



Minister of Health
Minister for Food Safety
MP for Rongotai (incl Chatham Islands)

RECEIVED
08 JAN 2003
BY:

23 DEC 2002

Sue Kedgley
MP
Parliament Buildings
Wellington

Dear Ms Kedgley

Thank you for your letter of 9 December 2002 requesting information regarding growth in pharmaceuticals.

I have transferred this request to Pharmac pursuant to Section 14 of the Official Information Act 1982 as the information is held by PHARMAC.

Pharmac has 20 working days from the receipt of the transfer to make a decision on your request.

Yours sincerely

Hon Annette King
Minister of Health

cc. Wayne McNee, Pharmac

RECEIVED
08 JAN 2003
BY: _____



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www.pharmac.govt.nz

23 December 2002

Sue Kedgley MP
Parliament
Wellington

Dear Mrs Kedgley

OFFICIAL INFORMATION ACT REQUEST: GROWTH IN PHARMACEUTICALS

We refer to your letter dated 9 December 2002 and your Official Information Act 1982 (OIA) request for:

"information, written advice or reports that PHARMAC may have prepared over the past year about what the reasons or the drivers of the recent volume growth in pharmaceuticals or prescriptions may be."

In response to your request we are attaching a memorandum on the fiscal impact of direct to consumer advertising that was presented to the PHARMAC Board at its meeting on 28 November 2003. 1

We are withholding a few portions of the memorandum under sections 9(2)(b)(ii) of the OIA for the following reason:

- [9(2)(b)(iii)] withholding some of the information is necessary to protect information where making it available would be likely to unreasonably prejudice the commercial position of either the person who supplied it or who is the subject of the information.

In the circumstances of this case, we do not consider that there are any other considerations which render it desirable in the public interest to make the information available.

Please note that under the OIA you have the right to ask the Ombudsman to investigate and to review our decision to withhold some of the information that you have requested under section 28(3) of the OIA. However, following our discussions with your office, I believe that the memorandum as disclosed will provide the information you require.

Please let us know if you require anything further.

Yours sincerely

Wayne McNee
Chief Executive

MEMORANDUM FOR BOARD MEETING OF 28 NOVEMBER 2003

To: PHARMAC Directors
From: Rachel Wilson
Date: November 2002

FISCAL IMPACT OF DIRECT TO CONSUMER ADVERTISING (DTCA)

Recommendations

It is recommended that you:

- note** the impact of direct to consumer advertising on pharmaceutical expenditure and volume growth; and
- note** the attached report on the impact of direct to consumer advertising that PHARAMAC staff provided to Medsafe in August 2002 (Appendix One).

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Executive Summary

- At its meeting of October 2002 the PHARMAC Board directed PHARMAC staff to bring a further report to the Board on the impact of Direct to Consumer Advertising (DTCA) outlining the impact of DTCA on expenditure and volume growth.
 - DTCA is used as part of a marketing mix pharmaceutical companies use to increase product sales. Other tools include advertising in trade magazine, detailing, sample drops, meetings, conference sponsorship, paying for clinician's attendance at conferences, and funding research. Differentiate the impact of DTCA from the other components of the marketing mix can be difficult. The rapid increase in expenditure on DTCA in New Zealand indicates that it is an effective component of the marketing mix used to increase pharmaceutical sales and it can be assumed DTCA has become a primary driver for any increase in volume or expenditure growth.
 - A review of Pharmhouse data for the top four subsidised pharmaceuticals advertised directly to consumers (Flixotide, Losec, Oxis and Lamisil) identified growth in expenditure of \$3.66 million from 1999 to 2001. Growth in prescription numbers was higher than expenditure growth. The containment of expenditure growth can be attributed to PHARMAC's expenditure management strategies. If subsidy levels had remained constant over time expenditure growth would have been higher. For example, using May 2002 as a constant subsidy level, there would have been expenditure growth in these four pharmaceuticals of over \$11.2 million from 1999 to 2001.
 - In line with previous years, total dispensing volumes for the year 2001/02 for pharmaceuticals listed on the Pharmaceutical Schedule showed an appreciable increase over that of the previous year. Dispensings totalled 42.0 million in 2001/02, compared with 39.7 million in 2000/01, and hence increased 5.7%, with 2.26 million extra dispensings. Of this growth, DTCA possibly accounted for 21.8% (495,034 dispensings) based on the analysis of Pharmhouse data for Flixotide, Losec, Oxis and Lamisil. (See Appendix Two for a copy of the analysis of the increase in dispensing volumes for 2001/02.)
 - Analysis has not been done on all the subsidised products that are advertised directly to consumers. Due to the historical lack of data at a brand level it is not possible to review the impact of advertising on expenditure for advertised brands of pharmaceuticals which have competing brands of the same chemical subsidised. For example, if there were two brands of beclomethasone fully subsidised and one of them was advertised, generic level data would not identify whether an increase in expenditure was for the advertised brand or the non-advertised brand.
- In August 2002 PHARMAC staff provided Medsafe with an updated report on issues associated with DTCA (Appendix One). A key issues is that it creates fiscal risk on the limited government pharmaceutical budget as it:
- drives up demand for subsidised pharmaceuticals,
 - shifts demand to high cost medicines by encouraging patients to move from older less expensive medicines to newer high cost medicines;
 - increases demand for PHARMAC to subsidise pharmaceuticals that are advertised;
 - does not meet accepted international standards for health promotion; and
 - the current regulatory system of self-monitoring and compliance is not optimal. A number of reports have found that DTCA continues to be in breach of the regulations, and the current system is not easy for complainants to use.

As requested by the Board, Karen Guilliland reviewed a copy of the report before it was sent to Medsafe.

Findings

Effect of DTCA on expenditure

DTCA is increasingly being used to generate demand for subsidised prescription medicines. In 2001 at least eighteen prescription products were advertised directly to consumers, through television, press, radio, cinema or in magazines. This trend poses a significant risk over the longer term, as growth in the volume of pharmaceuticals is a major driver of pharmaceutical subsidy expenditure.

Many more than eighteen subsidised products were advertised in magazines but as advertising in magazines includes advertising to health professionals through trade/technical magazines, products advertised only in magazines have not been included in this review. It would not be possible to differentiate whether the magazine advertising spend was just for trade/technical magazines or included DTCA as well. This may mean that the number of products advertised to consumers may have been higher than eighteen but this is unable to be confirmed.

