Oral Liquid Paracetamol from the Republic of Ireland

Non-Confidential Initiation Report

Dumping and Countervailing Duties Act 1988

Dumping Application

Ministry of Economic Development

October 2004

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Abbreviations

The following abbreviations are used in this Report:

Act	Dumping and Countervailing Duties Act 1988 (and its subsequent amendments)
ACP	Alternative Commercial Proposal
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
Customs	New Zealand Customs Service
DHB	District Health Board
Douglas	Douglas Pharmaceuticals Limited
EBIT	Earnings Before Interest and Tax
EUR/(€)	Euros
Exel	Exel New Zealand Limited
FOB	Free on Board
HMG	Healthcare Manufacturing Group
Ireland	The Republic of Ireland
MedSafe	New Zealand Medicines and Medical Devices Safety Authority
Minister	Minister of Commerce
Ministry	Ministry of Economic Development of New Zealand
mg	Milligram
ml	Millilitre
NZD	New Zealand Dollars
OLP	Oral liquid paracetamol
OTC	Over the counter
Pharmac	Pharmaceutical Management Agency
Pinewood	Pinewood Laboratories Limited
PSM	PSM Healthcare Limited
YTD	Year to Date

1. Executive Summary

Introduction

1. On 27 May 2004, the Ministry of Economic Development (the Ministry) accepted a properly documented application for a dumping investigation from Healthcare Manufacturing Group, trading as PSM Healthcare Ltd (PSM), alleging that imports of oral liquid paracetamol from the Republic of Ireland (Ireland) are being dumped and by reason thereof are causing and threatening to cause material injury to the New Zealand industry.

Goods Subject to the Investigation

2. The goods subject to the investigation are described as follows:

Oral liquid paracetamol (OLP) in various strengths and pack sizes excluding paracetamol in other forms.

Grounds for the Application

3. PSM claims that the imports of allegedly dumped OLP from Ireland are affecting the prices of like goods produced by the New Zealand industry and consequently adversely impacting on the industry.

Dumping

4. The Ministry is satisfied that PSM has provided sufficient evidence of export prices and normal values for the purposes of initiation of an investigation. On the basis of the information provided in the application, dumping is alleged to have occurred in 2003 and 2004. Dumping margins range from [redacted] to [redacted] percent, expressed as a percentage of the export price for goods imported from Ireland.

Injury

5. The Ministry is satisfied, on the basis of the information and evidence provided by PSM, that there is sufficient evidence that the import volumes of the subject goods have increased significantly, and the New Zealand industry's prices have been undercut, depressed and suppressed by the imports resulting in significant declines in output, sales, market share, and profit.

Injury Factors Other Than the Dumped Goods

6. PSM addressed the volume of non-dumped imports, the patterns of consumption, restrictive trade practices, developments in technology, its exports, imports and productivity in its application and stated that there are no other known causes of injury than from the allegedly dumped imports.

7. The Ministry is aware that the sole supply status and associated subsidies for OLP awarded by New Zealand's Pharmaceutical Management Agency to the New

Zealand importer of Irish goods for a substantial part of the market, have impacted on PSM. The extent of this impact will be considered in any investigation.

Causal Link

8. PSM has provided evidence in support of its claim that material injury has been caused by the allegedly dumped goods.

Provisional Measures

9. PSM believes that the continued importation of allegedly dumped goods during any investigation will increase the materiality of injury and, therefore, has requested the imposition of provisional anti-dumping duty in accordance with section 16 of the Dumping and Countervailing Duties Act 1988.

Recommendation

10. Being satisfied that sufficient evidence has been provided in the application to demonstrate that goods imported into New Zealand are being dumped and by reason thereof are causing material injury to the New Zealand industry producing like goods, this report recommends that the Chief Executive of the Ministry formally initiate an investigation to determine both the existence and effect of any alleged dumping of OLP from Ireland.

2. Proceedings

2.1 Proceedings

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

12. In accordance with section 10 of the Dumping and Countervailing Duties Act 1988 (the Act), the Chief Executive of the Ministry may, on receipt of an application from the industry, initiate an investigation to determine both the existence and effect of any alleged dumping of any goods on being satisfied that sufficient evidence has been provided that:

a. the goods imported (or intended to be imported) into New Zealand are being dumped; 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).

13. In considering an application, the Chief Executive is required to be satisfied that there is evidence going beyond mere assertion and of a nature and extent that indicates a likelihood of dumping and resultant material injury, requiring investigation. The evidence is to be scrutinised with due scepticism, bearing in mind the commercial context.[1] The Chief Executive is to be satisfied of the sufficiency of the evidence only, not of dumping or material injury.

2.2 Basis for the Application

14. PSM claims that as a result of the alleged dumping, material injury is resulting from:

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

and is resulting in a:

- decline in output and sales;
- decline in market share; and
- decline in profits.

[1] [1] Kerry (NZ) Limited v Taylor (1991) 2 PRNZ 393

15. PSM stated in its application that the material injury resulting from the importation of allegedly dumped OLP commenced in 2003.

16. PSM has requested the imposition of provisional anti-dumping duties to prevent material injury being caused during any investigation and they will be considered if this application is initiated. Provisional anti-dumping duties may be imposed no earlier than 60 days after initiation of an investigation, if the Minister of Commerce of New Zealand (the Minister) has reasonable cause to believe that the imported goods are being dumped and are causing material injury to an industry, and is satisfied action is necessary to prevent material injury being caused during any investigation.

2.3 Interested Parties

New Zealand Industry

17. The application was submitted by PSM which advised that it is the only company in New Zealand that manufactures OLP.

18. Research by the Ministry discovered sales in the New Zealand market by another New Zealand manufacturer Douglas Pharmaceuticals Limited (Douglas). PSM stated that it believes that Douglas is no longer manufacturing OLP and the sales may be of stock produced in earlier years.

19. The Ministry is unable to determine from the Customs data whether Douglas is importing OLP but from the limited volumes of Douglas product in the sales data accepts the explanation given by PSM for Douglas's sales.

Importers

20. PSM identified the following importer of the subject goods:

AFT Pharmaceuticals Limited (AFT)
Takapuna
Auckland
New Zealand

21. There are no other known parties that imported OLP from Ireland during the period.

Exporters

22. PSM has identified the following manufacturer and exporter of the subject goods:

Pinewood Laboratories Limited (Pinewood)
Ballymacarbry
Clonmel
County Tipperary
Ireland

23. OLP which is manufactured in New Zealand and is a "like good" is defined in section 3(1) of the Act. OLP has been classified for tariff purposes by the New Zealand Customs Service (Customs) from the description of the goods provided by PSM.

24. Any investigation will need to confirm the identity of the supplier of the goods and confirm that such goods are, in fact, manufactured in the country of export.

2.4 Imported Goods

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

"Oral liquid paracetamol in various strengths and pack sizes excluding paracetamol in other forms."

26. Customs has stated that OLP enters New Zealand under the two tariff items and statistical keys 3003.90.09.10K, and 3004.90.19.19G (see below). All the applicable duty rates are "free of duty".

27. The Tariff items and statistical keys below that are in italics are included only for comprehension of the relevant 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

2.5 Report Details

28. In this report, unless otherwise stated, years are the twelve months to December and values are New Zealand dollars (NZD). Year to date (YTD) figures are from 1 January to 16 May 2004. In tables, column totals may differ from individual figures because of rounding.

29. The period for considering claims of dumping is the year ending 31 August 2004, while the consideration of injury involves evaluation of data for the period 1 January 2002 to 31 August 2004. PSM has also provided forecast data to 31 May 2005 as it considers that injury will increase during 2004.

30. Exchanges rates used in the report are those provided by PSM in its application. The Ministry checked the exchange rate used by PSM with the average interbank exchange rate over one year from www.oanda.com and consider that the exchange rate used by PSM was reasonable.

31. It should be noted that the inclusion of any information in this report does not indicate that the Ministry necessarily accepts that information or any conclusions arising from it. Any determination of whether or not goods are dumped and causing injury can be made only after a full investigation has been carried out in accordance with the Act.

3. New Zealand Industry

32. Section 3A of the Act 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.

33. Like goods is defined in section 3 of the Act:

> "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

34. Having identified the subject goods, for the purpose of any anti-dumping investigation that may be initiated, it is necessary to establish the existence and extent of any New Zealand industry. Defining the domestic industry requires identifying any New Zealand producers of goods that are like to the allegedly dumped goods in all respects.

35. If there are not any goods that are like to the subject goods in all respects the Act requires that any New Zealand producers of other goods that have characteristics closely resembling the subject goods be included in the assessment of like goods.

The Subject Goods

36. The imported subject goods have been identified at paragraph 25 as:

> *Oral liquid paracetamol (OLP) in various strengths and pack sizes excluding paracetamol in other forms.*

37. PSM does not consider paracetamol in tablet, capsule or suppository form to be like goods for the purpose of an investigation. Reasons given for the exclusion of these forms of the product from the like goods consideration, are given below.

Like Goods Considerations

38. 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).

39. The Ministry has firstly compared the allegedly dumped imported good and 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 allegedly dumped goods.

a. Physical characteristics.

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

41. 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.

AFT Product

42. PSM stated Parapaed OLP is manufactured according to the British Pharmacopoeia guidelines.

43. PSM provided information 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 alcohol.

44. PSM stated that the subject goods have been imported in the form of OLP in 120 and 250 milligrams (mg) strengths in both plastic and glass bottles in 100, 200, 500 and 1,000 millilitres (ml) sizes.

PSM Product

45. PSM stated that its OLP is also manufactured to meet similar guidelines to the British Pharmacopoeia guidelines.

46. 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.

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

Oral Liquid Paracetamol

48. 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 themselves.

49. 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.

50. 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 glass or plastic bottle. The packaging for OLP can vary depending on whether it is destined for the dispensary or OTC market.

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

Tablets

52. 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 per 5ml.

53. 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 dispensary.

Capsules

54. Capsules, like the tablets, are stated as containing only four added excipients in the MedSafe composition report. Each capsule contains 250mg of paracetamol per 5ml.

55. 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 dispensary.

Suppository

56. Suppositories are stated as containing only one added excipient in the MedSafe composition report. Each suppository contains 250mg of paracetamol per 5ml.

57. 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 dispensary.

Physical Characteristics Conclusion

58. The OLP products produced by AFT 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.

59. PSM's other Paracare paracetamol goods 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.

b. Function/usage

60. The use of medicines within New Zealand has to be approved by MedSafe of the Ministry of Health, who 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 dispensary only medicines.

