ministry has made an error of law in looking at the causal link in the above manner and that it has "affected the conclusions reached by the Ministry". The Ministry notes that the approach it used is its established practice and is also that which the EC uses (as outlined in Muller, Dr Wolfgang, Khan, Nicholas, Neumann, Dr Hans-Adolf (1988) *EC Anti-Dumping Law- A Commentary on Regulation 384/96*, John Wiley & Sons, Chichester, UK p.209ff) and it is considered acceptable practice under the Agreement and is consistent with the Act. The Ministry has in light of PHARMAC's submission reconsidered whether this is an appropriate method of establishing if a causal link between the dumping and the injury exists.

579. The Ministry is satisfied that looking at the causal link in such a manner is not an error of law and does not favour any particular outcome and may even be more neutral than the alternative of looking at the cause of injury before injury itself. In looking at causal link as a two limb process, it merely breaks injury into assessing the injury indicators first, to see if injury is occurring, and then secondly assessing the causes of any injury that are found. This means that if there was dumping and, for

example, a drop in profit, the Ministry would then look to see if there are any other known causes that could be responsible for this injury. If the Ministry were to look at the reasons for injury before determining if an industry was suffering any injury it could lead to a situation where a determination of injury caused by dumping is made before any injury is measured or assessed. By taking the alternative approach of assessing the cause of injury before establishing whether there was any injury, could give the appearance of a pre-determination to find injury caused by dumping when no negative effects are shown in the injury indicators.

580. First, the analysis shows that 91 percent of the goods are dumped and that material injury has occurred. The material injury incurred by PSM is largely as a result of lost volume and the consequent loss of sales revenue, market share, profits and declines in return on investment, capacity utilisation, productivity and cash flow. There is evidence, therefore, of an inference of dumping causing injury. PHARMAC states that the preceding sentence is incorrect and goes on to state that "rather than analysing the other factors in a neutral and objective manner, the Ministry has made assumptions and relied on leaps of reasoning to support the inference that it started with". PHARMAC also stated that "[t]he whole tenor of the [EFC] report is consistent with the Ministry setting out to find that there is dumping, injury, causation and reason to impose anti-dumping duties" and also "[w]here the Ministry has been unable to find hard evidence to allow it to make a positive finding, it appears to have manufactured an argument or relied on a self-serving argument manufactured by PSM, based on conjecture and assumption, to justify it coming to a conclusion in favour of imposing duties." The Ministry does not consider that it has assessed the other injury factors in a manner other than one which is neutral and objective and notes that PHARMAC's comments relate largely to the Ministry's reliance upon the best information available, pursuant to the Act, as outlined in paragraph 56. The Ministry's use of the best information available is necessary due to limited information from several parties, including from PHARMAC, in relation to matters involving PSM and the processes under which AFT was awarded sole and hospital supply status.

581. The second question in determining whether there is a causal link is have any other factors caused injury to PSM. None of the factors referred to in sub-section 8(2)(e) of the Act, namely goods not sold at dumped prices, contraction in demand or changes in patterns of consumption, restrictive trade practices, developments in technology, and the industry's export performance and productivity have been a cause of injury to PSM. The other causes of injury listed in the Act, although not exhaustive, do not specifically cover the situation of not entering a tender.

582. By PSM not entering a tender bid it had no possibility of being awarded the tender. PSM has given a number of reasons why it thought that the PHARMAC tender would not be awarded. These include that, at the time PSM's product had good market acceptance, its prices were the lowest in the market, it thought it would be consulted if OLP was to be tendered and by inference would have the opportunity to negotiate on the matter. OLP had not been tendered before, and PSM was wary of PHARMAC's contracts, and decided not to enter a tender bid if it could continue to supply the market without being subject to the sole supply contract terms. All of these considerations are against the background of 75 to 80 percent of products that are tendered not being awarded sole supply status by PHARMAC. However, PHARMAC in this case did award the sole supply status under the tender to dumped goods. PHARMAC stated in response to the EFC report that "PSM's beliefs as to the

outcome of the tender had no bearing on the awarding of the tender to AFT. This is therefore irrelevant to the investigation." The Ministry accepts that PSM's understanding of the market at the time obviously could not influence the award of the tender to AFT but its understanding of the market situation does mean that its decision not to enter the tender means that there is no tender bid against which to compare AFT's un-dumped price. PHARMAC also considers that "the rate of tenders awards is also irrelevant, as in this case it did award a tender." The Ministry considers that the rate of tenders that are awarded is relevant, as in a situation where 100 percent of tenders are awarded the causal link between the dumping and the injury would immediately be broken, as the failure to enter a tender bid would in every instance result in material injury to the domestic industry. The relevance of whether Pfizer or GSK entered the tender is that if none of the (then) current market participants entered a tender bid it creates a situation where the normal competitive behaviour may be not to submit a bid.

583. In order to assess whether the dumped goods caused material injury, or whether that injury was caused by the failure of PSM to submit a tender bid, a question to address is whether PSM would have suffered material injury, through a loss of volume, if it had not entered a tender bid and where dumped goods were not offered in the tender. Given the circumstances at the time the tender was entered into, and given that PSM had the lowest price in the market, it is reasonable to assume that the other two products in the market at the time might not have reduced their bid prices sufficiently (assuming they did submit a tender bid) for PHARMAC to award sole supply. Table 7.1 shows the prices that were in the market prior to the tender. PHARMAC stated in response to the EFC report that the Ministry was erroneous in stating that the two other products in the market would not have reduced their prices sufficiently to award the tender. PHARMAC stated that "the Ministry should not rely on any assumptions at all in reaching important conclusions" without regard to the relevant facts and without responses from the companies concerned the Ministry should not be making assumptions about whether or not other parties entered the tender. Following PHARMAC's EFC report submission the Ministry asked Pfizer and GSK whether they did, in fact, enter the 2001 tender as outlined in paragraph 465 but although only limited information was received no information was provided that contradicted the Ministry's above statements and the Ministry still considers that if tender bids were submitted by GSK and Pfizer that these would have not been low enough for PHARMAC to award sole supply to either of these companies.

584. PHARMAC also stated that "the Ministry's reasoning ignores the possibility that a supplier other than AFT, Pfizer or GSK may have bid…" The Ministry's analysis has not ignored this possibility, but in the absence of any other MedSafe registered OLP and in the absence of any information from PHARMAC about whether any other unregistered party actually entered the tender it is reasonable to conclude from the information available that no other unregistered product was bid, other than Parapaed by AFT.

Table 7.1 Prices in the Market

	Paracare (June 2003)	Paracare (July 2003)	AFT's 120mg tender bid	AFT's 250mg tender bid	Pamol	Panadol
120mg and 250mg 1000ml price	8.10	8.75	7.29	7.70	14.80	18.95
Price as a % of PSM's June 2003 price	100%	108%	90%	95%	183%	234%
Price as a % of AFT's 120mg tender bid	111%	120%	100%	105%	203%	259%
Price as % of AFT's 250mg tender bid	105%	114%	95%	100%	192%	246%

585. PHARMAC stated that the price a supplier was selling at in a multi-supplier environment is "irrelevant because of the different circumstances that exist in a market without sole supply to those that exist with sole supply." While the Ministry agrees that by looking at a supplier's multi-supplier price cannot indicate what its tender bid may be, the quantum of the difference between the successful tender bid and the multi-supply price goes towards assessing how substantive the decrease would need to be in order to be successful.

586. Alternatively, if the Irish goods were in the market but at un-dumped prices would PSM's failure to enter a tender bid have been the cause of injury? The un-dumped tender prices of the imported Irish OLP are similar to PSM's multi-supplier market prices at the time of the tender, as illustrated in Table 5.25, being between [redacted] and [redacted] percent of PSM's pre-tender prices. It should be reiterated that PSM's prices were those in a multi-supplier market and as PHARMAC has pointed out tender bids are normally well below prices in a multi-supplier market. In response to the above comments in the EFC report, PHARMAC stated that it considered that "AFT would likely have won the tender at a price that the Ministry does not consider to be dumped". PHARMAC considered this a "very strong possibility" and stated that the dumping margin was [redacted] percent. PHARMAC stated "a price [redacted] percent higher bid by AFT would have produced very similar savings to PHARMAC, and would have otherwise been identical to the bid that was accepted under PHARMAC's decision criteria at the time". PHARMAC stated that it would be irrelevant to consider how an un-dumped price might have fared against a hypothetical PSM tender bid because PSM, did not enter the tender, and it could only consider the bids it received against the subsidy level in the market at the time. The Ministry's analysis has never attempted to create a tender bid for PSM but has merely noted the limitations of comparing multi-supplier prices with sole supply prices.

587. There is also a question of whether there is injury caused by loss of volume through PSM's exclusion from the DHB hospital market. This was not a tender situation but a request for an ACP. Goods were bundled together in the ACP that

PHARMAC accepted from AFT. The ACP included OLP at a price higher than PSM's price in the market, and PHARMAC presumably made cost savings over the package of pharmaceutical products in the bundle. PSM responded to PHARMAC's request for consultation on the ACP it proposed to accept by stating that its price was the lowest in the market (NZD5.00) and queried why PHARMAC was proposing to agree to higher prices (NZD5.50 and 5.60) for these products.

588. The Ministry notes that none of the 500ml presentations imported from Ireland are dumped but there are injury effects occurring in the DHB hospital segment through price suppression and depression. Under the Act and the Agreement anti-dumping duties may only be imposed if goods are dumped. In this case the Ministry has analysed dumping and injury effects by size of presentation for ease of analysis given the different size of the units and the varying prices to the market. The Ministry notes that treating the like goods as a whole is an acceptable practice. However, when dumping margins are calculated using the transaction-to-transaction methodology any dumping would usually be addressed only for goods or models causing, or threatening to cause material injury, unless there is a serious threat of circumvention of the duties by transferring imports to another model. Also only one line, or transaction, of the 200ml OLP imported from Ireland is dumped.

