COST DRIVER ANALYSIS OF PROVINCIAL DRUG PLANS

ONTARIO

1992/93 - 1998/99

Federal/Provincial/Territorial

Working Group on Drug Prices

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EXECUTIVE SUMMARY

- The F/P/T Task Force on Pharmaceutical Prices[1] was established to examine pharmaceutical pricing issues facing provincial drug plans and Canadians in general.
- This Study is an update which reports on pharmaceutical cost drivers in Ontario Drug Benefit (ODB) Program over the period 1992/93 to 1998/99.
- An examination of cost drivers, produced by the Patented Medicine Prices Review Board (PMPRB) on behalf of the F/P/T Working Group on Drug Prices, provides both public and private drug plan managers, policy makers and other stakeholders, including consumers, with a better understanding of the major components that influence annual changes in pharmaceutical spending.
- The focus of the report was to disaggregate annual changes in the cost of drugs into five components: price effect, volume effect, entry of new drugs, exiting drugs and others. A further break out of cost drivers was done by therapeutic class and patent status.
- Between 1992/93 and 1998/99 total drug expenditures have increased by $625.7 million. On average, between 1992/93 and 1998/99 per unit price changes seen by the province were responsible for -15.9% of the expenditure change, volume change or utilization was responsible for 90.4%, entry of new drugs were responsible for 47.1%, and both exiting drugs and other factors were responsible for -10.3% and -11.3% of expenditures changes respectively. The findings suggest that utilization and entry of new drugs accounted for the largest increase in expenditures over the period with expenditures rising significantly despite a little change in the average per unit price. The contribution of each of these factors changes dramatically in from year to year. Further work is required to understand the sensitivity of the model, the impact of cost containment policies and the entry and market penetration of new drug therapies.
- In 1998/99, drugs that existed in 1992/93 and newer drugs (drugs that were introduced after 1992/93) accounted for 47.5% and 52.5%, respectively, of total drug expenditures.
- In 1992/93 the proportion of total expenditures accounted for by patented drugs was 34.8%. By 1998/99, patented drugs accounted for 59.0% of total expenditures.
- Among patented medicines, category 3 drugs made up the largest share of total patented drug expenditures. In 1998/99, drugs categorized as having little, moderate or no improvement (category 3) accounted for 56.4% of total patented drug expenditures. The share of line extension (category 1) and break through or substantial improvement (category 2) drugs were 32.4% and 6.2%, respectively.

[1] Presently known as F/P/T Working Group on Drug Prices

- In 1998/99 drugs in eight Anatomical Therapeutic Chemical (ATC) groups (Alimentary Tract and Metabolism, Cardiovascular Systems, Genito-Urinary System and Sex Hormones, General Anti-Infectives, Anti-neoplasmatics and Immunomodulating Agents, Central Nervous System, Respiratory System, and Sensory Organs) accounted for $1,213.2 million or 92.5% of total expenditures.
- Over the period 1992/93 to 1998/99, drugs in the Cardiovascular Systems contributed to the largest share of the increase in drug expenditures, accounting for 41.4% of growth. This group was followed by drugs in the classes Central Nervous System (18.8%) and Alimentary Tract and Metabolism (12.7%).
- In order to identify which disease groups are contributing proportionately more to increases in pharmaceutical expenditures, the analysis was broken down to the second level of their Anatomical Therapeutic Chemical (ATC) classification. The study revealed that Lipid Reducing Agents in Cardiovascular Systems made the largest contribution increases in expenditures over the period 1992/93 to 1998/99. The second largest contributor was Agents Acting on the Renin-Angiotensin System (also Cardiovascular Systems), followed by Psychoanaleptics. These disease groups contributed 19.3%, 12.7% and 9.3% , respectively, to increases in pharmaceutical expenditures over the period.

COST DRIVER ANALYSIS OF PROVINCIAL DRUG PLANS

ONTARIO 1992/93-1998/99

1.0 Introduction

In April 1997, the Task Force on Pharmaceutical Prices[2] prepared an overview paper which provided a description of the pharmaceutical sector in Canada, price and expenditure trends, and existing mechanisms used by private and public payers for regulating and/or influencing pharmaceutical prices.

The Task Force on Pharmaceutical Prices has made progress in the following areas:

- comparisons of prices of non-breakthrough or non-substantial improvement (category 3) patented drugs introduced in 1995 and 1996 to other medicines in their therapeutic class; and,
- price trend analyses for the period 1990 to 1997 for prescription drug products covered by six provincial drug plans;
- an analysis of the relationship between price levels of generic and brand name drugs over the period 1990 to 1997;
- international price comparisons for the 1996 top selling non-patented single source drug products;
- comparisons of prices of non-breakthrough or non-substantial improvement (category 3) patented drugs introduced in 1995 and 1996 to other medicines in their therapeutic class; and,
- a comparison of prescription drug prices in six provincial drug plans (1990-1997).

[2] The Task Force has representatives from British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia, Health Canada and the Patented Medicine Prices Review Board. It was established to examine one of six pharmaceutical issues identified at the April, 1996 meeting of federal/provincial/territorial Ministers of Health. The other issues included utilization, marketing, wastage, consumer education and research and development. The work is overseen by the Pharmaceutical Issues Committee, which reports to the Conference of Deputy Ministers of Health.

This study updates a report on cost drivers of total pharmaceutical spending in Ontario Drug Benefit (ODB) Program over the period 1992/93 to 1998/99[3]. Information on prices, quantities, total expenditures and market shares were obtained from the Ontario Drug Benefit Program database. Health Canada's Drug Product database was used to ensure that only those drugs defined by the *Food and Drug Act* were included. The Drug Product database was also used to identify all drug products by their respective Anatomic Therapeutic Chemical (ATC) classification. Finally, the Patented Medicine Prices Review Board database was used to group drugs according to patent status and category.

The report is divided into the following sections: section 2 describes why a study of cost drivers provides important information to all stakeholders in the health care sector; section 3 describes the focal points of the cost driver analysis; section 4 reports on the growth of total drug costs in public and private drug plans for Ontario over the period 1992/93 to 1998/99; section 5 presents the findings followed by a conclusion in section 6.

[3] The previous study was conducted on a calender basis and price was calculated at the din level, this study is based on a fiscal year and price is calculated at the chemical level, ie. price for a chemical with an identical ingredient, strength, route, schedule and form. This change in definition was adapted in order to better capture the substitution within multi-source markets and better represent the contribution of each cost driver component in the model.

2.0 Why Study Cost Drivers?

An examination of cost drivers provides both public and private drug plan managers, policy makers and other stakeholders including consumers with a better understanding of the major components that influence annual increases and trends in pharmaceutical spending. During the 1990's, increases in the annual cost of drugs in Canada was, on average, approximately 10% per year[4]. This growth in total spending was occurring while average annual increases in overall prices was less than 3%[5]. This demonstrates that changes in annual costs of pharmaceuticals are reflective of a combination of many factors. These factors are summarized in Figure 1.[6]

Figure 1

Factors Affecting Total Drug Expenditures

1. Changes in the total population
2. Changes in the demographics and health status of the population (i.e. towards those with increased medication needs)
3. Changes in the unit prices of drugs (both patented and non-patented)
4. Changes in retail and wholesale mark-ups, and dispensing fees
5. Changes in the prescribing habits of physicians (i.e. from older, less expensive medications to newer, relatively more expensive medications [± improved therapeutic effect] to treat the same underlying diagnosis)
6. Changes in utilization of drugs on a per patient basis (i.e. more medications per patient per year)
7. Trends towards using drug therapy instead of other treatments (e.g. as alternatives to surgery in some cases)
8. New diseases to be treated and old diseases to be treated or better treated
9. Extended patent protection, barriers to entry and reduction in competition

[4] 1994 and 1996 had exceptionally low growth rates of approximately 3%

[5] Statistics Canada, CANSIM, Series P200202

[6] This Figure was reproduced from the PMPRB's Discussion Paper, "*Examining the Role, Function and Methods of the Patented Medicine Prices Review Board.*", November 1997.

While it is difficult to quantify the relative effect that the above factors[7] may have on increases in drug costs, some studies have attempted to do so.[8] These studies have employed different methodologies to assess the impact of the different factors. The main findings from these studies are that price changes represent only one factor which influence changes in the total cost of drugs. Other important factors include utilization (i.e. changes in the amount of drugs consumed) and the influence from the introduction of new drugs.

[7] Another factor worth mentioning is the shift to community care over the last several years. In addition to replacing surgery, community based drug plans are experiencing utilization increases because more treatment is taking place in the community, that previously may have required hospitalization. An example of this trend is the growth in community based palliative care.

[8] See for example Green Shield Canada *"A Report on Drug Costs", 1994*; Gorecki, P.K., *"Controlling Drug Expenditures in Canada, The Ontario Experience, 1991*; Angus, D.E. et al. *"Sustainable Health Care for Canadians, 1995;* and, Brogan Inc. (1998) "Handbook on Private Drug Plans: 1993 - 1996.

3.0 Focus of Report

This analysis attempts to break out annual changes in the cost of drugs into the following major components:

- annual volume (utilization) changes of older and newer drugs;
- annual price changes of older and newer drugs[9];
- annual influence from the introduction of new drugs (patented and non-patented); and,
- annual influence of newer drugs by therapeutic class or disease groups.

This analysis provides some insight into several factors outlined in Figure 1. Each of these factors is examined to assess their individual influence on annual drug cost changes. In other words, an evaluation of what percentage of the increase in annual cost of drugs are attributed to each of the above components will be done[10]. It is important to note that a more detailed review of price levels (rather than annual price change), substitution of older drugs and trends in treatment costs are areas that need to be considered in much greater detail in further research and analysis.

A further disaggregation of cost drivers by therapeutic class allows an investigation of whether certain disease groups are experiencing proportionately greater increases in annual costs. Furthermore, an investigation of the extent to which new drugs are being substituted for older drugs and the relative cost of new drugs to older drugs can be done. Finally, breaking out the drugs into patented and non-patented drugs allows us to examine drugs by therapeutic novelty. In other words, to what extent is the introduction of new patented drugs that are line extensions (category 1), breakthrough or substantial improvement drugs (category 2) or, moderate, little or no improvement drugs (category 3) influencing annual changes in drug costs.

[9] New drugs are defined at the chemical, dose, form and route level. Generic bioequivalent products are not considered as new drugs in the major component decomposition.

[10] See Appendix 1 for methodology details and methodological and definitional changes from previous cost driver studies.

4.0 Trends in Ontario Drug Expenditures

4.1 General Information

The Ontario Drug Benefit (ODB) Program was implemented on September 1, 1974. The ODB is administered through the Ministry of Health, Drug Programs Branch. The Ontario program covers over 3000 drug products listed in the Drug Benefit Formulary (DBF) / Comparative Drug Index (CDI). The program also includes 278 other products which are approved as limited-use products to eligible residents of Ontario. For detailed information on the plan, please consult Appendix 2.

4.2 Major Changes since 1991/92

- In 1993, introduction of 75/90 pricing rule for generic products.
- In 1994, introduced price freeze for all drugs listed on the formulary.
- In 1995, introduced the Trillium Drug Program (see above).
- In 1996, co-payment program was introduced.
- Effective Fall, 1998, the 75/90 pricing rule for multiple source products was changed to 70/90.

4.3 Total Retail Private and Public Expenditures[11]

Public and private spending on prescription drugs in Ontario grew substantially over the period 1991 to 1998. In 1998, total retail spending on prescription drugs was $3,940.4 million[12], up from $2,676.7 million in 1991. Spending in 1998 consisted of 1,898.3 in public spending and 2,042.1 million in private spending. Total retail spending (i.e., public and private spending including OTC drugs) was $5,230.4 million in 1998. Total spending (public and private) on prescription drugs was 75.3% of total retail spending in 1998, a share that has remained largely unchanged since 1991 (75.2%).

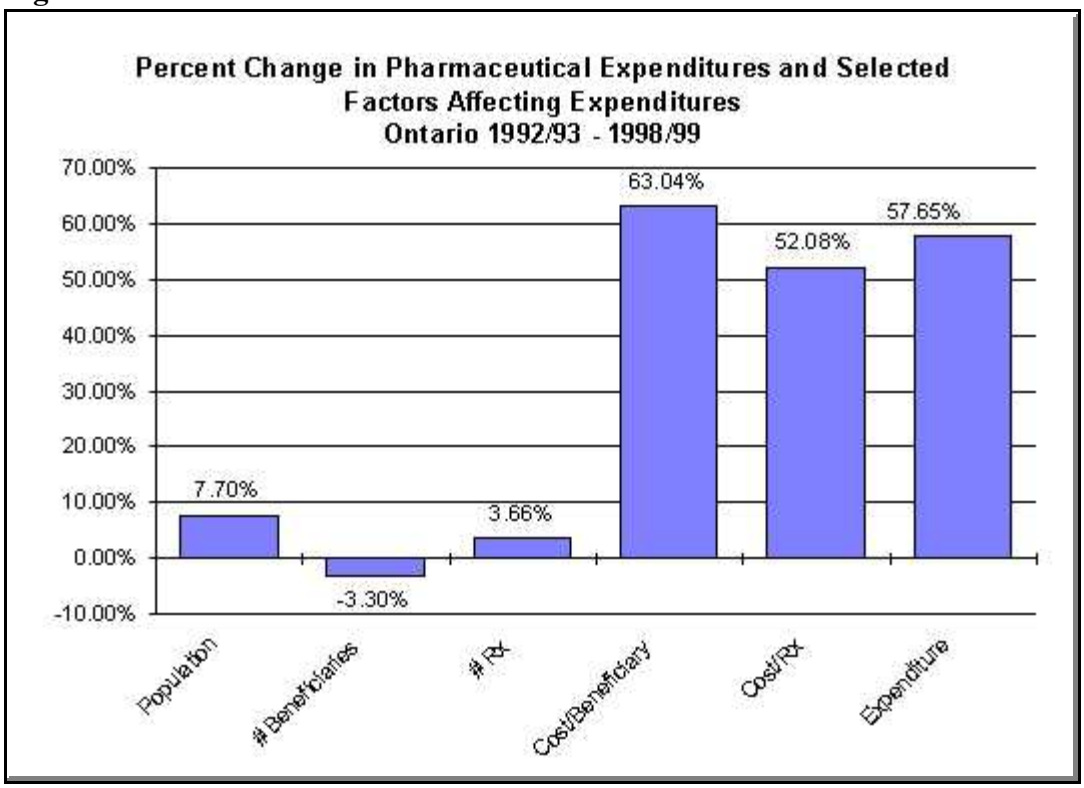
Over the years the share of total public spending on prescription drugs as a part of total spending on prescription drugs has decreased. In 1991, public spending on prescription drugs accounted for 55% of total spending on prescription drugs, In 1998, public spending on prescription drugs accounted for 48.2%.

[11] The source for the figures in this part is Health Canada and CIHI. 1998 figures are preliminary estimates.

[12] Health Canada and CIHI.

Figure 2[13] summarizes some of the important factors described above in Figure 1 and that may have contributed to growth in total pharmaceutical expenditures over the period 1992/93 to 1998/99. Including costs borne by both recipients and government plans, expenditures rose from $1,065.9 million in 1992/93 to $1,680.4 in 1998/99, amounting to an increase of 57.7%. The figure shows that Ontario's population increased by 7.7% over this period. Prescriptions covered under public programs rose by 3.7%. The average cost per prescription rose by 52.1%.

Figure 2



[13] In Figure 2, growth in cost/prescription and growth in expenditures were calculated using total prescription cost which includes the patients' portion of the cost. Thus expenditures presented do not represent the net cost of the prescription to the drug plan. It is important to note that in 1992/93, the government share of the prescription cost was 100%, in 1998/99 the share dropped to 87% of the total cost of the prescription.

It is important to note that many factors may influence the cost of a prescription. These include: manufacturers' unit price; wholesale and retail mark-ups; changes in the size of prescriptions; changes in prescribing habits of physicians (i.e. from older less expensive therapies to newer relatively more expensive ones); the trend towards using drug therapy instead of other treatments; and, the inclusion of new indications and new drugs for diseases in which drug therapy was not previously available .

Section 5 below provides a more complete evaluation of the relative magnitude different factors have on changes in annual drug expenditures.

