Tamoxifen from the United Kingdom: Initiation Report

Status:Archived

Dumping and Countervailing Duties Act 1988

Table of Abbreviations

The following abbreviations are used in this Report:

Act (the)	Dumping and Countervailing Duties Act 1988
Amendment Act (the)	Dumping and Countervailing Duties Amendment Act 1994
Anti-Dumping Code (the Code)	WTO Agreement on Implementation of Article VI of the GATT 1994
CIF	Cost, Insurance and Freight
Douglas	Douglas Pharmaceuticals Limited
EBIT	Earnings Before Interest and Tax
FOB	Free on Board
Generics	Generics (UK) Ltd
IMSNZ	IMS (NZ) Limited
LDC	Less Developed Countries
LLDC	Least Developed Countries
Medsafe	New Zealand Medicines and Medical Devices Safety Authority
Ministry (the)	Ministry of Economic Development
Pac	Forum Island Members of the South Pacific Regional Trade and Economic Co-operation Agreement
Pacific	Pacific Pharmaceuticals Ltd
PHARMAC	Pharmaceutical Management Agency Ltd
Secretary (the)	Secretary of Commerce
VFD	Value for Duty
WTO	World Trade Organisation
_____	Confidential Information

1. Proceedings

1.1 Proceedings

On , the Ministry of Commerce accepted a properly documented application from Douglas Pharmaceuticals Limited (Douglas), alleging that imports of from the United Kingdom were being dumped and by reason thereof causing and threatening to cause material injury to the New Zealand industry.

In accordance with section 10 of the Dumping and Countervailing Duties Act 1988 (hereinafter also referred to as "the Act"), the Secretary of Commerce 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.

In considering an application, the Secretary 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, and requiring investigation. The evidence is to be scrutinised with due scepticism, bearing in mind the commercial context, and the Secretary is to be satisfied of the sufficiency of the evidence, not of dumping or material injury.

Basis for the Application

Douglas has claimed that as a result of the alleged dumping, there is a threat of material injury resulting from:

- a significant rate of increase in the volume of imports of the allegedly dumped goods, and the likelihood of substantially increased imports from the United Kingdom;
- price undercutting, and likely price depression and price suppression,

which will cause:

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

Douglas has stated that injury will result from the importation of allegedly dumped from , the date on which the importer reduced prices for Tamoxifen in the New Zealand market.

It should be noted that the Ministry approaches investigations on the basis that injury and threat of injury are alternatives, i.e. an industry is either injured or threatened with injury, but both cannot apply at the same time.

1.2 Interested Parties

New Zealand Industry

The application was submitted by Douglas, the sole producer of like goods in New Zealand.

Importers and Exporters

Exporters

Douglas has identified the following exporter from the United Kingdom as allegedly dumping Tamoxifen:

Generics (UK) Ltd (Genox)

Douglas has provided a letter from the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), dated 29 June 2000, which identifies additional registered United Kingdom sources of manufacture and packing of the subject goods as:

Regent Laboratories Ltd (Genox)

Medeva Pharma Ltd (Alpha-Tamoxifen)

Zeneca Pharmaceuticals Ltd (Nolvadex)

Douglas has expressed concern specifically about imports of Genox and, therefore, in any investigation the Ministry will also inquire whether Genox manufactured by Regent Laboratories has been exported to New Zealand. Packers of Genox in the United Kingdom may also need to be contacted and these were listed by Medsafe as Generics (UK) Ltd and Unipack Ltd.

Any investigation will need to confirm the source and the supplier of the products, and establish whether such goods have any degree of manufacture in the country of export, or whether they are merely trans-shipped.

Douglas has also noted that "the decision . . . to injuriously dump Genox may cause other suppliers of imported Tamoxifen to adopt similar pricing on the New Zealand market." The application does not claim that other brands are being dumped and accordingly brands other than Genox will not be the subject of any subsequent dumping investigation.

Importers

Douglas has listed the following importer of Genox:

Pacific Pharmaceuticals Ltd (Pacific)

Douglas has explained that Pacific was successful in a Pharmaceutical Management Agency Ltd (PHARMAC) tender for sole state-subsidised supply of Tamoxifen.

1.3 Imported Goods

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

Tamoxifen Citrate (with brand name Genox) in any form or presentation

Douglas is concerned specifically about imports from the United Kingdom of Tamoxifen sold under the brand name Genox and sold by Pacific.