589. There are cross-over effects between the community pharmacy and hospital portions of the dispensary market segment due to volume and branding, as they are different parts of the same market segment rather than completely distinguishable segments or markets. PSM also sells 500ml product to private hospitals and rest homes and to the community pharmacy market. It is likely that the price of the dumped 1000ml size has exerted the downward pressure observed on the selling price of the 500ml presentations. PHARMAC stated in response to the EFC report that "[t]here is no basis to conclude that the 1000ml pack has depressed the price of the 500ml pack. As the…1000ml pack is only sold for use in the dispensary market, and is almost entirely used for subsidised dispensing under the tender agreement between AFT and PHARMAC. The 500ml pack conversely is only supplied privately or to DHB Hospitals." The Ministry notes that the Aztec data shows that PSM sold 500ml in 2004, but as shown in Tables 5.13 and 5.17 there are no sales by AFT recorded. As the Aztec data is only collected from community pharmacies the lack of sales from AFT indicates that AFT is not selling any 500ml OLP to community pharmacies. Therefore 500ml OLP that PSM is selling into the community pharmacy market segment are competing with the 1000ml OLP sold by AFT and it is the price of the 1000ml that will be responsible for any price effects in the community pharmacy market segment. The 500ml imported OLP is responsible for influencing PSM's prices only in the DHB hospital portion of the dispensary market segment.

590. In addition, the OTC presentations have reasonable dumping margins. Increased production costs due to lost volume and a consequent decline in PSM's EBIT indicates that the dumped goods are likely in future to have a negative effect on PSM in the OTC market segment. However, there is little indication of any direct price or volume effects to date or any consequent economic impact. PSM has stated that because AFT has sole supply status in the community pharmacy market customers who are prescribed Parapaed will begin to ask for it with more frequency in the OTC market segment without a prescription, as it becomes a more familiar brand, so increasingly affecting PSM's OTC market sales. PHARMAC disagrees with this point and stated in response to the EFC that "…those patients who get

subsidised paracetamol are more likely to continue getting subsidised paracetamol rather than purchasing it unsubsidised." This is ignoring the time savings that parents for example, who would normally incur a co-payment for subsidised OLP, gain by going directly to a pharmacy and picking up OTC product rather than needing to go to a doctor first. Also as access to pharmacists increases with time, and brand awareness builds, pharmacists will also be induced to purchase the Parapaed brand and will therefore begin to offer it as an alternative to the brand leaders Panadol and Pamol, which is likely to replace the current alternative Paracare and to a lesser extent impact upon the Unichem and Amcal brands of OLP.

591. PSM has been injured by the awarding of PHARMAC supply agreements to the dumped Irish imports. However, from the Ministry's analysis of AFT's un-dumped prices, and the savings they would have offered to PHARMAC compared with the prices that PSM was offering in the market at the time, it is considered that this injury would have occurred even in the absence of the dumping.

592. The Ministry considers that in this situation, PHARMAC would have made significant savings if any company had put in a bid that was higher than AFT's dumped tender bid (the current subsidy price), but low enough when multiplied by the considerable volumes involved to give PHARMAC large savings relative to PHARMAC's total market expenditure on other pharmaceuticals listed within the Pharmaceutical Schedule.

593. PSM's existing multi-supplier prices were not competitive enough when compared with the absolute effect that a non-dumped tender bid would have, and therefore PSM's failure to have a price at which a non-dumped bid could not have been accepted, (and perhaps the only way to achieve this was through entering a competitive tender bid), caused it material injury rather than the dumped imports. This, therefore, breaks the inferred causal link in the current investigation on the relevant facts. This, does not, however, mean that a failure to enter a tender in itself is sufficient to break the inferred causal link in any circumstance. Whether or not a failure to enter a tender is the cause of injury depends on the result that an un-dumped bid would have had, the analysis of which effectively separates the effect of dumping from the winning of the tender.

594. The award of the sole supply status to the dumped goods is clearly the major cause of the injury PSM has suffered. If dumped goods were not put forward in the tender it was likely to still have been awarded to AFT, as while the savings per unit that an un-dumped tender bid offered were not so large that PHARMAC would have had to accept them, but the relatively good decrease in price combined, with the volume of the product that is subsidised, would have meant that the absolute savings from accepting an un-dumped tender bid when compared with PSM's prices, (the lowest in the market at the time), meant that the savings were of such a level that an un-dumped bid would have been accepted.

595. The Ministry considers that injury has been caused to PSM by the quantum of savings that an un-dumped tender bid would have delivered to PHARMAC. The acceptance of dumped prices in the tender and ACP and a relatively small dumping margin, means the dumping appears to be more incidental to the decision to accept the tender bid, rather than the cause of it.

596. Injury however, is threatened and likely to be caused in the future in both the OTC market segment and in the community pharmacy part of the market as recognition of the Irish product grows. The assessment of whether this constitutes a threat of material injury occurs in section 7.

597. The LECG submission bases its consideration of causation on the premise that Pinewood is more competitive than PSM and that Pinewood's prices to AFT are not below cost, which LECG states must be the case in order for dumping to be remedied. LECG stated that "[c]onsistent with our discussion of the Act and the relevant case law…for any alleged dumping to cause material injury…it must involve pricing to N[ew] Z[ealand] below an appropriate level of cost, including a reasonable profit." In coming to this conclusion LECG rely on a statement made in *Kerry (New Zealand) Ltd v Taylor* (High Court, Auckland, CP 1614/88, 2 November 1988, Gault J) that "imports purchased at prices which do not reflect real costs of production, distribution and a reasonable profit". The Ministry respectfully notes that dumping is about price discrimination between markets that may be remedied when it causes injury and while both the Act and the Agreement allow for prices to be calculated or constructed using costs of production, distribution and profit, these components are not required to be absent from the selling price before dumping can be remedied.

598. LECG states that duties should only be imposed, due to causation existing, when one particular seller has material influence on prices in the market and the exports are below cost. The Ministry notes again, that LECG seems to be applying competition policy type tests that relate to abuse of market power and predatory pricing, which are quite distinct from the injurious price discrimination between a manufacturer's domestic and export market that may be remedied by the imposition of anti-dumping duties. The Ministry notes that price effects form only part of the analysis that both the Act and the Agreement require. LECG comes to a conclusion from this that PSM is less efficient than Pinewood and that the Ministry should have addressed this. First and foremost competitiveness is not a matter that explicitly is required to be addressed under the Act but competitiveness should be considered in causes of injury and also in the assessment of a tender bid's possible success in the current investigation. Second the Ministry has seen the financial data and production costs for both PSM and Pinewood and is satisfied that PSM is competitive.

599. The LECG submission continues on the Ministry's failure to assess the relative efficiencies of PSM and Pinewood and infers that this is the likely cause of any harm. LECG submits that because AFT won the hospital supply status on a bundled tender that this is another legitimate source of competitive advantage. LECG finally states that the cause of any injury to PSM is as a "...result of their own inefficiency and inability to compete." The Ministry notes the price comparisons outlined in paragraph 106, conclude that has a competitive cost structure.

Conclusion

600. In the EFC the Ministry considered that PSM's failure to submit a tender bid for the community pharmacy portion of the dispensary market was not of itself enough to sever the causal link in this particular case and that the failure to participate in a competitive process would in each instance turn on the facts, having regard to the market situation at the time, among other factors.

601. The Ministry noted that PSM had substantive reasons for not submitting a tender bid and that differing factual circumstances may have produced an alternative result. PHARMAC stated in response to the EFC report that it was "…particularly concerned by the statement 'differing factual circumstances may have produced an alternative result'…This statement shows a willingness to ignore the factual in favour of the hypothetical." The Ministry's intent in the statement in question was not to favour the hypothetical but to illustrate that a decision not to enter a tender would not always result in the finding of a causal link and should not be taken as a precedent without regard to the facts.

602. PHARMAC's response to the EFC report included statements that the Ministry erred in its assessment of causal link and that the "Principles of statutory interpretation provide that where an enactment would penalise or impose a serious detriment on a person if certain facts were established, the enactment should be interpreted by erring on the side of not imposing the penalty in the absence of absolute clarity." However, the Act provides a statutory framework for imposing duties (which are not punitive in nature and therefore should not be regarded as a penalty) that allows the Ministry to reach conclusions on the basis of the best information available, as outlined in paragraph 56. The Ministry considers that any other interpretation would be to render the Act inoperable and no principle of statutory interpretation would support that result. The purpose of such a provision is to encourage participation by interested parties within the transparent investigation process that provides ample opportunity for all interested parties to be heard. Consequently the ability to base a decision upon the best information available must be read as overriding the principle of statutory interpretation espoused by PHARMAC, otherwise the Ministry would be in a nonsensical situation where unless it was in the position of having full and perfect information (which is a very rare, if at all existent, situation) it would be unable to recommend that the injury being suffered by the New Zealand industry would be able to be remedied. Therefore while the principles of statutory interpretation are important they cannot be applied in a manner that would render the underlying legislation completely inoperative.

603. PHARMAC's response to the EFC report included a statement that the Ministry has a "lack of confidence" in its finding of a causal link "[h]owever, despite that lack of confidence it goes on to rely on assertions and conjecture to back up its positive finding in causation." The Ministry did not lack confidence in its finding on the facts that were available to it at the time, however, it was very aware that it lacked a substantial amount of information and that the matter was not simple. The Ministry has, since the EFC report, received more information from a number of parties, including PHARMAC, and has taken that information into account but still has imperfect information upon which it must base its conclusions and make recommendations.

604. The Ministry has concluded, based on PHARMAC's submission that it would have awarded the tender to AFT at un-dumped prices (using a [redacted] percent dumping margin, which was close to the actual dumping margin and in a later submission a [redacted] percent dumping margin). This submission is supported by the consequent analysis the Ministry has undertaken on the level of the savings PHARMAC would have made by accepting AFT's un-dumped prices when compared with PSM's prices prior to the tender. The Ministry considers that it is highly likely that PHARMAC

would have accepted non-dumped prices and consequently PSM would still have been materially injured, despite the dumping.