5.0 Analysis

5.1 Drug Expenditures in Ontario's Drug Benefit Program: 1992/93 to 1998/99

During the period 1992/93 to 1998/99, total ODB's allowed drug cost on products considered in this analysis increased from $685.9 million to $1,311.6 million. These amounts differ from the total ODB Program expenditures, for the following reasons:

- drugs were only included in this analysis if they could be matched to those drugs in the Health Canada Health Protection Branch (HPB) database;
- the expenditure figures do not include dispensing fees and non-drug expenditures such as diagnostic test strips.
- the expenditure figures include patients portion of the accepted ingredient cost[14];

5.2 Breakdown of Changes in Expenditure by Components

The change in total annual expenditures has been broken out into the following components: Price Effect, Volume Effect, Entry of New Drugs, Exiting drugs and Others[15]. Table 1 summarizes the relative contribution each of the above components have on the total annual change in expenditures.

On average, between 1992/93 and 1998/99 per unit price changes seen by the province were responsible for -15.9%[16] of the expenditure change, volume change or utilization was responsible 90.4%, entry of new drugs were responsible for 47.1%, and both exiting drugs and other factors were responsible for -10.3% and -11.3% of expenditures changes. The findings demonstrate that utilization and the entry of new drugs accounted for the largest increase in expenditures over the period. Table 1 also indicates that the impact of new drugs was significant in both the year of their introduction (19.0%) and the following year (28.1%).

[14] Expenditures were based on total approved acquisition cost as this was the only available field which excluded pharmacy mark-up and dispensing fees. Patients portion of the drug cost is included in expenditures.

[15] Others represent the cross effect of price and volume. The cross effect is an interaction term between changes in prices and changes in quantity. That is, it is a measure of the correlation between price changes and the quantity changes. If a large change in price corresponds with a large change in quantity the cross effect will be significant. The negative sign indicates that the changes are moving in opposite directions and are significant in magnitude. A negative cross effect is recorded when a large decrease in price is accompanied by a large increase in quantity, or conversely, a large increase in price is accompanied by a large decrease in quantity.

[16] It is important to note that this does not mean that prices declined by 15.9% over the time frame, a marginal decline in a popular drug may drive large negative price effects, as well, the introduction of LCA and generic substitution played a critical role in reducing the cost of multiple source markets over the period of analysis.

Table 1

Average Contribution to Pharmaceutical Expenditures by Major Components Ontario: 1992/93 - 1998/99						
Year	Price Effect (%)	Quantity Effect (%)	Exiting Drug Effect (%)	New Drug Effect Year of Introduction (%)	New Drug Effect Second Year (%)	Cross Effect (%)
1993/94	-22.30	124.40	-3.80	6.40	0.00	-4.60
1994/95	-41.70	66.50	-17.20	60.80	36.40	-4.90
1995/96	-7.20	68.90	-37.90	43.40	36.10	-3.40
1996/97	-28.80	101.70	-0.50	14.50	32.70	-19.60
1997/98	-20.80	90.90	-7.10	10.30	33.30	-6.60
1998/99	7.60	85.40	0.00	1.50	29.30	-23.80
Average	**-15.86**	**90.37**	**-10.29**	**18.98**	**28.08**	**-11.28**

The findings presented above suggest that increases in utilization and coverage of new drugs significantly influence annual changes in expenditures. The expenditure decomposition provides a sense of the relative importance of changes in utilization of existing and newer drugs. It is important to keep in mind that the effects reported represent the impact each component had on changes in expenditure levels and are not absolute changes. The price effect of -15.86% over the time frame of analysis, may be a result of a marginal decline in a popular drug, the introduction of price ceilings and generic substitution. The negative price effect in this analysis is greatly influenced by generic competition, which reduces the cost of the entire therapeutic class, and cost containment policies. Absolute price reductions at the DIN level, particularly of top selling newer drug products, are not the main source of the large negative price effect. Future analysis of price level of new drugs and changes in prescribing patterns toward newer therapies; changes in treatment costs and/or the price levels (rather than annual change); marketing strategies for new drugs, rate of new drug market penetration and displacement of older drugs, and impact of public policy would provide more insight into results presented above.

Table 2 breaks out annual total expenditures into "existing" drugs and "newer" drugs. Existing drugs are those drugs that were on the market in 1992/93, i.e., drugs that were introduced in 1992/93 or before. Newer drugs are those drugs that were introduced in 1993/94 or during subsequent years. Expenditures on drugs that existed in 1992/93 fell by an average of -1.6% between 1992/93 and 1998/99, while expenditures on all drugs which includes both existing and newer drugs, increased by an average of 11.4% over this period. The share of expenditures on newer drugs rose steadily throughout this period.

Table 2

Pharmaceutical Expenditures (Total Allowed Drug Cost) Ontario: 1992/93 -1998/99 (millions of dollars)						
Year	All Drugs			Existing Drugs		
	Total Expenditure	Difference in Expenditure	% Growth	Total Expenditure	Difference in Expenditure	% Growth
1992/93	685.90			685.90		
1993/94	779.80	93.90	13.70	765.60	79.70	11.60
1994/95	839.50	59.70	7.70	724.00	-41.60	-5.40
1995/96	944.80	105.30	12.50	704.20	-19.80	-2.70
1996/97	1047.70	102.90	10.90	685.20	-19.00	-2.70
1997/98	1178.50	130.80	12.50	650.20	-35.00	-5.10
1998/99	1311.60	133.10	11.30	623.70	-26.50	-4.10

Figure 3

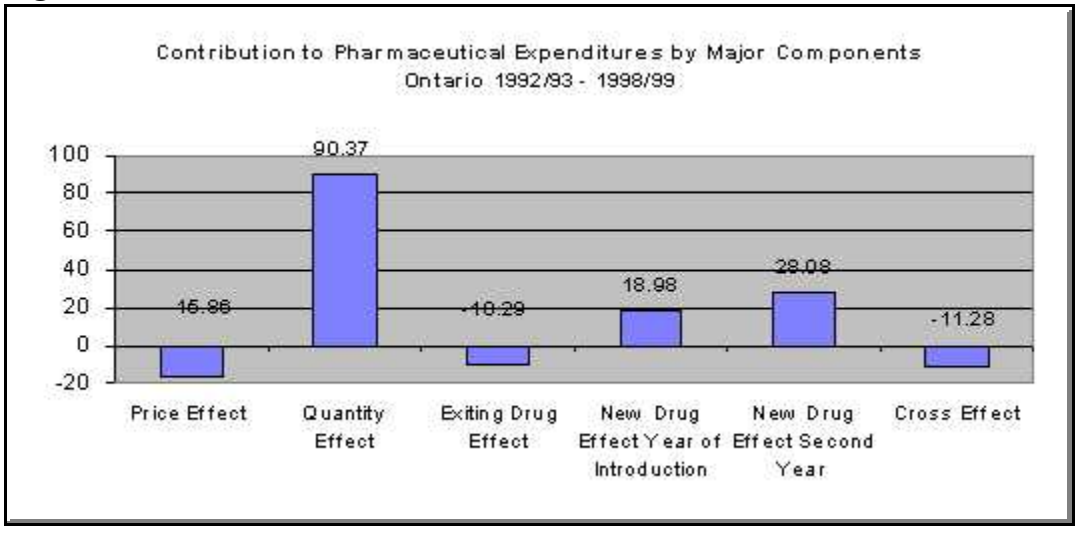


Figure 4 shows the contribution of each component in another way. As shown in Figure 4, pharmaceutical expenditures were increasing on average at a rate of 11.4% during the period 1992/93 to 1998/99. Figure 4 shows that both utilization and new drugs were each responsible for that growth, with utilization contributing 10.3% and new drugs contributing 5.4%. (Their joint contribution was partially offset by the negative contribution other factors.)

Figure 4

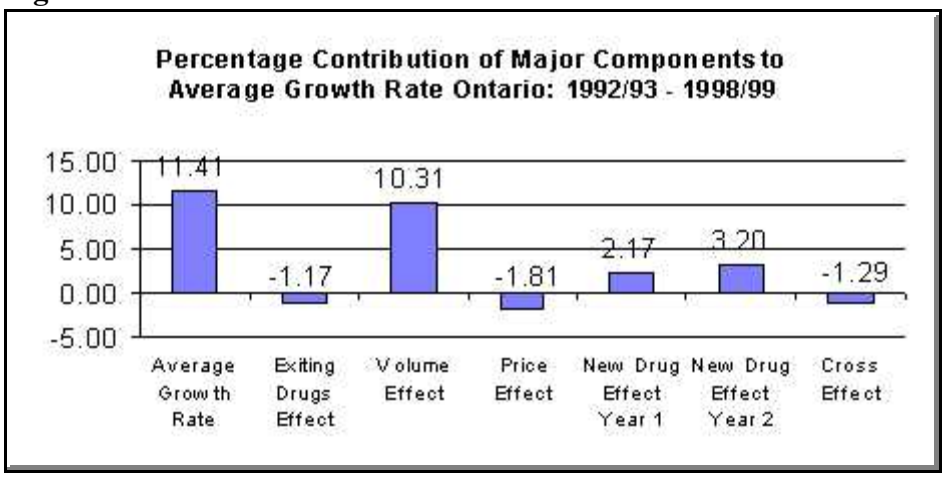


Figure 5

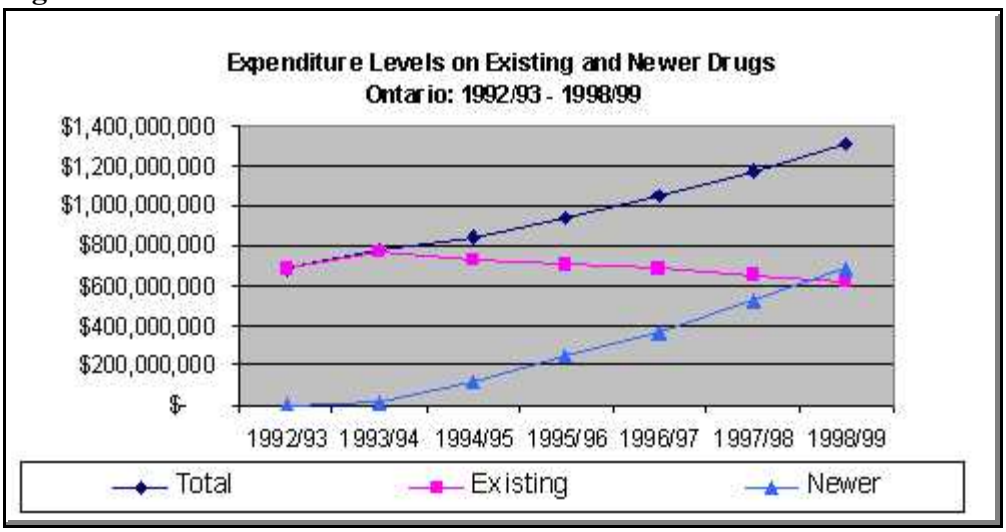


Figure 5 corresponds to Table 2, in that it shows the trends of expenditures on all, new and existing drug products. Figure 5 illustrates that although expenditures on existing drug products were falling over the years expenditures on new drug products increased sufficiently to cause total expenditures to rise. Other than replacement of newer drug products for older drug products, an overall decrease in the utilization of older drugs and a reduction in the average price of older drugs (potentially as a result of patent expiration and competition) play a role in reducing expenditures on existing drug products

Figure 6 breaks out total pharmaceutical expenditures into expenditures on newer and existing drugs. Newer drugs accounted for 52.5% of expenditures in 1998/99. In this study, newer drugs are defined as those products that were included on the formulary in or after 1993/94. In 1998/99, drugs that were included on the formulary in 1992/93 alone accounted for 18% of overall expenditures that year. Expenditures on drugs that entered the market in or after 1992/93 accounted for approximately 70% of overall expenditures in the final year of analysis.

Figure 6

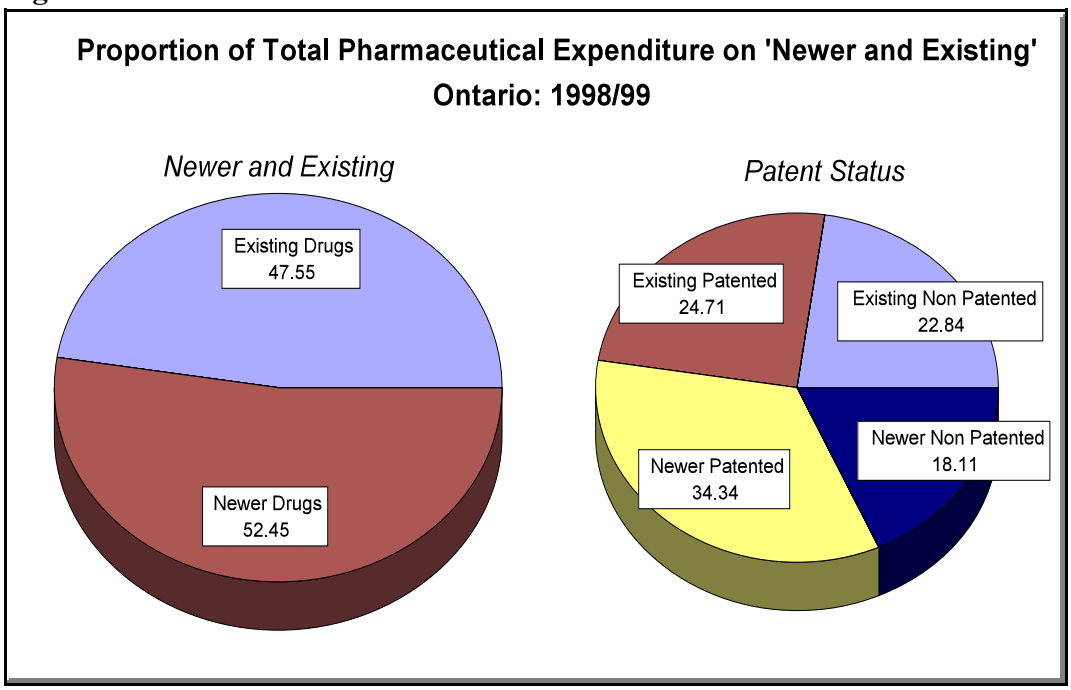


Figure 7 provides a more detailed breakdown out total pharmaceutical expenditures. In 1992/93, the proportion of patented and non-patented expenditures in total drug costs were 34.8% and 65.2%, respectively. In 1998/99 the share of expenditures absorbed by patented drugs had increased to 59.0%. More than 40% of these expenditures on patented pharmaceuticals were for existing drugs. The growth in patented drug expenditures is consistent with the impact of increased patent protection resulting from the passing of Bills C-22 and C-91 in 1987 and in 1993[17].

[17] This is consistent with overall growth in the share of patented drugs as reported by the PMPRB (1998). See S-9811, Trends in Patented Drug Prices.

5.3 Breakdown of Pharmaceutical Expenditure: (By Patent Status and Category)

Figure 7 shows the share of patented and non-patented drug products in total pharmaceutical expenditures. The patented portion is broken out into category 1 (line extensions of an existing drug product); category 2 (a breakthrough drug or substantial improvement over an existing drug product); category 3 (moderate, little or no improvement over an existing drug product) and older non-categorized patented drug products. However, it should be noted that, while the expenditures for category 1, category 2 and category 3 drug products are reported separately, they are often different brands, strengths and dosage forms of a single medicine. Category 1 products are sometimes a line extension of a category 2 or category 3 product and a category 3 drug product is often a moderate, little or no improvement over a category 2 product.[18]

Figure 7

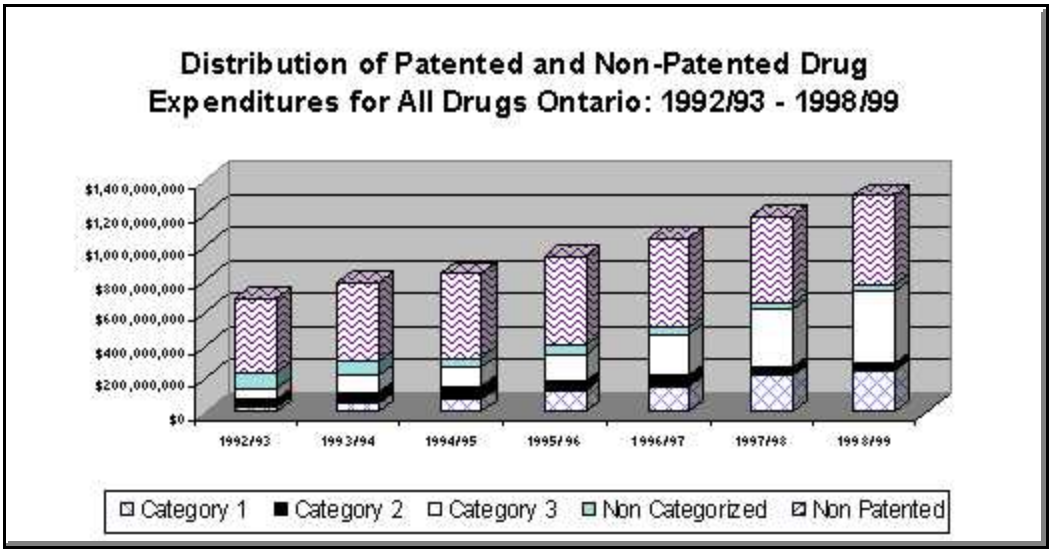


Figure 7 shows that in 1992/93 of the $238.8 million of expenditures accounted for by patented drugs, category 1 drugs made up 10.3% ($24.6 million) , category 2 drug

[18] For example, the Asthma medication Budesonide is available in many brands, strengths and dosage forms. Pulmicort Inhaler and Pulmicort Spacer, which are two different dosage forms of the brand Pulmicort, were introduced in 1988 as moderate improvements (category 3). Pulmicort Turbuhaler was introduced in 1990 as a line extension (category 1) and Pulmicort Nebuamp was introduced in 1992 as a breakthrough (category 2) product. Also, for example, Losec (20 mg/Cap) a brand of the medicine Omeprazole was introduced as a breakthrough (category 2) product in 1989. Losec (20 mg/Tab) was reintroduced in the same strength but different dosage form as a line extension (category 1) in 1996.

products accounted for 20.1% ($48.0 million) , category 3 drug products accounted for 29.4% ($70.2 million) , and older non categorized drug products accounted for 40.2% ($96.1 million). In 1998/99 of the $774.5 million of expenditures accounted for by patented drugs category 1 drugs made up 32.4% ($251.3 million) , category 2 drugs accounted for 6.2% ($48.0 million) , category 3 drugs accounted for 56.4% ($432.1 million) , and older non-categorized patented products accounted for 4.9% ($38.1 million) of total patented expenditures.