The New Zealand Customs Department has advised that Tamoxifen Citrate enters under the following tariff classification:

3004		Medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale:
[*3004.10*	-	*Containing penicillin's or derivatives thereof, with a penicillanic acid structure, or streptomycin's or their derivatives*
3004.20	-	*Containing other antibiotics:*
	-	*Containing hormones or other products of heading No. 29.37 but not containing antibiotics:*
3004.40	-	*Containing alkaloids or derivatives thereof but not containing hormones, other products of heading No. 29.37 or antibiotics:*
3004.50	-	*Other medicaments containing vitamins or other products of heading No. 29.36:]*
3004.90	-	Other
[3004.90.01 00K	- -	*For veterinary medicine]*
	- -	Other
[3004.90.11 00E	- - -	*Organo-therapeutic glands and other goods of heading No. 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	. . . . .	*Containing* chlorofluorocarbons
08A	. . . .	*Other]*
19G	. . . .	Other

Imports of the goods subject to this application have been free of duty since 1 July 1997.

In this report, unless otherwise stated, years are years and dollars values are NZ$. In tables, column totals may differ from individual figures because of rounding.

The period for considering claims of dumping is from 1 September 1999 to 31 August 2000. Because the application is based on a threat of injury, the consideration of injury involves evaluation of information relating to the likely effect of the allegedly dumped imports. Any investigation will, however, need to consider certain historical financial information as a basis against which claims of injury can be evaluated. The period over which the historical information will be considered is 1 April 1997 to 31 March 2000, but may include more recent information if available.

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 final determination of whether or not goods are dumped and causing injury can be made only after a full investigation carried out in accordance with the Act.

2. New Zealand Industry

Section 3a provides the definition of "industry":

3a. Meaning of "industry"—For the purposes of this Act, the term 'industry', in relation to any goods, means—

(a) The New Zealand producers of like goods; or

(b) Such New Zealand producers of like goods whose collective output constitutes a major proportion of the New Zealand production of like goods.

"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:

2.1 Like Goods

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

The subject goods have been identified in section 1.3 of this Report as:

Tamoxifen Citrate (with brand name Genox) in any form or presentation

Douglas produces Tamoxifen in the form of Tamoxifen Citrate under the brand name Tamofen. Douglas states that the citrate is present to stabilise the Tamoxifen for the purpose

of manufacture and shelf life. The subject goods (Genox) are also manufactured in the form of Tamoxifen Citrate.

Both Tamofen and Genox are put up in 10mg and 20mg tablets. Markings on the tablets differ and there are some differences in packaging. Tamofen is put up in both bottles of 100 tablets and blister packs of 30 tablets, whereas Genox is only put up in blister packs.

Tamoxifen is a prescription pharmaceutical used in the treatment and prevention of some types of breast cancer. Tamoxifen is understood to inhibit the effects of oestrogen probably by binding with oestrogen receptors.

Tamoxifen Citrate (Tamofen) produced by Douglas contains the same active ingredient (Tamoxifen) as the imported Tamoxifen Citrate (Genox). Both products are grouped together in the New Zealand Pharmaceutical Schedule which lists pharmaceuticals subsidised by Government. Both products have the same end uses. There are some differences between the products in terms of tablet markings and packaging. On the basis of the information available, the Ministry considers that the produced by Douglas, while not identical in all respects, has characteristics closely resembling the subject goods and are therefore like goods to the subject goods.

2.2 New Zealand Industry

An investigation may not be initiated unless the Secretary 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.

The application was submitted by Douglas Pharmaceuticals Limited. Douglas is the sole producer of Tamoxifen in New Zealand. Medsafe's letter of 29 June 2000 does not identify any other New Zealand manufacturers of Tamoxifen. The Ministry's research has not revealed any other manufacturers of Tamoxifen in New Zealand.

The Ministry considers that in investigating injury under section 8 of the Act, it should have regard to the effects of importations of dumped goods on the New Zealand industry as a whole, notwithstanding that a complaint has been accepted from a producer responsible for a major proportion of domestic production of like goods. The use of the definition of industry to establish the standing of one or several producers or their representative to lodge a complaint does not preclude the Ministry from looking wider in establishing whether and to what extent injury is being caused to New Zealand producers as a result of dumping. However, this does not mean that all producers in the industry, or all of those investigated, must suffer material injury before any action is taken, but such injury must have been caused

to at least those producers whose output constitutes a major proportion of production of like goods.

2.3 Imports of Tamoxifen

Tamoxifen is not identified separately in the Tariff of New Zealand. Douglas has used market survey figures collected by IMS (NZ) Limited (IMSNZ) to estimate import volumes. To ensure figures are comparative, Douglas has converted all sales data into equivalent packs of 30 x 20 mg tablets.