7. Threat of Material Injury

Introduction

605. The investigation has found that the New Zealand industry has suffered material injury, but that the material injury has not been caused by dumping. The industry has suffered injury to some extent from dumping, but analysis of the savings that PHARMAC would have been able to achieve accepting an un-dumped price from AFT, has led the Ministry to conclude that, injury would have occurred even in the absence of the dumping, although it is likely that the injury suffered in the unsubsidised portion of the dispensary market may have been less.

606. Section 8 of the Act, as set out in paragraph 316 outlines the matters that must be considered when assessing the threat of material injury to the New Zealand industry and the Ministry must also consider the factors set out in Article 3.4 and Article 3.7 of the Agreement.

607. Footnote 9 of the Agreement states that "the term 'injury' shall, unless otherwise specified, be taken to mean material injury to a domestic industry, threat of material injury to a domestic industry, or material retardation of the establishment of such an industry". In the circumstances of this case the Ministry must consider, therefore, whether dumping of OLP is threatening to cause material injury to PSM.

608. The Ministry's conclusions in relation to the Article 3.4 injury factors are described under paragraphs 555 to 572 and accordingly the Ministry does not consider that each of these factors need to be addressed in detail again in this section.

Article 3.7 of the Agreement

609. In relation to the types of injury described in footnote 9 of the Agreement, The World Trade Organisation Dispute Settlement Panel *United States – Investigation of the International Trade Commission in Softwood Lumber from Canada* (WT/DS277/R at paragraph 7.56) noted that:

> It seems clear to us that these three concepts describe different types of injury, occurring at different times and potentially in different ways. [Footnote omitted.] Thus, the focus of Article 3.7 . . . , in the context of Articl[e] 3 . . . as a whole, is the determination of one of these three types of injury, threat of material injury. The factors set out in Article 3.7 . . . are elements that should be considered in making a determination of threat of material injury.

610. Article 3.7 of the Agreement states (emphasis added):

> A determination of a threat of material injury shall be based on facts and not merely on allegation, conjecture or remote possibility. **The change in circumstances which would create a situation in which the dumping would cause injury must be clearly foreseen and imminent**[10]. In making a determination regarding the existence of a threat of material injury, the authorities should consider, inter alia, such factors as:

(i) a significant rate of increase of dumped imports into the domestic market indicating the likelihood of substantially increased importation

(ii) sufficient freely disposable, or an imminent, substantial increase in, capacity of the exporter indicating the likelihood of substantially increased dumped exports to the importing Member's market, taking into account the availability of other export markets to absorb any additional exports;

(iii) whether imports are entering at prices that will have a significant depressing or suppressing effect on domestic prices, and would likely increase demand for further imports; and

(iv) inventories of the product being investigated.

No one of these factors by itself can necessarily give decisive guidance but the totality of the factors considered must lead to the conclusion that further dumped exports are imminent and that, unless protective action is taken, material injury would occur.

10One example, though not an exclusive one, is that there is convincing reason to believe that there will be, in the near future, substantially increased importation of the product at dumped prices.

611. The factors listed in the Article 3.7 of the Agreement are not exhaustive**.**

612. The World Trade Organisation Dispute Settlement Panel *United States – Investigation of the International Trade Commission in Softwood Lumber from Canada* (WT/DS277/R, paragraph 7.105) (*Softwood Lumber*) considered that once an analysis of the Article 3.4 factors had been carried out, there is no requirement to carry out "an assessment of the likely impact of future imports by reference to a consideration of projections regarding each of the Article 3.4 . . . factors" nor is there "an obligation to conduct a second analysis of the injury factors in cases involving threat of material injury". This means that each of the injury factors do not need to be considered separately again.

613. The World Trade Organisation Dispute Settlement Panel *Egypt – Rebar* (DS211/R, paragraph 7.91) clarifies that "the text of this provision makes explicit that in a threat of injury investigation, the central question is whether there will be a 'change in circumstances' that would cause the dumping to begin to injure the domestic industry".

Change in Circumstances

614. *Softwood Lumber* (paragraph 7.54) refers to footnote 10 of the Agreement when it states that: "the sole example given of a 'change of circumstances' in the text is that there will be substantially increased importation of the product at dumped prices". It also states at paragraph 7.55 that "while the change in circumstances must be clearly foreseen and imminent, the text does not clearly require the identification of a single event as the relevant change in circumstances. Thus, the text does not give us clear guidance as to the nature of the change in circumstances, or the degree of specificity with which it must be identified". Further, at paragraph 7.57 "we consider that the relevant 'change in circumstances' referred to in Articl[e] 3.7 . . . is one element to be considered in making a determination of threat of material injury. .

. . in our view, the change in circumstances that would give rise to a situation in which injury would occur encompasses a single event, or a series of events, or developments in the situation of the industry, and/or concerning the dumped…imports, which lead to the conclusion that injury which has not yet occurred can be predicted to occur imminently".

615. The Ministry considers, therefore, that both the changed circumstances and the resulting material injury must be clearly foreseen and imminent. In the following analysis, the Ministry considers whether there is a foreseeable change in circumstances, then considers the factors identified in Article 3.7, before considering the injury factors in their totality.

616. The New Zealand industry has suffered material injury through the award by PHARMAC of sole and hospital supply status to AFT. The closing date for the 2004 tender, which includes both the DHB hospital and community pharmacy parts of the market, was on 28 February 2005. The Ministry notes that the tender is now closed and considers that the clearly foreseen and imminent change in circumstances is the new Pharmaceutical Schedule listing for OLP by PHARMAC, whether that be by awarding a new sole supply status to a supplier or setting a new multi-supplier subsidy level.

617. PHARMAC stated in its response to the EFC report that "[t]he closing date for the current tender round cannot be foreseen and is not imminent - it has passed. Any findings made in, or measures taken as a result of, the current investigation are irrelevant to whether any dumping will exist in the market in future, in whatever [the] circumstances may be should sole supply status be awarded following the current tender round." The 2004 tender's closing date was shortly after the release of the EFC report on, 23 February 2005, and PHARMAC's Consultation on the Tender of Certain Pharmaceuticals dated 23 September 2004, indicated that the decisions of the PHARMAC board on tender winners are to be announced from early April 2005. However, the imminent award of sole and hospital supply status or other change in the current listing based on the tender bids submitted, has not yet occurred. Therefore changed circumstances remain clearly foreseen and imminent despite the closing date for tender bids to be submitted having already past.

618. PHARMAC also stated that "[t]he prices that have been bid in the current tender round cannot now be changed by the parties." The Ministry asked PHARMAC to comment on the effect of one of its contract clauses that allows PHARMAC to initiate limited negotiations on tender bids. PHARMAC stated that "…the tender process is a single bid closed tender process. It is extremely rare for PHARMAC to negotiate on price at all as part of the tender process, as an expectation of price negotiation would compromise the process, and result in suppliers not making their best bids initially in order to allow some room to move in negotiation."

619. The outcome of the 2004 tender has not been announced to market participants and the Ministry has no way of assessing definitively what the outcome will be as it does not know how many suppliers entered bids or the prices of those bids. The Ministry does however know that PSM has entered the tender and considers it likely that AFT has also entered the tender. The Ministry considers that there are three possible outcomes, although there may be other possible outcomes that the Ministry has been unable to identify.

- The first is that PHARMAC, due to the current market situation, or for any other reason, decides not to award sole supply status and re-establishes a multi-supplier environment.

- The second is that AFT is awarded sole and/or hospital supply status.

- The third is that a supplier other than AFT is awarded sole and/or hospital supply status.

620. The outcome is not certain and any threat of material injury exists only in the first and second scenarios above. Because the Ministry does not have access to the information contained in the tender bids, it can only assess the likelihood of the three scenarios above based on the evidence presented during the investigation.

621. Given the comments made by AFT and Pinewood during the investigation it appears both companies are eager to continue selling Parapaed in New Zealand. It is likely, therefore, that AFT has entered a tender bid. PSM has confirmed that it did enter a tender bid but the Ministry is unaware if any of the other suppliers of OLP in the New Zealand market entered the tender. AFT's previous tender bid was based on dumped prices and its current 1000ml prices are dumped. PHARMAC's statutory objective is to "secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the funding provided". As part of achieving its objective PHARMAC uses the tender process to gain lower prices and secure supply from suppliers in return for granting sole supply and in this environment prices for established pharmaceuticals, such as paracetamol, generally decrease over time. Therefore it is likely that PHARMAC will accept lower prices if they are presented to it. Putting all of these factors together the Ministry considers that the likelihood of AFT being awarded sole supply status based on a dumped price is very real and if a multi-supplier environment were re-established, AFT would have the advantage of supplying dumped goods.

622. The Ministry has considered, in the following paragraphs, the factors of Article 3.7 to the extent they may be relevant.

Rate of Increase of Dumped Imports

623. There has been a 945 percent increase in the volume of dumped imports of OLP from 2003 to 2004. The Ministry considers that this constitutes a significant rate of increase in the volume of dumped goods. However, given that this increase has largely resulted from the awarding by PHARMAC of sole and hospital supply status to AFT, it is not necessarily indicative of substantially increased imports in future years. The absolute volumes of dumped goods imported in 2004, however, are indicative at least of the continuation of import volumes at existing levels, should AFT be successful in gaining sole supply status through the 2004 tender and would increase in parallel with the forecast market growth.

624. The discretionary variance amount of the DHB hospital market, which is available to all listed suppliers, is proposed to drop from 20 percent to 1 percent in the 2004 tender. A successful tender bid by AFT could, therefore, result in increased

imports by AFT as the 19 percent decrease in the discretionary variance amount will have to be filled by the supplier that has hospital supply status.