61. The Pharmaceutical Management Agency (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.

62. 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 held to be substitutes for others within the sub-category.

63. 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 as such are designed to be used for pain relief.

64. The administration of paracetamol to control pain is used in both the dispensary and OTC markets. 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.

AFT Product

65. Parapaed OLP was granted MedSafe approval in August 2003. Parapaed OLP currently has preferred sole subsidised product status for paracetamol in oral liquid form in the Pharmaceutical Schedule, under the analgesics, antipyretics and non-opioid analgesics sub-category. Parapaed OLP is used both in the OTC and dispensary markets.

PSM Product

66. Paracare OLP has MedSafe approval; however the Ministry was unable to find any information on when this was granted. 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 as a subsidised product, but enjoyed preferred supplier status for OLP prior to the Parapaed OLP listing, and is

listed in the same category as the Parapaed OLP in Section H of the schedule. Paracare OLP is used both in the OTC and dispensary markets.

OLP

67. 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.

Tablet

68. Tablets provide a pre-measured dosage and therefore no additional preparation is required in administering the drug. 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.

69. Adults purchase tablets when looking for an adequate form of pain relief which does not require consideration of other special circumstances that alternate forms of paracetamol can require.

Capsule

70. 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.

71. Adults purchase capsules when looking for an adequate form of pain relief which does not require consideration of other special circumstances that alternate forms of paracetamol can require.

Suppository

72. 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.

73. 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.

Function/Usage Conclusion

74. 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 Parapaed OLP. This is illustrated by both products being considered to be in the same sub-category of the Pharmaceutical Schedule.

75. 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.

76. 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 or consumer market, where customer preferences and the circumstances in which the pain relief is to be administered are more varied.

c. Pricing structures

AFT Product

77. PSM did not provide information on the formal pricing structures for the Parapaed product, but stated that in New Zealand the price for the dispensary market is controlled by Pharmac. The fully subsidised price listed in the Pharmaceutical Schedule cannot be lower than the cost of production.

78. Parapaed is available to the dispensary market at a fully subsidised price as 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

79. 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. Comparing the amount of PSM's cost to manufacture and sell Paracare OLP to the subsidised price that AFT are receiving for Parapaed in the Pharmaceutical Schedule it would appear that the Parapaed product may be achieving approximately a [redacted] percent net profit at this subsidy rate. This is [redacted] that PSM has achieved in the past for Paracare OLP.

80. PSM provided product listings for Parapaed, as they appeared in the March 2004 "Over the Counter" Health Support Limited promotional leaflet sent to pharmacies. 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 Product

81. PSM provided a detailed breakdown of its cost structure and its costs were used as a proxy for the cost structure underlying the pricing of Parapaed.

82. Paracare was listed in 2003 at a fully subsidised rate in the Pharmaceutical Schedule as listed in Table 3.3:

Table 3.3 Paracare 2003 Subsidised Price

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

83. 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

84. On the copy of the March 2004 “Over the Counter” Health Support Limited flyer displaying Parapaed OLP prices PSM provided to the Ministry there was a [redacted]

[redacted] products. [redacted] indicates that despite the price differential PSM considered that the pricing structures of the product should be similar to allow the prices to be at a comparative level.

OLP

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

Tablet

86. 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.

Capsule

87. PSM's price to the OTC market 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

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

Pricing Structures Conclusion

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

90. It appears that both Paracare and Parapaed have distinct pricing structures for the OTC and dispensary markets. The price to the dispensary market for 1000ml of the 120mg strength at NZD7.29 represents only 13 percent of the price of Paracare to pharmacies (for the OTC market) being NZD5.53 for 100ml of the 120mg strength (i.e. NZD55.30 for 1000mls). Similar comparisons for Parapaed show the price to the dispensary market to be approximately 13 percent of the OTC prices for the equivalent product.

91. 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.

d. Marketing.

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

AFT Product

93. AFT's OLP product 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, which is intended to be enticing to young patients and the Six-Plus product comes in an orange flavour, which is also intended to increase the product's palatability for younger patients.

94. Parapaed products display the phrase "Sugar Free" on the packaging presented to the OTC market, which is probably intended as a marketing tool to distinguish the Parapaed OLP from other brands.

95. PSM provided a copy of AFT's deals sheet, a marketing device used commonly in the pharmaceutical industry, valid until 12 September 2003 offering prices to pharmacies that included Parapaed products. PSM also provided the Ministry with the "Over the Counter" Health Support Limited March 2004 leaflet, which featured Parapaed advertising. Both the leaflet and the deal sheet offered the same bulk-buy specials where an increasing percentage was deducted from the price as the number of units purchased increased.

96. PSM stated that a normal distribution channel for the pharmaceutical industry would be from a supplier or manufacturer to a wholesaler and then onto a pharmacy. This supply chain seems to apply only to the OTC market. PSM did not provide any details of any variations from this industry standard supply chain that it thinks may apply to AFT's.

97. PSM stated that wholesalers are not involved in the dispensary market supply chain. It is likely that manufacturers and suppliers sell directly to District Health Boards (DHB's) or hospitals and pharmacies, and that all brands are able to be purchased for discretionary variance purchases made by the DHB's, which can be up to 20 percent of their total purchases of OLP (see paragraph 141) .

98. 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. PSM stated that this clause equates to a "demand by Pharmac that the product cannot be promoted." PSM did not provide any further information in relation to the advertising of Parapaed.

PSM Product

99. 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 any infant patient's parents may have about the effect of colouring and alcohol in the medicine upon their children.

100. 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.

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

102. PSM provided a copy of its Winter Product Order Form 2004, which 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 and it is possible that a discount is available either based upon the volume of each individual purchase or at a rate determined by PSM based on previous sales or to make the product competitive given other offers in the market at any given time.

103. PSM stated that a normal distribution channel would be as outlined in paragraph 97 and states that its general distribution is from the supplier to a wholesaler and then onto a pharmacy.

OLP

104. OLP is a pharmacy only or restricted medicine, this means that it cannot be sold in supermarkets or other non-pharmacy outlets. When a medicine is restricted a prescription is not required in order to purchase the product but it must be purchased from a pharmacist and therefore is often stored behind the counter in a pharmacy to reflect the nature of the drug.

105. Pharmacists must advise consumers of the correct dosage of OLP to be administered, stressing that OLP should be carefully dispensed to ensure no overdosing occurs.

Tablet

106. Paracetamol in tablet form is not a restricted medicine and can be purchased from a range of fast moving consumer goods outlets, such as supermarkets, in addition to pharmacies, without requiring specialist advice.

107. General distribution is from a manufacturer or supplier to a wholesaler and then to the retailer.

Capsule

108. Paracetamol in capsule form is not a restricted medicine and can be purchased from a range of fast moving consumer goods outlets, such as supermarkets, in addition to pharmacies, without requiring specialist advice.

109. General distribution is from a manufacturer or supplier to a wholesaler and then to the retailer.

Suppository

110. Paracetamol in suppository form is not a restricted medicine, however this form is only available from pharmacies since the volumes sold are too low for other outlets such as supermarkets to desire stocking the product. This form is usually purchased under the direction of a healthcare professional.

111. General distribution is from a manufacturer or supplier to a wholesaler and then to the retailer.

Marketing Conclusion

112. Parapaed and Paracare OLP seem to be marketed in a very similar manner. Both products appear to use separate packaging for the OTC and dispensary markets. Both products use similar chains of distribution to reach the end-user.

113. The marketing for Parapaed OLP is allegedly limited due to the advertising clause inserted into Pharmac sole supply agreements, however PSM presented no further evidence on the restriction.

114. Due to OLP being a restricted medicine it is marketed in different ways to other forms of paracetamol (tablets, capsules and suppositories) that are sold as unrestricted medicines.

e. Other

115. 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.

116. 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 it thought that the Parapaed product should be entering under.

117. 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 for the purpose of any investigation that may be initiated.

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

Conclusions Relating to Like Goods

OLP Manufactured by PSM

119. The imported Parapaed OLP is not identical in every way to the Paracare 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.

120. Therefore the allegedly dumped goods and the domestically produced goods manufactured by PSM are considered to be like goods for the purposes of any anti-dumping investigation.

Other Forms of Paracetamol Manufactured by PSM

121. 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.

122. 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.

123. However there are sufficient distinguishing characteristics to exclude non-OLP forms of paracetamol from the definition of the like goods for the purpose of any anti-dumping investigation. 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

124. 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.

125. The application was submitted by PSM which stated that it is the sole manufacturer of OLP in New Zealand. The Ministry's research also found sales of OLP manufactured by Douglas in the New Zealand market. PSM stated that it believed Douglas had ceased manufacture of OLP some time ago. The Ministry found a Gazette notice relating to Douglas OLP from 1999 but could not find any other information on OLP manufactured in New Zealand by Douglas and there was no mention of OLP in the product listing on Douglas' website. Any investigation that is initiated would have to confirm whether or not Douglas is currently manufacturing OLP.

126. Sales by PSM for the year ended December 2003 represented ▒ percent of the total New Zealand market and ▒ percent of the sales of all New Zealand manufacturers, with Douglas accounting for ▒ percent, therefore the industry support required by sub-section 10(3) of the Act is met in the application. PSM, therefore, has standing in terms of the Act to make an application for a dumping investigation as the sole manufacturer in the New Zealand industry.

3.3 Imports of Oral Liquid Paracetamol

127. The industry was unable to obtain volume import data for the relevant tariff items which contain OLP because 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 entering under the tariff items come in different forms and units. PSM, therefore, provided point of sale data from Aztec Information Systems Ltd (Aztec) in its application.

128. 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 the products at the point of sale in pharmacies. 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 and is available on a daily basis. These figures include all sales through pharmacies, both OTC and dispensary, but do not include dispensary sales to hospitals (see paragraph 134).

129. PSM believes that Aztec data is a reasonable reflection of sales of all OLP in the New Zealand market. The Ministry notes that in 2003 the Aztec sales figures for PSM represented ▒ percent of the actual production.