Table 2.1: Imports of Tamoxifen
(30 x 20mg equivalent packs)

	1998	1999	2000
Subject Goods			
- Genox		Decrease	Increase
Other Imports			
- Nolvadex (UK)		Decrease	Increase
- Estroxyn (Hungary)		Static	Static
Total Imports		Decrease	Increase

Section 11(1) of the Act provides that where the Minister is satisfied in respect of some or all of the goods under investigation, that there is insufficient evidence of dumping or injury to justify proceeding with the investigation then the investigation shall be terminated. 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 Anti-Dumping Code. The Code deals with the negligibility of dumped imports under Article 5:8 as follows:

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

The following table shows imports of the subject goods and total imports in the most recent year covering the period of investigation of dumping:

Table 2.2: Share of Imports

(30 x 20mg equivalent packs)

	2000	%
Subject Goods (Genox)		>50%
Other Imports		
Total Imports		100%

On the basis of this information, imports of the subject goods from the United Kingdom are not negligible.

2.4 New Zealand Market

The following table shows the New Zealand market for Tamoxifen and was prepared from IMSNZ data provided by Douglas.

Table 2.3: New Zealand Market
(30 x 20mg equivalent packs)

	1998	1999	2000
Subject Goods (Genox)		Decrease	Increase
Other Imports		Decrease	Increase
Total Imports		Decrease	Increase
NZ Industry Sales		Increase	Decrease
NZ Market		Increase	Increase

3. Evidence of Dumping

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:"*

3.1 Export Prices

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

Douglas has used a deductive method to calculate export prices for the allegedly dumped Tamoxifen. Douglas has based its calculations on the fully subsidised ex-manufacturer prices resulting from Pacific's successful tender. These prices are at the first point of resale in arm's length transactions in New Zealand.

Douglas has made the following estimated deductions from the ex-manufacturer prices to calculate export prices: New Zealand supplier's margin, clearance, handling and cartage costs in New Zealand, overseas freight and insurance, and wharfage, handling and inland freight charges in the country of origin.

The deduction for New Zealand supplier's margin has been based on Douglas's experience of the industry. The other deductions have been based on what Douglas considers to be conservative estimates. No deduction has been made for any discounting. Exchange rate conversions from New Zealand dollars to United Kingdom pounds have been made at the rate of 0.31, being the Customs exchange rate for entries lodged in early July.

The tender results only listed prices for 10mg and 20mg tablets. Douglas has noted that Genox is also sold in 40mg tablets and has calculated an export price for that tablet size. Douglas has assumed that, because the price for a 20mg tablet is only 15 percent above that of a 10mg tablet it is reasonable to assume that a 40mg tablet will be priced 15 percent above the price of a 20mg tablet.

The table below shows Douglas's estimated export prices for 10mg, 20mg and 40mg Tamoxifen (Genox) from the United Kingdom.

Table 3.1: Export Prices

	10mg	20mg	40mg	Ministry 40mg
Price (NZ$) ex-manufacturer (excl GST)	2.60	2.99	3.44	5.98
Margin (__% on costs)				
Estimated into-store Cost				
Less:				
- clearance/handling/NZ cartage				
- overseas freight/insurance				
Estimated FOB				
Less:				
- wharfage/handling/cartage				
Ex-factory export prices (NZ$)	2.01	2.32	2.68	4.71
Conversion rate	0.31	0.31	0.31	0.31
Ex-factory export prices (UK pounds)	0.62	0.72	0.83	1.46

The Ministry considers that export prices for 40mg tablets, assessed by Douglas in the manner explained above in paragraph 3.1.5, may be understated. The Ministry notes that Douglas provided information on prices in the United Kingdom that included prices for 40mg tablets. Prices for 40mg tablets more than doubled the prices of 20mg tablets. The Ministry considers that a more reasonable method for assessing export prices for a 40mg tablet, for purposes of initiation, would be to double the price assessed for a 20mg tablet. On this basis, the ex-manufacturer starting point would be NZ$5.98 and, after deductions, the ex-factory export price for a 40mg tablet would be 1.46 UK pounds.

The Ministry considers that the information on export prices provided by Douglas is sufficient for the purposes of initiation.

3.2 Normal Values

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

Douglas has based normal values on published information available on prices of Tamoxifen in the United Kingdom. In the United Kingdom, manufacturers sell to wholesalers which on-sell to retail outlets (pharmacies), some of which are owned by wholesalers. A Competition Commission Report provided by Douglas states that "The pricing of branded ethicals at both wholesale and retail levels is constrained by a voluntary scheme agreed by the manufacturers with the Department of Health."