Capacity of the Exporter

625. Pinewood has told the Ministry that it [redacted] and that it is in fact [redacted]. Pinewood was in the process of [redacted] at the time the Ministry carried out its verification visit with Pinewood, although this was classified as [redacted] Pinewood to [redacted] in a [redacted]. Pinewood told the Ministry that it wished to maintain its export volumes of OLP to New Zealand as the [redacted] and the PHARMAC situation offers [redacted] sales, with [redacted] involved, for a three year period. The Ministry considers that Pinewood is already manufacturing and exporting large volumes of OLP to New Zealand and that [redacted] has the facilities to continue to export the volumes required in the New Zealand market, [redacted] where the market continues to grow. Pinewood does export its OLP to other markets but the Ministry considers that, due to the registration process and the size of Pinewood's exports to New Zealand, it is unlikely any other export market exists that would be able to absorb the volumes of OLP exported to New Zealand. An important factor in assessing the capacity of the manufacturer is that OLP has to be manufactured specifically for the export market for which it is intended. As OLP is a pharmaceutical there is no ability to manufacture OLP for one export market and then sell it to an alternative export market. For this reason inventories of the OLP in Ireland are irrelevant, as Parapaed OLP exported to New Zealand is manufactured to order and stocks manufactured for any other market are unable to be sent to New Zealand.

626. Pinewood responded to the EFC by stating that "Pinewood, as any other company in business for profit, has a long term plan for growth and investment for future sales. We are constantly researching other markets and currently are in the process of registering [p]aracetamol in other markets that have the potential to absorb similar volumes of OLP." The Ministry notes that the statement in the previous paragraph was taken from comments made by Pinewood at its verification visit and that the strength of the threat of material injury argument is not changed by any subsequent registrations that Pinewood may have begun, due to [redacted]. The EC also responded on the above point and the Ministry notes that the discussion was recorded in Pinewood's verification report and that an EC representative was present during the Ministry's verification visit with Pinewood.

627. For the purpose of assessing threat of material injury the important factor to note is that Pinewood does have the ability to continue to export similar or slightly increased volumes of OLP to New Zealand.

Effect of Prices of Imports

628. The current imports of OLP have been illustrated in paragraphs 345 to 361, at their current pricing levels, to have significant price suppression and depression effects. The potential for the prices of imports to increase the demand for further

dumped imports relates not only to the market segments covered by PHARMAC supply arrangements in the 2004 tender that is currently being assessed, but also to the OTC market segment.

629. AFT already enjoys the sole and hospital supply status. The demand for further dumped imports in the dispensary market will not increase beyond the current level, with an allowance for growth, as its current sales levels are already constrained by market demand. The demand for further dumped imports could in fact decrease if PHARMAC re-establishes a multi-supplier environment following the 2004 tender.

630. PSM's OTC market segment prices are likely to come under increasing pressure from the dumped Irish product if a sole supply and/or hospital supply status is awarded to Parapaed OLP based on dumped prices. PHARMAC, in response to the EFC report, rejects that there is a link between the OTC and dispensary market segments and therefore the statement that the OTC market segment will come under increasing pressure, as discussed in paragraph 565.

631. The Ministry considers given the evidence presented by interested parties to the investigation and their behaviours that there are some cross over effects between the two market segments, which indeed reflects that they are two segments of the same market rather than two distinct markets. If the status quo continues, with Parapaed being the sole subsidised brand of OLP in the New Zealand market, there will be increasing market pressure from customers switching to the subsidised brand. This will be especially evident in those customers whose first child has received only the Parapaed brand of OLP upon prescription, with the effect of this compounding over time. PHARMAC in its response to the EFC report incorrectly attributed the previous statement to PSM, when in fact the Ministry made this statement based on information gathered during the investigation and comments several parties made on brand capture and the buying patterns of consumers. The Ministry considers that the statement that Parapaed's brand power will increase is not reliant solely upon the argument that parents of a first-born child will be loyal to this brand in the OTC market. PHARMAC commented that it considers it an "unlikely event" that a parent seeks to buy OTC OLP but the Ministry notes that the Pamol and Panadol brands have high brand awareness and many consumers search for them by name.

632. PSM's OTC sales of OLP declined 5 percent by volume (and decreased 2 percent by value) of the market in 2004. In a sole supply period for a further three years this is likely to result in PSM losing sales volume and revenue in the OTC market.

Submissions

633. The EC and PHARMAC made submissions arguing that no threat of material injury exists. The EC stated in response to the EFC that "it is . . . implausible to imagine that there would be a threat for PSM to lose a market it does not have at the moment. The only way PSM can be awarded the tender is by participating with a bid in the tender process." The Ministry notes that PSM has confirmed that it has placed a bid for OLP in the 2004 tender. The EC considered that, on the basis of a *de minimis* overall weighted-average dumping margin, the Ministry cannot conclude that the likelihood of dumping is high and in fact cannot conclude that there is a threat of material injury. The EC also stated that "…the analysis of threat of material injury

pursuant to Article 3.7 of the [Agreement] cannot stand alone" and that the threat of injury must be related back to the impact of the dumped goods upon the domestic industry. The EC considered that all the injury indicators need to be analysed in relation to the impact of the dumped goods. The Ministry agrees that the threat of material injury is not a threat of dumping *per se,* but involves the assessment of whether dumping threatens to cause material injury to the domestic industry in the imminent and foreseeable future.

634. PHARMAC further stated that "[t]he current, and future, tender rounds will involve different prices, different parties and the pre-existing situation will have little bearing on this." The Ministry accepts that tender bids will necessarily involve a change in market prices and due to the nature and aims of PHARMAC it is likely that most of the price movements will be downwards ones. Dumping investigations inevitably involve the assessment of historical information, although as most recent as is possible, to interpret what levels of dumping may occur in the future. The Ministry recognising this limitation of using historical information to consider future transactions attempts when setting duties to impose duties via a method that means un-dumped imports will not incur anti-dumping duties. This is, however, distinct from what PHARMAC is indicating, which is an inability to impose measures for the future without knowing for certain what will occur. The fact that the goods are, at the current subsidy levels, dumped, that PHARMAC in including OLP in the 2004 tender is seeking lower prices for that pharmaceutical (in addition to secure supply) and that the importer and exporter both wish to continue with OLP in the New Zealand market, means that all the pre-requisites for dumping to continue are present.

635. PHARMAC stated that the Ministry was incorrect in stating that PSM would enter the 2004 tender and lose and that PHARMAC would award the 2004 tender to dumped goods. The Ministry notes that in order to assess a threat of injury it is necessary to look to the future and make an assessment about future behaviours based on current information and trends, which must be more than allegation, conjecture or remote possibility. Subsequent to the tender closing the Ministry sought confirmation from both PSM and AFT as to whether they entered tender bids in respect of OLP. PSM confirmed that it did enter a tender bid for OLP. However, AFT [redacted] declined to respond. Given that PHARMAC has made repeated submissions on the importance of the tender process and the award of sole supply status to fulfilling its statutory objectives and that a "large number" of the pharmaceuticals that are tendered but for which no sole supply is awarded are the result of no tender bids being submitted, the Ministry considers it likely that sole supply status will be awarded for OLP. The reasons that the Ministry considers any tender bid by AFT is likely to be dumped, and therefore continue the situation of dumping, are canvassed above.

636. PHARMAC submitted in response to the EFC report "For the assertion that the new tender would result in dumped prices to be accurate the Ministry would need to be satisfied that nobody in the world would be able to manufacture OLP more efficiently than PSM..." This is incorrect. Dumping is about price discrimination between a manufacturer's domestic prices and its export prices to New Zealand. It does not involve the assessment of the efficiencies or competitiveness of the New Zealand manufacturer. PHARMAC also stated that the Ministry "would need to be satisfied that PSM would be able to make a bid lower than any 'un-dumped price', and that PHARMAC would consider PSM's bid acceptable under other evaluation

criteria including its supply record." The Ministry has seen both Pinewood's and PSM's cost to manufacture OLP and believes based on those costs that PSM has a competitive cost structure. PHARMAC has awarded PSM sole supply status for at least one other product since the tender for OLP indicating that PSM could in certain circumstances satisfy the other criteria. PHARMAC has repeatedly stated its concerns regarding PSM's supply performance. The majority of the examples PHARMAC provided actually related to PSM's attempts to increase prices, rather than its failure to supply. The Ministry believes, for reasons covered from paragraph 501, that if the cost savings were great enough that PHARMAC would award sole and/or hospital supply status to PSM.

637. PHARMAC also stated that in order for the Ministry to determine that a threat of injury exists it "would also be satisfied that no other supplier was going to bid, or if there were other suppliers, that these suppliers would be unable to provide pricing competitive with PSM, and that in the event that any other supplier was competitive (including under other criteria) that this supplier would be dumping." The Ministry is not satisfied that all of the factors listed by PHARMAC are pre-requisites to a finding of threat of material injury, as a threat of material injury can never be foreseen with absolute certainty and the current situation has enough indicators to show that a dumped tender bid by AFT is a threat and that the resulting material injury is likely to result in similar injury effects to PSM as found in section 5 of the report.

638. This dumping investigation is only concerned with imports of OLP from Ireland, therefore whether any other tender bids were made based on OLP sourced from other countries is irrelevant for the purpose of determining whether there is a threat of material injury. PHARMAC stated that "…given the complexities of the process and the large number of associated variables, the Ministry has no basis to conclude that future dumping is 'likely' without relying on mere conjecture, a willingness to believe in remote possibilities, or reliance on accusations made by the New Zealand industry. Such a conclusion would show a disregard for the facts, rather than have any basis in them." The Ministry has demonstrated the factual basis for the finding that there is a threat of material injury. The factual support for this conclusion is largely provided by Pinewood's and AFT's stated intentions in regard to the future supply of OLP in the New Zealand market, PHARMAC's legislative goals and its use of sole supply and the tender process to achieve them and the current prices, volumes and stock levels in the New Zealand market.

Ministry's Analysis

639. There are two significant factors known to the Ministry that have the potential to alter the extent of the impact of material injury upon PSM, as the New Zealand OLP industry.

- The first is the introduction of new manufacture to PSM that is being transferred from one of its parent company's Australian manufacturing sites. Media reports have shown that there is going to be an increase in the number of products that are manufactured by PSM and also the introduction of some large pieces of manufacturing plant. This will increase the plant value and will result in a corresponding increase in overheads that need to be recovered from the products manufactured. However, an increase in the product range is likely to increase the number of individual units from which overhead recovery is sought.