5.4 Growth of Expenditures on Newer Drug Products

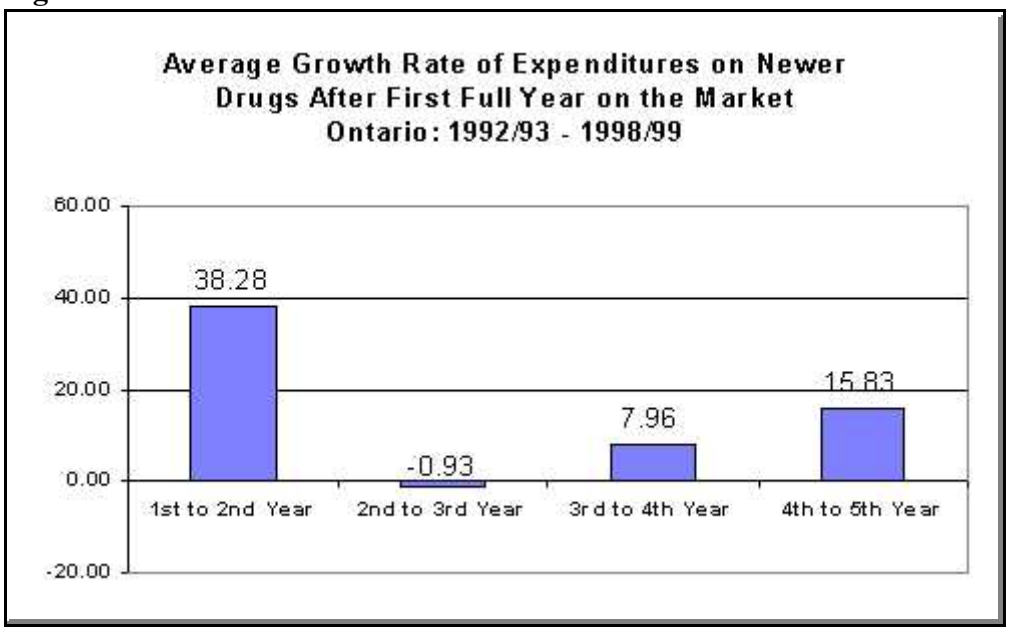
The information in Table 3 demonstrates how fast the market responds to new drugs. For example, expenditures on drugs introduced in 1993/94 were $14.2 million in that year, but had risen to $74.0 million in 1994/95 and $111.2 million in 1996/97. A similar increase in expenditures following the year of introduction can be observed for drugs that appeared in the following years. After the first couple of years of rapid increase, expenditures on new drugs seems to taper off as they mature and newer drugs come into the market. However, it should be noted that, depending on the month of introduction, expenditures during the year of introduction may represent expenditures of a "partial" year. For example, if a drug was introduced on July of any year, the data on expenditures would represent expenditures for six months only.

Table 3

Expenditures on Newer Drug Products
Ontario: 1992/93 - 1998/99
(millions of dollars)

Year of Introduction	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1993/94	14.15	74.03	96.25	96.55	96.02	111.22
1994/95		41.48	85.73	116.19	84.78	99.74
1995/96			58.61	101.06	154.32	182.03
1996/97				48.70	115.15	153.13
1997/98					78.03	132.33
1998/99						9.51
Total	**14.15**	**115.51**	**240.59**	**362.49**	**528.31**	**687.96**

Figure 8



In order to avoid over estimating the growth of new drugs by comparing expenditures between a "partial" year and a "full" year, the information in Table 3 is used to derive the average growth of expenditures on new drugs between each "full" year on the market, following the year of introduction.

In Figure 8, 1st-2nd Year represented the average growth of expenditures of new drugs between their first and second full year on the market. On average, the growth of expenditures was highest between their first and second full year on the market, at 38.3%. Average growth of expenditures fell to –0.9% between the second and third year, rose to 8.0% between the third and fourth year and rose again to 15.8% between the fourth and fifth year.

5.5 Therapeutic Class Analysis

In order to identify which disease groups are contributing proportionately more to increases in pharmaceutical expenditures, the analysis of is expenditure growth was undertaken at the second level of the Anatomical Therapeutic Chemical (ATC) classifications. The second level of the ATC classification groups drugs of different pharmacological classes that have the same main therapeutic use. Sixteen therapeutic classes were identified based on their level of expenditures relative to other therapeutic classes. Table 4 shows the percentage contribution of the top sixteen therapeutic classes in total expenditures and their contribution to the changes in expenditures between 1992/93 and 1998/99.

Table 4

Percentage Contribution of Selected Therapeutic Classes to Total Expenditure
Ontario: 1992/93 - 1998/99

Therapeutic Class	Code	Contribution in 1992/93		Contribution in 1998/99		$ of Total Expenditure Change	Average Rate of Expenditure Growth
		$ (000's)	% of Total Expenditure	$ (000's)	% of Total Expenditure		
Alimentary canal and metabolism	A	127,770	18.60	206,949	15.8	12.7	8.4
Antacids	A02	88,957	13.00	140,842	10.7	8.3	8.0
Drus used for diabetes	A10	16,440	2.40	31,469	2.4	2.4	11.4
Others	Others	22,372	3.30	34,638	2.6	2.0	7.6
Cardiovascular system	C	241,434	35.20	500,348	38.1	41.4	12.9
Cardiac therapy	C01	20,128	2.90	32,365	2.5	2.0	8.2
Beta blocking agents	C07	25,415	3.70	35,368	2.7	1.6	5.7
Calcium channel blockers	C08	97,408	14.20	130,428	9.9	5.3	5.0
Agents Acting on the Renin-Angiotensin System	C09	51,223	7.50	130,581	10.0	12.7	16.9
Serum lipid reducing agents	C10	35,156	5.10	155,669	11.9	19.3	28.1
Others	Others	12,104	1.80	15,937	1.2	0.6	4.7
General anti-infectives for systemic use	J	41,003	6.00	84,080	6.4	6.9	12.7
Anti-bacterials for systemic use	J01	37,772	5.50	54,544	4.2	2.7	6.3

Therapeutic Class	Code	Contribution in 1992/93		Contribution in 1998/99		$ of Total Expenditure Change	Average Rate of Expenditure Growth
		$ (000's)	% of Total Expenditure	$ (000's)	% of Total Expenditure		
Anti-virals for systemic use	J05	1,551	0.20	26,664	2.0	4.0	60.6
Others	Others	1,680	0.20	2,872	0.2	0.2	9.4
Anti-neoplastic and immunomodulating agents	L	17,490	2.50	59,905	4.6	6.8	22.8
Endocrine therapy	L02	13,635	2.00	39,010	3.0	4.1	19.1
Others	Others	3,854	0.60	20,895	1.6	2.7	32.5
Musculo-skeletal system	M	56,294	8.20	53,696	4.1	-0.4	-0.8
Anti-inflammatory and anti-rheumatic products	M01	50,928	7.40	37,792	2.9	-2.1	-4.9
	Others	5,366	0.80	15,904	1.2	1.7	19.9
Nervous system	N	73,223	10.70	190,729	14.5	18.8	17.3
Analgesics	N02	15,095	2.20	27,847	2.1	2.0	10.7
Psycholeptics	N05	16,337	2.40	47,503	3.6	5.0	19.5
Psychoanaleptics	N06	19,004	2.80	77,369	5.9	9.3	26.4
Others	Others	22,787	3.30	38,011	2.9	2.4	8.9
Respiratory system	R	54,101	7.90	92,645	7.1	6.2	9.4
Anti-asthmatics	R03	47,551	6.90	84,960	6.5	6.0	10.2
Others	Others	6,550	1.00	7,684	0.6	0.2	2.7
Sensory organs	S	17,181	2.50	24,805	1.9	1.2	6.3
Opthalmologicals	S01	16,017	2.30	23,896	1.8	1.3	6.9
Others	Others	1,164	0.20	909	0.1	0.0	-4.0
Total ATC's at Level 2		**552,617**	**80.60**	**1,076,307**	**82.1**	**83.7**	**11.8**
Total ATC's at Level 1		**628,495**	**91.60**	**1,213,157**	**92.5**	**93.4**	**11.6**
Total Expenditure		**685,913**	**100.00**	**1,311,637**	**100.0**	**100.0**	**11.4**

The top sixteen therapeutic classes, which were approximately 15% of the total number of therapeutic classes (at second level), accounted for 82.1 % of total pharmaceutical expenditures in 1998/99.

The fourth and sixth columns of Table 4 show the percentage share of the top sixteen second-level therapeutic classes to total expenditures, as well as the contribution of each of the eight first level ATC groups to which these sixteen therapeutic classes belong. (These eight ATC groups are: Alimentary Tract and Metabolism, Cardiovascular Systems, Genito-Urinary System and Sex Hormones, General Anti-Infectives, Anti-neoplasmatics and Immunomodulating Agents, Central Nervous System, Respiratory System, and Sensory Organs.) Expenditures on these eight ATC groups were $1,213.2M or 92.5% of total expenditures in 1998/99.

The second-to-last column in Table 4 shows the contribution of each of the eight ATC groups and top sixteen therapeutic classes to the total increase in expenditures between 1992/93 and 1998/99. Among the eight first-level ATC groups, drugs related to the Cardiovascular System made by far the largest contribution to the increase in expenditures (41.4%), followed by the Central Nervous System (18.8%) and Alimentary Tract and Metabolism (12.7%).

Among the second-level therapeutic classes, Lipid Reducing Agents (Cardiovascular Systems) made the largest contribution to expenditure growth. The second largest contributor was Agents Acting on the Renin-Angiotensin System (Cardiovascular Systems), followed by Psychoanaleptics (Central Nervous System). These disease groups contributed 19.3%, 12.7% and 9.3%, respectively, to increases in pharmaceutical expenditures over the period 1992/93 to 1998/99. Antacids (8.3%) and Anti-Asthmatics (6.0%) also contributed significantly to expenditure growth.

The share of Lipid Reducing Agents rose from 5.1% in 1992/93 to 11.9% of total expenditures in 1998/99. Agents Acting on the Renin-Angiotensin System accounted for 7.5% of total expenditures in 1992/93. This share rose to 10.0% of total expenditures by 1989/99. Psychoanaleptics rose from 2.8% of total expenditures in 1992/93 to 5.9% in 1998/99.

Table 5 reports on the average component contribution to expenditure change for the top 16 second-level therapeutic classes.

Table 5

Therapeutic Class	ATC	Average Price Effect (%)	Average Quantity Effect (%)	Average New Drug Effect Year of Introduction (%)	Average New Drug Effect Second Year (%)	Exiting Drug Effect (%)	Cross Effect (%)
Antacids and drugs used to treat peptic ulcer and flatulence	A02	-54.50	135.80	97.70	17.40	-91.30	-5.10
Drugs used for diabetes	A10	-38.60	143.60	1.70	8.40	0.00	-15.10
Cardiac therapy	C01	-13.70	136.00	0.00	0.20	-0.90	-21.60
Beta Blockers	C07	-43.90	145.80	6.10	8.40	-12.20	-4.10
Calcium channel blockers	C08	-79.60	10.80	102.50	82.20	-20.70	4.90
Agents Acting on the Renin-Angiotensin System	C09	0.40	92.60	0.90	6.40	0.00	-0.20
Serum lipid reducing agents	C10	-8.30	62.20	8.80	36.60	0.00	0.80
Anti-bacterials for systemic use	J01	-0.80	88.60	4.10	15.00	-0.10	-6.70
Anti-virals for systemic use	J05	-5.40	43.80	23.20	47.10	0.00	-8.70
Endocrine therapy	L02	-3.90	34.10	12.50	54.80	-0.20	2.60
Anti-inflammatory and anti-rheumatic products	M01	-31.50	-65.40	9.30	53.30	-67.20	1.40
Analgesics	N02	-6.30	101.30	1.60	5.30	0.00	-1.90
Psycholeptics	N05	-10.30	76.30	1.60	32.70	-0.50	0.20
Psychoanaleptics	N06	-15.40	86.40	8.20	21.00	0.00	-0.10
Anti-asthmatics	R03	-55.70	171.60	6.00	23.30	-0.70	-44.50
Opthalmologicals	S01	-20.70	67.40	10.90	60.90	-15.30	-3.30
Total Average		**-22.10**	**86.70**	**21.10**	**30.60**	**-11.50**	**-4.80**

It is clear that there are significant differences among the classes. Generally speaking, the average trends reported in Table 1 are consistent with the average reported for the top 16 therapeutic classes. There are, however, some interesting exceptions. For instance, although price change contributes a substantial negative impact overall, price change had a negligible effect in the case of Agents Acting on the Renin-Angiotensin System, where expenditure growth was driven almost entirely by rising volume. In the case of Calcium Channel Blockers large negative price effects were more than offset by the expenditure impact of new drugs. The variations reported below suggest that therapeutic markets are different, and understanding these differences and the reasons behind them is one of the future research challenges.

The following provides a more detailed analysis of the impact of existing and newer drugs for Lipid Reducing Agents, Agents Acting on the Renin-Angiotensin System and Psychoanaleptics. Appendix 4 provides a detailed analysis of the remaining top sixteen therapeutic classes.

Lipid Reducing Agents

Expenditures in this therapeutic class had the highest average annual growth (28.1%) among the top sixteen therapeutic classes. Table 4 shows that expenditures rising from $35.2 million in 1992/93 to $155.7 million in 1998/99.

In 1992/93 patented drugs accounted for 90.4% of total expenditures in this therapeutic class, falling to 83.7% in 1998/99. Category 3 drugs absorbed 13.1% of expenditure in 1992/93. This share had risen to 57.3% by 1998/99. Expenditures on Category 2 drugs, accounting for 63.1% expenditures in 1992/93, were negligible (0.2%) by 1998/99.

In 1998/99 the top drug products in this class were Pravachol 20 mg and Zocor 10 & 20 mg. These products accounted for 46.6% of total expenditures within Lipid Reducing Agents.