The Pharmaceuticals Price Regulation Scheme of July 1999, inter alia, sets out rules for determining maximum prices that may be charged by scheme members for branded health service medicines, including branded generics. Generics is a member of the scheme. Douglas was unable to obtain a domestic selling price of the Generics product.

The prices of branded medicines sold for national health service purposes by companies which do not belong to the voluntary price regulation scheme are controlled by the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000. Maximum prices for such medicines are based on "initial" prices, being either 95.5 percent or 100 percent of the initial prices. Initial prices are published and include two suppliers of Tamoxifen, Zeneca and Pharmacia & Upjohn – the latter company also listed for the voluntary price scheme. Pharmacia & Upjohn supply Tamoxifen in the United Kingdom under the brand name Tamoxifen in the same tablet sizes Generics uses to supply Tamoxifen under the brand name Genox. In the absence of information on prices for Genox, Douglas has based normal values on initial prices for Tamoxifen sold under the brand name Tamofen by Pharmacia & Upjohn. Genox and Tamofen both contain the same active ingredient, Tamoxifen, have the same end uses and are considered to be like goods. Douglas has stated that, since Pacific is supplying a branded generic, it is appropriate to use the price of a branded generic, such as Tamofen, in the United Kingdom. The Ministry believes that this information can be categorised as that which is reasonably available to Douglas.

Douglas has adjusted Pharmacia & Upjohn’s Tamofen initial prices to 95.5 percent and has deducted a further 60 percent to allow for advertising and sales including discounts and rebates, and any other allowable adjustments to normal values for branded Tamoxifen.

Douglas considers it unlikely that Pacific will supply an unbranded generic, but, in the event, has provided information on prices proposed under Pharmaceutical Price Regulations for the sale of generic medicines to community pharmacies and dispensing doctors. A deduction of 40 percent has been made to account for advertising and sales including discounts and rebates, and any other allowable adjustments to normal values.

Normal values for branded Tamoxifen and unbranded generic Tamoxifen from the United Kingdom are shown in the table below:

Table 3.2: Normal Values

(UK pounds per pack)

	10mg	20mg	40mg
Branded Tamoxifen	1.78	2.68	6.30
Unbranded Tamoxifen	1.21	1.38	5.06

The Ministry considers that the information provided by Douglas is sufficient evidence of normal values for the subject goods.

3.3 Comparison of Export Price and Normal Value

Based on the information provided to the Ministry, the following is the evidence of dumping:

Table 3.3: Dumping Margins
(UK pounds per pack)

	10mg	20mg	40mg	Ministry 40mg
Normal Values				
- Branded	1.78	2.68	6.30	6.30
- Unbranded	1.21	1.38	5.06	5.06
Export Prices	0.62	0.72	0.83	1.46
Dumping Margins				
- Branded	1.16	1.96	5.47	4.84
- Unbranded	0.59	0.66	4.23	3.60
Margins % of EP				
- Branded	186%	272%	658%	331%
- Unbranded	94%	92%	509%	246%

The dumping margins for 40mg product are significantly higher than for 10mg and 20mg product. This may be due in part to Douglas's estimation of export prices for the 40mg tablet by adding 15 percent to the price for a 20mg tablet. If the starting price for the 20mg tablet were doubled to arrive at a 40mg ex-manufacturer price, as explained above in paragraph 3.1.7, the export price for the 40mg tablet would be 1.46 UK pounds. On this basis, dumping margins for the 40mg tablet would be 246 percent for unbranded product and 331 percent for unbranded product. These are considered to be more reasonable estimates, given the pricing differences between the 20mg and 40mg tablets provided for normal values.

The evidence provided shows that the alleged margins of dumping are not de minimis in terms of Article 5.8 of the Agreement as set out above in paragraph 2.3.2. The Ministry is satisfied on the basis of the information provided that the comparison of export prices and normal values provides sufficient evidence of dumping for the purposes of initiation in respect of the importation of Tamoxifen from the United Kingdom.

Any investigation will need to give consideration to the provisions of section 4 (export price) and section 5 (normal value) of the Act as they should apply, and in particular to the application of the appropriate adjustments required by section 4(1)(a)(i) and (ii) and section 5(3).

4. Evidence of Injury

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 Secretary 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.*

4.1 Threat of Injury

The application is based on claims of a threat of injury arising from the contract price reduction of Tamoxifen sold under the brand name Genox.