130. Table 3.5 shows the estimated imports into New Zealand based on the Aztec data.

Table 3.5: Import Volumes of OLP into New Zealand (1000ml)

	2001	2002	2003	YTD 2004*
Imports from Ireland	0	0	2,072	61,628
Other Imports	33,654	35,627	30,654	5,415
Total Imports	33,654	35,627	32,726	67,043

*1 January to 16 May 2004

3.4 New Zealand Market

131. Table 3.6 shows the New Zealand market volume using Aztec data.

Table 3.6: New Zealand Market Volume (1000ml)

	2001	2002	2003	YTD 2004*
NZ Industry Sales	157,124	187,760	165,556	16,328
Imports from Ireland	0	0	2,072	61,628
Other Imports	33,654	35,627	30,654	5,415
NZ Market	190,778	223,387	198,282	83,372

* 1 January to 16 May 2004

132. The Ministry notes that if PSM's actual sales (from its own records) are compared with the data above, the industry's sales are within [redacted] percent of the amounts listed in the Aztec data. The Ministry considers that the Aztec data is a reasonable representation of the market for comparison purposes, as it shows the relativity between the imports and New Zealand industry sales and is also used by PSM to monitor its market share.

Market Segmentation

133. The New Zealand market for OLP is viewed as having two sub-markets; dispensary and OTC.

134. The dispensary market covers OLP dispensed in hospitals and through pharmacies for a prescription from a registered physician. The dispensary market is based on 500ml and 1000ml presentations. Hospitals account for 8 to 10 percent of the dispensary market with the rest being prescriptions issued by community pharmacies. The dispensary market accounts for approximately 80 percent of the total New Zealand market.

135. 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 20 percent of the total New Zealand market.

Government Participation

136. 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.

137. 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. Being a pharmacy-only medicine also means that OLP is required to be purchased from a registered pharmacist and cannot be sold by a retail assistant in a pharmacy. The pharmacist 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.

138. The second body is Pharmac. Pharmac is the Pharmaceutical Management Agency, 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]."

139. 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 drugs 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 price that the Government will pay the manufacturer(s) for certain pharmaceuticals. This means that New Zealanders will have some pharmaceuticals fully subsidised by the Government, others only partially so, 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 sales and hospitals.

140. As part of the way that 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 pharmaceutical from the listed supplier. Not all pharmaceuticals listed in the Pharmaceutical Schedule have a sole supply status attached to them.

141. The Pharmaceutical Schedule lists the subsidy prices that will apply to hospitals in section H of the Pharmaceutical Schedule. Section H has an allowance for DHB's (or individual hospitals) to have a discretionary variance spending amount for some pharmaceuticals that have a sole supplier status attached to them. Discretionary variances vary between pharmaceuticals and some have no discretionary variance, meaning that only the brand with sole supply status may be purchased. The discretionary variance only applies to hospitals and does not exist in other parts of the Pharmaceutical Schedule.

142. OLP currently has sole supplier status awarded to Parapaed. The Ministry understands that AFT's Parapaed received sole supply status as a result of an alternative commercial proposal (ACP) it put forward to the tender and that as a result, received sole supply status for OLP (see paragraph 218). Sole supply status means that community pharmacies must purchase Parapaed OLP in order to receive the listed subsidies. Section H of the schedule has a 20 percent discretionary variance allowed for OLP so DHB's (or individual hospitals) may purchase up to 20 percent of their total requirements for OLP from any of the other brands that are listed in the schedule (currently Paracare Junior Suspension, PSM paracetamol elixir paediatric, Paracare Double Strength Suspension, Douglas, and Pamol).

143. Effectively this means that for hospitals the sole supply status applies to only 80 percent of their purchases and they have the discretion to purchase the remaining 20 percent of their OLP needs from any of the listed suppliers and still receive the listed subsidy.

4. Evidence of Dumping

144. 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.

145. Information provided by PSM on the export prices and normal values of the subject goods is assessed below.

4.1 Export Prices

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

147. PSM stated in its application that it does not have any information that would suggest that the relationship between the New Zealand importer and the Irish exporter is other than "arm's length". In addition, the Ministry has found no information which would suggest that the export price is affected by the relationship between the importer and exporter.

Base Prices

148. The base prices are usually the prices in the New Zealand market from which export prices can be calculated for the purposes of initiation of a dumping investigation.

149. PSM stated that actual export prices were not reasonably available to it as the relevant commercial documents that relate to sales between Pinewood (the exporter) and AFT (the importer) are not publicly available.

150. PSM has also stated that there is not a linear relationship between presentation and the cost to produce OLP and that "doubling the size [of the presentation] won't normally double the cost". This is because of the extra packaging, labelling and handling costs incurred in preparing product for the OTC market.

151. PSM has provided two sets of base prices from which to calculate export prices, one set for the 500 and 1000ml presentations supplied to the dispensary market and the other for 100 and 200ml presentations sold into the OTC market.

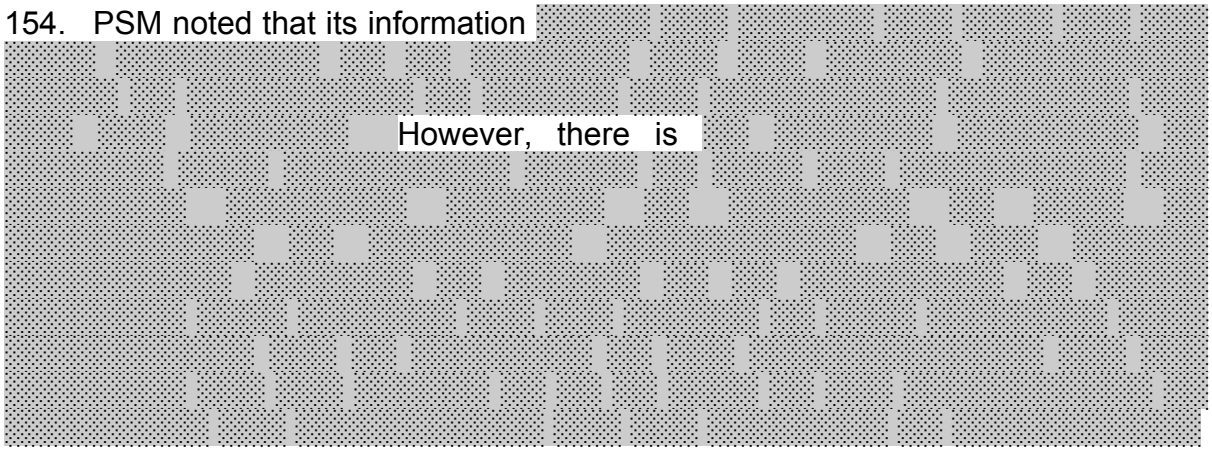
Dispensary Market

152. PSM stated that the 500ml and 1000ml presentations (in addition to some of the 200ml presentations when purchased under a practitioner's supply order) imported by AFT, are subsidised by New Zealand's health funding authority

153. The 500ml and 1000ml products are only sold into the dispensary market. PSM stated that the best information available to it to calculate the export prices of these sizes was the fully subsidised ex-supplier/wholesaler price per 1000ml, published by Pharmac. PSM, however, also advised that there were, in fact, two different

subsidised prices in the dispensary market. The 500ml subsidised price is listed in Section H of the Pharmaceutical Schedule applicable to hospitals and the subsidised price for the 1000ml presentation is listed in Section B for community pharmacies.

154. PSM noted that its information



155. As there are two different subsidy rates for essentially the same product in this market, and in the absence of AFT's actual sales prices to hospitals and pharmacies, the Ministry has allocated the subsidy prices and costs for the 500 and 1000ml product by calculating a per ml rate.

156. This has been done by adding the two different subsidy rates for each same strength presentation, that is, combining the 500ml and 1000ml 120mg rates, and dividing by 1500 to reach a per ml price. The same approach has been used to work out the costs on a per ml basis. The subsidy rate and the per ml costs have then been allocated to the different presentation sizes. A deductive method has then been used, starting with the allocated subsidy rate to estimate export prices for the 500ml and 1000ml presentations.

157. The Ministry considers that a per ml approach is conservative given the market commentary on prices offered being below the listed subsidy rates and that any prices that are lower than the subsidy rates would increase any dumping margins.

OTC Market

158. Base prices for the OTC market 100 and 200ml presentations have been taken as the prices of OLP advertised in the March 2004 "Over the Counter" Health Support Limited leaflet to pharmacies. There is no subsidised price for the 100 and 200ml presentations, as they are only subsidised in the specific circumstances of a practitioners supply order.

159. PSM used a deductive method from these prices to calculate ex-factory prices.

Import Data

160. PSM provided Aztec data in its application for the reasons discussed in paragraph 127.

Product Range

161. PSM stated that the subject goods are likely to be imported in 100, 200, 500ml and 1000ml presentations. The active ingredient in the imports comes in 120 and 250mg strengths.

Adjustments

162. PSM provided what it considers to be the costs, charges and expenses incurred in preparing the goods for shipment to New Zealand, which would be additional to those generally incurred on sales for domestic consumption in Ireland.

Retail Discount

163. PSM provided the March 2004 "Over the Counter" Health Support Limited advertising leaflet to New Zealand pharmacies showing that prices in the OTC market for the Irish product Parapaed were being discounted from 20 to 40 percent depending on the number of units purchased. PSM used the average discount price of 30 percent off the ex-wholesale price as representative in calculating the discount to pharmacies. This adjustment has been applied only to the OTC 100 and 200ml presentations export price calculations.

Wholesalers' Margin

164. PSM has stated that based on its industry experience it has allowed 15 percent as the wholesaler mark-up that would be added to the importer's price. This adjustment has been applied only to the OTC export price calculations, as it is not a cost incurred for dispensary market products.

Importer's Margin

165. PSM estimated an importer's margin of 25 percent, based on the cost of the product, to cover the costs associated with the AFT's overheads, distribution, selling expenses and profit. PSM stated that this is a conservative estimate of the margin based on its industry experience. This adjustment has been applied to both the dispensary and the OTC market products.

Importer's Clearance, Handling and Cartage Costs

166. PSM used a door-to-door quote from [redacted]) for a shipment for a 20-foot container of OLP from Ireland to New Zealand to approximate the costs incurred in New Zealand by the importer for clearance, handling and local cartage costs.

167. PSM allocated costs on the assumption that the container is packed with 10,000 1000ml presentations, but considered it likely that a shipment would contain between 10,000 and 14,000 presentations, being a mixture of all size presentations, with the majority being 1000ml presentations, as this size presentation serves the largest part of the market.

168. The shipping quote specified costs for the delivery order, shipping company documents, New Zealand port service charges, and Customs clearance fees.

169. The combined cost for these services was NZD[redacted] or NZD[redacted] per 1000ml. This adjustment has been applied to both the dispensary and the OTC market products.