Figure 9

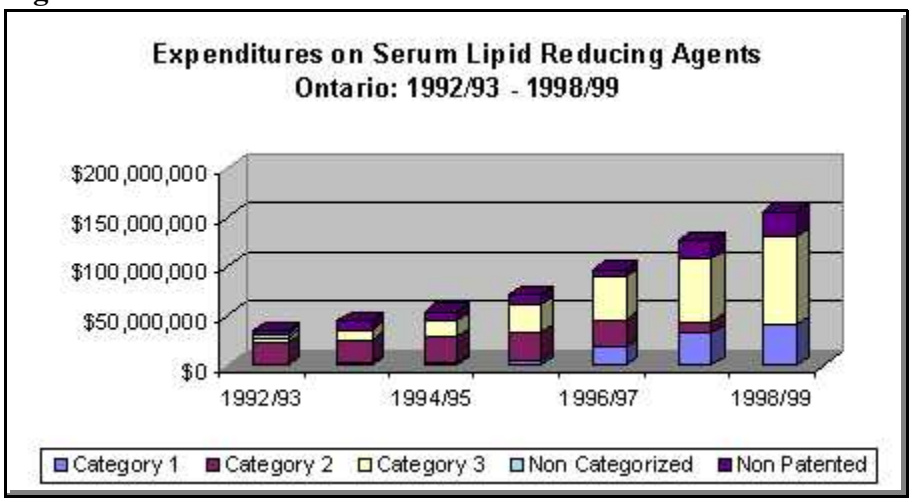


Table 6

Impact of Existing and Newer Drug Products
Serum Lipid Reducing Agents
Ontario: 1992/93 - 1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93*		3,386	3,497	3,023	1,022	518	543	515
1992/93	1	795	1,903	2,796	3,917	5,082	2,956	705
1992/93	2	22,194	23,964	25,676	27,119	27,288	11,422	285
1992/93	3	4,597	11,296	18,490	32,053	43,003	53,707	54,890
1992/93	NC	4,184	4,110	2,153	1,764	1,280	727	326
1993/94		0	272	1,816	2,181	2,157	1,761	1,365
1994/95		0	0	285	1,648	1,407	910	757
1994/95	3	0	0	49	830	1,701	2,581	2,574
1994/95	NC	0	0	0	1	1	0	0
1995/96		0	0	0	65	212	126	92
1995/96	1	0	0	0	1,201	13,604	26,701	32,626
1995/96	NC	0	0	0	42	610	1,083	1,470
1996/97		0	0	0	0	167	299	214
1996/97	1	0	0	0	0	156	2,072	3,404
1997/98		0	0	0	0	0	13,316	20,603
1997/98	1	0	0	0	0	0	1,187	4,093
1997/98	3	0	0	0	0	0	7,637	31,747
1998/99	3	0	0	0	0	0	0	1
Total Expenditure		**35,156**	**45,040**	**54,287**	**71,843**	**97,187**	**127,029**	**155,669**
Patented Expenditure		**31,764**	**36,011**	**44,462**	**61,634**	**89,316**	**108,241**	**130,313**
Non-Patented Expenditure		**3,392**	**9,030**	**9,825**	**10,209**	**7,872**	**18,788**	**25,356**

* drugs identified as being introduced in the first year of analysis, ie.1992/93, were introduced that year or in previous years.

Agents Acting on the Renin-Angiotensin System

Expenditures in this therapeutic class grew at an average annual rate of 16.9%.

In 1992/93, patented drugs accounted for 76.7% of expenditures on this therapeutic class. Expenditures on patented products were heavily concentrated on category 3 drugs. By 1998/99, the patented drug share had risen to 84.7% of total expenditures, with almost all of this being category 3 drugs.

In 1998/99 the top drug products in this class were Vasotec 5 & 10 mg, and Cozaar 50 mg. These products accounted for 41.1% of total expenditures within Agents Acting on the Renin-Angiotensin System.

Figure 10

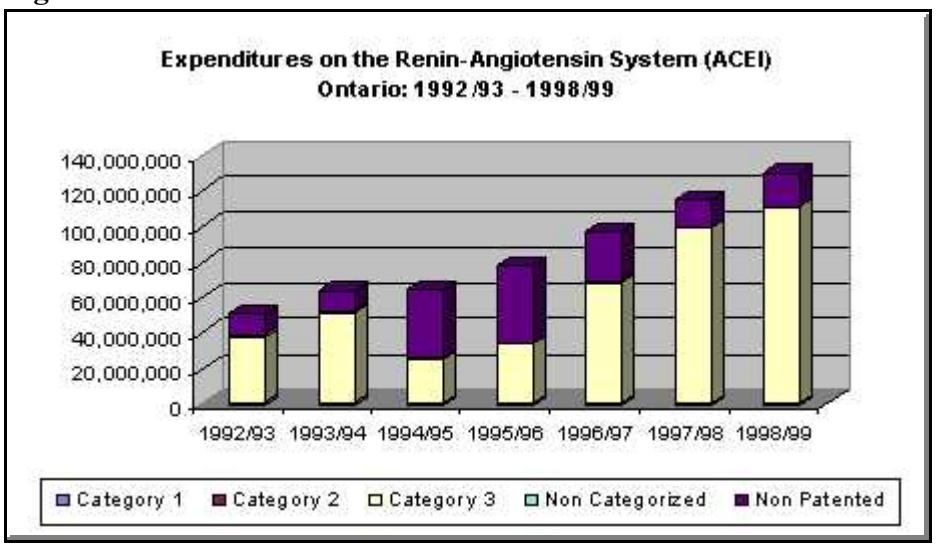


Table 7

Impact of Existing and Newer Drug Products
Agents Acting on the Renin-Angiotensin System (ACEI)
Ontario: 1992/93 - 1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93*		11,933	10,950	10,036	9,156	8,043	6,279	5,068
1992/93	1	1,350	1,135	1,034	966	804	446	224
1992/93	3	36,564	51,026	24,271	31,220	64,159	89,886	95,404
1992/93	NC	1,375	1,058	860	715	349	481	468
1993/94		0	60	28,141	33,014	15,871	0	0
1994/95		0	0	77	1,386	2,927	4,647	7,029
1994/95	3	0	0	379	1,466	2,421	3,394	4,481
1995/96		0	0	0	137	1,256	3,040	4,466
1995/96	1	0	0	0	10	148	363	536
1995/96	3	0	0	0	0	922	4,264	8,463
1996/97	1	0	0	0	0	13	49	88
1996/97	3	0	0	0	0	157	788	1,448
1997/98		0	0	0	0	0	1,304	2,773
1997/98	3	0	0	0	0	0	0	109
1998/99	3	0	0	0	0	0	0	25
Total Expenditure		**51,223**	**64,230**	**64,799**	**78,070**	**97,070**	**114,941**	**130,581**
Patented Expenditure		**39,290**	**53,219**	**26,544**	**34,377**	**68,973**	**99,671**	**110,553**
Non-Patented Expenditure		**11,933**	**11,010**	**38,254**	**43,694**	**28,097**	**15,271**	**20,028**

* drugs identified as being introduced in the first year of analysis, ie.1992/93, were introduced that year or in previous years.

Psychoanaleptics

Total expenditures in this therapeutic class rose from $19.0 million in 1992/93 to $77.4 million in 1998/99, with the share of patented drugs rising from 44.9% to 61.1%. This increase was largely driven by rising expenditures on category 3 drugs, whose share of total expenditures rose from 43.8% of total expenditures 58.4% over this period.

In 1998/99 the top drug products in this class were Paxil 20 mg, Zoloft 50 mg and Apo-fluoxetine 20 mg. These products accounted for 52.8% of total expenditures within Psychoanaleptics.

Figure 11

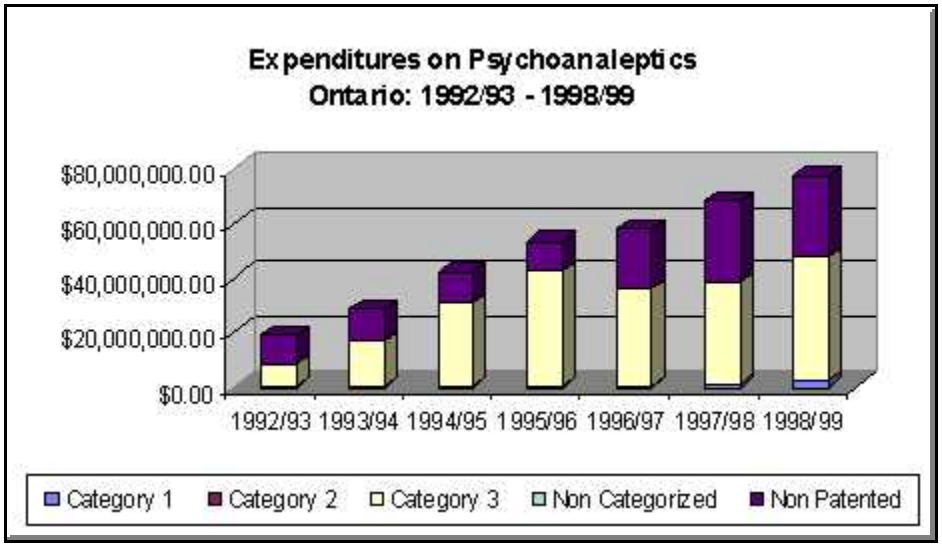


Table 8

Impact of Existing and Newer Drug Products
Psychoanaleptics
Ontario: 1992/93 - 1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93*		9,324	9,562	8,163	7,169	5,004	3,419	3,343
1992/93	1	200	271	307	250	25	12	12
1992/93	3	8,330	14,463	20,168	22,857	8,226	5,809	4,776
1992/93	NC	1,151	1,164	83	52	24	19	30
1993/94		0	817	2,208	2,112	1,565	1,418	1,203
1993/94	3	0	2,016	8,052	11,753	14,973	18,543	21,453
1994/95		0	0	572	1,797	2,182	2,004	1,945
1994/95	3	0	0	2,323	7,399	12,431	17,950	23,039
1995/96		0	0	0	133	861	1,166	1,473
1995/96	1	0	0	0	0	2	128	214
1995/96	3	0	0	0	18	65	196	303
1996/97		0	0	0	0	3,703	10,495	11,718
1996/97	1	0	0	0	0	8,941	6,764	6,289
1997/98		0	0	0	0	0	51	92
1997/98	1	0	0	0	0	0	0	0
1997/98	3	0	0	0	0	0	6	167
1998/99		0	0	0	0	0	0	1,099
1998/99	1	0	0	0	0	0	0	165
1998/99	3	0	0	0	0	0	0	49
1998/99	NC	0	0	0	0	0	0	0
Total Expenditure		**19,004**	**28,294**	**41,876**	**53,542**	**58,003**	**67,981**	**77,369**
Patented Expenditure		**8,530**	**16,751**	**30,850**	**42,279**	**36,063**	**38,279**	**47,856**
Non-Patented Expenditure		**10,475**	**11,543**	**11,026**	**11,263**	**21,939**	**29,702**	**29,513**

* drugs identified as being introduced in the first year of analysis, ie.1992/93, were introduced that year or in previous years.

6.0 Conclusions

The study reports on the cost drivers of total pharmaceutical spending in Ontario's Drug Benefit Plan program over the period 1992/93 to 1998/99.

During the period under review expenditures increased from $685.9 million to $1,311.6 million. Growth in spending was largely driven by higher utilization of existing drug products and by newer drug products introduced in 1992/93 or subsequent years, which more than offset a substantially negative price effect.

On average, between 1992/93 and 1998/99, per unit price changes seen by the province were responsible for -15.9% of the expenditure change, volume change or utilization was responsible for 90.4%, entry of new drugs were responsible for 47.1%, while exiting drugs and other factors were responsible for -10.3% and -11.3% of expenditures changes, respectively. The findings suggest that utilization and entry of new drugs accounted for the largest increase in expenditures over the period with expenditures rising significantly despite a decrease in the average per unit price. The contribution of each of these factors changed markedly in from year to year, indicating that further work is required to understand the sensitivity of the model, the impact of cost containment policies and the entry and market penetration of new drug therapies.

The report also analyzes the extent to which the top ATC groups are contributing to increases in pharmaceutical expenditures. In 1998/99, drugs in eight Anatomical Therapeutic Chemical (ATC) groups (Alimentary Tract and Metabolism, Cardiovascular Systems, Genito-Urinary System and Sex Hormones, General Anti-Infectives, Anti-neoplasmatics and Immunomodulating Agents, Central Nervous System, Respiratory System, and Sensory Organs) accounted for $1,213.2 million or 92.5% of total expenditures. A single ATC group - Cardiovascular System - accounted for 41.4% of total expenditure growth.

The Ontario Drug Benefit Plan Program underwent several changes since 1992/93 with a view to manage the growth in drug costs. Further analysis is necessary to fully understand the effect that those changes had on total pharmaceutical expenditures and utilization trends.

Appendix 1

Methodology

This study analyses the cost drivers in total pharmaceutical spending from 1993 to 1998 in Ontario.

In order to conduct the analysis, information on prices, quantities and expenditures were obtained from the Ontario Drug Benefit Plan database. Health Canada's Drug Product Database was used to ensure that only those drugs defined by the Food and Drug Act were included. The Patented Medicine Prices Review Board data base was used to group drugs according to patent status.

Prices used in this study are based on recognized actual acquisition cost; wholesale mark-ups are included, however, dispensing and/or compounding fees are excluded. The expenditures presented in this analysis include the patients portion of the cost in order to capture the full ingredient cost of the drug products.

This study reports expenditures by year of introduction of drugs. Year of Introduction is defined as the year of first sales recorded in the Ontario Drug Plan Database. Drugs with sales in 1992/93 or before, are termed as "existing" drugs while drugs with sales in 1993/94 and subsequent years are termed as "newer" drugs.

The study focuses on two aspects of expenditures change:

- the influence from existing drugs in terms of growth in price and quantity and exit
- the impact of new drugs in terms of replacement of older drugs

For this purpose, the annual change in pharmaceutical expenditures is broken down into five components: price effect, volume effect, entry of new drugs, exiting drugs and others. The following model was used to obtain the results.

$TE_o = P_oQ_o$ o = base period.....(1)

$\Delta TE_1 = P_1Q_1 - P_oQ_o$ 1= first period.....(2)

$= P_o(Q_1 - Q_o) + Q_o(P_1 - P_o) + (P_1 - P_o)(Q_1 - Q_o) + P_{1n}Q_{1n} - P_o^oQ_o^o$

Where:

TE = Total Expenditure

$P_o(Q_1 - Q_o) = VolumeEffect$

$Q_o(P_1 - P_o) = PriceEffect$

$(P_1 - P_o)(Q_1 - Q_o) = InteractionTerm$

$P_{1n}Q_{1n} = NewDrugExpenditureInfluence$

$P_o^oQ_o^o = ExitingDrugs$

$P_o(Q_1 - Q_o) + Q_o(P_1 - P_o) + (P_1 - P_o)(Q_1 - Q_o)$ = Existing Drug Influence, E_i

After the first period,1, New drugs can be separated into Volume and Price influence on annual change in total expenditures:

$\Delta TE = P_2Q_2 - P_1Q_1$ 2 = Second Period.....(3)

$= P_1(Q_2 - Q_1) + Q_1(P_2 - P_1) + (P_2 - P_1)(Q_2 - Q_1) + P_{1n}(Q_{2n} - Q_{1n}) + Q_{1n}(P_{2n} - P_{1n})$

$+ (P_{2n} - P_{1n})(Q_{2n} - Q_{1n}) + P_{2n}^*Q_{2n}^*$

Where,

$P_{2n}^*Q_{2n}^*$ = New Drugs inPeriod 2 = N_i^*

$P_1(Q_2 - Q_1)$ = New Drug Volume Influence

$Q_1(P_2 - P_1)$ = New Drug Price Influence

$(P_2 - P_1)(Q_2 - Q_1)$ = Interaction Term

$P_1(Q_2 - Q_1) + Q_1(P_2 - P_1) + (P_2 - P_1)(Q_2 - Q_1) = N_i$, New Drug Influence

$\therefore \Delta TE_i = E_i + \sum N_i + N_i^*$.....(4)

Divide(4) *by* ΔTE_i

$\Delta TE_i / \Delta TE_i = 1 = E_i / \Delta TE_i + \sum N_i / \Delta TE_i + N_i^* / \Delta TE_i$

Estimates the influence of each component

The previous study was conducted on a calender basis and price was calculated at the din level, this study is based on a fiscal year and price is calculated at the chemical level, i.e. price for a chemical with an identical ingredient, strength, route, schedule and form. This change in definition was adapted in order to better capture the substitution within multi-source markets and better represent the contribution of each cost driver component in the model.[19]

The impact of new drugs is tracked not only during the year of introduction, but also in the subsequent year. After the two periods, the effect of new drugs is recorded as part of the price, utilization and other effect.

The other major focus of the report was a breakdown of expenditures by therapeutic class and patent status over the period 1992/93 to 1998/99. This would enable us to:

- identify the extent to which each therapeutic class contributed to the increases in total ODB expenditures over the period 1992/93 and 1998/99; This was done by calculating the difference between the level of expenditures of each therapeutic class between 1992/93 and 1998/99, and dividing the difference by the difference between the level of total expenditures between 1992/93 and 1998/99.
- identify the extent of substitution between new drugs and exiting drugs in each therapeutic class;
- identify the impact that category 1, 2 and 3 drugs have on the market.

[19] The previous version of cost drivers treated all new DIN's as new drugs, including generics.