Douglas has explained that Pacific was successful in a PHARMAC tender for sole subsidised supply of Tamoxifen. PHARMAC is the sole buyer of state-subsidised prescription pharmaceuticals in New Zealand and manages the Pharmaceutical Schedule which lists medicines and related products subsidised by the Health Funding Authority. Douglas provided evidence that PHARMAC notified the results of its tender on 30 May 2000 and advised that the new subsidy for Tamoxifen would reduce from 1 August 2000. The reduced subsidy levels are at prices which Pacific has agreed to supply. Douglas states that dumped prices resulted in it being unsuccessful in the tender to supply Tamoxifen and Pacific will be the only supplier of Tamoxifen (under the brand name Genox) from 1 December 2000.

Douglas has stated that doctors will prescribe the subsidised Genox in preference to its brand of Tamoxifen (Tamofen) which is not being subsidised and for which patients have to pay the full charge. The application is based on the argument that material injury will be incurred as patients are switched to the fully subsidised Genox brand of Tamoxifen.

Article 3.7 of the GATT Anti-Dumping Agreement (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[10]. In making a determination regarding the existence of a threat of material injury, the authorities should consider, inter alia, such factors as:

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

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

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

(iv) inventories of the product being investigated.

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

[10] 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.

The sufficiency of the evidence of threat of injury in the application has therefore been examined against the criteria of the Act and Article 3.7 of the Agreement.

4.2 Import Volumes

Section 8(2)(a) of the Act provides that the Secretary 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 or subsidised goods either in absolute terms or in relation to production or consumption in New Zealand.

Douglas has used IMSNZ data to estimate import volumes for the years ended 31 March 1998, 1999 and 2000. Douglas has forecast the impact that Pacific's successful tender to become the sole supplier of Tamoxifen will have on import volumes and sales by the New Zealand industry.

The following table shows the estimated volume of imports of the subject goods into New Zealand over the period 1998 to 2002 and compares them with the New Zealand industry's production and consumption in the New Zealand market.

Table: 4.1: Estimated Import Volumes

(30 x 20mg equivalent packs)

	1998	1999	2000	2001 est.	2002 est.
Subject Goods (Genox)		Decrease	Increase	Increase	Increase
Other Imports		Decrease	Increase	Decrease	0
Total Imports		Decrease	Increase	Increase	Increase
NZ Industry Sales		Increase	Decrease	Decrease	0
NZ Market		Increase	Increase	Static	Static
Change on previous year:					
Subject Goods (Genox)		Decrease	Increase	Increase	Increase
Other Imports		Decrease	Increase	Decrease	Decrease
Total Imports		Decrease	Increase	Increase	Increase

NZ Industry Sales		Increase	Decrease	Decrease	Decrease
NZ Market		Increase	Increase	Static	Static
% Change:					
Subject Goods (Genox)		Decrease	Increase	Increase	Increase
Other Imports		Decrease	Increase	Decrease	-100%
Total Imports		Decrease	Increase	Increase	Increase
Douglas Sales		Increase	Decrease	Decrease	-100%
NZ Market		Increase	Increase	Static	0%
Subject goods as % of:					
- NZ Industry Sales		Decrease	Increase	Increase	
- NZ Market		Decrease	Increase	Increase	100%

These figures show that in the year to 31 March 2000 imports of the subject goods increased significantly in absolute terms and relative to production and consumption in New Zealand.

Douglas considers that dumped goods will have been sold in the New Zealand market from 12 July 2000. Douglas has also stated that "there will be a significant increase in shipments of Genox to New Zealand to build up the stock necessary to meet the demand resulting from Pacific being the sole supplier of the fully subsidised Tamoxifen". Pacific will be the sole supplier of fully subsidised Tamoxifen from 1 December 2000. It is unlikely that the increased import volume of subject goods in the year to March 2000 consists of the allegedly dumped goods.

Douglas has forecast that import volumes of subject goods in 2000 and 2001 will increase significantly in absolute terms and relative to production and consumption in New Zealand. In support of its contention that there will be substantially increased imports of the subject goods, Douglas has observed that Pacific would not have tendered if it could not supply the goods and as the sole supplier of Tamoxifen, imports by Pacific will increase at or close to the forecast volumes. Douglas has provided evidence that the manufacturer of the subject goods, Generics (UK) Limited - a subsidiary of Merck UK, is a substantial company. Douglas has provided evidence that prices of the subject goods will undercut significantly Douglas's prices, thereby winning the PHARMAC tender. The price undercutting and sole supplier status will lead to substantially increased imports of the subject goods.