Overseas Freight and Insurance

170. The importer's overseas freight costs have been taken from the [redacted] quote.

171. The itemised costs quoted for sea freight from Dublin to Auckland was NZD[redacted] The cost of the insurance was estimated by PSM to be NZD[redacted] or [redacted] percent of the total cost of a container based on 10,000 1000ml presentations. The total cost therefore for freight and insurance was NZD[redacted] or NZD[redacted] per 1000ml. These adjustments have been applied to both the dispensary and the OTC market products.

Costs from Ex-factory to FOB

172. Wharfage, handling fees and cartage to the wharf were also included in the [redacted] quote. These costs were itemised separately. The costs were listed as origin charges (NZD[redacted]), inland transport to Dublin port and terminal handling charges (NZD[redacted]).

173. The total costs amounted to NZD[redacted], or NZD[redacted] per 1000ml. This adjustment has been applied to both the dispensary and the OTC market products.

Export Price Calculation

Dispensary Market

174. Table 4.1 shows the calculation of the exported ex-factory price for 500 and 100ml presentation for both strengths of OLP for the dispensary market products.

Table 4.1: Deductive Export Price: Parapaed, 500ml and 1000ml (NZD)

	500 ml		1000 ml	
	120mg	**250mg**	**120mg**	**250mg**
Price Ex-supplier (ex GST)	4.26	4.43	8.53	8.87
Less:				
AFT Suppliers Margin (25%)	0.85	0.89	1.71	1.77
Into Importers Store Cost:	3.41	3.55	6.82	7.09
Less:				
Importers Clearance, Handling, Local Cartage	[redacted]	[redacted]	[redacted]	[redacted]
Overseas Freight, Insurance	[redacted]	[redacted]	[redacted]	[redacted]
FOB price (Dublin, Ireland)	[redacted]	[redacted]	[redacted]	[redacted]
Less:				

Wharfage, Handling Fees, Cartage to Wharf	[redacted]	[redacted]	[redacted]	[redacted]
Ex-factory Price (Ireland) NZD	[redacted]	[redacted]	[redacted]	[redacted]
Converted to EURO@0.54	[redacted]	[redacted]	[redacted]	[redacted]

OTC Market

175. Table 4.2 shows the calculation of the exported ex-factory price of the100ml and 200ml presentations for both the 120mg and 250mg strengths.

Table 4.2: Deductive Export Price: Parapaed, OTC Packs (NZD)

	100ml		**200ml**	
	120mg	**250mg**	**120mg**	**250mg**
Price to Pharmacy	6.05	6.11	8.14	8.20
Less discount (30%)	1.82	1.83	2.44	2.46
Price to Pharmacy	4.23	4.28	5.70	5.74
Less Wholesalers Margin (15%)	0.55	0.56	0.74	0.75
Ex-supplier Price (excluding GST)	3.68	3.72	4.96	4.99
Less:				
AFT Supplier's Margin (25%)	0.74	0.75	0.99	1.00
Into Importers Store Cost	2.94	2.98	3.97	3.99
Less:				
Importer's Clearance, Handling, Local Cartage	[redacted]	[redacted]	[redacted]	[redacted]
Overseas Freight, Insurance	[redacted]	[redacted]	[redacted]	[redacted]
FOB Cost Ireland	[redacted]	[redacted]	[redacted]	[redacted]
Less:				
Wharfage, Handling Fees, Cartage to Wharf	[redacted]	[redacted]	[redacted]	[redacted]
Ex-factory Price (Ireland) NZD	[redacted]	[redacted]	[redacted]	[redacted]
Converted to EURO@0.54	[redacted]	[redacted]	[redacted]	[redacted]

176. Table 4.3 contains the ex-factory export prices.

Table 4.3 Export Prices

Presentation and Strength		**Export Price**
100ml	120mg	[redacted]

	250mg	[redacted]
200ml	120mg	[redacted]
	250mg	[redacted]
500ml	120mg	[redacted]
	250mg	[redacted]
1000ml	120mg	[redacted]
	250mg	[redacted]

177. The Ministry considers that PSM has provided information that is reasonably available to it and this information has been used to calculate the ex-factory export prices shown in Table 4.3 above. The evidence provided is sufficient for calculating an export price for the purpose of initiation of any investigation.

4.2 Normal Values

178. Normal values are determined in accordance with section 5 of the Act.

Introduction

179. The normal value of any goods imported or intended to be imported into New Zealand is 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.

Base Prices

180. The information provided by PSM for normal values relates to two markets.

Dispensary Market

181. The first category of information provided was for the larger presentation products sold into the dispensary market, that is, to hospitals and dispensing pharmacies. PSM could not find any evidence that the exporter manufactured and sold similar presentations in the Irish domestic market as those it exported to New Zealand, nor could it find any other sellers in Ireland of 1000ml OLP. The 500 and 1000ml presentations are assumed not to be sold into the Irish OTC market for similar safety reasons that prohibit their sale to the New Zealand OTC market. PSM was only able to obtain selling prices for the smaller sized presentations in Ireland and stated that these could not reliably be extrapolated to the larger presentations as costs relating to presentation size are not linear. If PSM used the smaller sizes and extrapolated them to the larger presentations, the prices could be several times higher than they should be, and would give artificially high normal values for the Irish domestic market.

182. In order to approximate Irish ex-factory prices for the 500 and 1000ml presentations, PSM used its own costs, as the best available information, to substitute for the costs of manufacturing and selling in Ireland. PSM stated that it had considered using costs that may apply in Ireland (from publicly available information), but that this would involve making a number of assumptions that would amount to "guesses" thereby introducing uncertainty into the calculations. PSM noted that its raw material costs were expected to be similar to the Irish costs, but that the allocation of fixed costs applying in Ireland would be problematic.

183. PSM stated it considers that 25 percent of the cost to make and sell is a conservative estimate for a profit margin on the manufacture of the 500 and 1000ml presentations. PSM stated that this estimate is based on an efficient pharmaceutical plant providing a gross profit margin of about [redacted] percent. PSM used [redacted] profit margins to calculate the Irish base prices from which a normal value was constructed. The Ministry notes that [redacted] from 2001 to 2003 for its production of OLP.

184. The Ministry considers it reasonable that PSM has used its costs to approximate Irish costs for making the same or similar product because the cost of the active ingredient, paracetamol, is sold at world prices and the manufacturing methods and underlying cost structures could reasonably be expected to be similar given the parallels between the Irish and New Zealand economies and due to Pinewood and PSM both upgrading their manufacturing facilities in the early 2000's.

185. Table 4.4 contains PSM's own costs to make and sell OLP for the 250mg 1000ml presentation. PSM has used these costs to approximate the ex-factory prices for the Irish domestic market. The Ministry has used the average costs across the three years as the base price for the 1000ml presentation.

Table 4.4: PSM's Cost to Make and Sell: Paracare (250mg, 1000ml)

	2001	2002	2003
Sales	[redacted]	[redacted]	[redacted]
Volume	[redacted]	[redacted]	[redacted]
Variable Costs	[redacted]	[redacted]	[redacted]
Fixed Costs	[redacted]	[redacted]	[redacted]
Total	[redacted]	[redacted]	[redacted]
Gross Profit (%)	[redacted]	[redacted]	[redacted]
Sales and Advertising	[redacted]	[redacted]	[redacted]
Other	[redacted]	[redacted]	[redacted]
Total	[redacted]	[redacted]	[redacted]
Total Cost	[redacted]	[redacted]	[redacted]
Unit Cost (NZD)	[redacted]	[redacted]	[redacted]

186. Table 4.5 contains PSM's calculations of the ex-factory prices for the 120mg 1000ml presentation estimated as applying to the Irish domestic market.

Table 4.5: PSM's Cost to Make and Sell: Paracare (120mg, 1000ml)

	2001	2002	2003
Sales			
Volume			
Costs: Variable			
Costs: Fixed			
Total			
Gross Profit (%)			
Sales and Advertising			
Other			
Total			
Total Cost			
Unit Cost (NZD)			

187. Table 4.6 contains PSM's calculations of the ex-factory prices for the 250mg 500ml presentation estimated for the Irish domestic market.

Table 4.6: PSM's Cost to Make and Sell: Paracare (250mg, 500ml)

	2001	2002	2003
Sales			
Volume			
Costs: Variable			
Costs: Fixed			
Total			
Gross Profit (%)			
Sales and Advertising			
Other			
Total			
Total Cost			
Unit Cost (NZD)			

188. Table 4.7 contains PSM's calculations of the ex-factory prices for 120mg 500ml presentation estimated for the Irish domestic market.

Table 4.7: PSM's Cost to Make and Sell: Paracare (120mg, 500ml)

	2001	2002	2003
Sales	[redacted]	[redacted]	[redacted]
Volume (L)	[redacted]	[redacted]	[redacted]
Costs: Variable	[redacted]	[redacted]	[redacted]
Costs: Fixed	[redacted]	[redacted]	[redacted]
Total	[redacted]	[redacted]	[redacted]
Gross Profit (%)	[redacted]	[redacted]	[redacted]
Sales and Advertising	[redacted]	[redacted]	[redacted]
Other	[redacted]	[redacted]	[redacted]
Total	[redacted]	[redacted]	[redacted]
Total Cost	[redacted]	[redacted]	[redacted]
Unit Cost (NZD)	[redacted]	[redacted]	[redacted]

OTC Market

189. The second category of information provided by PSM is for the sale of smaller presentation products. These are sold to pharmacies for the OTC market and (mostly) do not receive a subsidy. To approximate normal value ex-factory prices for the 100 and 200ml presentations equivalent to those exported to New Zealand, PSM has obtained information on prices to pharmacies for two similar presentation products on the Irish market. These were sales to pharmacies for a 120mg strength in 70 and 140ml presentations. These prices have been used as base prices for the normal values of these presentations.

Adjustments

OTC presentations (70 and 140 ml)

190. As PSM based the normal values for the 500 and 1000ml presentations on its own costs of production no adjustments were required. However as the smaller presentations were based on actual prices in the Irish market some adjustments were required to arrive at ex-factory domestic values that are comparable with ex-factory export prices.

Physical Adjustment

Adjustment for strength (mg)

191. Sales on the Irish domestic market were found only for a 120mg strength, in 70ml and 140 ml presentations.

192. In order to approximate an Irish domestic trade price for a 250mg strength, equivalent to that exported to New Zealand, PSM took the price difference between the strengths for AFT's advertised price to pharmacies in New Zealand.