Appendix 2

General Plan Information

PROVINCIAL DRUG PLANS: ONTARIO

Beneficiaries Covered

Ontario Drug Benefit Program provides coverage for the following:

b) all persons 65 and over who are eligible for Ontario Health Insurance

c) persons receiving persons receiving benefits under the Ontario Disability Support Program;

d) persons receiving persons receiving benefits under the Ontario Works Program;

e) residents of Homes for Special Care;

f) residents of Long Term Care facilities;

g) persons receiving professional services under the Home Care Program;

h) persons eligible under the Trillium Drug Program.

Trillium Drug Program is designed to aid people with high drug costs in relation to their incomes. All Ontario residents are eligible for assistance under this program, however deductibles are set according to income levels.

Special Drugs Program covers disease specific drugs and is designed to assist Ontario residents suffering from cystic fibrosis, AIDS, Gaucher's disease, end stage renal disease, schizophrenia, solid organ or bone marrow transplant recipients and children with growth deficiencies.

Deductibles, Co-payments and Professional Fees

In Ontario, cost sharing was introduced July 15, 1996. All ODB recipients are required to pay a portion of their prescription drug costs. ODB recipients paying up to $2.00 per prescription include:

- single seniors with an annual net income of less than $16,018;
- senior couples with a combined annual net income of less than $24,175;
- those receiving general welfare benefits or family benefits;
- those receiving home care under the Health Insurance Act;
- residents of a nursing home, home for the aged or Home for Special Care;
- Trillium Drug Program beneficiaries.

Single seniors who have an annual income of $16,018 or more and seniors in couples with a combined annual income of $24,175 or more must pay the first $100 in ODB eligible prescription drug costs each year. After that these seniors will pay up to $6.11 towards the dispensing fee for each prescription.

Trillium Drug Program recipients must pay a deductible based on their net income and family make-up. Deductibles range from $350 for a single person whose net income is less than $6,500 to $150 for a family of four with the same net income. Deductibles range from $4,089 for a single person whose net income is less than $100,000 to $3,889 for a family of four with the same net income. After the above deductibles have been reached they are required to pay $2 for each prescription thereafter.

Cost Reimbursements[20]

Pharmacies - for all prescription drugs, pharmacies are paid the lesser of:

- the Drug Benefit Price (DBP) of the lowest cost interchangeable listed drug product in the DBF/CDI, plus 10%, plus a dispensing fee of $6.11(currently $6.47).
- the usual and customary amount charged to a person who is not eligible for ODB for the same quantity of the same drug.

Drug Costs - the price of drugs in the ODB Formulary is the price agreed to between the Ministry of Health and the pharmaceutical manufacturer. A 10% mark-up is added to the DBP to cover distribution costs.

Dispensing Physicians - these physicians are paid the lowest interchangeable DBP listed in the DBF/CDI, plus 10% plus a dispensing fee less applicable co-payment. Dispensing fees (prior to March 1, 1999) were $4.05 (currently $4.24) for dispensing physicians located withing 20 km of a pharmacy and $4.83 (currently $5.05) for physicians located more than 20 km of a pharmacy.

Hospitals - pharmacies in hospitals are paid the lowest interchangeable DBP listed in the DBF/CDI, plus 10%, plus a dispensing fee of $2.83 (currently $3.00) less the applicable co-payment.

Cost and Service Data (drug claims only)

The total cost of the program was $1.7 billion in 1998/99.

[20] The dispensing fees in this section reflect fees that existed during the time period of this study, which is, 1992 to 1997. Since March 1, 1999 dispensing fees were changed to their pre-Social Contract legislation levels. Dispensing fees for community pharmacies are $6.47, hospital pharmacies dispensing to community patients are $3.00, dispensing fees for physicians located within 20 km from a pharmacy is $4.24 and dispensing fees for physicians located more than 20 km from a pharmacy is $5.05.

Special Considerations

Under exceptional cases, Section 8(1) of the Ontario Drug Benefit Act allows for coverage of drugs not listed in the DBF/CDI. A physician can request consideration for coverage of an unlisted drug for a particular patient, providing there is no Formulary alternative to treat severe, life threatening, or organ threatening conditions, or diseases that would otherwise cause severe debilitating effects.

Appendix 3

Population Change and Top Selling Drugs

The following table reports on population growth in Ontario between 1992 and 1998 by age group. In 1992, the 30-39 age group represented the highest proportion of the total population, at 17.5%. This was followed by the 20-29 age group (16.4%), the 0-9 age group (13.9%) and the 40-49 age group (13.7%). In 1998, the 30-39 age group remained the largest group at 17.3% of the total population. The 40-49 age group increased to 15.2%. The 0-9 age group decreased to 13.3%.

Between 1992 and 1998, the highest growth rate was achieved by the 50-59+ (24.6%) age group. This group was followed by 70-79 (20.0 %) and 80-90+ (19.2%) age groups.

Population Growth[21]

Ontario: 1991 - 1998

[22]Age Groups	1991		1998		Change 1991 - 1998	% Growth 1991 - 1998
	Population (thousands)	% of Total	Population (thousands)	% of Total		
0 - 9	1,463,935	13.85	1,513,134	13.29	49,199.00	3.36
10 - 19	1,384,417	13.10	1,501,615	13.19	117,198.00	8.47
20 - 29	1,735,703	16.42	1,564,872	13.75	-170,831.00	-9.84
30 - 39	1,849,458	17.50	1,965,429	17.26	115,971.00	6.27
40 - 49	1,452,535	13.74	1,728,685	15.18	276,150.00	19.01
50 - 59	988,196	9.35	1,230,756	10.81	242,560.00	24.55
60 - 69	878,525	8.31	900,597	7.91	22,072.00	2.51
70 - 79	558,399	5.28	670,233	5.89	111,834.00	20.03
80 - 90+	259,307	2.45	309,058	2.71	49,751.00	19.19
Seniors (65+)	1,238,367	11.72	1,416,053	12.44	177,686.00	14.35
All Ages	10,570,475	100.00	11,384,379	100.00	813,904.00	7.70

[21] Source: Statistics Canada Catalogue Number 91-213.

Top 25 Patented and Non-Patented Drug Products
Ontario: 1997/98 and 1998/99

DIN	BRAND	Ingredient	ATC	Year of Introduction	Expenditure 1997/98	Expenditure 1998/99
2190915	LOSEC 20 MG	OMEPRAZOLE (OMEPRAZOLE MAGNESIUM)	A	1995	66,191,526	70,829,449
878928	NORVASC TAB 5MG	AMLODIPINE (AMLODIPINE BESYLATE)	C	1993	25,237,982	31,268,646
893757	PRAVACHOL TAB 20MG	PRAVASTATIN SODIUM	C	1992	28,626,136	29,138,910
708879	VASOTEC TAB 5MG	ENALAPRIL MALEATE	C	1992	24,617,051	24,164,171
884332	ZOCOR TAB 10MG	SIMVASTATIN	C	1992	21,390,325	21,870,498
884340	ZOCOR TAB 20MG	SIMVASTATIN	C	1995	17,069,168	21,538,324
670901	VASOTEC TAB 10MG	ENALAPRIL MALEATE	C	1992	20,156,789	20,986,101
2215055	BECLOFORTE INHALER - AEM INH 250MCG/AEM	BECLOMETHASONE DIPROPIONATE	R	1992	24,693,973	20,614,693
1940481	PAXIL TAB 20MG	PAROXETINE (PAROXETINE HYDROCHLORIDE)	N	1994	16,151,382	20,186,610
2155907	ADALAT XL - SRT 30MG	NIFEDIPINE	C	1992	19,214,122	18,171,434
2230711	LIPITOR 10MG	ATORVASTATIN (ATORVASTATIN CALCIUM)	C	1997	4,343,501	17,143,450
733059	APO-RANITIDINE TAB 150MG	RANITIDINE (RANITIDINE HYDROCHLORIDE)	A	1992	16,502,555	16,708,528
2220172	APO-LOVASTATIN - TAB 20MG	LOVASTATIN	C	1997	10,745,993	16,175,739
1962817	ZOLOFT CAP 50MG	SERTRALINE (SERTRALINE HYDROCHLORIDE)	N	1993	13,314,915	15,365,834
878936	NORVASC TAB 10MG	AMLODIPINE (AMLODIPINE BESYLATE)	C	1993	10,988,297	14,454,972
1917056	ARTHROTEC 50 TAB	MISOPROSTOL	M	1994	13,218,575	14,002,672
836311	PREPULSID TAB 5MG	CISAPRIDE (CISAPRIDE MONOHYDRATE)	A	1992	13,600,404	13,407,405
2155966	CIPRO 500 - TAB 500MG	CIPROFLOXACIN (CIPROFLOXACIN HYDROCHLORIDE)	J	1992	10,489,927	11,407,055
2230713	LIPITOR 20MG	ATORVASTATIN	C	1997		

DIN	BRAND	Ingredient	ATC	Year of Introduction	Expenditure 1997/98	Expenditure 1998/99
		(ATORVASTATIN CALCIUM)			2,545,621	11,397,263
2213613	FLOVENT INHALERS - AEM INH-ORL 250MCG/AEM	FLUTICASONE PROPIONATE	R	1995	6,838,470	11,164,593
2146959	LIPIDIL MICRO - CAP 200MG	FENOFIBRATE	C	1995	9,632,332	11,088,027
2225905	ZOLADEX LA INJ DEPOT 10.8MG	GOSERELIN (GOSERELIN ACETATE)	L	1996	7,393,556	10,833,949
2229285	ZYPREXA - 10MG	OLANZAPINE	N	1996	4,582,703	10,784,071
2230998	APO-DILTIAZ CD	DILTIAZEM HYDROCHLORIDE	C	1997	4,077,526	9,741,846
1984853	BIAXIN TAB 250MG	CLARITHROMYCIN	J	1992	8,535,039	9,691,954
Total Expenditures					**400,157,869**	**472,136,193**

Top 10 Category 1 Patented Drug Products Ontario 1997/98 and 1998/99						
DIN	**BRAND**	**Ingredient**	**ATC**	**Year of Introduction**	**Expenditure 1997/98**	**Expenditure 1998/99**
2190915	LOSEC 20 MG	OMEPRAZOLE (OMEPRAZOLE MAGNESIUM)	A	1995	66,191,526	70,829,449
884340	ZOCOR TAB 20MG	SIMVASTATIN	C	1995	17,069,168	21,538,324
2155907	ADALAT XL - SRT 30MG	NIFEDIPINE	C	1992	19,214,122	18,171,434
836311	PREPULSID TAB 5MG	CISAPRIDE (CISAPRIDE MONOHYDRATE)	A	1992	13,600,404	13,407,405
2213613	FLOVENT INHALERS - AEM INH-ORL 250MCG/AEM	FLUTICASONE PROPIONATE	R	1995	6,838,470	11,164,593
2146959	LIPIDIL MICRO - CAP 200MG	FENOFIBRATE	C	1995	9,632,332	11,088,027
2225905	ZOLADEX LA INJ DEPOT 10.8MG	GOSERELIN (GOSERELIN ACETATE)	L	1996	7,393,556	10,833,949
2155990	ADALAT XL - SRT 60MG	NIFEDIPINE	C	1992	9,515,814	9,590,537
2176017	DIDROCAL -400MG TAB AND 1250MG TAB(500MG CA)	CALCIUM CARBONATE	M	1996	4,600,785	8,372,285
1911902	NITRO-DUR 0.4MG/H DISC	NITROGLYCERIN	C	1994	6,100,119	8,300,579
Total Expenditures					**160,156,298**	**183,296,582**

Top 10 Category 2 Patented Drug Products
Ontario 1997/98 and 1998/99

DIN	BRAND	Ingredient	ATC	Year of Introduction	Expenditure 1997/98	Expenditure 1998/99
2155966	CIPRO 500 - TAB 500MG	CIPROFLOXACIN (CIPROFLOXACIN HYDROCHLORIDE)	J	1992	10,489,927	11,407,055
2229196	CRIXIVAN - CAP 400MG	INDINAVIR (INDINAVIR SULFATE)	J	1996	6,022,705	5,500,059
2155958	CIPRO 250 - TAB 250MG	CIPROFLOXACIN (CIPROFLOXACIN HYDROCHLORIDE)	J	1992	4,336,801	4,767,860
2169649	BETASERON	SODIUM CHLORIDE	L	1995	2,388,452	3,509,821
2213575	ZOFRAN - TAB 8MG	ONDANSETRON (ONDANSETRON HYDROCHLORIDE DIHYDRATE)	A	1992	3,009,914	3,287,935
2025302	RISPERDAL TAB 3MG	RISPERIDONE	N	1993	2,955,995	3,027,841
2025299	RISPERDAL TAB 2MG	RISPERIDONE	N	1993	2,481,989	3,013,133
2216965	INVIRASE - CAP 200MG	SAQUINAVIR (SAQUINAVIR MESYLATE)	J	1996	2,927,397	2,753,438
1968017	NEUPOGEN INJ LIQ 0.3MG/ML	FILGRASTIM (R-METHUG-CSF)	L	1994	2,013,663	2,541,521
2025310	RISPERDAL TAB 4MG	RISPERIDONE	N	1993	1,189,502	1,287,112
Total Expenditures					**37,816,344**	**41,095,776**

Top 10 Category 3 Patented Drug Products
Ontario 1997/98 and 1998/99

DIN	BRAND	Ingredient	ATC	Year of Introduction	Expenditure 1997/98	Expenditure 1998/99
878928	NORVASC TAB 5MG	AMLODIPINE (AMLODIPINE BESYLATE)	C	1993	25,237,982	31,268,646
893757	PRAVACHOL TAB 20MG	PRAVASTATIN SODIUM	C	1992	28,626,136	29,138,910
708879	VASOTEC TAB 5MG	ENALAPRIL MALEATE	C	1992	24,617,051	24,164,171
884332	ZOCOR TAB 10MG	SIMVASTATIN	C	1992	21,390,325	21,870,498
670901	VASOTEC TAB 10MG	ENALAPRIL MALEATE	C	1992	20,156,789	20,986,101
1940481	PAXIL TAB 20MG	PAROXETINE (PAROXETINE HYDROCHLORIDE)	N	1994	16,151,382	20,186,610
2230711	LIPITOR 10MG	ATORVASTATIN (ATORVASTATIN CALCIUM)	C	1997	4,343,501	17,143,450
1962817	ZOLOFT CAP 50MG	SERTRALINE (SERTRALINE HYDROCHLORIDE)	N	1993	13,314,915	15,365,834
878936	NORVASC TAB 10MG	AMLODIPINE (AMLODIPINE BESYLATE)	C	1993	10,988,297	14,454,972
1917056	ARTHROTEC 50 TAB	MISOPROSTOL	M	1994	13,218,575	14,002,672
Total Expenditures					**178,044,954**	**208,581,863**

Appendix 4

Therapeutic Class Analysis

Percentage Contribution by Therapeutic Classes to Total Expenditure Ontario: 1992/93 - 1998/99 (millions of dollars)						
Therapeutic Class	**ATC**	**Contribution in 1992/93**	**% of Total Expenditure**	**Contribution in 1998/99**	**% of Total Expenditure**	**% of Total Expenditure Change**
Cardiovascular System	C	241.4	35.2	500.3	38.1	41.40
Alimentary Tract and Metabolism	A	127.80	18.60	206.90	15.8	12.70
Nervous System	N	73.20	10.70	190.70	14.5	18.8
Respiratory System	R	54.10	7.90	92.60	7.10	6.2
General anti-infectives for Systemic use	J	41.00	6.00	84.10	6.40	6.9
Antineoplastic and Immunomodulating agents	L	17.50	2.50	59.90	4.60	6.80
Musculo-skeletal system	M	56.30	8.20	53.70	4.10	-0.40
Genito-Urinary system and sex hormones	G	24.60	3.60	38.30	2.90	2.20
Sensory organ	S	17.20	2.50	24.80	1.90	1.20
Dermatologicals	D	15.40	2.20	23.80	1.80	1.30
Blood and blood forming agents	B	3.80	0.60	23.00	1.80	3.10
Systemic hormonal preparations, exc. sex hormones	H	4.10	0.60	8.90	0.70	0.80
Anti-Parasitic products, insecticides and repellents	P	1.60	0.20	2.70	0.20	0.20
Unclassified		7.60	1.10	1.00	0.10	-1.00
Various		0.40	0.10	0.70	0.10	0.00
Total		**686**	**100**	**1,312**	**100**	**100**

Anatomical Therapeutic Chemical (ATC)

The Anatomical Therapeutic Chemical (ATC) classification system [and the Defined Daily Dose (DDD)] as a measuring unit are recommended by the WHO for drug utilization studies.