PHARMAC data from 2002 demonstrates the ongoing impact of DTCA on growth in government expenditure for four subsidised directly marketed pharmaceutical products (NZ dollars). During 2001 some \$4.9 million was spent by the pharmaceutical industry on DTCA for Oxis (efornoterol, a long-acting beta agonist for asthma), Flixotide (fluticasone, an inhaled corticosteroid for asthma), Losec (omeprazole, a proton pump inhibitor), and Lamisil (terbinafine, an anti-fungal agent):

2001 Advertising spend (at rate card) for four pharmaceuticals marketed directly to consumers

Product	Formulations	Press	Magazine	TV	Radio	Total
Flixotide	11		\$117,980	\$1,711,824		\$1,829,804
Lamisil	2		\$141,385	\$618,836		\$760,221
Losec	2	\$15,652	\$148,784	\$809,610	\$109,834	\$1,080,281
Oxis	2		\$123,793	\$1,099,337		\$1,243,130
Turbuhaler	2					

(note: magazine spending was included in this data as we know these products were advertised DTCA through other media, so advertising is not limited to a health professional audience only)

Table Two below shows expenditure and prescription data all formulations for the four products reviewed. Formulation data includes all information about a product at a generic level. However as these products had no generic competition the formulation data, in effect, represents brand data. Expenditure and prescription data has been reported by formulation as prior to 2001 brand data was not collected consistently. The third section of the table shows expenditure at May 2002 subsidy prices. Expenditure data for 1999, 2000 and 2001 have been priced at May 2002 prices to show the growth in expenditure if subsidies had been consistent over time.

Table Two: 1999 - 2001 increases in expenditure and prescription numbers for four products advertised DICA

Formulation	Year Dispensed			% increase 01 vs. 99
	1999	2000	2001	
Prescriptions				
Flixotide	184,608	216,021	269,589	46%
Lamisil	10,161	13,415	15,661	53%
Losec	294,888	357,076	327,589	41%
Oxis Turbuhaler	2,012	4,094	11,017	545%

Real growth in expenditure on these products was greater than \$3.6m from 1999 to 2001. Growth in prescription numbers is higher than expenditure growth, for example there was a reduction in expenditure in Losec though there was an increase in prescription numbers. Differences in expenditure growth and prescription growth can be attributed to PHARMAC's expenditure management strategies such as innovative contracting, risk sharing arrangements and reference pricing. If subsidy levels had remained constant over time expenditure growth would have been higher. For example using May 2002 as a constant subsidy level there could have been expenditure growth in these four products of over \$11.2m from 1999 to 2001.

It is important to note that PHARMAC's activity not only manages expenditure growth, it also impacts on overall product growth through introducing and/or changing subsidies. Below is a summary of any PHARMAC supply side activity that may have impacted on these products.

Flixotide - Flixotide comes in 2 Formulations - Metered Dose Inhalers (MDIs) and Breath Activated Devices (BADs). Over the time period reviewed there has been no change to access criteria or subsidies for MDIs recently though there was a BAD subsidy reduction in August 2001. Since August 2001 there has been a surcharge on Flixotide BADs.

Oxis Turbuhaler - there was a de-restriction of access plus price and subsidy reductions in May 2001. Oxis Turbuhaler being the only inhaled Long Acting Beta Agonist available without Special Authority. This will have increased usage since May 2001. Other inhaled Long Acting Beta Agonist BADs were reference priced in May 2001.

Losec - there was about a seven-month period between September 2000 and April 2001 when Losec carried a manufacturers surcharge. It became fully funded from April 2001. Before September 2000 although there was officially a surcharge on Losec PHARMAC staff understand it was effectively fully funded as AstraZeneca was providing bonus stock to wholesalers and pharmacies at that time. We understand that Losec was heavily advertised in 1998 and 2001.

Lamisil - PHARMAC staff note that there has not been any supply side activity with Lamisil in this time period. It was advertised in 1999/2000.

Effect of DTCA on volumes growth

These four pharmaceuticals in turn experienced a 42% increase in dispensing volumes, with some 493,000 extra dispensings (some 41,100 pyc).

Dispensings of four pharmaceuticals subjected to DTCA

	2002	2001 minus 2002	% increase
Omeprazole	980,763	357,109	57%
Fluticasone	585,211	77,077	15%
Eformoterol fumarate	76,899	55,093	253%
Terbinafine	33,175	3,755	13%
totals	1,676,048	493,034	42%

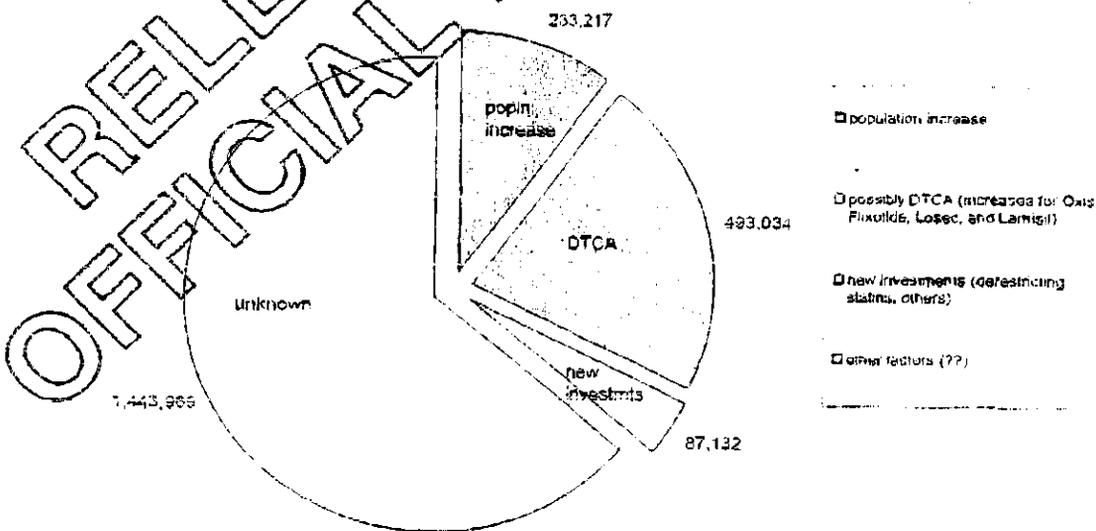
This represents 21.8% of the extra 2.26 million dispensings (188,000 pyc) occurring in 2001/02. The other causes have been identified as:

1. Population increase (unadjusted for any changes in age distribution).
2. New investments occurring during 2001/02, particularly deregulating most statins;
3. Other factors as yet unknown or unquantified. This group includes changes in population age distribution/mix, changes in disease prevalence/need, promotion of pharmaceuticals outside of DTCA, etc.

Population increase accounted for 10.3% of the 2.26 million extra dispensings in 2001/02 (233,217 dispensings), new investments 2.9% (87,132), and other factors yet unknown/unquantified 64.0% (1,443,969):

Figure 2. Pie chart of causes of increase in dispensing volumes FY2002 vs. 2001

Causes of increase in dispensing volumes FY2002 vs 2001



AAA

Checklist for Board papers

Paper: Fiscal Impact of DTCM

Date of Board Meeting: 28 November 2002

The Author(s) confirm that appropriate processes were followed for the development of this paper, including appropriate consultation and consideration of consultation responses.