It is important as a large portion of the material injury current suffered by PSM is due to increased overhead under-recovery. PSM has stated to the Ministry that despite the introduction of new manufacture the pharmaceutical plant still requires the OLP business. The announcement of the transfer of additional manufacture to PSM is recent and has not yet occurred, as a result the Ministry is not in a position to evaluate the extent of the effect that this change in manufacturing operations will have on OLP.

- The second factor that will alter the extent of any injury that would be incurred by PSM is the proposed decrease of the discretionary variance amounts for supply to the DHB hospital market segment. Under the current supply arrangements the discretionary variances are 20 percent and under the 2004 tender, for which bids have recently closed, this amount is set to drop to 1 percent. This change would obviously have a negative impact on PSM if hospital supply status was awarded to AFT, as it almost totally eliminates the residual amount of the dispensary market that it can sell into.

Totality of Factors

640. Article 3.7 concludes that "No one of these factors [in Article 3.7] by itself can necessarily give decisive guidance but the totality of the factors considered must lead to the conclusion that further dumped exports are imminent and that, unless protective action is taken, material injury would occur". *Softwood Lumber* at paragraph 7.54 states that "the text indicates that both the change of circumstances, and further dumped…imports, must be imminent, and the likelihood of increased imports is both a relevant change of circumstances and a factor to be considered in determining the existence of threat".

641. The changed circumstance which constitutes a threat of material injury is based on a reasonable assumption that dumped prices have likely been bid by AFT in the 2004 tender and will be successful, therefore continuing the situation of dumping. The Ministry has based this finding on the following evidence, including positive evidence that:

- AFT's current prices for the community pharmacy market which are published, are dumped;

- both AFT and Pinewood have indicated their desire to continue to supply the dispensary market;

- in order for AFT to be competitive one very likely option is that it could drop its prices thereby increasing the likelihood of offering dumped prices;

- PSM has indicated that it entered the tender;

- PSM's costs enable it to be able to be competitive on price (which AFT is aware of);

- a result of the PHARMAC tender process is that over time, prices for pharmaceuticals are driven down;

- the injury analysis shows that the potential for material injury is large if dumped goods win the tender; and

- the injury that PSM is currently suffering in the non-subsidised dispensary market, is likely to continue.

642. There is the possibility that AFT's pricing behaviours may have been altered by the existence of a dumping investigation. The Ministry provided information on the likely method by which any anti-dumping duties would be calculated in the EFC report in order to give Pinewood an indication of how any duties that may be imposed would operate and allow them to have this information prior to AFT submitting any tender bid for OLP in the 2004 tender. This information was passed onto AFT and may have been incorporated into its tender bid and pricing decisions. However, AFT would have also known that PSM was likely to enter the recent tender, given the injury PSM suffered as a result of the 2001 tender being awarded to AFT and is likely to have bid below the current subsidy prices in order to attempt to win the sole supply situation, (bearing in mind that PSM does not have access to the dumping margins established by the Ministry and only knew that the 500ml product was not dumped). AFT being aware of this, combined with PHARMAC's overall goal of reducing prices, especially for well established pharmaceuticals such as OLP, is likely to have entered a lower price than its current price level, and any price below and some prices above the 1000ml current subsidy rate would be dumped.

643. Another possibility is that AFT has submitted a tender bid for both community pharmacy and DHB hospital supply based on 500ml presentations, which were found not to be dumped. Overall, though there is a strong possibility that AFT has submitted a tender bid with dumped prices.

644. Another way of looking at the scenario is to say if sole supply status was awarded to AFT under the 2004 tender based on dumped prices, or that AFT is able to compete in a multi-supplier environment with its prices that are dumped, (which are two of the three possible outcomes in the 2004 tender round) and material injury was caused to PSM, could that outcome be described as not being clearly foreseen and imminent to the Ministry at the time the final report was compiled and its recommendations to the Minister were made? The answer is no. While the possibility cannot be estimated with any degree of certainty or percent of likelihood it is not a requirement of a finding of a threat of material injury that the threat be an absolute certainty or even precisely estimated. Even looking at the least damaging, and perhaps least likely, outcome of the current tender, being that a multi-supplier environment is created for the subsidised portion of the dispensary market segment, if AFT remained a competitor within that market and competed on its current prices, injurious dumping would be occurring.

645. There is little likelihood that dumped OLP in the OTC market segment will contribute significantly to any threat of material injury. Loss of volume in the dispensary market would result in increased per unit costs of OLP for PSM, but this has been offset to a certain extent by PSM's prices increases in the OTC market, although it has experienced a small reduction in sales volume which was replaced by the Irish goods. The limited extent to which AFT has penetrated the OTC market so far indicates that a substantial increase in OTC market participation is unlikely in the clearly foreseen and imminent future, particularly given AFT's stated inability to sell to

major pharmaceutical chains, Amcal and Unichem, which are owned by a related party to PSM.

646. The Ministry considers that upon assessment of the above a threat of material injury exists.

Special Care

647. Article 3.8 of the Agreement states:

> With respect to cases where injury is threatened by dumped imports, the application of anti-dumping measures shall be considered and decided with special care.

648. *Softwood Lumber* at paragraph 7.33, noted that this provision is part of Article 3 covering the overall determination of injury, including threat of material injury. The WTO Panel considered that the Article 3.8 provisions of special care "reinforce this fundamental obligation" in Article 3.7 "that investigating authorities shall base a determination of threat of material injury on facts and not allegation, conjecture or remote possibility".

649. In its application, PSM stated that "[g]iven the sole supply status won by AFT, and the lowering of the ex-manufacturer/supplier price through the effects of dumping, it is not unreasonable to conclude that the threat of material injury goes beyond mere allegation, conjecture or remote possibility". On the other hand, PHARMAC stated in response to the EFC report that it "believes the threat of material injury postulated by the Ministry is based on conjecture, and accusations made by PSM and has little factual basis."

650. The Ministry notes that most of the matters it has considered in assessing the threat of injury are based on submissions made by PHARMAC, AFT and Pinewood, with very little of the analysis being based upon information presented by PSM, because the drivers of the threat of material injury are largely beyond PSM's control. The Ministry is satisfied that the information relied on, while not certain, goes beyond mere allegation, conjecture or remote possibility.

651. A threat of material injury exists even though there was found to be no causal link between the dumping and the current material injury suffered by PSM because PSM has confirmed it entered the 2004 tender and as outlined in paragraph 506 the test from the precedent Tamoxifen investigation, illustrates that PSM could enter a competitively priced tender bid and the Ministry considers it very likely, given the injury that PSM suffered as a result of not being able to compete in the subsidised portion of the dispensary market, that it will enter a competitively priced bid.

Conclusion on Threat of Material Injury

652. The Ministry has considered the following key matters in deciding whether there a threat of material injury exists:

- The volume of imports of the dumped goods;
- The effect of the dumped goods on prices in New Zealand for like goods; and

- The consequent impact of the dumped goods on the relevant New Zealand industry.

In particular:

- whether there will be a change of circumstances that would cause the dumping to materially injure the domestic industry;
- whether further dumped exports are imminent; and
- whether, in the absence of anti-dumping duties, material injury would occur.

653. Clearly, there is a significant volume of goods that have been dumped and this situation is likely to occur again if the 2004 tender is awarded to AFT. The new tender is a change in circumstances where the likelihood of dumping continuing is high. The change in circumstances is clearly foreseen and imminent with tender awards to be announced from April 2005 onwards.

654. The injury analysis in section 5 has illustrated the injurious effects of not being able to compete in the subsidised portion of the dispensary market and had AFT's un-dumped prices not have offered PHARMAC the level of savings that they did, this injury would have been attributed to the dumped imports. If the 2004 tender is awarded to a bid containing dumped prices, material injury is likely to continue at levels up to, and perhaps exceeding, those already evidenced in the analysis of actual material injury. The major difference between the analysis of actual injury and threat of material injury in this investigation is that the existing injury is not caused by dumping, whereas the threatened material injury is caused by dumping. In this sense, the dumping will begin to cause material injury. If PSM had entered the 2001 tender, the major argument put forward by interested parties that PSM injured itself by a failure to enter the tender for such a large volume of the market (but not value), would be removed and the analysis of the savings that AFT's un-dumped tender bid would have offered PHARMAC would have been compared with PSM's tender bid. PSM would still be in a position where the goods were dumped and depending on the level of the savings offered, if any, at AFT's un-dumped price the injury may have been attributed to dumping.

655. The continuation of dumped exports is likely and may increase because of the decrease in discretionary variance in the DHB hospital segment of the market and also due to the small amount of forecast market growth. Further dumped exports are imminent, that is dumped exports that, while not necessarily greater in magnitude than existing levels, are additional to those that were imported under the existing tender arrangements.

656. The Ministry considers that the 2004 tender is likely to involve dumping and that such dumping will cause material injury that is imminent. In the absence of anti-dumping duties, material injury is clearly foreseen and imminent.

657. The Ministry concludes, therefore, that there is a clearly foreseen and imminent threat of material injury to the New Zealand industry.

8. Conclusions

658. The Ministry given its analysis of all the material before it concludes that:

- the OLP from Ireland is being dumped;
- by reason thereof material injury to an industry has not been caused but is threatened; and
- factors other than the dumping are the cause of the material injury PSM is currently experiencing.

9. Anti-Dumping Duties

659. Section 14 of the Act relates to the imposition of anti-dumping duties, the relevant parts of which are set out below:

> (1) At any time after the Minister makes a final determination under section 13(1) of this Act in relation to goods, the Minister may give notice of the rate or amount of duty determined under subsection (4) of this section (which notice may be given simultaneously with, or at any time after, the notice given under section 13(2) of this Act) and there shall, with effect on and from the applicable date referred to in section 17 of this Act, be imposed,–
>
> (a) In respect of those goods that are dumped, a duty to be known as anti-dumping duty:
>
> …
>
> (2) Anti-dumping duty … imposed under subsection (1) of this section, shall be collected and paid on the demand of the [[Customs]] on and from the day after the date on which the notice under subsection (1) of this section is published in the Gazette.
>
> …
>
> (4) The anti-dumping duty … in the case of goods to which this section applies shall be a rate or amount determined by the Minister,–
>
> (a) In the case of dumped goods, not exceeding the difference between the export price of the goods and their normal value; and
>
> …
>
> (5) In exercising the discretion under subsection (4) of this section, the Minister shall have regard to the desirability of ensuring that the amount of anti-dumping … duty in respect of these goods is not greater than is necessary to prevent the material injury or a recurrence of the material injury or to remove the threat of material injury to an industry or the material retardation to the establishment of an industry, as the case may require.