As discussed below in section 4.4.1 while Douglas has disclosed various assumptions used in estimating its forecast sales in the year ended March 2001, and has provided calculations, the company has not explained the basis on which its forecast sales figure has been calculated. On the basis used by Douglas to calculate sales for other companies whose products will be delisted by PHARMAC (that is, sales at normal levels from April to October, followed by no sales), Douglas's sales in 2001 are forecast by the Ministry to be _____ equivalent 20 x 30mg packs.

On the basis that the market for 2001 remains at the same level of sales as in 2000, the Ministry's revised forecast results in estimated imports of subject goods in 2001 being _____ packs. This figure still represents a significant forecast increase in import volumes of the subject goods in absolute terms and relative to production (subject goods would increase

to ___%) and consumption (subject goods would increase to __% of the New Zealand market).

There is evidence that import volumes of the subject goods will increase significantly in absolute terms and relative to production and consumption in New Zealand.

4.3 Price Effects

Price Undercutting

Section 8(2)(b) of the Act provides that the Secretary shall have regard to the extent to which the prices of the dumped or subsidised 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.

In considering price undercutting, the Ministry will normally seek to compare prices at the ex-factory and ex-importer's store levels, to ensure that differences in distribution costs and margins do not confuse the impact of dumping.

Douglas has stated that, from 1 August 2000, Pacific will reduce its ex-manufacturer list price of Tamoxifen under the brand name Genox from $6.28 to $2.60 for packs of 30 x 10mg tablets and from $11.93 to $2.99 for packs of 30 x 20mg tablets.

Table 4.2: Comparison of Pack Prices
(NZ$ Ex-Manufacturer/Distributor Price)

	Genox		Tamofen	Undercutting	%
	Previous	From 1 Aug			
10mg x 30	6.28	2.60	6.28	3.68	59%
20mg x 30	11.93	2.99	11.93	8.94	75%

There is evidence that the prices of the allegedly dumped imports are undercutting significantly the prices of the New Zealand industry.

Price Depression

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

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

Douglas has provided actual and projected financial information that allowed sales revenue per equivalent 30 x 20mg pack of Tamofen to be calculated as shown in the following table:

Table 4.3: Average Selling Prices of Tamoxifen

(Price per 30 x 20mg pack)

	1998	1999	2000	2001
Douglas		Decrease	Decrease	Increase

The table shows that average prices declined significantly in 1999 and 2000, however these declines preceded introduction of the allegedly dumped imports. An increase in average price is projected for 2001. Douglas has decided not to drop its prices to meet the reduced prices that PHARMAC will fully subsidise. While Douglas does not intend to reduce its ex-manufacturer price to the level of the allegedly dumped imports, it has stated that it "may be forced to alter this strategy".

There is no evidence of price depression due to dumped imports.

Price Suppression

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

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 able to be recovered by price increases will be reflected by an increased ratio of costs to sales revenue. Where cost 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.

Douglas has stated that cost increases per tablet will arise as its sales volume decreases because fixed and other costs will have to be allocated over a smaller production volume. Douglas will not be able to recover these per unit cost increases as "any further price increase above the price set by the dumped product would further jeopardise any sales that Douglas may make." Douglas has noted that there is no evidence of actual price suppression, but prices will be suppressed in the future.

The following table, which was calculated from actual and projected financial data and IMSNZ data provided by Douglas, shows gross margin and EBIT as a percentage of sales.

Table 4.4: Price Suppression

(NZ$ per 30 x 20mg Pack)

	1998	1999	2000	2001
Ave Selling Price		Decrease	Decrease	Increase
Cost of Production		Decrease	Static	Increase
Gross Margin		Decrease	Decrease	Increase
Selling and		Decrease	Decrease	Increase

Admin.				
EBIT		Decrease	Decrease	Increase
GM as % of Sales		Decrease	Decrease	Decrease
EBIT as % of Sales		Decrease	Decrease	Decrease

Gross margin and gross margin as a percentage of sales declined significantly from 1998 to 2000. Per unit cost of production declined in 1999 and remained steady in 2000. EBIT also declined from 1998 to 2000. Per unit selling and administration costs decreased in 1999 and 2000. The declines in gross margin and EBIT from 1998 and 2000 occurred before the impact of allegedly dumped imports.

Based on Douglas's projected figures, gross margin in 2001 will increase, despite increased per unit cost of production, because of increased sales revenue per unit. Gross margin as a percentage of sales revenue will decrease because the sales revenue increase is greater than the increased gross margin. Per unit EBIT is projected to increase in 2001, although it will decrease as a percentage of sales revenue. Selling and administration costs per unit will increase from 2000, but not will not exceed the 1999 level. The figures provided by Douglas show that in 2001 it will be able to recover per unit cost increases through increased per unit sales revenue. The figures provided do not indicate price suppression.