193. To adjust the 70ml 120mg presentation to a 250mg strength, PSM added the difference, in AFT's advertised price to pharmacies in New Zealand, between the 120mg and 250mg strengths of the 100ml Parapaed OLP, to the 120mg price. An adjustment of [redacted] EUR, or [redacted] percent of the 100ml price, was made.

194. To adjust the 140ml 120mg presentation to a 250mg strength, PSM added the difference, in AFT's advertised price to pharmacies in New Zealand, between the 120mg and 250mg strengths of the 200ml Parapaed OLP to the 120mg price. An adjustment of [redacted] EUR, or [redacted] percent of the 200ml price, was made.

Adjustment for Volume (ml)

195. To compare the presentations (volumes) of each product found in the Irish market with the presentations exported to New Zealand, PSM took the Irish domestic prices for the 70 and 140ml presentations and proportionately adjusted these prices to calculate 100 and 200ml respectively. For example the 70ml price was multiplied by 1.43 (being 100ml divided by 70ml) to achieve a 100ml price.

196. Table 4.8 outlines the adjustments that have been made from 70 to 100 ml and from 140 to 200ml respectively.

Table 4.8: Volume Adjustments to 70ml and 140 ml Presentation

	120 mg		250 mg	
Mls	**70 to 100**	**140 to 200**	**70 to 100**	**140 to 200**
Adjustment (EUR)	[redacted]	[redacted]	[redacted]	[redacted]

Promotional Discounts

197. PSM stated that it had made an allowance of 20 percent of the sales price for promotional discounts and any other costs that might arise for the 70 and 140 ml presentations sold on the Irish market. PSM stated that it considered that 20 percent would cover all other costs likely to be incurred and was conservative in allocating 20 percent to cover promotional activities and incentives that could be directly related to the sales of OLP.

198. PSM stated that from its own experience in the New Zealand market, promotional discounts directly related to OLP averaged [redacted] percent of the sales price.

199. The Ministry requested that PSM specify what the extra [redacted] percent might cover. PSM responded that it was a contingency amount and that it could include cover of inland freight. PSM has since provided an estimate of inland freight

separately as well as further information on its discounts to substantiate the [redacted] percent promotional discount by evidence of a promotion from January to July 2004 that covered approximately [redacted] percent of its sales.

200. The discounts offered in PSM's promotion ranged from [redacted] percent to [redacted] percent and an additional discretionary amount for the "A+" category, [redacted]. The Ministry considers that [redacted] percent is a reasonable representation of the discounts available, and in the absence of any other information, can be used to approximate a manufacturer's discounts in the Irish market.

201. Table 4.9 shows the adjustments that have been made for discounts for the smaller presentations of product.

Table 4.9: OTC Market Products: Promotional Discount

	70ml/120mg	**140ml/120mg**	**70ml/250mg**	**140ml/250mg**
Promotional Discounts ([redacted]%)	[redacted]	[redacted]	[redacted]	[redacted]

Inland Freight

202. In response to a request by the Ministry, PSM provided an estimate of the Irish inland freight cost because it was considered that this would be in excess of the freight costs of exports.

203. PSM provided information based on its own average domestic freight costs for the North Island of New Zealand as an estimate, which was [redacted] per 1000ml or [redacted] per ml. This equates to [redacted] per ml at an exchange rate of 0.54.

204. The normal values of the imported Parapaed are recorded in Table 4.10:

Table 4.10: Normal Values

Presentation and Strength		**Normal value**
100ml	120mg	[redacted]
	250mg	[redacted]
200ml	120mg	[redacted]
	250mg	[redacted]
500ml	120mg	[redacted]
	250mg	[redacted]

1000ml	120mg	[redacted]
	250mg	[redacted]

205. The Ministry considers that the information provided by PSM supporting the ex-factory normal values shown in Table 4.10 is sufficient for considering the initiation of an investigation.

4.3 Comparison of Export Price and Normal Value

206. Table 4.11 shows the export price, normal value and dumping margin calculations for imports from Ireland.

Table 4.11: Dumping Margins

Presentation and Strength		Normal Value	Export Price	Dumping Margin	Dumping Margin as % of Export 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]	[redacted]
	250mg	[redacted]	[redacted]	[redacted]	[redacted]
1000ml	120mg	[redacted]	[redacted]	[redacted]	[redacted]
	250mg	[redacted]	[redacted]	[redacted]	[redacted]

207. The dumping margins are expressed as a percentage of the export prices. These are all dumped and range from [redacted] to [redacted] percent. PSM stated that the dumping began during 2003 and will continue in 2004.

208. The Ministry considers PSM has provided information to show that the dumping margins are not *de minimis* in terms of Article 5.8 of the World Trade Organisation Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (the Agreement) as they are greater than 2 percent, as expressed as a percentage of the export prices, shown in Table 4.12.

Volume of Dumped Goods

209. Section 11(2) of the Act provides that evidence of dumping shall be regarded as insufficient if the volume of imports of dumped goods, 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. The Agreement deals with the negligibility of dumped imports under Article 5.8 of the Agreement as follows:

> ….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 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.

210. Table 4.12 shows estimated imports of the subject goods and other imports of OLP using Aztec data figures.

Table 4.12: Volume of OLP Imports

	2003	%	YTD 2004	%
Irish Imports	2,072	6	61,628	92
Other Imports	30,654	94	5,416	8
Total Imports	32,726	100	67,044	100

211. On the basis of this information, imports of the subject goods from Ireland are not negligible as defined by the Agreement.

Conclusions Relating to Dumping

212. PSM stated that the costs of producing OLP in larger volumes and the costs of selling these products into two separate markets were not necessarily linear and so could not be used for all of the products. Normal values for the larger sizes (500 and 1000ml presentations) were calculated from PSM's data, ex-factory prices for the smaller sizes being deducted from sales prices in the OTC market in Ireland. Ex-factory export prices were deducted from sales prices in New Zealand.

213. The Ministry found dumping margins ranging from [redacted] percent to [redacted] percent when expressed as a percentage of the export price, which were greater than 2 percent and therefore not *de minimis* in terms of Article 5.8 of the Agreement. The volume of imports from Ireland is greater than 3 percent of the total imports of like goods and therefore is not negligible.

214. The Ministry is satisfied on the basis of the information and evidence provided by PSM that the comparison of the export price and normal value has provided sufficient evidence of dumping for the purposes of initiation.

215. Any investigation will need to consider export price and normal value in terms of sections 4 and 5 of the Act and in particular the application of the appropriate adjustments under s4(1)(a)(i) and (ii) and s5(3).

5. Evidence of Injury

216. The basis for considering material injury is set out in section 8(1) of the Act:

> 8. Material injury to industry—(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 or subsidisation 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.

217. PSM stated in its application that material injury has been and is being caused and is threatened by OLP being dumped into the New Zealand market. PSM stated that it had the most competitive prices in the New Zealand market prior to the introduction of Parapaed, and stated that it had invested considerable developmental costs into its OLP and had made significant gains in market acceptance of the product as a result.

5.1 Pharmac Tenders

218. In considering the injury which PSM stated is being caused by the allegedly dumped imports from Ireland, the impact of Pharmac accepting an alternative commercial proposal (ACP) for dispensary market OLP from AFT must be considered. For the purposes of deciding whether an investigation should be initiated, the Ministry only assesses, at this stage, information submitted to it by the applicant and that which is publicly available. Therefore the impact of Pharmac's activities in relation to OLP can only be assessed in detail during the course of any investigation that may be undertaken. When considering initiation it is sufficient to analyse the injury effects of the allegedly dumped goods and the effects that they have had upon PSM.

219. PSM stated that AFT would not have won the sole supply status awarded by Pharmac if its prices were not based on dumped goods.

220. PSM did not offer a price in the OLP tender issued by Pharmac. PSM stated in its application that as it had good product acceptance in the market and also had the lowest priced product in the market prior to the tender, it did not consider that it needed to submit a tender price. However, it is not clear whether Pharmac actually awarded the tender for OLP, as the information available suggests that a sole supply contract was awarded to AFT after further negotiation with Pharmac, resulting in Pharmac's later acceptance of the ACP from AFT. The ACP that AFT presented contained Parapaed OLP and also included at least one other drug and in effect was a bundled offer.

221. It is important to note that the sole supply status awarded to AFT affects about 80 percent of the dispensary market for OLP, (with the remaining 20 percent of that market able to be supplied by any brand under DHB's discretionary variance purchases) but it does not directly affect the OTC portion of the market.

222. It is possible for a registered physician to issue a prescription for OLP for 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.

223. The Ministry believes it is likely that the activities of Pharmac have been influential in affecting current domestic prices for OLP in New Zealand and the impact of this on PSM would be considered in any investigation that may be initiated.

224. The Ministry believes that any issues in relation to the tender are ones that should properly be considered in greater detail in the context of any dumping investigation.

Activity by Pharmac and PSM relating to OLP

225. Pharmac and PSM activity concerning OLP, highlighted by PSM is shown below.

Prior to 9 December 1999

Several brands were listed in the Pharmaceutical Schedule for OLP, including PSM's Paracare, at $9.15 per 1000ml, with Pamol and Panadol dominating the market.

9 December 1999

Pharmac entered into a tender protection period for OLP until June 2002 with PSM. PSM had preferred supplier status but any brand was able to be purchased. The listed subsidy price dropped to $8.15 per 1000ml.

20 December 2001

A tender was issued by Pharmac for a wide range of products, one of which was OLP. PSM did not enter this tender due to Pharmac's contracting sole supply conditions, which it perceived as onerous, its current price that is considered to be competitive and market acceptability of Paracare OLP. (It is unknown if AFT entered this tender.)

4 March 2002.

The 20 December 2001 tender closed.

7 August 2002

PSM increased prices of 500ml Paracare OLP from $4.05 to $5.00 due to increased costs of manufacture effective from 12 August 2002. PSM also advised Pharmac that price increases may be necessary in the 1000ml presentations as well.

5 November 2002

PSM informed Pharmac of increased prices to be effective from 12 January 2003 for the 1000ml presentations from $8.10 to $9.15 for the 120mg strength and to $9.35 for the 250mg strength.

7 November 2002

PSM responded to Pharmac's consultation on AFT's ACP proposal to supply 500ml OLP to the dispensary market for $5.50 for the 120mg strength and $5.60 for the 250mg strength, compared to PSM's price of $5.00 for both strength products.

20 December 2002

AFT was confirmed as the sole supplier to dispensary market through Pharmac's notification of its acceptance of the ACP from AFT. Parapaed's listing was still subject to MedSafe approval with all other listed brands of OLP able to be sold until the end of the transition period 1 February 2004.