In the ATC classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into fourteen main groups (1st level), with two therapeutic/pharmacological subgroups (2nd and 3rd levels). The 4th level is a therapeutic/pharmacological/chemical subgroup and the 5th level is the chemical substance.

Medicinal products are classified according to the main therapeutic use of the main active ingredient, on the basic principle of only one ATC code for each pharmaceutical formulation (i.e. similar ingredients, strength and pharmaceutical form). A medicinal product can be given more than one ATC code if it is available in two or more strengths or formulations with clearly different therapeutic uses. The second level of the ATC classification system is used to represent a general disease grouping within the study.

ATC	Therapeutic Class	Subgroups*
A02	Antacids, drugs for treatment of peptic ulcer and flatulence	Antacids; H_2-receptor antagonists; Prostaglandins; Proton pump inhibitors; Combinations for eradication of *Helicobacter pylori* & Others such as sucralfate
A10	Drugs used in diabetes	Insulins and analogues; Biguanides; Sulfonamides; Alpha glucosidase inhibitors; Thiazolidinediones & Others such as repaglinide
C01	Cardiac Therapy	Cardiac glycosides (digoxin); Antiarrhythmics; Cardiac stimulants (adrenergic and dopaminergic agents, phosphodiesterase inhibitors); Vasodilators (organic nitrates) & Others such prostaglandins
C07	Beta blocking agents	Beta blocking agents; Beta blocking agents and Thiazides; Beta blocking agents and other diuretics; Beta blocking agents and Vasodilators & Beta blocking agents and Other antihypertensives
C08	Calcium channel blockers	Selective Calcium channel blockers with mainly vascular effects; Selective Calcium channel blockers with direct cardiac effects; Non-selective Calcium channel blockers & Calcium channel blockers and diuretics
C09	Agents acting on the renin-angiotensin system	ACEIs, plain; ACEIs, combinations; Angiotensin II antagonists, plain; Angiotensin II antagonists, combinations & Others

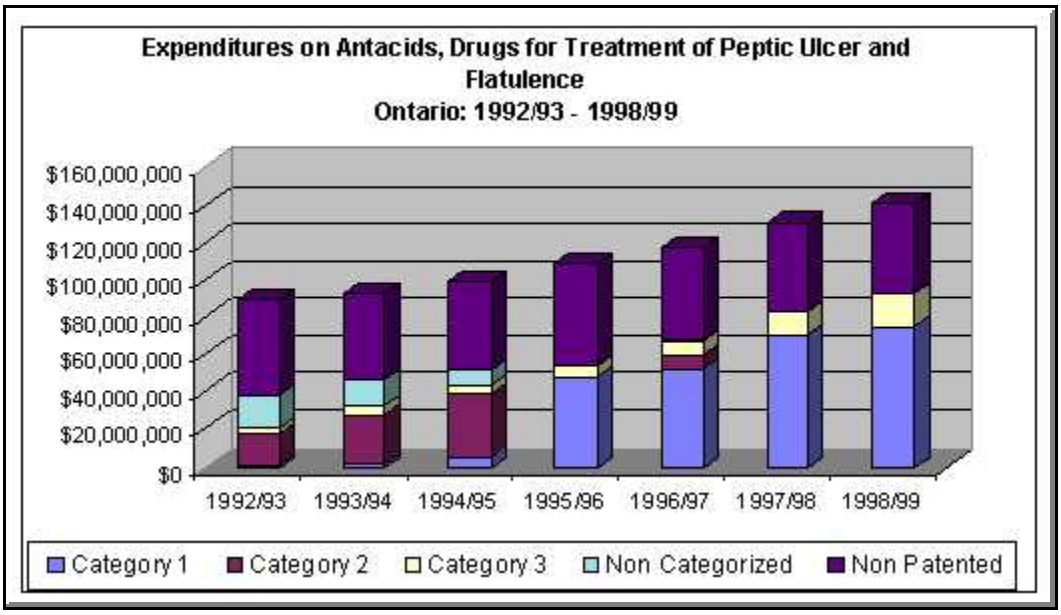
ATC	Therapeutic Class	Subgroups*
C10	Serum lipid reducing agents	HMG CoA reductase inhibitors; Fibrates; Bile acid sequestrants; Nicotinic acid and derivatives
J01	Antibacterials for systemic use	Tetracyclines; Amphenicols (chloramphenicol); Penicillins; Beta-lactamase inhibitors; Cephalosporins; Monobactams; Carbapenems; Sulfonamides and Trimethoprim; Macrolides and Lincosamides (clindamycin); Aminoglycosides; Quinolones & Others such as vancomycin, fusidic acid, metronidazole
J05	Antivirals for systemic use	Nucleosides and nucleotides excl. reverse transcriptase inhibitors (aciclovir, vidarabine, ribavirin, ganciclovir...); Cyclic amines; Phosphonic acid derivatives (foscarnet); Protease inhibitors; NRTIs, NNRTIs, Neuraminidase inhibitors (zanamivir, oseltamivir)
L02	Endocrine Therapy	Estrogens; Progestens; Gonadotropin releasing hormone analogues; Anti-estrogens (tamoxifen); Anti-androgens & Enzyme inhibitors such as anastrozole
M01	Anti-inflammatory and anti-rheumatic products	Anti-inflammatory and anti-rheumatic products, Non-steroids (butylpyrazolidines, acetic acid derivatives and related substances, oxicams, propionic acid derivatives, fenamates, coxibs & others such as nabumetone & glucosamine); Anti-inflammatory/anti-rheumatic agents in combination; Specific anti-rheumatic agents (gold preparations, penicillamine)
N02	Analgesics	Opioids (natural opium alkaloids such as morphine, codeine..; phenylpiperidines derivatives such as pethidine, fentanyl..; diphenylpropylamine derivatives such as methadone; pentazocine; morphinan derivative such as butorphanol and nalbuphine; opioids in combination with antispasmodics); Other analgesics and antipyretics (salicylic acid and derivatives, pyrazolones, anilides such as paracetamol); Antimigraine preparations (ergot alkaloids, selective $5HT_1$-receptor agonists & other antimigraine preparations such as pizotifen, clonidine)

ATC	Therapeutic Class	Subgroups*
N05	Psycholeptics	Antipsychotics (phenothiazines; butyrophenone derivatives; indole derivatives; thioxanthene derivatives; diphenylbutylpiperidine derivatives such as pimozide; diazepines, oxazepines and thiazepines such as clozapine, olanzepine & quetiapine; neuroleptics in tardive dyskinesia such as tetrabenazine; benzamides; lithium); Anxiolytics (benzodiazepine derivatives, carbamates, buspirone); Hypnotics and sedatives (barbiturates-plain, barbiturates-combinations,aldehydes and derivatives, benzodiazepine derivatives, piperidinedione derivatives, benzodiazepine related drugs such as zopiclone)
N06	Psychoanaleptics	Antidepressants; Psychostimulants and nootropics (centrally acting sympathomimetics, xanthine derivatives); Psycholeptics and psychoanaleptics in combination (antidepressants in combination with psycholeptics); Anti-dementia drugs
R03	Anti-asthmatics	Adrenergics, inhalants; Other anti-asthmatics, inhalants (glucocorticoids, anticholinergics, antiallergic agents); Adrenergics for systemic use; Other anti-asthmatics for systemic use (xanthines, xanthines and adrenergics, leukotriene receptor antagonists)
S01	Ophthalmologicals	Anti-infectives (antibiotics, sulfonamides, antivirals, other anti-infectives); Anti-inflammatory agents (corticosteroids, plain; corticosteroids and mydriatics in combination; anti-inflammatory agents, non-steroids); Anti-inflammatory agents and anti-infectives in combination; Anti-glaucoma preparations and miotics; Mydriatics and cycloplegics; Decongestants and antiallergics; Local anesthetics; Diagnostic agents; Surgical aids; Others such as artificial tears

* main one listed

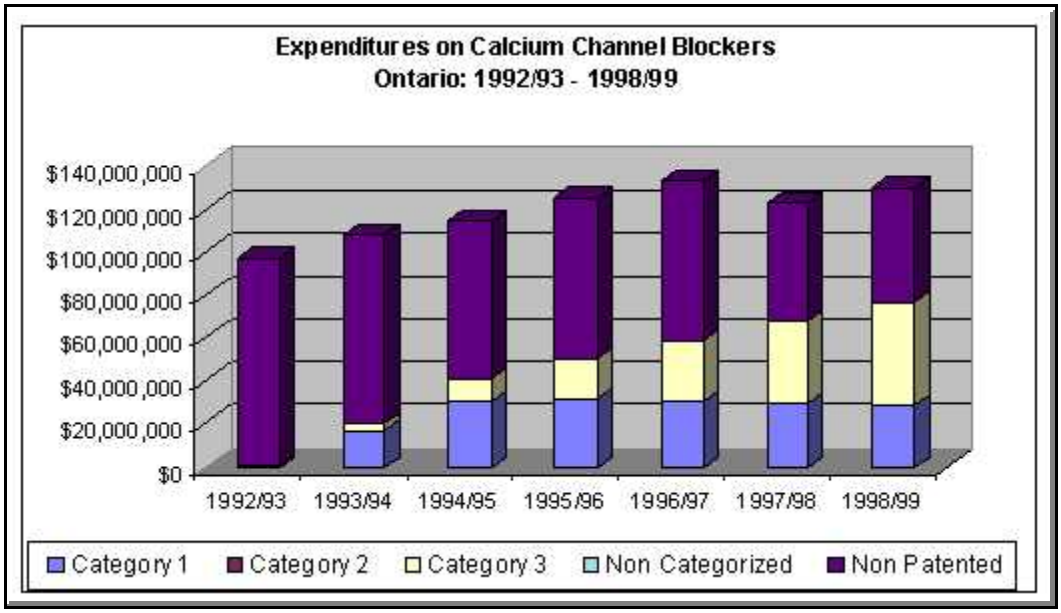
Impact of Existing and Newer Products
Antacids, Drugs for Treatment of Peptic Ulcer and Flatulence
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		50,919	41,837	40,344	39,816	36,362	32,297	31,758
1992/93	1	1,425	1,414	2,043	2,238	1,644	1,193	988
1992/93	2	15,377	25,305	32,772	0	7,637	0	0
1992/93	3	3,129	4,554	5,229	5,888	6,744	8,028	8,942
1992/93	NC	18,106	14,209	8,135	8,016	6,124	5,079	4,412
1993/94		0	4,221	5,568	5,048	4,852	3,897	4,045
1993/94	1	0	603	3,441	3,647	3,842	3,612	3,236
1994/95		0	0	1,308	1,760	1,197	955	752
1995/96		0	0	0	37	242	252	284
1995/96	1	0	0	0	42,426	47,128	66,192	70,829
1995/96	3	0	0	0	1	652	3,128	5,411
1996/97		0	0	0	0	792	2,510	4,274
1996/97	3	0	0	0	0	191	685	907
1997/98		0	0	0	0	0	2,125	2,542
1997/98	3	0	0	0	0	0	597	2,459
1998/99		0	0	0	0	0	0	2
1998/99	1	0	0	0	0	0	0	0
Total Expenditure		**88,957**	**92,144**	**98,839**	**108,879**	**117,409**	**130,549**	**140,842**
Patented Expenditure		**37,962**	**46,023**	**51,571**	**54,030**	**67,491**	**83,062**	**92,438**
Non-Patented Expenditure		**50,995**	**46,121**	**47,268**	**54,849**	**49,917**	**47,487**	**48,404**


Expenditures on Antacids, Drugs for Treatment of Peptic Ulcer and Flatulence
Ontario: 1992/93 - 1998/99
$160,000,000
$140,000,000
$120,000,000
$100,000,000
$80,000,000
$60,000,000
$40,000,000
$20,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

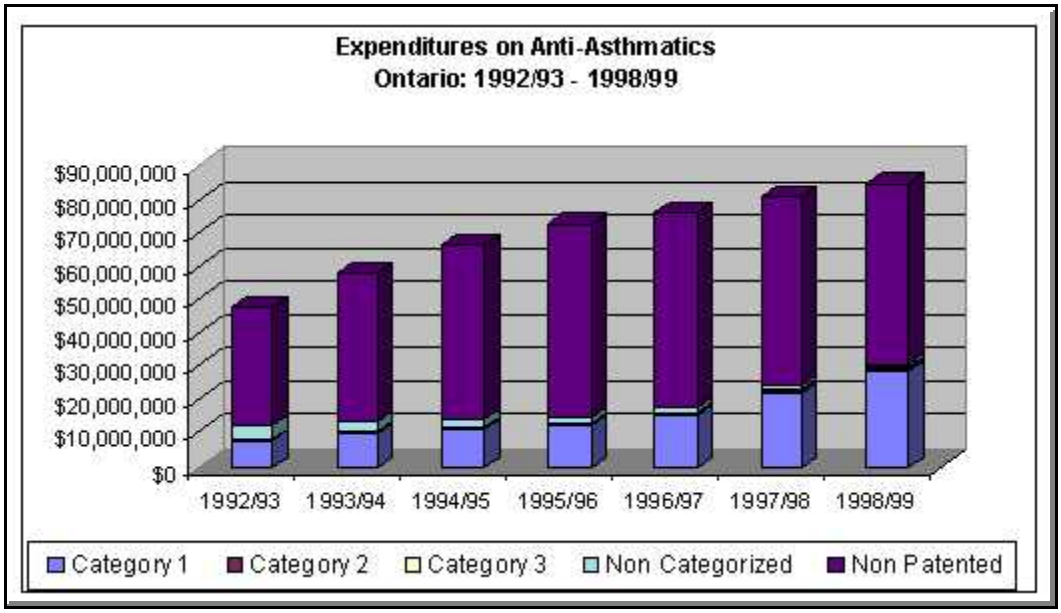
Impact of Existing and Newer Products
Calcium Channel Blockers
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of ntroduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		96,812	88,835	42,482	23,882	15,310	8,512	7,272
1992/93	1	447	16,187	29,824	31,246	29,821	28,730	27,762
1992/93	2	73	56	56	54	27	32	26
1992/93	3	75	1,037	1,772	2,012	2,209	2,428	2,614
1993/94	3	0	2,072	9,124	16,858	26,470	36,226	45,724
1994/95		0	0	31,729	51,614	56,231	3,116	809
1994/95	1	0	0	5	71	123	166	215
1995/96		0	0	0	7	136	160	118
1996/97		0	0	0	0	3,351	6,334	6,059
1997/98		0	0	0	0	0	37,775	39,215
1998/99		0	0	0	0	0	0	224
1998/99	1	0	0	0	0	0	0	390
Total Expenditure		**97,408**	**108,188**	**114,993**	**125,743**	**133,678**	**123,479**	**130,428**
Patented Expenditure		**596**	**19,353**	**40,782**	**50,240**	**58,650**	**67,583**	**76,472**
Non-Patented Expenditure		**96,812**	**88,835**	**74,211**	**75,502**	**75,028**	**55,897**	**53,956**


Expenditures on Calcium Channel Blockers
Ontario: 1992/93 - 1998/99
$140,000,000
$120,000,000
$100,000,000
$80,000,000
$60,000,000
$40,000,000
$20,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