Principal Author (sig): [Signature]

Other Authors (sig): [Signature]

Medical director (sig): [Signature]

The following parties were consulted with during the development of this paper: [Note: leave box blank in respect of parties who were not consulted]

- Minister of Health
- Ministry of Health
- DHBs
- PTAC
- Consumer Advisory Committee
- Affected health professionals (refer to attached distribution list)
- Affected patient/consumer groups (refer to attached distribution list)
- Affected suppliers (refer to attached distribution list)
- Other affected public groups and/or individuals (specify)

All relevant comments received from the following parties as a result of consultation have been included in this paper or are attached

- Minister of Health
- Ministry of Health
- DHBs
- PTAC
- Consumer Advisory Committee
- Health professionals
- Patient/consumer groups
- Suppliers
- Other affected public groups and/or individuals (specify)

Text proof read by (signed): [Signature]

Analysis checked by (signed): [Signature]

Approved for inclusion in Board Agenda: [Signature]

Chief Executive [Signature]

Date 21/11/02

Appendix One
Report to Medsafe on impact of DTCA - August 2002

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PHARMAC DIRECT TO CONSUMER ADVERTISING (DTCA) SUBMISSION TO MEDSAFE

Overview

In 2001 the Ministry of Health completed a review of Direct-To-Consumer Advertising (DTCA) in New Zealand. As a result of this review, the Minister of Health recommended that the Ministry of Health review the existing legislation and tighten controls of advertising medicines direct to consumers². PHARMAC understands that Medsafe has been charged with undertaking this work, and components of it are being linked with work on the Trans Tasman Agency to regulate therapeutic products.

PHARMAC supports the overriding objectives of the review, which are to:

- develop a trans Tasman therapeutic goods advertising regime;
- streamline the assessment processes for industry and consumers in dealing with advertising approval and complaints handling processes;
- ensure that streamlined complaint handling processes appropriately integrate self- and co-regulatory best practice principles; and
- ensure that the regime offers cost effective and timely processes that deliver ease of access, consistency and transparency to all stakeholders.

PHARMAC recognizes that the review will not address broad policy issues associated with advertising of therapeutic goods, including the advertising of prescription medicines. Therefore we have developed this report to provide an update of the issues associated with DTCA.

Key concerns

PHARMAC has three key concerns regarding DTCA:

- it creates fiscal risk on the limited government pharmaceutical budget as it
 - drives up demand for subsidised pharmaceuticals,
 - shifts demand to high cost medicines by encouraging patients to move from older less expensive medicines to newer high cost medicines and
 - increases demand for PHARMAC to subsidise pharmaceuticals that are advertised;
- in its current form it does not meet accepted international standards for health promotion; and
- the current regulatory system of self-monitoring and compliance is not optimal. A number of reports have found that DTCA continues to be in breach of the regulations, and the current system is not easy for complainants to use.

This report details the key concerns and outlines PHARMAC's recommendations on what it considers should be included in the review. Comments specific to the questions and recommendations discussed as part of the DTCA component of the TransTasman Agency project have been provided to the consultant leading this process. A copy of the document detailing PHARMAC's response to consultation will also be provided to Medsafe.

² "Direct to consumer advertising rules will become stricter" document www.beehive.govt.nz

Recommendations:

PHARMAC would welcome discussion with Medsafe and other key stakeholders on the following:

- Resolve that the work to tighten the DTCA legislation as per the Ministerial directive is treated as a priority and is undertaken as soon as possible.
- PHARMAC's concerns about the consultation process of the DTCA component of the TransTasman review. A key concern is whether all appropriate parties were given an opportunity to be engaged in the process either through consultation or through representation on the Expert Group.
- Development of protocols so that international standards of consumer health promotion are used whenever information is being promoted directly to the public through DTCA.
- DTCA should contain a balance of risk and benefit information in plain English and in the most appropriate format, for example voice-over in conjunction with writing.
- Development of routine monitoring of advertising by an independent body representing the key stakeholders including government.
- On-going monitoring of the fiscal impact of DTCA on the government pharmaceutical budget.
- Independent research on the impact of DTCA on the health sector in terms of fiscal impacts and measurable health outcomes.

Please note that any recommendations would need to be considered by the PHARMAC Board for approval.

We welcome feedback on this report.

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Background

DTCA is any promotional effort by a pharmaceutical company to present pharmaceutical information to the general public, through advertisements in any media including newspapers, television, magazine, and mail-outs. Pharmaceutical companies also promote pharmaceutical information via the Internet. DTCA may be for medicines or medical devices including subsidised and non-subsidised prescription pharmaceuticals, pharmacist only (restricted) medicines, pharmacy only medicines and general sale medicines. DTCA does not include advertising to medical professionals via medical journals and trade publications.

Pharmaceutical companies use paid advertisements to promote pharmaceuticals directly to the public through television, print and radio. They also promote products through "free to air" promotion, for example "news items" on the Holmes show. A review of DTCA ideally needs to address both paid advertising and unpaid "free to air" promotion.

* [New Zealand and the USA are the only two countries that allow DTCA. New Zealand has more lenient legislation than the USA. *W*

As the government agency charged with managing pharmaceutical subsidies and the national pharmaceutical budget, PHARMAC is focusing on the impact of DTCA on prescription medicines.

Concerns with DTC advertising

Fiscal strain

DTCA aims to increase consumer demand for the pharmaceuticals that are advertised. DTCA differs from advertising other products, as the consumer is not necessarily the purchaser. Part of the normal purchasing decision for consumers is consideration of price, however when the consumer is not the purchaser and there is a third party purchaser, such as PHARMAC, the decision-making process may be distorted.

A research report from the US National Institute for Health Care Management Research and Educational Foundation found that in the US between 1999 and 2000 sales of the 50 most heavily advertised DTC pharmaceuticals increased at 2.3 times the rate of all other drugs and the number of prescriptions for the most heavily DTC pharmaceuticals grew at a rate six times that of other drugs (24.6% compared with 4.3%). Spending on mass media increased 35% in the same period and has doubled since 1997. Retail sales of the most advertised drug, the anti-arthritis drug Vioxx, quadrupled from 1999 to 2000 from \$US329.5 million to \$US1.5 billion³.