9.1 Method of Imposing Duty

660. Anti-dumping duties can be applied in a number of ways and can be imposed as a rate or amount, including any rate or amount established by a formula. The basic approaches are:

- a specific amount per unit of product;
- an *ad valorem* rate; and
- a reference price approach.

661. The main objective of an anti-dumping duty is to remove the injurious impact of dumping. In deciding on the form of duty, considerations relating to ease of administration, ability to ensure the dumping margin is not exceeded, fairness between parties, and predictability all need to be taken into account. The objective of the anti-dumping duty is to remove injury attributable to dumping, and is not to punish

the exporter, or to provide protection to an industry beyond the impact of the dumping.

662. Section 14(4) of the Act provides that the Minister must not impose a duty that exceeds the margin of dumping for the dumped goods. The Solicitor-General has advised that the references to "export price" and "normal value" in this section are to be read as references to the export prices and normal values established in the investigation or to the values at the time the goods subjected to the duty are imported.[1] Given this, the Ministry's approach is to adopt a form of duty that minimizes the possibility of exceeding the margin of dumping on shipments subsequent to the imposition of the duty by the Minister.

Specific Duty

663. A specific duty is a set amount per unit of product based on the monetary value of a margin of dumping. It has the advantages of being convenient to apply and impossible to evade by incorrectly stating the value for duty and clearly indicates to the importer the amount of duty payable. However, difficulties can arise where there is a wide range of goods involved, where exchange rates fluctuate to the extent that the margin of dumping will be exceeded without constant reassessments of the duty, or where the exporter otherwise changes prices so that the duty is either greater than the margin of dumping or less than the margin of dumping previously established.

664. A specific duty, expressed as a monetary amount, can only really operate effectively when prices and exchange rates are consistent and stable and where the transaction-to-transaction comparison does not result in a range of different dumping margins. An alternative approach to deal with this problem is to express a specific duty as a formula, being the difference between equivalent prices to the normal value and the export price of a particular shipment, with the values for the normal value and export price being fixed. When those elements of the formula are expressed in terms of the currency of each transaction, the problem of exchange rate movements can be dealt with. However, a formula approach does not deal with the problem of changes in export prices for reasons other than exchange rate movements or movements in normal values such as a price change.

Ad Valorem Duty

665. An *ad valorem* duty is a duty based on the dumping margin, expressed as a percentage of the export price, and is expressed as a percentage of the dutiable value. An *ad valorem* duty is convenient to apply and is not substantially affected by exchange rate movements. However, collusion between exporters and importers can lead to the manipulation of the invoice value of the goods concerned. *Ad valorem* rates are often appropriate where there is a large range of goods or where new models appear, provided that the transaction-to-transaction comparison does not result in a range of different dumping margins.

[1] Plasterboard from Thailand, Reassessment, September 1999.

666. Because an *ad valorem* duty is imposed proportionate to the export price of the goods, a particularly low export price (and therefore a potentially more injurious export price) will result in a proportionately lower amount of duty, which may not be sufficient to remedy the injury caused by the dumping. Conversely, a particularly high export price (and therefore likely to be less injurious), will attract a proportionately higher amount of duty, which may be higher than is necessary to remove the injury caused by the dumping.

667. *Ad valorem* duties can also be used to impose duties where for some reason there is found to be dumping but that some circumstances exists to indicate that a duty should not be collected at the present time. In these circumstances an *ad valorem* duty at zero percent is imposed. This allows the Ministry to reassess or review the anti-dumping duty. For example if prices are dumped but the goods are considered to be entering above the industry's non-injurious price a zero duty may be imposed. However, if no duty was imposed then any changes in price or any other market situation that would normally result in a reassessment or review would require a new dumping investigation to be undertaken. Other methods of imposing a duty are also capable of achieving a similar outcome but *ad valorem* rates are most effective in the circumstances where a duty should not be collected in the interim, but a change in circumstances that would result in the need for a reassessment or a review are likely to occur in the near future.

668. An *ad valorem* rate gives an indication of the impact of the duty, but does not target the dumping as accurately as other forms of duty.

Reference Price Duty

669. Under the reference price approach, the duty payable is the difference between the transaction price and a reference price. The reference price would normally be based on the normal value, by means of Normal Value (Value for Duty Equivalent) (NV(VFDE)) amounts, or the non-injurious price (a price at which imports would not cause injury to the New Zealand industry), either at the Free on Board (FOB) or cost insurance and freight (CIF) level. A NV(VFDE) amount represents the un-dumped value of the goods at the FOB level.

670. A reference price duty has the advantage that it is best able to deal with movements in the export price and exchange rates (if expressed in the normal value currency), and is also suitable when a lesser duty is applicable. However, it has been argued that it is more easily evaded than the other forms of duty, by overstating the value for duty of the goods. Nevertheless, a reference price does have the advantage of clearly signalling to exporters and importers what price is un-dumped or non-injurious, and provided the like goods and the reference price are carefully described, the problem of evasion can be dealt with. In addition, a reference price duty only collects duty when the goods are priced below the non-injurious or un-dumped reference price. It therefore collects duty only to the extent necessary to remove injurious dumping.

Conclusion

671. It has been the normal practice of the Ministry to impose duties through the use of reference prices, when appropriate, for the reasons outlined above. However, in

the present case the Ministry considers that the decision on the imposition of anti-dumping duties should be deferred, pending the outcome of the current PHARMAC tender process, or any other event that changes the market supply situation and therefore the decision on the form of duty to be applied should also be deferred but a reference price duty would likely be recommended.

9.2 Level and Timing of Duty

672. Anti-dumping duties can not be applied at a level higher than the margin of dumping and section 14(5) of the Act requires that the Minister have regard to the desirability of ensuring the amount of duty is not greater than is necessary to prevent material injury to the New Zealand industry.

673. The Ministry has carefully considered the causal link between PSM's failure to enter a tender bid (see section 6) and has decided that the level of savings that would have been available to PHARMAC at AFT's un-dumped price is sufficient to disrupt the causal link between the dumped goods and the injury being suffered by PSM. However, the existence of these contracts needs to be considered in terms of the effectiveness of any anti-dumping duties recommended to be imposed based on the threat of material injury.

674. The material injury incurred by PSM has been found to be due to factors other than the dumping and to impose anti-dumping duties during the remaining period of the current PHARMAC supply arrangements would be attempting to remedy injury caused by factors, other than the dumped goods.

675. The current contracts under which OLP is supplied to the community pharmacies and DHB hospitals are set to end on 30 June 2005 and after this point a new contract for the supply of OLP may be awarded. The Ministry considers that to collect duties during the remainder of the sole and hospital supply periods that exist pursuant to PHARMAC agreements, which have approximately 3 months to run, would only serve to be punitive to AFT, as PSM would still be unable to access this portion of the market.

676. However, as the threat of material injury exists the Ministry is proposing that the imposition of anti-dumping duties be deferred, pending the outcome of the 2004 PHARMAC tender process, or any other event that changes the market supply situation. The Ministry may also need to carry out either a review or reassessment after the imposition of duties, whatever is required in the circumstances, upon the announcement by PHARMAC of the results of the 2004 tender round, or upon any other event that changes the ability of suppliers to compete in the subsidised dispensary portion of the OLP market, as the levels of dumping may change.

677. The Ministry is unable to calculate a price for the dumped goods that would be non-injurious to the New Zealand industry for the purpose of assessing whether a duty should apply at a rate less than the full margin of dumping and stated in the EFC report that it would do so before any recommendation to impose duties was made. The Ministry is in this case unable to calculate what a non-injurious price would be, as it would involve identifying the exact level at which PHARMAC would no longer accept an un-dumped tender bid from AFT. While the Ministry has reached conclusions based on the overall savings both dumped and un-dumped bids from

AFT would have provided in the 2001 tender, it does not have sufficient information to identify the exact point at which that decision changes and how this would apply to the 2004 tender.

678. The Ministry is recommending that the decision of the imposition of anti-dumping duties for the 1000ml OLP be deferred and a reassessment or review may be necessary after duties if the margins of dumping change. It is likely that the Ministry would recommend the use of a reference price duty for the reasons discussed in paragraph 670.

679. The Ministry is not recommending the imposition of duties on the 200ml and 500ml presentations as they are not dumped.

680. The Ministry is not recommending duties on the 100ml presentations because the effect of sales of these presentations does not significantly contribute to the threat of material injury. Also when considering the effectiveness that any duty would have the Ministry notes that AFT currently has [redacted] worth of 100ml and 200ml stock on hand.

681. The following is therefore illustrative of the method that would likely be used for the imposition of duties following PHARMAC's announcement of the current tender round, or any other event that affects market supply conditions.

Calculation of Potential NV(VFDE) Amounts

682. NV(VFDE) amounts are calculated by adding to normal values the costs incurred by exporters between the ex-factory and FOB levels. The NV(VFDE) therefore represents an un-dumped price at the FOB level.

683. The calculation of the ex-factory un-dumped price of OLP, on which the calculation of the NV(VDFE) amount is based is the weighted-average normal value calculated from those normal values used in calculating the transaction-to-transaction dumping margins over the POI.

684. The additions made to the weighted-average normal value to adjust it to the FOB level are amounts for: inland freight, BAF, bill of lading, and cost of credit. The costs are specific to the 1000ml presentation and the cost of credit used was the average cost of credit extended to AFT over the POI. Table 9.1 shows the calculation of the NV(VFDE) amounts, in euros, on the basis set out above.