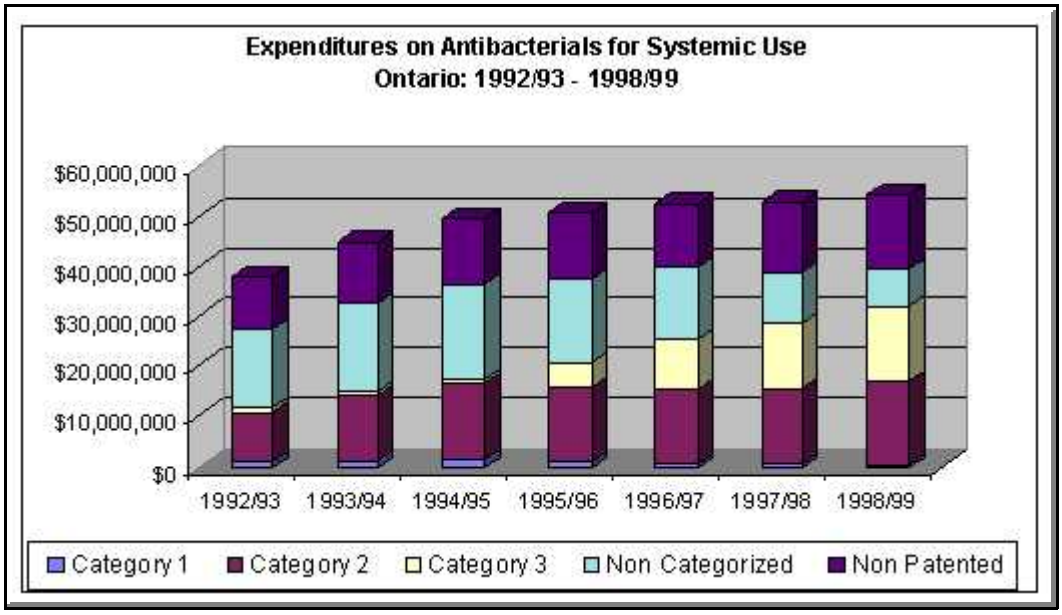
Impact of Existing and Newer Products
Anti-asthmatics
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		28,775	33,814	37,123	40,571	37,275	32,150	27,503
1992/93	1	9,643	12,388	13,395	13,834	13,338	12,866	12,324
1992/93	3	468	616	658	564	403	339	290
1992/93	NC	8,666	10,046	10,932	11,245	11,295	10,574	10,072
1993/94		0	936	3,035	3,077	3,202	2,900	2,553
1993/94	1	0	298	1,192	1,916	2,392	2,632	2,683
1993/94	2	0	0	18	30	254	481	638
1994/95		0	0	112	455	1,504	2,483	3,610
1994/95	2	0	0	7	17	173	292	331
1995/96		0	0	0	1,061	2,383	2,388	2,333
1995/96	1	0	0	0	0	3,081	9,700	16,135
1996/97		0	0	0	0	780	3,861	5,673
1997/98		0	0	0	0	0	481	609
1997/98	1	0	0	0	0	0	0	0
1997/98	3	0	0	0	0	0	14	57
1998/99		0	0	0	0	0	0	129
1998/99	1	0	0	0	0	0	0	18
1998/99	3	0	0	0	0	0	0	2
Total Expenditure		**47,551**	**58,100**	**66,471**	**72,771**	**76,079**	**81,162**	**84,960**
Patented Expenditure		**11,805**	**13,292**	**13,618**	**14,226**	**17,529**	**24,120**	**30,488**
Non-Patented Expenditure		**35,746**	**44,808**	**52,853**	**58,545**	**58,550**	**57,042**	**54,473**

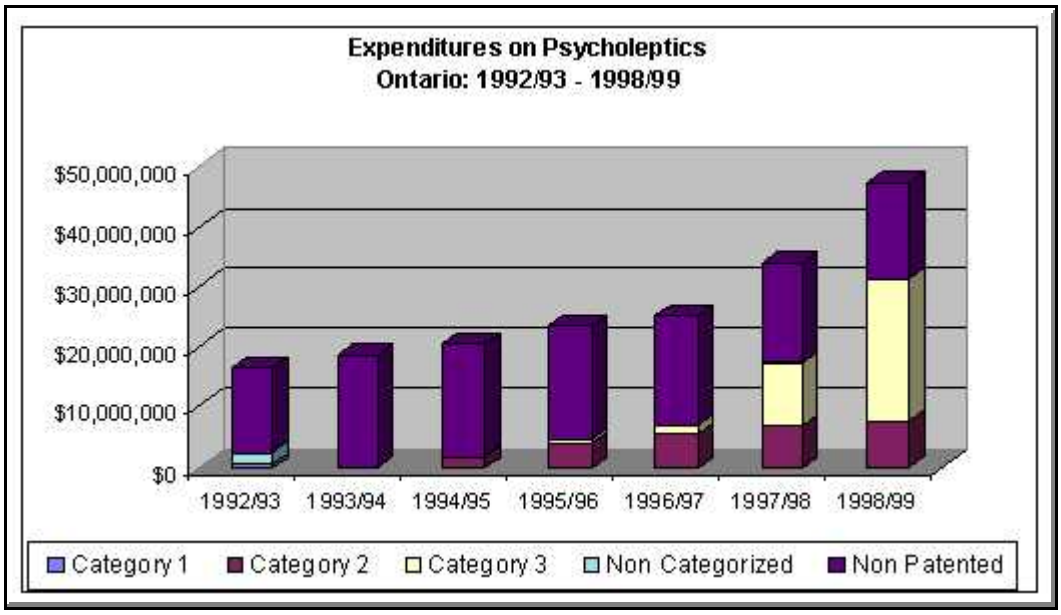

Expenditures on Anti-Asthmatics
Ontario: 1992/93 - 1998/99
$90,000,000
$80,000,000
$70,000,000
$60,000,000
$50,000,000
$40,000,000
$30,000,000
$20,000,000
$10,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

Impact of Existing and Newer Products
Antibacterials for Systemic Use
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		9,774	10,820	11,657	10,596	8,798	7,852	7,250
1992/93	1	1,139	1,332	1,553	1,183	822	614	487
1992/93	2	9,489	12,602	14,838	14,523	14,319	14,827	16,175
1992/93	3	880	900	980	4,318	8,261	9,358	10,522
1992/93	NC	16,490	19,347	20,620	18,364	15,994	11,493	8,699
1993/94		0	0	1	2	1	2	3
1993/94	3	0	2	22	44	33	55	52
1993/94	NC	0	0	0	1	3	2	1
1994/95		0	0	3	974	2,278	2,776	3,461
1994/95	3	0	0	3	322	1,031	2,345	2,981
1994/95	NC	0	0	5	12	2	2	0
1995/96		0	0	0	2	0	0	2
1995/96	1	0	0	0	12	0	0	0
1995/96	3	0	0	0	365	731	674	490
1995/96	NC	0	0	0	0	0	0	3
1996/97		0	0	0	0	156	465	777
1996/97	1	0	0	0	0	20	86	83
1996/97	3	0	0	0	0	117	624	1,113
1997/98		0	0	0	0	0	1,857	2,267
1997/98	3	0	0	0	0	0	31	59
1998/99		0	0	0	0	0	0	103
1998/99	1	0	0	0	0	0	0	4
1998/99	3	0	0	0	0	0	0	13
Total Expenditure		**37,772**	**45,004**	**49,682**	**50,719**	**52,570**	**53,062**	**54,544**
Patented Expenditure		**27,375**	**32,592**	**36,423**	**37,529**	**40,006**	**38,831**	**39,499**
Non-Patented Expenditure		**10,397**	**12,411**	**13,259**	**13,190**	**12,564**	**14,231**	**15,046**

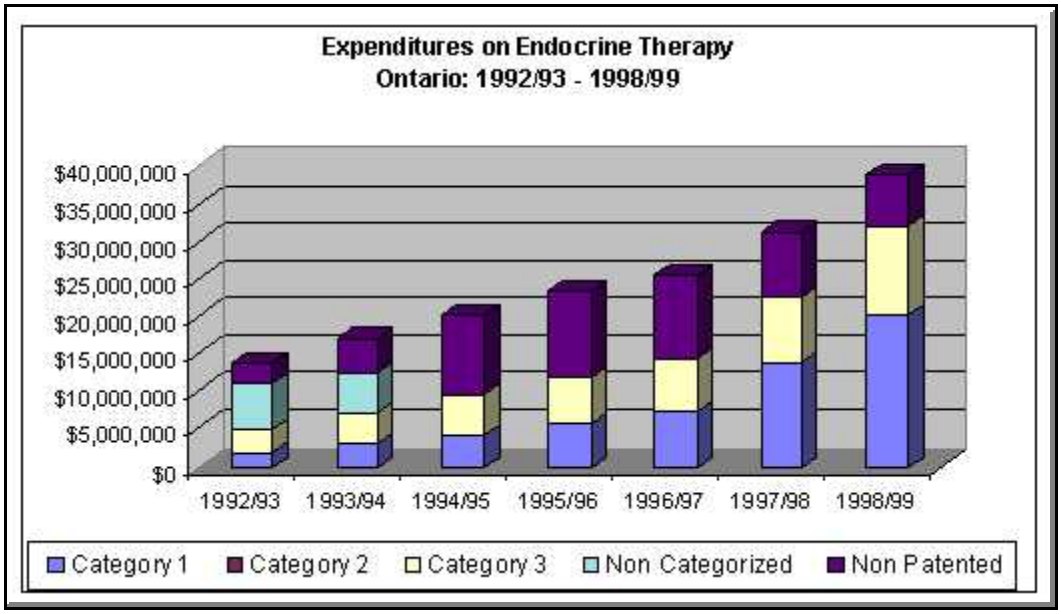

Expenditures on Antibacterials for Systemic Use
Ontario: 1992/93 - 1998/99
$60,000,000
$50,000,000
$40,000,000
$30,000,000
$20,000,000
$10,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

Impact of Existing and Newer Products Psycholeptics Ontario: 1992/93 -1998/99 (thousands of dollars)								
Year of Introduction	**Category**	**1992/93**	**1993/94**	**1994/95**	**1995/96**	**1996/97**	**1997/98**	**1998/99**
1992/93		12,389	14,552	14,654	14,828	14,355	12,935	12,075
1992/93	1	653	437	407	362	289	209	134
1992/93	NC	3,294	3,650	3,667	3,830	2,687	470	148
1993/94		0	1	28	70	108	151	193
1993/94	2	0	3	1,551	3,773	5,369	6,627	7,328
1993/94	3	0	0	209	669	1,288	2,313	3,755
1994/95		0	0	45	46	43	33	49
1994/95	3	0	0	1	2	2	7	13
1995/96		0	0	0	8	52	63	72
1996/97		0	0	0	0	885	1,896	1,881
1996/97	3	0	0	0	0	178	8,378	19,889
1996/97	NC	0	0	0	0	0	0	0
1997/98		0	0	0	0	0	1,047	1,467
1997/98	3	0	0	0	0	0	1	152
1997/98	NC	0	0	0	0	0	1	0
1998/99		0	0	0	0	0	0	46
1998/99	1	0	0	0	0	0	0	156
1998/99	3	0	0	0	0	0	0	144
Total Expenditure		**16,337**	**18,644**	**20,562**	**23,590**	**25,258**	**34,131**	**47,503**
Patented Expenditure		**2,407**	**101**	**1,764**	**4,448**	**6,842**	**17,327**	**31,435**
Non-Patented Expenditure		**13,930**	**18,543**	**18,798**	**19,142**	**18,416**	**16,805**	**16,068**


Expenditures on Psycholeptics
Ontario: 1992/93 - 1998/99
$50,000,000
$40,000,000
$30,000,000
$20,000,000
$10,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

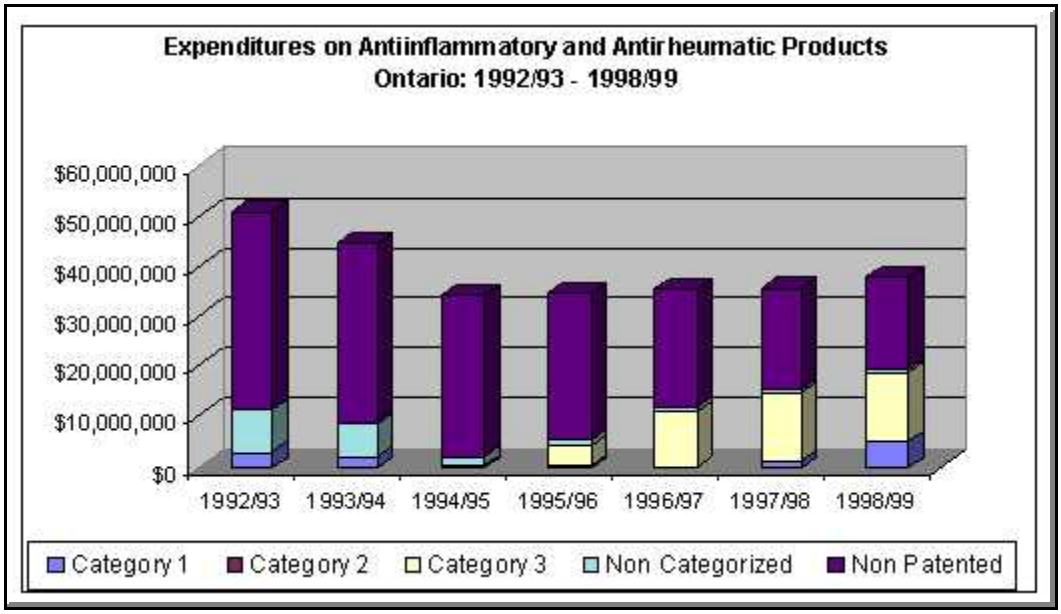
Impact of Existing and Newer Products
Endocrine Therapy
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		2,693	2,436	2,273	2,036	1,827	1,476	1,466
1992/93	1	1,765	2,837	3,870	5,044	5,637	4,505	3,425
1992/93	3	3,091	4,278	5,441	6,336	6,796	4,178	3,222
1992/93	NC	6,086	7,315	7,936	8,806	7,160	5,266	3,161
1993/94		0	164	462	604	729	729	703
1994/95		0	0	0	0	2	2	10
1994/95	1	0	0	161	481	454	461	454
1995/96		0	0	0	13	4	1	1
1996/97		0	0	0	0	1,333	1,263	1,096
1996/97	1	0	0	0	0	1,077	7,394	10,834
1996/97	3	0	0	0	0	422	4,507	8,691
1997/98	1	0	0	0	0	0	1,493	5,409
1997/98	3	0	0	0	0	0	2	63
1998/99		0	0	0	0	0	0	476
Total Expenditure		**13,635**	**17,030**	**20,143**	**23,319**	**25,440**	**31,275**	**39,010**
Patented Expenditure		**10,942**	**12,429**	**9,500**	**11,860**	**14,385**	**22,538**	**32,098**
Non-Patented Expenditure		**2,693**	**4,601**	**10,643**	**11,459**	**11,055**	**8,737**	**6,912**


Expenditures on Endocrine Therapy
Ontario: 1992/93 - 1998/99
$40,000,000
$35,000,000
$30,000,000
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

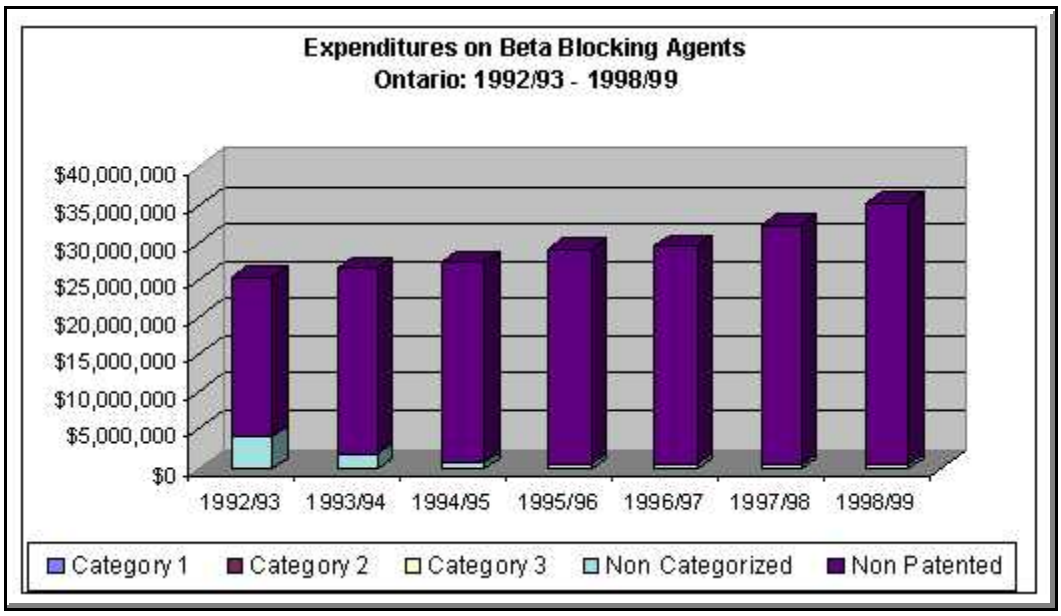
Impact of Existing and Newer Products
Antiinflammatory and Antirheumatic Products
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		24,024	25,458	25,267	22,785	18,449	15,324	13,671
1992/93	1	2,940	1,822	371	227	121	87	77
1992/93	3	30	42	39	39	33	35	33
1992/93	NC	23,934	17,137	7,364	6,554	3,530	1,858	1,441
1993/94		0	115	857	841	772	621	593
1993/94	1	0	47	256	246	185	138	114
1994/95		0	0	1	5	4	4	3
1994/95	3	0	0	1	3,664	10,725	13,227	14,010
1995/96		0	0	0	305	1,539	1,665	1,527
1996/97		0	0	0	0	171	725	771
1997/98		0	0	0	0	0	803	878
1997/98	1	0	0	0	0	0	1,188	4,543
1998/99		0	0	0	0	0	0	132
Total Expenditure		**50,928**	**44,621**	**34,157**	**34,667**	**35,529**	**35,674**	**37,792**
Patented Expenditure		**11,113**	**8,299**	**1,848**	**5,269**	**11,879**	**15,364**	**19,356**
Non-Patented Expenditure		**39,815**	**36,323**	**32,309**	**29,397**	**23,650**	**20,310**	**18,436**