* While DTCA may not be responsible for all of the growth it is an intrinsic part of an overall marketing mix. Increasing expenditure on DTCA shows that it is being used as a key promotional tool. Pharmaceutical companies would not invest in advertising if they didn't reap the benefits through increased sales. By 2000, pharmaceutical direct-to-consumer advertising is projected to increase to \$7 billion annually in the US alone. In New Zealand, one company GlaxoSmithKline (GSK) spent over NZ\$15 million (rate card) on advertising in New Zealand in 2001⁴. *W*

DTCA increases expenditure by driving up demand for subsidised products

DTCA is increasingly being used to generate demand for subsidised prescription medicines. In 2001 at least eighteen prescription products were advertised directly to consumers, through television, press, radio cinema or in magazines⁵. This trend poses a significant risk over the longer term, as growth in the volume of pharmaceuticals is a major driver of pharmaceutical subsidy expenditure. *W*

³ National Institute for Health Care Management Research and Educational Foundation 2001

⁴ Marketing Magazine April 2002

⁵ AC Neilsen (NZ) Ltd

Many more than eighteen subsidised products were advertised in magazines, but as advertising in magazines includes advertising to health professionals through trade/technical magazines, we have not included products advertised only in magazines in this review. It would not be possible to differentiate whether the magazine advertising spend was just of trade/technical magazines or included DTCA as well. This may mean that the number of products advertised to consumers may have been higher than eighteen but we are unable to confirm this.

PHARMAC data from 2002 demonstrates the ongoing impact of DTCA on growth in government expenditure for four subsidised directly marketed pharmaceutical products (NZ dollars). Table One below shows 2001 advertising spend (at rate card) for the four subsidised products. Table Two shows the effect DTCA has on pharmaceutical expenditure and script numbers in the four products.

Table One: 2001 Advertising spend (at rate card) for four pharmaceuticals marketed directly to consumers

Product	Formulations	Press	Magazine	TV	Radio	Total
Flixotide	11		\$117,980	\$1,711,824		\$1,829,804
Lamisil	2		\$145,385	\$618,876		\$764,261
Losec	4	\$15,052	\$145,785	\$809,610	\$199,834	\$1,080,281
Oxis						
Turbuhaler	2		\$143,793	\$1,099,307		\$1,243,100

(note: magazine spending was included in this data as we know these products were advertised DTCA through other media, so advertising is not limited to a health professional audience only)

Table Two shows expenditure and prescription data for all formulations for the four products reviewed. Formulation data includes all information about a product at a generic level. However as these products had no generic competition the formulation data in effect represents brand data. Expenditure and prescription data has been reported by formulation as prior to 2001 brand data was not collected consistently. The third section of the table shows expenditure at May 2002 subsidy prices. Expenditure data for 1999, 2000 and 2001 has been priced at May 2002 prices to show the growth in expenditure if subsidies had been consistent over time.

Table Two: Increases in expenditure and script numbers from 1999 - 2001 on four products advertised DTCA - including all formulations of the products.

Formulation	Year Dispensed			% increase 01 vs. 99
	1999	2000	2001	

Prescriptions	1999	2000	2001	% increase 01 vs. 99
Flixotide	184,608	216,021	269,584	46%
Lamisil	10,161	13,415	15,661	54%
Losec	294,888	337,076	327,583	11%
Oxis Turbuhaler	2,012	4,094	21,017	945%

Real growth in expenditure on these products was greater than \$3.66m from 1999 to 2001. Growth in prescription numbers is higher than expenditure growth, for example there was a reduction in expenditure in Losec through there was an increase in prescription numbers. Differences in expenditure growth and prescription growth can be attributed to PHARMACs expenditure management strategies such as innovative contracting, risk sharing arrangements and reference

pricing. If subsidy levels had remained constant over time expenditure growth would have been higher. For example, using May 2002 as a constant subsidy level, there would have been expenditure growth of over \$11.2m from 1999 to 2001.

It is important to note that PHARMAC activity not only manages expenditure growth, it also impacts on overall product growth through introducing and/or changing subsidies. Below is a summary of any PHARMAC supply side activity undertaken in regard to the products detailed above.

Flixotide - Flixotide comes in 2 formulations – Metered Dose Inhalers (MDIs) and Breath Activated Devices (BADs). There has been no change to access criteria or subsidies for MDIs recently, though there was a BAD subsidy reduction in August 2001. Since August 2001 there has been a surcharge on Flixotide BADs.

Oxis Turbuhaler - there was a de-restriction of access plus price and subsidy reductions in May 2001. Oxis Turbuhaler 6mg is the only inhaled Long Acting Beta Agonist available without Special Authority. This will have increased usage since May 2001. Other inhaled Long Acting Beta Agonist BADs were reference priced in May 2001.

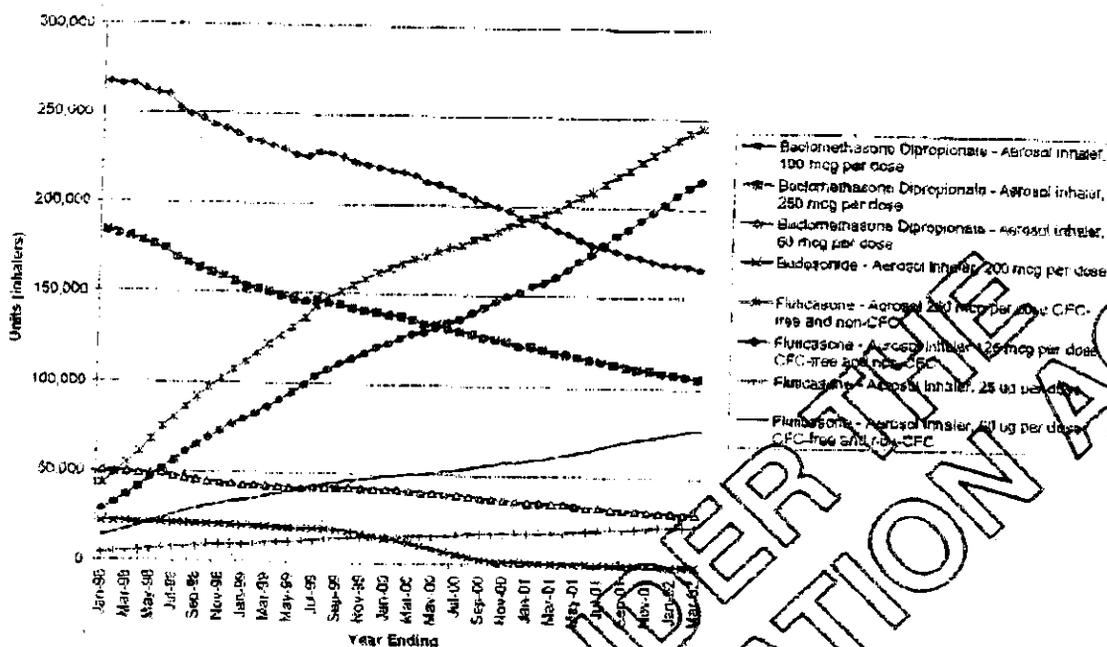
Losec - there was about a seven-month period between September 2000 and April 2001 when Losec carried a manufacturers surcharge (also known as a pati charge). It became fully funded from April 2001. Before September 2000 although there was officially a surcharge on it, PHARMAC staff understand it was effectively fully funded as AstraZeneca was providing bonus stock to wholesalers and pharmacies at that time. We understand that Losec was heavily advertised in 1998 and 2001.