Table 9.1: Calculation of 1000ml NV(VFDE) Amounts (€)

Weighted-average normal value	[redacted]
Plus costs from ex-factory to FOB:	
- Inland Freight	[redacted]
- Bunker Adjustment Fee	[redacted]
- Bill of Lading	[redacted]

- Cost of Credit	[redacted]
NV(VFDE) € for 1000ml	[redacted]

685. Therefore if 1000ml OLP imported into New Zealand was to enter at a NV(VFDE) amount equal to or above € [redacted] the importer would not pay any anti-dumping duty, as the goods would effectively be entering New Zealand at an un-dumped level. However, as indicated earlier these duty levels are only indicative and the decision to impose duties has been deferred.

686. In response to the EFC report AFT stated that the NV(VFDE) calculations contain a number of "serious irrelevant facts and illogical conclusions." AFT considered that the BAF should not be included in the calculations as it relates to a fuel surcharge for ocean freight, a cost that occurs after the goods have passed the ship's rail and is rightly the responsibility of the importer. AFT provided comments from an ocean freight company to this effect. The Ministry normally includes the BAF fee in a NV(VFDE) amount as it is part of the payment that must be paid in order for the goods to be loaded onto the ship, despite the fact that it may be an adjustor amount relating to ocean freight activities.

687. AFT also stated that it was illogical and biased to add the cost of credit "to the NV(VFDE) or constructed like price" and commented on the appropriateness of the credit adjustment as outlined from paragraph 209.

688. AFT also raised the freight cost adjustment used in the NV(VFDE). The freight costs are those averages taken from Pinewood's overhead information and do not specifically relate to the selected Irish customer. The Ministry has used Pinewood's average freight costs on the domestic market in the absence of Pinewood being able to provide satisfactory information on freight related to OLP for the domestic customer.

9.3 Impact of Anti-Dumping Duties

689. The impact that any final anti-dumping duties may have is of particular importance in this case, due to the sole and hospital supply contracts that exist between AFT and PHARMAC. It must be noted that these contracts only impact upon the dispensary portion of the market, with the OTC portion of the market not being directly affected by PHARMAC's activities.

690. PHARMAC submitted in response to the EFC report that "because the outcome of the tender cannot be altered protective action cannot affect whether or not material injury would occur" and that "[g]iven the current tender round has closed, any duties imposed will have no effect until the end of the next tender round."

691. PHARMAC also stated that "[i]mposition of duties based on the threat of material injury will not redress any injury suffered by PSM." The Ministry notes that when the recommendation on the imposition of duties is made to the Minister very careful consideration will have to be given to whether a duty would be effective in remedying the material injury caused or threatened to be caused to the domestic industry. As the imposition of anti-dumping duties in circumstances where the duties

could never be effective in remedying the material injury caused or threatened to the New Zealand industry would only serve to be punitive to the importer, in those circumstances the Ministry would be unlikely to recommend the imposition of duties.

692. PHARMAC stated that "[t]he amount of imports of OLP will depend on the outcome of the tender. Because the outcome of the tender cannot be altered, protective action cannot affect whether or not material injury will occur." The Ministry agrees that the amount of Irish OLP imported into New Zealand in the future will depend on the outcome of the 2004 tender process. PHARMAC's statement that the outcome of the tender cannot be altered, supports its statement that negotiations on tender bids are not commonly entered into and at the time of making its comments on the EFC report the outcome of the tender, or the drivers thereof, are already set, as would be expected in a single bid process. The Ministry notes that anti-dumping duties cannot determine who will be awarded the tender.

693. Anti-dumping duties are not punitive in nature and are designed only to remedy the material injury being caused to the domestic industry. However, if AFT has submitted a dumped price and this is accepted by PHARMAC for sole and/or hospital supply this will cause injury to PSM. While the imposition of anti-dumping duties would not automatically allow PSM to compete in the dispensary market the imposition of a duty may be such that AFT would be required to terminate or alter the terms of its agreement for sole supply with PHARMAC.

694. The exact nature of any duties and an assessment of whether they could be effective would be a matter for a reassessment or review in the circumstances outlined in paragraph 676. However, it is clear that the acceptance of a dumped bid for sole and/or hospital supply from AFT alone would not be sufficient to render any duties that may be imposed ineffective and the matter would have to be carefully analysed. The effectiveness of any duties that are recommended is a matter that interested parties would have the opportunity to comment on.

500ml OLP

695. The 2004 tender for which PHARMAC is currently assessing bids combines the DHB hospital (which currently has a subsidy rate for 500ml OLP) and community pharmacy portions of the dispensary market, (which currently has a subsidy level for the 1000ml OLP). The invitation to tender dated 23 December 2004 included at clause 1.14 the following:

> Where a Tender item is specified as being available for a Tender Bid for Hospital Supply Status, it is the preference of DHB Hospitals that the pack size for such a tender item is:
>
> (a) 500ml or less, where the Tender item is in liquid form;

696. The possibility of the 500ml product being the subject of a tender bid from AFT is high because: AFT currently supplies 500ml to the DHB hospital market and it is aware that the current 500ml subsidy prices are not dumped. However, the Ministry is not recommending imposing any duties on the 500ml product as none of the 500ml presentations were dumped.

697. PHARMAC stated that it "…considers there is no basis for applying a duty to the 500ml presentation" as it cannot be sold in the OTC market. The Ministry is unsure as to the intent of this reasoning and is aware that the 500ml presentation may be more likely to be offered as the product in the tender bids that PHARMAC is currently assessing in order to avoid any duties that may be imposed upon the 1000ml presentations which are dumped. PHARMAC stated that any sales of the 500ml presentations to the community pharmacy market would not be able to claim a subsidy, as only the 1000ml is subsidised in this market. The Ministry notes that this only applies to the current supply arrangements and it may change with the announcement of new supply agreements following the 2004 tender. The Ministry notes that the OLP tender bids PHARMAC is currently assessing could be based on either the 500ml or 1000ml presentations.

698. The Ministry considers the treatment of the subject goods as a whole is consistent with the Agreement and the related jurisprudence. In *Softwood Lumber* comments were made by the Appellate Body which support the proposed imposition of anti-dumping duties on the subject goods as a whole.

699. PSM stated that the Ministry's decision in the dumping investigation *Washing Machines from Korea* to impose duties on all imported (and dumped) models of washing machines from Korea, despite one size model not being manufactured in New Zealand indicated that anti-dumping duties may be applied to goods as a whole, set a precedent for anti-dumping duties being imposed on the 500ml. The Ministry notes that the situation in that case is distinguishable as all the models were dumped and is essentially a like goods issue. PSM's submission also refers to the desirability of anti-dumping duties being imposed upon the 500ml product to avoid any circumvention of the duties on the 1000ml that may occur.

700. The Ministry considers that the use of the transaction-to-transaction methodology, which is intended to target only the goods that are dumped means that no duties should be imposed on the 500ml OLP. This is not inconsistent with the principles of treating the like goods as a whole, as the like goods as a whole have been assessed for the purposes of determining dumping and injury but the transaction-to-transaction methodology approach of targeting the dumped goods means that no duties are recommended to be imposed on the 500ml presentations.

701. If a PHARMAC supply agreement was awarded based on a 500ml dumped price then the industry would need to apply for a new investigation and provide sufficient evidence of dumping causing injury. However, the circumstances that exist in the present case indicate that if an investigation was taken the possibility of retrospective measures would need to be considered.

702. Section 17 of the Act relates to the imposition of retrospective anti-dumping duties. Subsection 3 states:

> (3) Where the Minister determines-
>
> (a) In respect of dumped goods-

> (i) Either that there is a history of dumping causing material injury or that the importer was or should have been aware that the goods were dumped and that such dumping would cause injury;…
>
> the Minister may [[impose]] an anti-dumping…duty…on goods…not more than [[60]] days prior to the application of provisional measures.

703. The Ministry included a discussion on the likely basis upon which any duties would be imposed if a positive final determination was made in the EFC report which included the possibility of imposing duties on the 500ml in treating the subject goods as a whole and a relevant NV(VDFE) amount. This effectively communicated to (Pinewood who then passed on the information to) AFT the price at which a tender bid would be un-dumped, placing AFT on notice. PHARMAC agrees that "…AFT would have realised the risks of bidding in the tender at dumped prices."

704. The Ministry considers that any anti-dumping duties that may be imposed on the 1000ml OLP could be effective in ensuring that subsidy prices for OLP from Ireland are based on un-dumped or non-injurious prices.

705. PHARMAC has stated that no anti-dumping duties should be imposed as "it would not cure any injury to PSM" due to the fact that the sole and hospital supply arrangements with AFT would still stand. The Ministry is recommending the deferral of the decision on the imposition of duties until such a point that the current supply agreements expire or are superseded or any other event that changes the market supply situation, therefore current supply arrangements are not relevant in considering the effectiveness of any proposed duties.

706. A reassessment may be requested by any interested party, or initiated by the Chief Executive of the Ministry of his own initiative, at any time after duties have been imposed if it is considered that the duty levels are no longer appropriate, for example if the margin of dumping has changed. Any reassessment would likely be able to assess the duty levels using the information gained during the investigation. AFT is aware of the un-dumped prices and therefore if it was awarded sole and/or hospital supply status on the basis of a dumped price, is aware of the potential for anti-dumping duties to be incurred.

707. [redacted]PHARMAC raised the issue of the Minister's discretion to impose duties. Section 14(1) of the Act states (emphasis added)

> At any time after the Minister makes a final determination under section 13(1) of the Act in relation to goods, the Minister **may** give notice of the rate or amount of duty determined under subsection (4) of this section…

708. This wording also reflects the Agreement which states at Article 9.1 that:

> The decision whether or not to impose an anti-dumping duty in cases where all the requirements for the imposition have been fulfilled, … are decisions to be made by the authorities of the importing Member. It is desirable that the imposition be permissive in the territory of all Members…

709. Therefore the Act provides the Minister with discretion as to whether or not a duty is imposed and this discretion is consistent with New Zealand international obligations under the Agreement. The question is, what is the extent of the Minster's discretion not to impose a duty when recommended by the Ministry?