17 January 2003

PSM writes to Pharmac following disputes over whether the price increases were notified for the 1000ml presentations and mediation follows.

1 July 2003

Pharmac agrees to price increases on 1000ml presentations from $8.10 to $8.75 for the 120mg strength and from $8.10 to $8.90 for the 250mg strength.

1 November 2003

Listed prices in the Pharmaceutical Schedule were changed to $5.50 for the 120mg and $5.60 for the 250mg for 500ml presentations in section H and to $7.29 for 120mg and $7.70 for 250mg 1000ml presentations for the community pharmacies.

1 February 2004

Sole supply for the OLP dispensary market commenced.

5.2 Import Volumes

226. 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.

227. PSM provided Aztec data for the period 1 January 2001 to 16 May 2004, with information relating to Douglas's sales covering the period from 1 January 2001 to 13 June 2004. Because the Aztec data is collected only from pharmacies it does not include the amount that is sold to hospitals either under the Pharmaceutical Schedule sole supply status or under the DHB discretionary variance purchases.

228. Table 5.1 shows the volumes of OLP sold in New Zealand of the allegedly dumped Irish product, OLP from other sources and OLP produced by the New Zealand industry. These figures are compared with the total New Zealand market.

229. Amounts used for the domestic industry's sales in Table 5.1 will differ from amounts used in other parts of the report where PSM's actual sales data has been used, however, to allow comparability the amount used for the domestic industry's sales (PSM and Douglas) are those that appear in the Aztec data.

Table 5.1: OLP Import Volumes (litre equivalents)

	2001	**2002**	**2003**	**YTD 2004***
Irish Imports	0	0	2,072	61,628
Other Imports	33,654	35,627	30,654	5,416
Total Imports	33,654	35,627	32,726	67,044
NZ Industry Sales	157,124	187,760	165,556	16,328
NZ Market	190,778	223,387	198,282	83,372
Change on Previous Year:				
Irish Imports		0	2,072	59,556
Other Imports		1,973	-4,973	-25,238
Total Imports		1,973	-2,901	34,318
NZ Industry Sales		30,636	-22,204	-149,228
NZ Market		32,609	-25,105	-114,911
Percentage Change:				
Irish Imports		0%	2072%	n/a
Other Imports		6%	-14%	n/a
Total Imports		6%	-8%	n/a
NZ Industry Sales		19%	-12%	n/a
NZ Market		17%	-11%	n/a
Irish Imports as a percentage of:				
NZ Industry Sales	0%	0%	1%	377%
NZ Market	0%	0%	1%	74%

*1 January to 16 May 2004

230. Import volumes from Ireland have increased significantly in absolute terms and relative to New Zealand production and consumption. In absolute terms the imports from Ireland increased from 2,072 litre equivalents in 2003 when the alleged injury commenced, to 61,628 litre equivalents in YTD2004.

231. This increase in Parapaed sales to YTD2004 was 59,556 litres higher than the Parapaed sales in 2003, albeit the goods only entered the market in late 2003 after

gaining sole supply status on the Pharmaceutical Schedule and MedSafe registration.

232. Relative to New Zealand production the Irish imports increased from 1 percent to 377 percent from 2003 and relative to consumption they increased from 1 percent to 74 percent in the four and a half months to YTD May 2004 from 2003.

Conclusion

233. There is sufficient evidence that import volumes of the subject goods have increased significantly in absolute terms and relative to the New Zealand manufacturer's sales and total consumption in New Zealand.

5.3 Price Effects

Price Undercutting

234. 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.

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

236. PSM claimed that the prices used in determining price undercutting should not be the subsidised prices that Pharmac agreed to from 1 July 2003 but should be those that it was attempting to achieve during the mediation it was involved in with Pharmac prior to 1 July 2003. It claimed that the amount by which the price could be increased in this mediation was effectively suppressed by the lower price of the sole supply status that had been awarded to the imported Parapaed product, which at that stage was only contingent upon obtaining Medsafe approval.

237. For the purpose of determining whether to initiate an investigation the Ministry has used the actual prices that PSM received rather than those it was hoping to achieve because no sales were made at these prices. However this does not preclude different values being used for price undercutting in any investigation.

238. PSM provided the subsidised ex-manufacturer price for 1000ml OLP prior to 1 November 2003, when the allegedly dumped goods imported by AFT entered the market, and the prices after 1 November 2003. Table 5.2 illustrates those prices.

Table 5.2 Price Undercutting by Parapaed in the Dispensary Market

OLP Product Strength per Presentation		Paracare* Subsidised Price before November 2003 (NZD)	Parapaed Subsidised Price after November 2003 (NZD)	Price Undercutting (NZD)	Price Undercutting as % of Original Price
500ml	120mg	5.00	5.50	-0.50	None
	250mg	5.00	5.60	-0.60	None
1000ml	120mg	8.75	7.29	1.46	17%
	250mg	8.90	7.70	1.20	13%

*This price applied to all OLP brands listed and with Paracare listed as preferred supplier

239. Table 5.2 illustrates that Parapaed is undercutting the price of Paracare by [redacted] percent for the 120mg strength product and [redacted] percent for the 250mg strength product for the 1000ml product, but that there is no price undercutting for the 500ml product. The subsidy prices for Parapaed are likely to remain in force until 2006 when its contract with Pharmac expires, unless there are any applications for price increases pursuant to the contract terms.

240. Table 5.3 compares the prices of Parapaed and Paracare in the OTC market where the imports are not subsidised. The 100ml product is a new product for PSM and has only recently been offered to the market.

Table 5.3 Price Undercutting by Parapaed for OTC product

OLP product strength		Paracare Cost to Pharmacy	Parapaed Cost to Pharmacy	Price undercutting	Price undercutting as % of Paracare price
100ml	120mg	[redacted]	[redacted]	[redacted]	[redacted]%
	250mg	[redacted]	[redacted]	[redacted]	[redacted]%
200ml	120mg	[redacted]	[redacted]	[redacted]	[redacted]%
	250mg	[redacted]	[redacted]	[redacted]	[redacted]%

241. The Parapaed prices used in Table 5.3 are from March 2004 OTC Health Support Limited leaflets sent to pharmacies. These prices were calculated from updated information, rather than those presented by the applicant originally. The leaflet featured discounts ranging from 20 to 40 percent depending on the volume of

product purchased. The Ministry has applied the median discount rate of 30 percent which was available when 72 assorted Parapaed products were purchased. The order form, within the same leaflet, also stated "Your regular discounts apply" therefore the Ministry considers that the 30 percent is a conservative discount to apply for the purpose of price undercutting and that the undercutting by Parapaed is likely to be greater than that calculated above. The leaflet also stated "Buy now don't pay until 20th June 2004", however the Ministry has not made any adjustment to the list price for this extension of credit and considers that these prices are sufficient for the purposes of assessing the application.

242. The Paracare prices have been taken from PSM's net selling price data to May 2004, so is the average return achieved from the sale of these products after discounts.

Price Undercutting Conclusion

243. There is some evidence of price undercutting for the OTC products and evidence of price undercutting by Parapaed of the Paracare product by ▒ to ▒ percent in the 1000ml product but no evidence of price undercutting in the 500ml presentation in the dispensary market.

244. When the OTC Parapaed and Paracare prices were compared, price undercutting ranging up to ▒ percent was found, however this amount is likely to be higher if actual discounts given and credit offered are taken into account.

Price Depression

245. 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.

246. Price depression occurs when prices are lower than those in a market unaffected by dumping and are usually prices from a previous period.

247. PSM stated that after the announcement that AFT's ACP, including OLP, was accepted by Pharmac, subsidised prices decreased. PSM stated Pharmac's acceptance of the ACP affected the outcome of its negotiations with Pharmac for a price increase in the intervening transition period, after the AFT proposal had been accepted and before Parapaed had received MedSafe approval.

248. PSM stated that the price depression began around 1 November 2003 when the listed subsidy price was lowered. There were still a limited number of sales of Paracare to the dispensary OLP market between 1 November 2003 and 1 February 2004, (the transition period) at this lower price, but after 1 February 2004 sales of Paracare to the dispensary market are not permitted (except as they fit into the discretionary variance purchases by DHB's).

249. Table 5.4 illustrates the price depression that PSM has incurred. Prices used are the average ex-factory prices achieved, rather than the subsidy figures presented by the applicant. The prices used for the 120mg strength 200ml

presentation is the weighted-average price of the Paracare Junior Strawberry and Junior Colour-Free Strawberry products.

Table 5.4 Price Depression

Product Size and Strength		2003	2004	Price Depression	Price Depression as % of 2003 price
200ml	120mg	[redacted]	[redacted]	None	N/A.
	250mg	[redacted]	[redacted]	None	N/A.
500ml	120mg	[redacted]	[redacted]	[redacted]	[redacted]%
	250mg	[redacted]	[redacted]	[redacted]	[redacted]%
1000ml	120mg	[redacted]	[redacted]	[redacted]	[redacted]%
	250mg	[redacted]	[redacted]	[redacted]	[redacted]%

250. PSM has only just started to produce its 100ml product therefore there is no comparison price to use to determine whether there is any price depression on the 100ml presentations, however it is listed in PSM's product list.

251. Table 5.4 illustrates that PSM has not experienced any price depression in its 200ml presentations. However for the 500ml and 1000ml presentations there is price depression ranging from [redacted] to [redacted] percent of PSM's 2003 prices.

Conclusion on Price Depression

252. PSM has not experienced any price depression in the OTC market for its 200ml presentation of OLP. However there is evidence of significant price depression in the dispensary market for the 500ml and 1000ml presentations.

Price Suppression

253. 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 goods is, or is likely significantly to, prevent price increases for those goods that otherwise would have been likely to have occurred.

254. 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) when expressed as a percentage of sales. 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 raised as positive evidence of price suppression.

255. PSM did not provide information for prices, costs and profits on an individual product basis, therefore, due to the different costs of manufacturing OLP product for

the OTC market (due to the packaging and presentation) and the dispensary market, the Ministry has completed its price suppression analysis on figures provided for total domestic production of OLP.