Lamisil - PHARMAC staff note that there has not been any supply side activity with Lamisil in this time period. It was advertised in 1999/2000.

DTCA distorts demand by moving patients to high cost medicines

DTCA is not fiscally neutral - it is not simply a case of one medicine gaining at the expense of a competitor - DTCA tends to be for newer more expensive medicines when older less expensive medicines may work equally well in many patients. Patients often see the advertisements and then request these newer medicines rather than stay on their existing medicines. For example, there was a significant shift in the mix of Metered Dose Inhalers from beclomethasone to fluticasone (Flixotide) following Glaxo Wellcome's Flixotide DTCA campaign, which started in 1998. This is shown in the following graph. A similar situation exists with a switch from H2Antagonists to Proton Pump Inhibitors.

Graph One – Dispensings of Metered Dose Inhaler Units (Pharmhouse data July 2002)



Note: units refer to inhalers not doses

DTCA creates an increased demand for PHARMAC to subsidise advertised products

Advertising is designed to increase the demand for a product. Advertising non-subsidised prescription medicines aims to increase demand for these medicines, which in turn can increase the demand for the government to subsidise these products. The Ministry of Health DTCA discussion paper noted this and commented that increasing numbers of unsubsidised medicines could reduce patient confidence in the wider health system.

Many patients who see a drug advertised on television or in the paper presume it has to be better and safer than what they are currently on. National Consumer surveys in the USA show that 43% of consumers surveyed thought DTCA was only allowed for completely safe medicines, 22% thought it was only allowed for extremely effective medicines and 21% thought it was banned for drugs with serious side effects. The push of DTCA to promote products as being better than existing products is evidenced in the phone calls PHARMAC staff receive from patients asking why Celebrex isn't funded, stating that they've seen it on TV and therefore it must be better. The RMI in its report "DTCA Advertising Can Enhance Public Health" (June 2000) states, "the intent of DTCA advertising is to open up the market, not to pressurise PHARMAC". However there is evidence that some drug companies promote DTCA either for products that currently attract a government subsidy or for those that they may propose applying for an application for subsidy.

DTCA does not meet health promotion standards

Proponents of DTCA contend that it enhances consumer understanding of health topics, and enables consumers to seek medical assistance for supposed health problems. They argue that there is a substantial reservoir of undiagnosed and untreated disease in the community and that DTCA can

6 Ministry of Health DTCA of prescription medicines in NZ. A discussion paper. November 2000
 7 National random digit dialed surveys, 1000 – 12000 respondents; US FDA, 2000; Prevention Magazine, 1997, 1998, 1999; Time Magazine, 1998, 1999; National Consumers' League, 1998. Barbara Mintzes article "Crying Cure in a Crowded Hospital? DTCA advertising of prescription drugs." Appendix Four
 8 RMI report "DTCA Advertising Can Enhance Public Health" June 2000

* prompt people to seek help. However this argument overlooks a key issue from a consumer perspective, namely the quality of the information provided through DTC advertising.

Consumers are actively seeking health information and want to be part of the decision-making process about their healthcare. Informed consent and informed choice are integral to this decision-making process. In a review of DTCA, Mintzes⁹ states 'the question is not whether consumers should obtain information about treatment options; the question is whether drug promotion - whose aim is to sell a product - can provide the type of information consumers need'.

* Internationally there is a growing interest in the development of quality consumer health information. Consumers have supported the development of an evidence-based approach to health care and provision of information for consumers that is evidence-based. Consumers are actively involved in initiatives such as the Cochrane Collaboration (www.cochraneconsumer.com) and other projects that translate the results of research and systematic reviews into information that is accessible to consumers. For example see the New Zealand Guidelines Group website www.nzgg.org.nz for evidence-based consumer resources developed following systematic reviews and guidelines development.

There are several internationally recognised standards for health promotion information, such as the Ottawa Charter for Health Promotion, the DISCERN handbook (www.discern.org.uk), the Kings Fund (www.kingsfund.org.uk) and criteria for assessing the quality of health information on the Internet (<http://hitweb.mit.tetek.org>). It is a concern that prescription pharmaceuticals advertised directly to consumers do not tend to meet these standards.

The DISCERN handbook was produced by an expert panel of clinical specialists, self-help group representatives, general practitioners, a consumer health information expert, a lay medical publisher, a health journalist, a health consumer, a Community Health Council representative, a Plain English Campaign representative and a representative from the NHS Centre for Reviews and Dissemination. While the tool was developed for the assessment of information on the Internet, it can also be used to assess other forms of consumer information. DISCERN scores 15 aspects regarding the quality of patient/public health information, namely it must:

- Have explicit aims
- Achieve its aims
- Be relevant to consumers
- Make sources of information explicit
- Make date of information explicit
- Be balanced and unbiased
- List additional sources of information
- Refer to areas of uncertainty
- Describe how the treatment works
- Describe the benefits of the treatment
- Describe the risks of the treatment
- Describe what would happen without treatment
- Describe the effects of treatment choices on overall quality of life
- Make it clear there may be more than one possible treatment choice
- Provide support for shared decision-making

⁹ Mintzes, Barbara. *Blurring the Boundaries: New Trends in Drug Promotion*, HAI-Europe, Amsterdam, 1998
M5-12-15 #67496

A review of DTCA in New Zealand would indicate that many advertisements fail to meet a significant number of these criteria.

The New Zealand Code of Health and Disability Services' Consumer Rights (developed under the Health Commissioner Act 1994) can also be applied to DTCA (www.hdc.org.nz). There are ten rights under the Code and many have relevance to DTCA. Right Six is particularly relevant. This describes the information that health consumers must receive to make an informed choice and exercise informed consent. Included in the requirements are that consumers should receive information about options, including the expected risks, side effects, benefits and costs.

DTCA does not perform well at presenting evidence-based information about risks and benefits. A major fault in DTCA is the failure to provide information about options. Rather than meeting standards for health promotion information, DTCA has more in common with social marketing/social advertising techniques, i.e. it aims to sell a product. Wolfe¹⁰ notes that DTCA contains powerful, emotion-arousing images and frequently unbalanced information on safety and effectiveness.