Conclusion on Price Effects

There is sufficient evidence that prices will be undercut, but not that prices will be depressed or suppressed.

4.4 Economic Impact

Section 8(2)(d) of the Act provides that the Secretary 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

Output

Douglas has not provided production figures.

Sales

Douglas has stated that PHARMAC will reduce the subsidy on Tamoxifen to Pacific's reduced price levels for Genox, Genox will be fully subsidised at these price levels and Pacific will become the sole supplier of Tamoxifen to the New Zealand market from 1 December 2000. Douglas has projected that its sales volumes will decline significantly in the year to March 2001 and there will be no sales in 2002. Douglas has provided the following sales figures, derived from IMSNZ data, for equivalent packs of 30 x 20mg tablets:

Table 4.5: Volume of Sales
(30 x 20mg Equivalent Packs)

	1998	1999	2000	2001	2002
Douglas		Increase	Decrease	Decrease	0

Projected sales volume figures for 2001 are based on an assumption that there will be a lag between the new price for Genox taking effect on 12 July 2000 and patients switching to Genox from other products including Douglas's Tamofen. Douglas considers that sales of brands other than Genox will start declining after the changes are announced on 1 August and "doctors will begin switching patients to the fully subsidised and exclusively listed Genox" from September 2000.

Douglas has also advised that, in forecasting its sales figure for 2001, it took into account "the rapid drop in the price of the dumped product, the realisation that wholesalers and pharmacists would stop purchasing the product, the recognition that wholesalers and pharmacists would be aware that supplies of Tamofen would be at a premium price over Genox and recognition that Douglas could not manufacture and distribute the product at a profit given the dumped price."

While Douglas has disclosed various assumptions used in estimating its forecast sales in the year ended March 2001, and has provided calculations, the company has not explained how each of its assumptions have been fed into the forecast sales figure it has calculated. The Ministry notes that the forecast sales figure for 2001 is equivalent to sales in the 2000 year covering only two months. While Douglas considers that its forecast sales figure is turning out to be accurate, it has not provided supporting monthly sales figures for the months of April to date. In addition, the Ministry notes that Douglas has used a different basis for calculating its sales figure than it applied to other companies supplying Tamoxifen other than Genox.

Douglas has calculated forecast sales figures for other companies whose products will be delisted by PHARMAC on the basis that sales will be at normal levels from April to October and no sales thereafter. To calculate the forecast sales figures for these companies for 2001 Douglas took sales figures for the year to March 2000 and multiplied by 7/12. On this basis, Douglas's sales in 2001 are forecast by the Ministry to be _____ equivalent 20 x 30mg packs.

The Ministry's revised forecast sales volume figure still represents a significant decline in sales for the year ended March 2001.

Douglas has provided the following actual and forecast sales revenue figures:

Table 4.6: Sales Revenue

	1998	1999	2000	2001	2002
Douglas		Decrease	Decrease	Decrease	0

Based on its revised forecast of sales volume and per pack average revenue, the Ministry has revised the forecast sales revenue for the year ended March 2001 to $_____. This figure still represents a significant decline in sales revenue in the year ended March 2001.

There is sufficient evidence that the New Zealand industry's sales volumes and revenues will decline significantly in the years ended March 2001 and 2002.

Market Share

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.

The table below shows actual and forecast market share and changes in market share as estimated by Douglas from IMSNZ data:

Table 4.8: Market Share
(30 x 20mg Equivalent Packs)

	1998	1999	2000	2001	2002
NZ Market		Increase	Increase	Static	Static
Domestic Production		Increase	Decrease	Decrease	0
Subject Goods		Decrease	Increase	Increase	Increase
Other Imports		Decrease	Increase	Decrease	0
% Share Held By:					
Domestic Production		Increase	Decrease	Decrease	0%
Subject Goods		Decrease	Increase	Increase	100%
Other Imports		Decrease	Increase	Decrease	0%

The table shows that the market share held by the New Zealand industry declined in the year ended March 2000 and is forecast to fall dramatically in 2001 resulting in total loss of market share in the year ending March 2002. At the same time market share for the subject goods is forecast to increase dramatically, until the subject goods capture the total market in the year ending March 2002.

The Ministry revised the imports of sales figure forecast for the New Zealand industry for the year ended March 2001, as explained above in section 4.4.1. The volume of imports of subject goods forecast for that period has also been revised by the Ministry as explained above in paragraph 4.2.7. For the year ended March 2001, the revised forecast figure for New Zealand industry sales is _____ packs and for imports of subject goods is _____ packs.