Table 5.5 Price Suppression: Revenue, Costs and Gross Profit

	2001	2002	2003	YTD 2004
Total OLP revenue				
Cost of Production				
Gross Profit				
S & A Expenses				
Total Costs				
As a % of Revenue				
- Cost of Production	%	%	%	%
- Gross Profit	%	%	%	%
- S & A Expenses	%	%	%	%
- Total Costs	%	%	%	%

256. Total costs expressed as a percentage of revenue decreased substantially in 2002 and further in 2003 following the initial stage of development, (as PSM's OLP has only been manufactured in its current form since 1999), but rose percentage points from 2003 to YTD2004, illustrating that prices may have been suppressed. However caution must be taken in comparing YTD figures with those of a full financial period as seasonalities may affect the trends seen, but given the circumstances of the present application it is likely that these trends will continue.

257. Revenue has decreased, with YTD2004 representing five months sales but only percent of 2003 revenue which may indicate both a loss in volume and unit price. This change in revenue is also accompanied by a percent rise in the cost of production and a corresponding decrease in gross profit indicating that prices have been suppressed.

258. PSM stated that it believes price suppression may have been evident in early 2003 when it was negotiating with Pharmac, to have the subsidy increased because of its increased costs of manufacture (manufacturers are prohibited from selling a pharmaceutical listed in the pharmaceutical schedule below cost). PSM stated following the 20th December 2002 Pharmac announcement that Parapaed OLP would be listed on a sole supply basis in the Pharmaceutical Schedule following the success of AFT's ACP, (with supply being subject to Medsafe approval) PSM could not fully recover its claimed increased costs in the negotiations.

259. When looking at price suppression on an individual product basis there is only price suppression for the 250mg 200ml presentation. This had a cost to manufacture of NZD[redacted] in 2003 which increased to NZD[redacted] in YTD2004, giving price suppression of [redacted] or [redacted] percent of the 2003 cost to manufacture. On a total unit basis the 250mg 200ml presentation accounts for approximately [redacted] percent of PSM's total OLP production.

Conclusions on Price Suppression

260. Total costs as a percentage of revenue decreased from [redacted] percent in 2001 to [redacted] percent in 2003. Total costs as a percentage of revenue for YTD2004, however, are [redacted] percent of total revenue indicating an increase of [redacted] percentage points from 2003 and an increase of [redacted] percentage points from 2002, the period preceding the commencement of alleged injury from the dumped goods. The only product that displays price suppression on individual costings is the Paracare 250mg 200ml presentation (OTC market), which accounts for approximately [redacted] percent of PSM's total production of OLP.

Conclusion on Price Effects

261. There is evidence of significant price undercutting for the dispensary market. There is no evidence of price undercutting for the OTC market, however, the pricing data provided represents listed prices to the pharmacies with an approximation of discounts given. The data only estimated discounts, it did not make any adjustment for credit extended and, therefore, price undercutting may be higher than that found in the OTC market.

262. There is no evidence of price depression in the OTC market. However there is evidence of significant price depression in the dispensary market.

263. There is evidence of price suppression for the Paracare 200mg 200ml presentation, which is likely, given the significant increase in the cost of production, to have resulted in a decrease in gross profit.

5.4 Economic Impact

264. 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—

i. Actual and potential decline in output, sales, market share, profits, productivity, return on investments, and utilisation of production capacity; and

ii. Factors affecting domestic prices; and

iii. The magnitude of the margin of dumping; and

iv. Actual and potential effects on cash flow, inventories, employment, wages, growth, ability to raise capital, and investments.

Output and Sales

265. Movements in sales revenue reflect changes in 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.

Output

266. PSM stated that it was being injured by the loss of output as it had lost significant sales in the New Zealand market due to the dumped goods from Ireland. PSM noted that despite its significant increase [redacted] in the volume of sales to the OTC market in 2003, there was a [redacted] percent decline in the total volume of sales of OLP from the 2003 year and a [redacted] percent decline for the 2004 forecast year, as shown in Table 5.6.

Table: 5.6 Output of OLP

	2001	2002	2003	YTD 2004	Forecast 2004
Production (litre equivalents)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Increase/decreas		[redacted]	[redacted]	[redacted]	[redacted]
Percentage		[redacted]%	[redacted]%	[redacted]%	[redacted]%

267. The YTD2004 decline is considerably greater than seasonal effects as, while winter months have higher sales of OLP than summer months, the variance would not be this large. PSM stated it has lost access to a large proportion of the dispensary market (the Ministry estimates 80 percent of the total market, that is, of the combined dispensary and OTC markets), and therefore the forecast seems reasonable in the circumstances.

Conclusion

268. There is sufficient evidence of an overall decline in output.

Sales Volume and Revenue

269. Table 5.7 shows the changes in PSM's sales volume and revenue.

Table 5.7: PSM's Sales Volume and Revenue

	2001	**2002**	**2003**	**YTD 2004**	**Forecast 2004**
Sales Volume (litre equivalents)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Sales Revenue	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Change	[redacted]	[redacted]	[redacted]	[redacted]
Percentage Change	[redacted]%	[redacted]%	[redacted]	[redacted]%
Revenue per litre	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Change	[redacted]	[redacted]	[redacted]	[redacted]
Percentage Change	[redacted]%	[redacted]%	[redacted]	[redacted]%

270. In Table 5.7 PSM's sales volume has been assumed to be equivalent to production volume, when considering the volume of sales compared to sales revenue. The table shows that both sales volume and sales revenue increased in 2002 when the allegedly dumped goods were not in the market. In 2003, PSM's sales volume declined, while sales revenue increased. PSM stated that the [redacted] percent decline in volume in 2003 reflected the entrance of Parapaed into the market, in particular impacting on hospital sales, for which Parapaed became the principal supplier in December 2003. PSM stated that the increase in sales revenue in 2003, despite the total volume decline, was the result of a [redacted] increase in the sales to the OTC market. The Ministry notes from Aztec data that prices to the OTC market were significantly higher, on a per ml basis, than those of the products sold into the dispensary market. This supports PSM's statement that an increase in revenue was accompanied by a decline in volume.

271. It should be noted that the revenue per litre increased [redacted] in YTD2004. On the face of it this looks contrary to the significant price depression found. However, the rapid decline in PSM's volumes sold into the dispensing market which showed a significant reduction in price, was countered by a significant increase in the sales of the 200ml product at a relatively much higher price, thereby increasing the revenue on a per litre basis overall.

272. PSM's sales volume and revenue were forecast to decline significantly from 1 February 2004 when the sole supply tender for dispensary OLP became effective and the transition period ended. This decline can be seen in the YTD2004 column in Table 5.7 where the total sales volume and revenue figures show significant declines [redacted] in the average revenue per litre. PSM's forecast sales revenue for the full 2004 year is only [redacted] percent of 2003 sales revenue.

Conclusion

273. There is sufficient evidence for the purposes of initiation, of a decline in both sales volume and sales revenue.

Market Share

274. The analysis of market share must take account of changes in the growth of the market as a whole. A decline in the share of the market held by the domestic industry in a situation where the market as a whole is growing will not necessarily indicate that injury is being caused to the domestic industry, particularly if the

domestic industry's sales are also growing. There is no "entitlement" to a particular market share.

275. PSM provided Aztec data in its application that shows sales for each brand of OLP sold in New Zealand (except sales to hospitals). Table 5.8 is a summary of the figures provided.

Table 5.8 New Zealand Market Share (Litre Equivalents)

	2001	**2002**	**2003**	**YTD 2004**
NZ Industry Sales	157,124	187,760	165,556	16,328
Irish Imports	0	0	2,072	61,628
Other Imports	33,654	35,627	30,654	5,416
NZ Market	190,778	223,387	198,282	83,372
As a Percentage of NZ Market:				
NZ Industry Sales	82%	84%	83%	20%
Irish Imports	0%	0%	1%	74%
Other Imports	18%	16%	15%	6%

276. The figures show that the industry's market share (PSM and Douglas sales) was between 82 and 84 percent from 2001 to 2003. The industry's market share in YTD2004 declined to 20 percent. As can be seen from Table 5.8 Parapaed was not sold in New Zealand until 2003, after Medsafe approval was obtained in August 2003. Parapaed sales reached 1 percent of the market in the calendar year 2003 and its market share increased to 74 percent in YTD2004.

277. The remaining imports of OLP are made up of the brands Pamol and Panadol, imported from Australia. Overall the market share held by these other imports declined from 18 to 6 percent.

278. Table 5.9 below shows a breakdown of the information on volume in the two market segments for OLP, dispensary and OTC, excluding sales to hospitals. PSM stated that the hospital market traditionally bought 500ml presentations and that this was 8 to 10 percent of the total OLP dispensary market, therefore the majority of the dispensary market would be 1000ml presentations.

Table 5.9: Dispensary and OTC Market Segments (Litre Equivalents)

	Market share	**2001**	**2002**	**2003**	**YTD2004**
*Dispensary Market**	120mg	90,113	102,177	116,067	33,907

	250mg	71,549	88,317	41,115	33,779
	Dispensary	161,662	190,494	157,182	67,686
OTC Market	120mg	23,010	25,790	28,770	9,975
	250mg	6,105	7,103	12,331	5,711
	Total OTC	29,115	32,893	41,100	15,685
*NZ Market %**	Dispensary	85%	85%	79%	81%
	OTC	15%	15%	21%	19%

* These figures exclude sales to DHB's/hospitals.

279. PSM stated that it will lose the majority of its sales in the dispensary market because of AFT's sole supply status, and that this is unable to be offset by increased sales in the OTC market. Table 5.9 shows that the dispensary market was approximately 79 percent of the total market (excluding hospitals) in YTD2004. The OTC market was approximately 21 percent of the market.

Conclusion

280. The Ministry considers there is sufficient evidence for the purposes of initiation to show that the industry's market share has declined significantly.

Profits

281. Changes in net profit reflects 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.

282. 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 have secured the sole supply status for the New Zealand dispensary market it will only be producing OLP in minimal quantities for the dispensary market in 2004 and its OTC volume sales are also forecast to decline. Table 5.10 shows trends in PSM's EBIT.

Table 5.10 PSM's Earnings Before Interest and Tax

	2001	2002	2003	YTD2004	Forecast 2004
Sales Revenue					
EBIT					
As % of	%	%	%	%	%

Revenue					
Per Litre EBIT	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
EBIT Change		[redacted]	[redacted]	n/a	[redacted]
% EBIT Change		[redacted]%	[redacted]%	n/a	[redacted]%
Per Litre Change		[redacted]	[redacted]	[redacted]	[redacted]
% Per Litre Change		[redacted]%	[redacted]%	[redacted]%	[redacted]%

283. Table 5.10 shows that sales revenue increased in dollar terms and per litre between 2001 and 2003. EBIT, however, declined slightly in 2003. In YTD2004 EBIT has already declined significantly, and is forecast to decline significantly for the 2004 year.