It has been stated that many of the advertisements in New Zealand would be in breach of the USA standards¹¹. In the USA where regulation is tighter than in New Zealand, a study based on a national telephone survey conducted by IRC Inc. in December 1998 (N = 1,110 with over-sampling of people aged 50 and older), showed that one-third of the audience for DTC advertising failed to notice the small print (risk information). Only 48% of those aged 60 and older said that they noticed the side effect information, compared with 67% if people aged 18 - 39. This is concerning, especially as the elderly are high consumers of pharmaceuticals and are the target audience for a number of DTC advertisements.

DTC advertising industry self-regulation isn't working

The New Zealand DTCA regulation system relies on a permissive legislative framework and compliance with the voluntary Code. Medsafe does not routinely monitor DTC advertising, however the monitoring it has undertaken shows that DTCA does not always comply with the voluntary Code.

On 24 July 1998 a report reviewing DTC advertising of prescription medicines was presented to the then Associate Minister of Health¹². The report investigated four DTC television advertisements and four DTC print advertisements for prescription medicines. Breaches to the Medicines Act 1981 were detected in three of the four television advertisements, Xenical, Havix and Flixotide (breach of section 57). This section relates to obligations in regulation 8 of the Medicines Regulations to specify authorised uses, appropriate precautions, contra-indications and adverse effects. There was also an issue of proper compliance with the obligation to include an address of the drug company.

The industry implemented self-regulation in an effort to improve compliance, including:

- The Advertising Standards Authority (ASA) Code for Advertising Therapeutic Products (voluntary): The ASA Therapeutic Code has been in place since 1 February 1999, and was updated in April 2000.
- The Association of NZ Advertisers Inc.'s Therapeutic Advertising Advisory Service (TAAS) was implemented to review advertisements and provide advice regarding compliance with the Medicines Act, Medicines Regulations and the ASA Code for Advertising Therapeutic Products. TAAS was replaced by TAPS in late 2000. TAPS operating mechanism is outlined below.

¹⁰ Wolfe, Sidney M (2002), "Direct-to-Consumer Advertising - Education or Emotion Promotion," *New England Journal of Medicine*, 346 (14 February): 524-26

¹¹ National Radio, Kim Hill interview with Barbara Mintzes, 17 August 2000

¹² Ministry of Health, Minister's Investigation into Prescription Medicine Advertising Direct to the Public, 24 July 2000. File ref: T105-18-6

In February 2000, Medsafe undertook an assessment of regulatory compliance for medicines advertised directly to consumers. The report found that only 69.3% of DTC advertisements for prescription medicines were compliant with the regulatory requirements. Only one of the television DTC advertisements that were reviewed was compliant.

- Of the 52 advertisements reviewed 46 were print and 6 were television.
- Of the print advertisements 35 (76%) were compliant.
- Only 1 of the 6 (16.6%) television advertisements was compliant with the regulations.

The biggest area of non-compliance noted in the report was in the provision of the risk information, i.e. the precautions, contra-indications and side effects. This is the part that requires the advertiser to provide balance.

The report noted that the DTCA of prescription medicines has improved since the introduction of the Therapeutic Advertising Advisory Service (TAAS). Given the non-compliance figures presented in the Medsafe report, non-compliance may still be seen to be an issue. PHARMAC understands the actions arising from the report were as follows:

- Medsafe was to write warning letters to companies who published non-compliant advertisements, requesting retraction of such ads, and refer them to the appropriate regulatory industry body for censure and discipline.
- For repeat offenders prosecution would follow.
- Medsafe was to work closely with the RMA to provide advice.
- Medsafe was to continue to work closely with TAAS and other regulatory affairs people to provide advice.
- Medsafe was to undertake a further assessment in 2001 and report back on the state of play.

The Therapeutic Advertising Pre-writing Scheme (TAPS) replaced the Association of NZ Advertisers Inc.'s Therapeutic Advertising Advisory Service (TAAS) in late 2000. TAPS previews advertisements and provides advice regarding compliance with the Medicines Act, Medicines Regulations and the ASA Code for Advertising Therapeutic Products.

PHARMAC understands that the Association of New Zealand Advertisers (ANZA) contracts out the TAPS scheme to consultants and provides administration. The consultants are paid from user charges and ANZA meets non-recoverable expenses. ANZA briefs and consults the consultant on all industry matters concerning advertising of Therapeutic products and arranges and chairs TAPS Code Consultative Committee, which discuss developments of the Code (Advertising Standards Authority 2002). PHARMAC would question whether the close links between ANZA, TAPS and the industry would impact on the degree of independence between the organisations.

Taking a complaint to the Advertising Standards Authority (ASA) requires considerable knowledge, commitment and effort. PHARMAC understands that the ASA system is not well known to the public. The process of taking a complaint requires considerable input. The complainant must identify where the advertisement breaches specific aspects of the Code. At times this can be difficult when the concern about the advertisement is in regard to the use of images and vague, emotive language.

The Advertising Standards Complaints Board (ASCB) has limited powers. Its decisions are not binding or enforceable. Its members are selected by the ASA. This would question the independence of this process.

Appendix Two
Analysis of the increase in dispensing volumes for 2001/02

RELEASED UNDER THE
OFFICIAL INFORMATION ACT

ANALYSIS OF THE INCREASE IN DISPENSING VOLUMES IN 2001/02

8 OCTOBER 2002

In line with previous years, total dispensing volumes for the year 2001/02 for pharmaceuticals listed on the Pharmaceutical Schedule showed an appreciable increase over that of the previous year. Dispensings totalled 42.0 million in 2001/02, compared with 39.7 million in 2000/01, and hence increased 5.7% with 2.26 million extra dispensings.

Dispensing volumes can translate to proxy patient-year equivalents of access/uptake by dividing by 12 (given the majority of items are dispensed monthly). Hence the above dispensing volumes translate to 3.50 million person-year equivalents (pye) of community pharmaceutical use in 2001/02, compared with 3.31 million in 2000/01, an extra 188,000 pye.

The extra 2.26 million dispensings (188,000 pye) occurring in 2001/02 can be attributed to four different categories of cause:

4. Population increase (unadjusted for any changes in age distribution);
5. Effects of direct-to-consumer advertising (DTCA), namely increases for Oxis, Flixotide, Losec, and Lamisil above 2000/01 dispensings;
6. New investments occurring during 2001/02, particularly de-restricting most statins;
7. Other factors as yet unknown or unquantified. This group includes changes in population age distribution/mix, changes in disease prevalence/mix, promotion of pharmaceuticals outside of DTCA, etc.