On the basis of the Ministry's revised figures, market share for the New Zealand industry would be __ percent and for subject goods would be __ percent. These figures represent an imminent and significant decrease in the New Zealand industry's market share at the same time as market share for the subject goods increases significantly.

There is sufficient evidence that the New Zealand industry will experience a significant decline in market share.

Profits

Changes in net profits reflect changes in prices, sales volumes or costs. Dumped or subsidised imports can impact on any or all of these. If possible, the extent of any decline in profit will be measured against the level achieved in the period immediately preceding the commencement of the dumping.

In an investigation, the Ministry's assessment of the impact of dumped imports is based on an examination of trends in actual profits in order to establish whether or not there is an actual or potential decline in profits. In some circumstances it may be possible to determine that injury is being caused where profits are not declining, but that would depend on the circumstances of the case, and would need to be based on positive evidence. Such an impact would also need to be attributable to the dumping of imports.

The table below shows an analysis of the actual and projected earnings before interest and tax achieved and forecast for Tamoxifen. The figures have been calculated from financial data provided by Douglas.

Table 4.9: Profit

	1998	1999	2000	2001	2002
EBIT		Decrease	Decrease	Decrease	0
EBIT per pack		Decrease	Decrease	Increase	0.00
As% of Revenue		Decrease	Decrease	Decrease	0%

The figures show significant declines in profitability in 1999 and 2000 which cannot be attributed to the allegedly dumped imports. Declines in profitability in 2001 and 2002 are related to forecast declines in sales revenue due to loss of sales to the subject goods.

As explained above in section 4.4.1, the Ministry has revised sales volume and revenue figures for the year ended March 2001. Based on the revised sales figures and using unit figures for the year ended March 2000, the Ministry has calculated indicative profit. On this basis, profit would be $_____, while unit profit and profit as a percentage of sales revenue would remain as shown in the table above. The figures still show that the New Zealand industry will suffer a significant decline in profitability.

There is evidence that profits will decline due to sales being lost to the allegedly dumped imports.

Productivity

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.

Douglas has provided no information on productivity.

Return on Investments

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.

Douglas has provided no information on return on investments.

Utilisation of Production Capacity

The utilisation of production capacity reflects changes in the level of production, 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.

Douglas has stated that there is no obvious impact on utilisation of production capacity because of dumping.

Other Adverse Effects

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

Douglas has provided no information on other adverse effects and considers that these effects will be come evident during an investigation.

4.5 Other Causes of Injury

Sections 8(2)(e) and (f) of the Act provide that the Secretary 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 or subsidised goods by New Zealand producers of like goods, including the value, quantity, frequency and purpose of any such importations.

Non-dumped Imports

Medsafe's letter of 29 June 2000 identifies a number of suppliers of Tamoxifen other than Pacific and Douglas. Any investigation will have to examine the effects that imports of non-dumped goods have had on the industry.

Export Performance

Douglas has advised that it "will continue to manufacture Tamoxifen in New Zealand for its export markets". Douglas states that financial details included in its application are not affected by the export business.

Other Factors

Douglas has stated that information to make a meaningful comment on other causes of injury is not available to it until an investigation has been initiated.

Any investigation will need to consider the extent to which injury to the industry is being caused by factors other than dumping.

Imports by the Industry

Customs data indicates that in _____ Douglas imported a shipment of __ mg Tamofen tablets from _____ with a value for duty of NZ$_____.

4.6 Conclusions Relating to Injury

There is evidence that import volumes of the subject goods will increase significantly in absolute terms and relative to production and consumption in New Zealand.

There is sufficient evidence that prices will be undercut, but not that prices will be depressed or suppressed.

There is evidence that there will be a consequent economic impact in the form of a decline in sales, market share and profits.

There is no evidence that factors other than dumping may have contributed to injury caused by the allegedly dumped imports.

5. Conclusions

On the basis of the information available, it is concluded that, for the purposes of initiation, there is sufficient evidence that:

(a) under the brand name Genox from the United Kingdom is being dumped; and

(b) By reason thereof material injury to the New Zealand industry is being threatened.

6. Recommendations

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 Secretary of Commerce formally initiate an investigation to establish whether imports of from the United Kingdom are being dumped and thereby threatening to cause material injury to the New Zealand industry producing like goods;

(b) that the Secretary sign the attached Gazette notice, and give notice to interested parties in accordance with section 9 of the Act.

[Signed by the Manager Trade Remedies, acting under delegated authority from the Secretary of Commerce on 30 August 2000]