Extent of the Discretion

710. The Ministry has previously sought Crown Law Office advice twice on the extent of the discretion to impose anti-dumping duties subject to the Act, once in 1991 in relation to a countervailing investigation on alloy wheels from Australia and again in 1998 in relation to a third country dumping investigation into clear float glass from China, Indonesia and Thailand. Copies of these opinions were placed on the public file for the current investigation.

711. The 1991 Crown Law opinion states at paragraph 7.4 that:

> It is possible to envisage circumstances in which, although satisfied of the matters set out in section 14(1)(a) and (b), the Minister might decline to impose duty. However, I consider that the circumstances would be restricted to where the imposition of the duty would not necessarily cure the injury, or the injury is no longer being caused or has been otherwise satisfactorily remedied. Again, it may be possible that circumstances where public interest considerations in not imposing a duty outweigh the need to remedy the industry. However, given the nature of the legislative commitment to protect New Zealand industry and the extensive process that has been undertaken to bring the Minister to this point, I cannot envisage circumstances where that may arise.

712. PHARMAC was initially established in 1993 and has been in its current form since 2000. PHARMAC has submitted that it was not in existence at the time the 1991 Crown Law Office opinion was written and has stated that PHARMAC's statutory obligations are precisely the public interest considerations that could not be foreseen in 1991.

713. The Ministry considers, given the comments in the 1991 opinion on the strength of the legislative commitments to the New Zealand industry, that the mere fact of PHARMAC's existence and its corresponding legislative obligations is unlikely to be, of itself, enough to override this. PHARMAC considers that "the Ministry is wrong in stating that there is no mandate in the New Zealand legislation for the Minister to take national interest considerations into account in exercising the discretion under the Act, and that the national interest is a relevant consideration to which the Minister should have regard."

714. The Ministry notes that the Minister has discretion under the Act and that this needs to be exercised in an appropriate manner. There is no mandate that the Minister "must have" regard to the national interest as it is not explicitly identified in the legislation.

715. Further, it is important to note, as is set out in the 1998 Crown Law opinion at paragraph 11, that the Act does not include a specific public interest test, as is contained in the legislation of some other countries. The opinion states that this indicates:

> "that Parliament has eschewed national interest in favour of international interests. If domestic interests are now advanced as grounds for not imposing anti-dumping duty,

> there is a danger that a court would hold that the Minister had unlawfully thwarted the purpose of the legislation."

716. That said, as outlined in the 1991 Crown Law opinion, a discretion does exist and there may be circumstances in which the public interest is so strong that it outweighs the strong commitment to industry made via the Act.

717. PHARMAC's submissions on the Minister's discretion have focussed on the imposition of duties in the pharmaceutical sector. The Ministry notes that PSM has responded to this by stating that there is no leeway in the Act to apply different standards for different industries and that if the Minister took into account and accepted the statements made in PHARMAC's submission, it would place a different standard upon the pharmaceutical industry than that placed on other industries.

718. PHARMAC has also stated that the Ministry should consider public interest considerations in determining whether anti-dumping duties should apply. The Ministry notes that, while some foreign jurisdictions do have a public interest test within their anti-dumping legislation, no such provision exists in the New Zealand legislation and that there is no express mandate in the Act to consider public interest considerations in the process of an anti-dumping investigation.

719. The Ministry reported to the Minister upon his discretion to not impose duties following a letter from the Minister of Health to the Minister. Recognising that PHARMAC was not in existence in 1991 and given the passage of time since the Crown Law Office opinions were received, the Minister chose to request further advice on this issue from the Crown Law Office. The details of the Minister's request and the response are subject to legal privilege and will not be discussed in this report.

720. The legitimate expectations created by the Ministry is another matter of importance when considering the Minister's discretion to impose duties. The Ministry detailed in the EFC report that anti-dumping duties would not necessarily be recommended but gave an indication of the method and levels that would likely be used to calculate duties if they were recommended. The Ministry does not consider that it has created any legitimate expectations that no anti-dumping duties would be imposed.

Other PHARMAC Reasons Not to Impose a Duty

721. PHARMAC asserted in its response to the EFC report that the purpose of the Act, as established in *Carlton v Minister of Customs* [1986] 1 NZLR 423, is to "protect New Zealand industry by requiring fair competition". PHARMAC is concerned that the imposition of duties would be seen by foreign pharmaceutical companies as unfairly protecting New Zealand industry and inhibiting importer's ability to compete in PHARMAC tenders. The Ministry considers that this concern is an oversimplification of the Act's purpose as the Act allows for remedial action where unfair competition (via price discrimination between a manufacturer's domestic and relevant export market) causes material injury to a New Zealand industry. This remedial action should have the effect of promoting fair competition (in that the foreign industry competes on the same terms in New Zealand as it does in its domestic market). This concern also does not appear to take account of the number

of other countries in the world that are party to the Agreement and thus have similar regimes to New Zealand. For example, India and the United States of America (who are considered to be global leaders in the pharmaceutical sector) both have strong trade remedies regimes. Of the reported 231 World Trade Organisation member anti-dumping investigations initiated in 2003[2], India accounted for approximately 20 percent of these and the United States of America for approximately 16 percent, respectively being the largest and second largest users of anti-dumping in that year.

722. Further, there are protections in the Act to ensure that the remedial action does not unduly protect the New Zealand industry, i.e. to ensure that the competition remains fair. For example, section 14(4) requires that the rate of any duty imposed must not exceed the difference between the export price of the goods and their normal value. Further, section 14(5) requires the Minister, when exercising his discretion under section 14(4), to have regard to the desirability of ensuring that the amount of anti-dumping or countervailing duty in respect of the dumped goods is not greater than is necessary to prevent the material injury, or a recurrence of the material injury, or to remove the threat of material injury to an industry.

723. Also, the imposition of anti-dumping duties would not prevent a pharmaceutical company from participating in any of PHARMAC's competitive processes as it is not a quantitative or restrictive measure. It would only ensure that any competition is fair and not at a level that embodies price discrimination between markets. While PHARMAC considers that the competitive processes it carries out are sufficient to effect the "fair competition interests of the dumping legislation…", it is unlikely that a tender process (for example) would ensure that a foreign tenderer does not discriminate between their domestic and New Zealand export markets to the extent that material injury is not caused to New Zealand industry. The Ministry notes that there is no mechanism in the PHARMAC tender process to ensure that injurious dumping does not occur and in fact PHARMAC's tender processes drive prices down, which may increase the potential for dumped prices to be tendered.

724. PHARMAC stated in its response to the EFC report that "…the national interest in acting consistently with free trade principles, such that a dumping remedy does not unduly protect the New Zealand industry at the expense of a foreign industry, is a relevant consideration to which the Minister should have regard when exercising his discretion." The interests of the Irish exporter are protected by the requirements in the Act and the Agreement that any anti-dumping duty must not exceed the full margin of dumping and regard shall be had to the desirability of a lesser duty. In this respect the imposition of an anti-dumping duty is only to ensure that the competition is fair and the exporter does not sell goods to New Zealand at a price lower than it would accept in its home market or a price below the price it would accept in its home market but that would not cause injury to the New Zealand industry. The Act specifically provides a mechanism for remedying injurious dumping but does not prohibit dumping and is part of an open environment where dumping that does not cause material injury to a New Zealand industry is allowed and the cost benefits that can accrue from dumping are able to be passed onto consumers.

[2] www.wto.org/english/tratop_e/adp_e/adp_stattab2_e.xls

725. PHARMAC has also submitted that the difficulties in establishing a normal value and the assessment of injury in this investigation is another reason that the Minister should decline to impose duties. The Ministry notes that, under the Act and Agreement, obtaining perfect information and co-operation from all interested parties is not a pre-requisite to imposing duties and that the use of best information available is permitted. To decline to impose a duty because interested parties have not supplied all of the requested information would be likely to render the regime ineffective.

726. The LECG submission in response to the EFC report stated that "a forward looking cost benefit analysis" should be undertaken before duties are imposed. The Ministry reiterates its previous comments about the purpose of the Act and that there is no specific allowance for this within the Act or the Agreement. LECG focuses on the increase in costs for PHARMAC that an anti-dumping duty would bring. This necessarily assumes that the cost would be passed onto PHARMAC and ultimately taxpayers; either directly, or indirectly through increased tender bids and ignores the possibility of the importer taking a smaller profit margin.

727. The LECG submission goes on to submit that "[t]he precedent of doing so may also have more widespread impacts in other industries all ensuring that consumers in New Zealand lose the benefits of increased international competition in the form of lower prices and more innovative products and services." The Ministry notes that the purpose of the Act allows the presence of domestic industry to supersede the low costs to consumers when those prices are dumped and cause injury to the New Zealand industry.

Implications for PHARMAC

728. It is also important to note the impact of any final anti-dumping duties on the operation of PHARMAC. While it has been submitted by PHARMAC that the imposition of anti-dumping duties will mean that , as , the Ministry . First it in New Zealand and is a on the PHARMAC and that the pharmaceutical industry has of , means that a makes the

729. . and PHARMAC

[redacted] anti-dumping duties [redacted]

10. Recommendations

730. It is recommended on the basis of the information obtained during the course of the investigation into the dumping of OLP from Ireland, that the Minister:

i. determine pursuant to section 13 of the Act that in relation to the importation or intended importation of OLP from Ireland into New Zealand:

- Most of the OLP is dumped;
- Material injury has been caused to the New Zealand industry by factors other than the dumped goods;
- Material injury to the New Zealand industry is threatened by the dumped OLP from Ireland; and

ii. defer the decision on the imposition of anti-dumping duties, pending review following the outcome of the current PHARMAC tender process, or any other event that changes the market supply situation.

iii. Sign the attached Gazette notice, and give notice of the final determination to interested parties in accordance with sections 9 and 13 of the Act.

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Investigating Team

Trade Remedies Group