The effect of these individual increases are summarised in the following tables and graphs, and then are detailed in the following text. Population increase accounted for 10.3% of the 2.26 million extra dispensings in 2001/02 (233,217 dispensings), DTCA possibly 21.8% (493,034 dispensings), new investments 3.9% (87,132), and other factors yet unknown/unquantified 64.0% (1,443,969):

Table 1

Extent of increase in dispensing volumes FY2002 vs 2001

new person-year equivalents (pyes) from new investments	7,261.0
additional pyes from Rx relating to DTCA (Oxis, Flixotide, Losec, Lamisil)	41,086.2
total additional pye dispensings (2002 vs 2001)	188,112.7
unadjusted % increase 2002 vs 2001	5.7%

Causes of increase in dispensing volumes FY2002 vs 2001

new investments (de-restricting statins, others)	3.9%
possibly due to DTCA (increases for Oxis, Flixotide, Losec, and Lamisil)	21.8%
population increase	10.3%
other factors (??)	64.0%

Figure 1. Growth in dispensing volumes 1998/99 to 2001/02, in context of volumes overall
(provisional analysis, awaiting cumulative new investment and DTCA volumes)

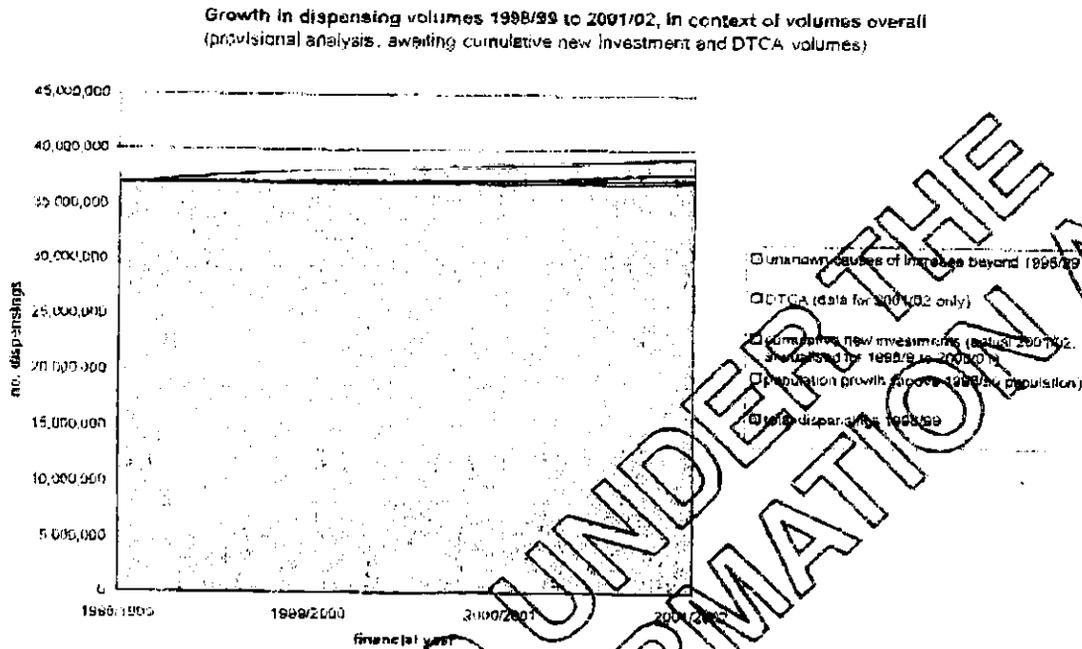
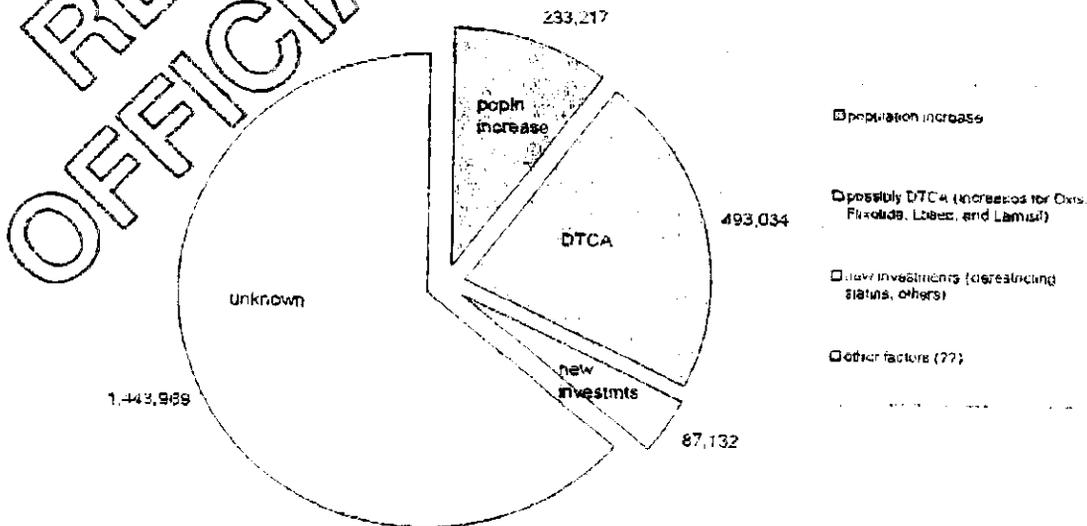


Figure 2. Pie chart of causes of increase in dispensing volumes FY2002 vs. 2001

Causes of increase in dispensing volumes FY2002 vs 2001



Effects of population increase (unadjusted for any changes in age distribution)

Population data available on the Statistics New Zealand website (<http://www.statistics.govt.nz/domino/external/webprod.srv.nsf/092edeb76ed5aa5bcc256afe0081d84e/f01fa6e217e11614cc256b4300054616?OpenDocument>) by calendar year (YE 31 Dec) relate well to financial year data, representing geometric average exposure. These population estimates suggest a 0.6% increase in total population between December 2000 and December 2001.

Applied to the above 5.7% increase in dispensing volumes, population increase hence may have contributed to 10% of volume growth (i.e. 0.6% pop increase / 5.7% dispensing increase = 10.3%). This would equate to some 19,400 pye (some 233,000 dispensings).

Effects of new investments

New investments during the 2001/02 financial year provided treatment for an estimated 38,600 new patients.

Investments included extending access to tranexamic acid for heavy menstrual bleeding, extending access to beta-interferon for multiple sclerosis, extending access to statins for cardiovascular risk (dyslipidaemia), listing of leflunomide for rheumatoid arthritis, listing of budesonide with eformoterol for asthma; extending access to Monogen (a special food); extending access to alendronate for severe osteoporosis; listing of erythropoietin beta for anaemia; listing of carvedilol for hypertension/heart failure; listing of Cosopt (combination dorzolamide & timolol) for refractory glaucoma; extending access to dorzolamide, Timoptol XE & Timpilo, and latanoprost for glaucoma; listing of coal tar with salicylic acid and sulphur; and extending access to quetiapine for schizophrenia, ranitidine and losartan).