Conclusion

284. The Ministry considers that there is sufficient evidence for the purposes of initiation of a significant decline in profits.

Productivity

285. 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.

286. PSM stated it did not have any comparative information between the relevant periods available to assist in making comment on this matter. However as there is likely to be a decline in return on investments and utilisation of production capacity (see below), productivity is also likely to be affected.

Return on Investments

287. 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 affect the ability of the industry to retain and attract investment.

288. PSM did not comment on the effect on return on investments caused by the allegedly dumped goods. However given the decline in EBIT it is likely that a decline in return on investments has also occurred.

Utilisation of Production Capacity

289. The utilisation of production capacity reflects changes in the level of product manufactured, although in some cases it will arise from an increase or decrease in production 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.

290. PSM did not comment on its utilisation of production capacity directly, but did state that due to AFT's sole supply status for OLP within the Pharmaceutical Schedule that it would not expect the volumes that it is currently producing to increase. As PSM was producing higher quantities of OLP in previous periods this would result in a decline in utilisation of production capacity unless capacity was reduced as well.

291. The Ministry notes, however, that the production data PSM provided indicates that there has been a significant decline in production volume which would likely significantly cause at least a temporary decline in the use of its production facilities.

Other Adverse Effects

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

293. PSM did not provide any information on these matters specifically, however given the information provided in other areas above it is likely that some of these factors will be negatively affected by the allegedly dumped goods and if an investigation is initiated, information will be required in these areas.

5.5 Threat of Injury

294. Paragraph 6 of Article 3 of the Agreement states:

> 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[1]. 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.

[1] One 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.

295. PSM's application was compiled on the basis of current injury and a future threat of injury. From the information provided the Ministry has found sufficient evidence that current material injury has occurred for the purposes of initiation. The requirements for the test of sufficient evidence of material injury have been met, and in this case the requirements of a test for threat of material injury are also met, therefore the Ministry considers that they do not need to be explicitly addressed when material injury is found.

5.6 Other Causes of Injury

296. Sub-section 8(2) of the Act, specifically (e) and (f), provides that the Chief Executive shall have regard to factors other than the dumped goods which have injured, or are injuring, the industry, including—

i. The volume and prices of goods that are not sold at dumped prices; and

ii. Contraction in demand or changes in the patterns of consumption; and

iii. Restrictive trade practices of, and competition between, overseas and New Zealand producers; and

iv. Developments in technology; and

v. *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.*

Factors Other Than Dumping

Non-dumped Goods

297. PSM stated that there were very few imports of OLP from other countries. The other imports are mostly from Australia and are minimal in volume. This comment is supported by the Aztec data. PSM expects that imports from Australia are likely to cease, or significantly decline, given the sole supply status awarded to AFT for the dispensary market.

Contraction in Demand or Changes in Patterns of Consumption

298. PSM stated that all brands of OLP were able to be sold in the dispensary market until 1 February 2004, after which AFT's Parapaed has sole supply status.

PSM stated that the market size available to it would "remain fairly constant" if Parapaed's sole supply status continues.

299. PSM also stated that the dispensary market for hospitals had previously been based on 500ml presentations but since Parapaed has been in the market that has shifted to 1000ml presentations. As PSM manufactures both 500ml and 1000ml presentations the Ministry does not consider that this is a change in demand for the product, but rather it is a change in the preferred presentation size, and is not likely to have any negative effect on PSM.

300. As a result of the prescription product only being subsidised for one brand (Parapaed), there is likely to have been a change in consumption in relation to the brands predominantly consumed in the dispensary market (but not the OTC market), that is, a shift in consumption to the imported Parapaed brand. The effect of this change would be considered in any investigation.

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

301. PSM stated that in its view there are no restrictive trade practices in the market in terms of the Commerce Act 1986. PSM also stated that prior to the sole subsidised supply status being awarded to AFT by Pharmac, the only barrier to entry was Medsafe registration. The sole supply status would need to be considered in greater detail in any investigation that is initiated as one of the driving factors affecting domestic prices.

302. Despite Parapaed's sole supply status within the Pharmaceutical Schedule, approximately 20 percent of the dispensary market is available to other suppliers of OLP through the discretionary variance purchases allowed for OLP.

Developments in Technology

303. PSM stated its OLP is superior to the imported Parapaed OLP in terms of composition and flavour and that it invested heavily in the manufacture of OLP to produce a competitive product. PSM stated that it manufactures to an international standard and that the technology for manufacturing both PSM's OLP and Parapaed is similar.

Export Performance and Productivity of the New Zealand Producers

304. PSM stated that it does not export the OLP it manufactures in New Zealand.

Imports by the Industry

305. PSM stated that it does not import OLP.

Conclusion on Other Factors

306. There is no evidence that factors other than dumping are a cause of injury to the industry and the effect on the New Zealand industry of AFT's sole supply status for part of the market would need to be considered in any investigation.

5.7 Conclusions Relating to Injury

307. There is sufficient evidence for the purposes of initiation of a significant increase in the volume of the allegedly dumped imports in absolute terms and relative to production and consumption in New Zealand.

308. There is sufficient evidence for the purposes of initiation of price undercutting of PSM's OLP by the imported Irish product in all but the 500ml presentation of OLP. There is sufficient evidence of price depression in the 500ml and 1000ml presentations but no price depression in the 200ml presentation. There is evidence of price suppression in the Paracare 200ml presentation, but not for the other sizes of OLP produced by PSM.

309. There is sufficient evidence for the purposes of initiation of actual declines in output, sales, market share and profits. No evidence was provided to show declines in productivity or return on investments.

310. Information on actual and potential effects on cash flow, inventories, employment, wages, growth, ability to raise capital, and investments were not directly provided, but negative effects on these factors are likely given the changes in production and sales volumes and profitability, and information on these matters would need to be assessed during the course of any investigation that is initiated.

5.8 Causal Link

311. The Ministry must be satisfied under 10(1) of the Act that:

Subject to this section, on receipt of a properly documented application made by or on behalf of New Zealand producers of like goods and on being satisfied that sufficient evidence has been provided that –

(a) Goods imported or intended to be imported into New Zealand 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,-

The [Chief Executive] may initiate an investigation to determine both the existence and the effect of any alleged dumping or subsidisation of any goods.

312. In addition, Article 5.2 of the Agreement states as follows:

> An application under paragraph 1 shall include evidence of (a) dumping, (b) injury within the meaning of Article VI of GATT 1994 as interpreted by this Agreement and (c) a causal link between the dumped imports and the alleged injury….

313. PSM has provided sufficient evidence that the goods imported from Ireland are being dumped. PSM has also provided sufficient evidence that it has suffered material injury.

314. The question to be addressed is whether there is sufficient evidence that the dumping has caused (and is causing) material injury. 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 of itself.

315. In the present application the extent to which a causal link exists between the dumping and the injury is called into question by the presence of Pharmac's sole supply status which applies to approximately 90 percent of the OLP dispensary market.

316. PSM did not enter Pharmac's tender for OLP. Following the issue of the tender process, Pharmac accepted an ACP from AFT giving it sole supplier status for approximately 90 percent of the OLP dispensary market. PSM has been significantly injured by the loss of access to this major part of the market.

317. There is sufficient evidence that the Irish imports of OLP supplied into the dispensary market were being dumped. PSM is also being injured in the OTC market (i.e. 20 percent of the total market) by dumped goods, and by an alleged effect of the dumped goods in the OTC market from the dispensary market to which it has lost access.

318. PSM stated that it had competitive prices in the dispensary market at the time the tender was issued, and that some of its prices were (and continue to be) lower than the subsidised prices agreed to by Pharmac with AFT, for OLP supply. The ACP from AFT accepted by Pharmac included at least one other pharmaceutical which was bundled with the OLP, and it is likely therefore that Pharmac would have been able to achieve lower average costs across these drugs.

319. PSM provided a number of reasons why it did not enter the tender, inter alia:

- it had a contract with Pharmac indicating prior consultation would occur;
- its prices were competitive;
- it understood that supply, pursuant to a tender could not be promoted; and
- it considered that there was uncertainty in a Pharmac contract, and that its nature and conditions were onerous, given its past experiences.

320. PSM's price for the 500ml product to the dispensary market from late 2002 was NZD5.00 for both strengths (120mg and 250mg) whereas the current subsidy prices paid to AFT are NZD5.50 and NZD5.60 respectively.

321. On the face of it, Pharmac agreed to at least two subsidy rates (out of four) that were higher than the prices already in the market, but it is not clear from the information available whether PSM would have won the contact for the dispensary market even if it had entered the tender with a lower price. There is also a question of the role the allegedly dumped price played in securing the tender, for which only Pharmac could provide information.

322. Despite the sole supply situation that exists for most of the dispensary market, there is injury being caused by the dumped goods in the OTC market. Sufficient evidence has been provided that injury is being caused by dumping in the OTC market and that is likely to be material of itself, the evidence being the price undercutting in the OTC market which is likely to be higher than that calculated, the price suppression shown on the 200ml product, (which accounts for ▒ percent of PSM's total production), and which has contributed to the significant increase in the cost of production and the decrease in gross profit. With the OTC segment representing ▒ percent of the total market for OLP, it is considered that this is still a significant part of the market to be caused material injury from the dumping. Even if there was considered to be no causal link between the dumping and injury in the dispensary market in the course of any investigation, this would not affect the OTC portion of the New Zealand OLP market.

Conclusion

323. For the purpose of initiation and on the information available, the Ministry considers that sufficient evidence exists of a causal link between the dumping and the injury as required by s10(1) of the Act, however, further information will need to be gathered in relation to causal link during any investigation that is initiated.

6. Conclusions

324. On the basis of the information available, it is concluded that there is sufficient evidence to indicate:

a. OLP from Ireland is being dumped; and

b. by reason thereof material injury to the industry has been or is being caused.

7. Recommendations

325. It is recommended on the basis of the conclusions reached and in accordance with section 10 of the Dumping and Countervailing Duties Act 1988:

a. that the Chief Executive of the Ministry initiate an investigation to establish whether imports of OLP from Ireland are being dumped, and are thereby causing and/or threatening to cause material injury to the New Zealand industry producing like goods;

b. that the Chief Executive sign the attached *Gazette* notice, and give notice to interested parties in accordance with section 9 of the Act.

Investigating Team
Trade Remedies Group