The above 17 investments accounted for some 87,100 dispensings (some 7,300 pye usage), contributing to 3.9% of the overall increase in dispensings in 2001/02:

Table 2

Numbers of patients benefitting from specific PHARMAC investment decisions, for 2001/02

Investment decision	No. mths on PS*	Estimated no. new patients
tranexamic acid	6	888
beta interferon	4	122
statins	3	31,097
leflunomide	2	380
budesonide with eformoterol	9	1,237
Monogen	8	13
alendronate	5	818
erythropoietin beta	3	205
carvedilol	3	253
Cosopt (combination dorzolamide & timolol)	3	895
dorzolamide	3	363
Timoptol XE & Timpilo	3	450
latanoprost	3	641
coal tar with salicylic acid and sulphur	1	191
quetiapine	1	322
ranitidine	4	2,254
losartan	3	182
Estimated total new patients	3.4	39,667
Total usage (person-year equivalents)	3.6	7,261

*no. of months implemented on the Pharmaceutical Schedule during the year (max = 12)

Note that the above 87,100 additional dispensings in 2001/02 occurred over around 3.6 months following the implementation of investment decisions (patient-weighted average duration of implementation). Total investments in 2001/02 (\$2.6 million) were 25% of that of the previous three

years (which averaged \$11 million per year), but this was where investments in those years had been implemented over 9 months on average.

Also note that by taking differences in investment duration into account by annualizing all data, then had each year's investments occurred over the entire year, PHARMAC would have invested \$55.5 million over the past four years for some 46,300 pyc, and saved some 4,200 known quality-adjusted years of life (QALYs), with 71% savings elsewhere (\$13.9 million known offsets). During 2001/02 this would have meant \$8.7 million annualized spending on all new investments with 2,800 QALYs saved over one year for tranexamic acid, beta-interferon, statins and leflunomide alone. This would equate to saving 290 statistical lives.

Such annualized figures for 2001/02 would mean that although spending was just half that of previous years' averages, numbers of new patients were five times and QALY gains were six times that of the average of previous years - largely due to investing in statins. The 321,600 annualised dispensings from new investments (46,300 annualised pyc) would account for 14.3% of the 2001/02 dispensing increase.

Further details regarding extent of possible savings to DHBs and QALY gains are available from PHARMAC.

Effects of direct-to-consumer advertising (DTCA)

During 2001 some \$4.9 million was spent by the pharmaceutical industry on DTCA for Oxis (efomoterol, a long-acting beta agonist for asthma), Flixotide (fluticasone, and inhaled corticosteroid for asthma), Losec (omeprazole, a proton pump inhibitor), and Lamisil (terbinafine, an anti-fungal agent):

Table 3. 2001 Advertising spend (at rate card) for four pharmaceuticals marketed directly to consumers

Product	Formulations	Press	Magazine	TV	Radio	Total
Flixotide	11		\$17,980	\$1,711,824		\$1,829,804
Lamisil	2		\$145,385	\$618,836		\$764,221
Losec	4	\$13,052	\$145,785	\$809,610	\$109,834	\$1,080,281
Oxis (efomoterol)	2		\$143,793	\$1,099,337		\$1,243,130

These four pharmaceuticals in turn underwent a 42% increase in dispensing volumes, with some 493,000 extra dispensings (some 41,100 pyc).

Table 4. Dispensings of pharmaceuticals subjected to DTCA

	2002	2001 minus 2002	% increase
Omeprazole	980,763	357,109	57%
Fluticasone	585,211	77,077	15%
Efonoterol fumarate	76,899	55,093	253%
Terbinafine	33,175	3,755	13%
totals	1,676,048	493,034	42%

These 493,000 extra dispensings accounted for 22% of the overall increase in dispensings in 2001/02.

Unknown other factors

Other factors as yet unknown or unquantified accounted for the remaining 1,443,969 dispensings (120,000 ppe), which accounted for the remaining 64% of the overall increase in dispensings in 2001/02.

This group includes changes in population age distribution/mix, changes in disease prevalence/need, promotion of pharmaceuticals outside of DTCA, and other causes. Further details as to specific causes are not available at this stage.

However, it is worth noting that the leading therapeutic subgroups of pharmaceuticals driving the increases in 2001/02 (some are mentioned already) in rank order are: proton pump inhibitors (statins); extemporaneously compounded preparations & galenicals; opioid analgesics; beta-blockers; selective serotonin reuptake inhibitors (SSRIs); antipyretics and non-opioid analgesics; low dose inhaled corticosteroids (MDIs); and ace inhibitors with diuretics.

The top 20 therapeutic subgroups accounting for the increase in dispensings in 2001/02 accounted for two-thirds of the increase across all subgroups:

Table 5. Top 20 therapeutic subgroups (ATC level 3) accounting for the increase in dispensing volumes 2001/02

ATCLevel3Name	ATCLevel2Name	Disp 2001	Disp 2000	% change	% total	cuml %
Proton Pump Inhibitors	(blank)	348448		33.6%	11.1%	11.1%
HMG CoA Reductase Inhibitors (statins)	(blank)	222788		26.6%	7.1%	18.2%
Extemporaneously Compounded Preparations & Galenicals	Extemporaneously Co	187548		482.0%	6.3%	24.4%
Opioid Analgesics	(blank)	167075		11.7%	5.9%	30.4%
Beta Adrenoceptor Blockers	Beta Adrenoceptor Bloc	143097		9.4%	4.6%	34.9%
Selective Serotonin Reuptake Inhibitors	(blank)	118911		13.1%	3.6%	39.7%
Antipyretics and Non-Opioid Analgesics	Analgesics	101325		7.6%	3.2%	41.9%
Low dose	(blank)	92660		10.9%	3.0%	44.9%
ACE inhibitors with Diuretics	Agents affecting the R	90583		48.1%	2.5%	47.7%
Oral Hypoglycaemic Agents	(blank)	70264		10.3%	2.2%	50.0%
Calcium	Minerals	59210		15.1%	1.9%	51.9%
Corticosteroids - Plain	(blank)	58396		10.4%	1.6%	53.7%
Breath activated devices	Inhaled beta-adrenoce	55845		136.4%	1.8%	55.5%
Multivitamin Preparations	Vitamins	54428		23.6%	1.7%	57.2%
General	(blank)	53584		8.6%	1.7%	58.9%
Angiotension II Antagonists	(blank)	52201		135.9%	1.7%	60.6%
High dose	Inhaled corticosteroids	48382		18.0%	1.5%	62.1%
Very high dose	(blank)	48286		25.9%	1.5%	63.7%
Control of Epilepsy	(blank)	46894		6.9%	1.6%	65.2%
Penicillins	(blank)	43127		3.7%	1.5%	66.6%
Grand Total		2095633		100.7.1%	66.6%	

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8 October 2002

Source spreadsheet #66527