Expenditures on Antiinflammatory and Antirheumatic Products
Ontario: 1992/93 - 1998/99
$60,000,000
$50,000,000
$40,000,000
$30,000,000
$20,000,000
$10,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

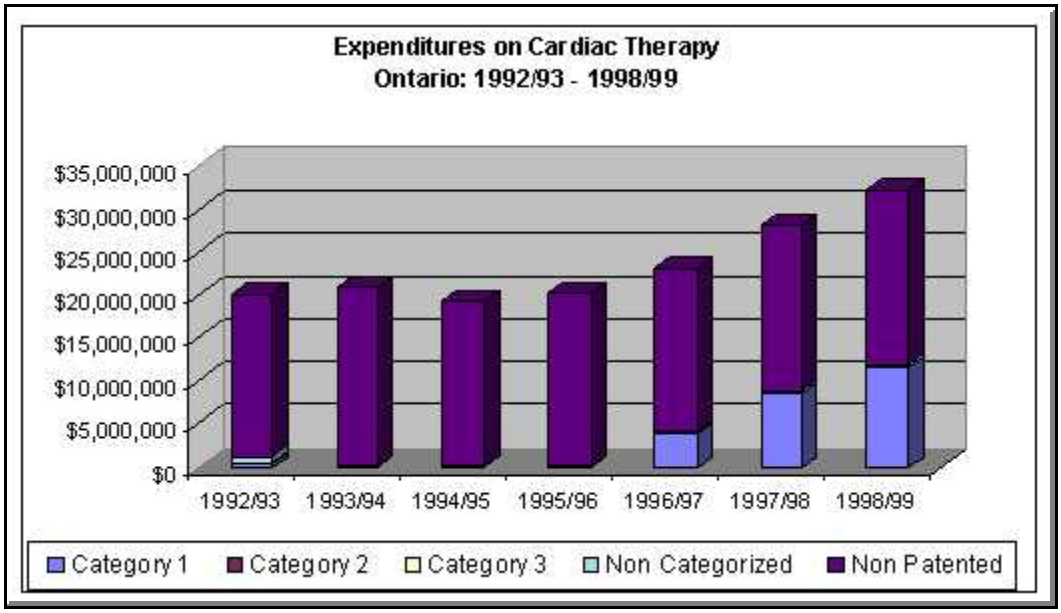
Impact of Existing and Newer Products
Beta Blocking Agents
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		21,103	23,766	26,079	26,334	20,614	19,898	20,994
1992/93	1	89	81	75	67	56	69	73
1992/93	NC	4,224	2,679	1,188	1,081	821	759	735
1993/94		0	8	39	54	72	81	79
1994/95		0	0	2	12	21	59	84
1995/96		0	0	0	1,650	4,054	4,442	4,828
1996/97		0	0	0	0	3,899	5,733	6,502
1997/98		0	0	0	0	0	1,362	2,007
1998/99		0	0	0	0	0	0	65
Total Expenditure		**25,415**	**26,534**	**27,382**	**29,198**	**29,537**	**32,403**	**35,368**
Patented Expenditure		**4,021**	**1,804**	**723**	**647**	**581**	**542**	**510**
Non-Patented Expenditure		**21,394**	**24,730**	**26,660**	**28,551**	**28,956**	**31,861**	**34,858**


Expenditures on Beta Blocking Agents
Ontario: 1992/93 - 1998/99
$40,000,000
$35,000,000
$30,000,000
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

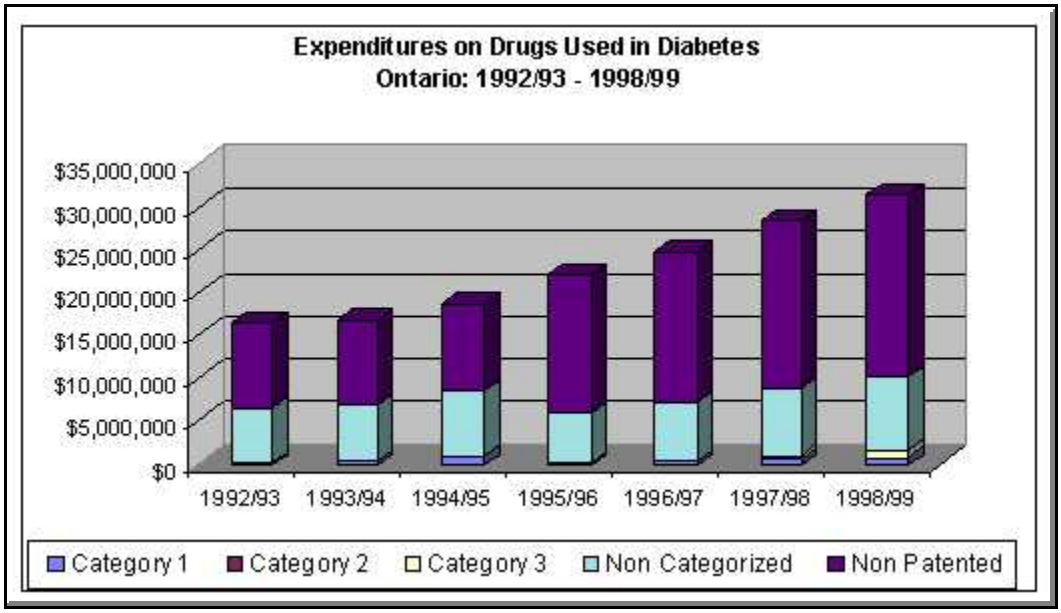
Impact of Existing and Newer Products
Cardiac Therapy
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		17,592	19,005	18,032	19,021	18,643	18,913	20,015
1992/93	1	475	428	352	281	219	215	217
1992/93	3	67	89	113	118	133	145	143
1992/93	NC	1,993	1,464	779	713	427	317	268
1993/94		0	0	22	48	71	112	148
1994/95		0	0	1	3	2	3	4
1994/95	1	0	0	1	7	3,481	7,696	10,476
1994/95	3	0	0	1	2	39	177	169
1995/96		0	0	0	1	1	0	0
1995/96	1	0	0	0	0	0	0	0
1996/97		0	0	0	0	0	1	2
1996/97	1	0	0	0	0	141	641	871
1997/98	1	0	0	0	0	0	25	30
1998/99		0	0	0	0	0	0	22
Total Expenditure		**20,128**	**20,986**	**19,300**	**20,193**	**23,157**	**28,245**	**32,365**
Patented Expenditure		**1,282**	**117**	**150**	**184**	**3,887**	**8,801**	**11,821**
Non-Patented Expenditure		**18,846**	**20,869**	**19,151**	**20,009**	**19,270**	**19,443**	**20,544**


Expenditures on Cardiac Therapy
Ontario: 1992/93 - 1998/99
$35,000,000
$30,000,000
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

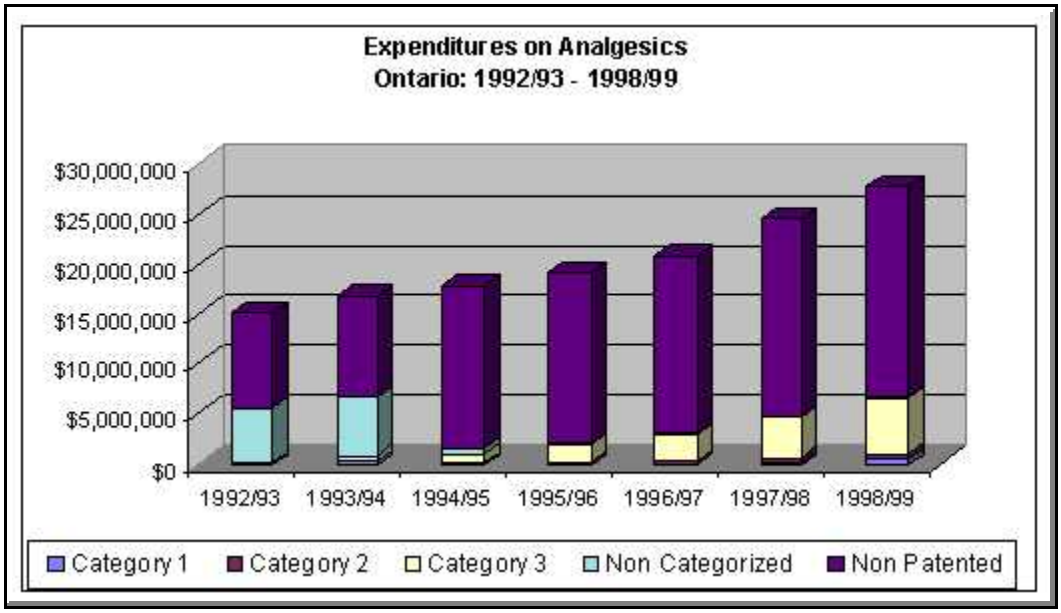
Impact of Existing and Newer Products
Drugs Used in Diabetes
Ontario: 1992/93 -1998/99
(thousands of dollars)

Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		9,987	9,997	8,796	5,453	5,819	5,872	6,119
1992/93	1	223	495	818	1,062	1,293	1,590	1,877
1992/93	NC	6,231	6,301	6,717	8,488	8,582	8,275	7,765
1993/94		0	0	3	4	5	11	21
1993/94	1	0	0	3	8	10	13	17
1994/95		0	0	1,510	4,480	4,321	4,087	4,124
1994/95	1	0	0	105	412	659	980	1,257
1994/95	NC	0	0	749	1,627	2,573	3,731	4,665
1995/96		0	0	0	507	1,108	1,498	1,932
1996/97		0	0	0	0	395	1,150	1,929
1996/97	3	0	0	0	0	44	418	774
1997/98		0	0	0	0	0	762	924
1997/98	NC	0	0	0	0	0	15	64
1998/99		0	0	0	0	0	0	1
Total Expenditure		**16,440**	**16,793**	**18,701**	**22,039**	**24,808**	**28,402**	**31,469**
Patented Expenditure		**6,453**	**6,795**	**8,392**	**5,883**	**7,156**	**8,821**	**10,115**
Non-Patented Expenditure		**9,987**	**9,997**	**10,309**	**16,157**	**17,652**	**19,581**	**21,353**

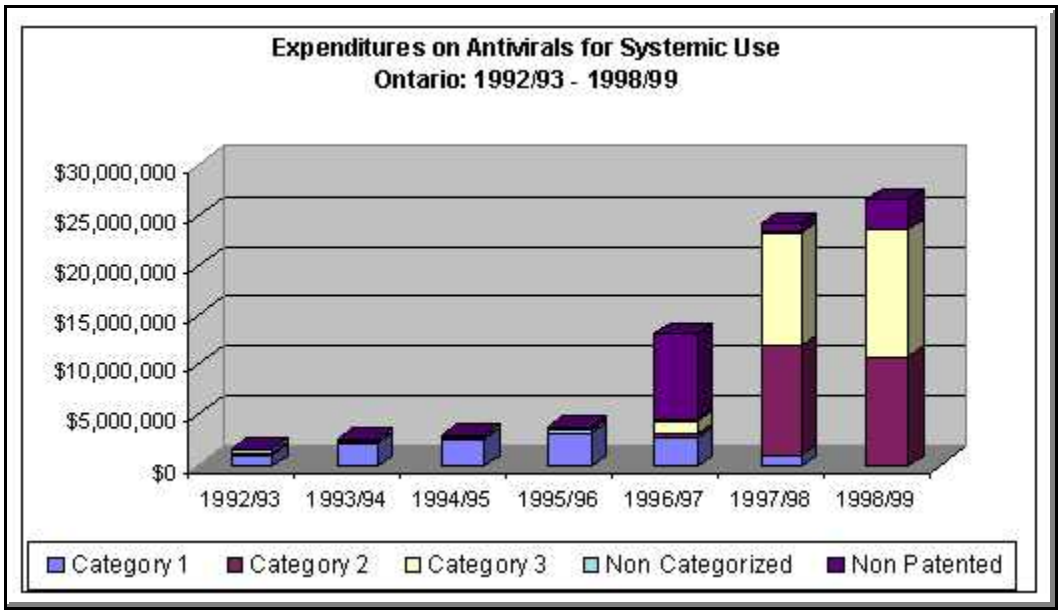

Expenditures on Drugs Used in Diabetes
Ontario: 1992/93 - 1998/99
$35,000,000
$30,000,000
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

Impact of Existing and Newer Products
Analgesics
Ontario: 1992/93 -1998/99
(thousands of dollars)

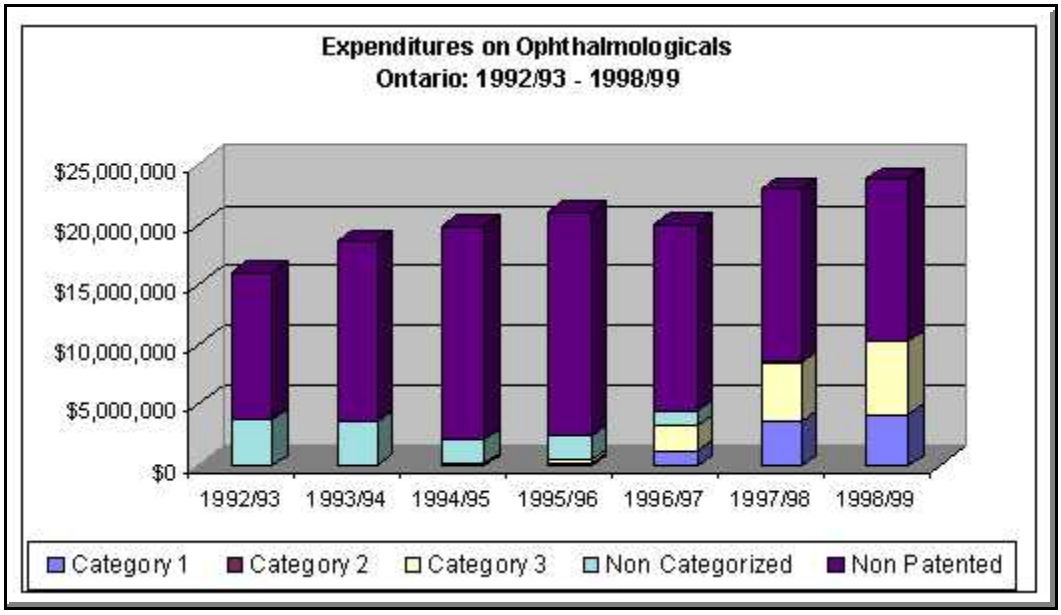
Year of Introduction	Category	1992/93	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99
1992/93		9,583	10,176	10,489	10,454	10,175	10,281	10,343
1992/93	1	146	394	459	595	730	1,018	1,017
1992/93	3	10	464	804	1,563	2,534	3,958	5,470
1992/93	NC	5,356	5,807	5,251	5,069	5,756	6,945	8,088
1993/94		0	6	26	45	60	33	32
1993/94	2	0	4	151	281	307	476	442
1994/95		0	0	638	1,056	1,060	1,051	1,064
1995/96		0	0	0	38	124	216	300
1995/96	1	0	0	0	1	18	47	52
1995/96	3	0	0	0	17	23	54	73
1996/97		0	0	0	0	60	186	226
1996/97	1	0	0	0	0	12	96	219
1996/97	NC	0	0	0	0	0	9	16
1997/98		0	0	0	0	0	101	143
1997/98	1	0	0	0	0	0	72	243
1997/98	3	0	0	0	0	0	2	20
1998/99		0	0	0	0	0	0	64
1998/99	1	0	0	0	0	0	0	35
1998/99	3	0	0	0	0	0	0	1
Total Expenditure		**15,095**	**16,852**	**17,818**	**19,118**	**20,859**	**24,545**	**27,847**
Patented Expenditure		**5,512**	**6,669**	**1,527**	**1,932**	**2,929**	**4,672**	**6,579**
Non-Patented Expenditure		**9,583**	**10,183**	**16,291**	**17,186**	**17,931**	**19,873**	**21,267**


Expenditures on Analgesics
Ontario: 1992/93 - 1998/99
$30,000,000
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

Impact of Existing and Newer Products Antivirals for Systemic Use Ontario: 1992/93 -1998/99 (thousands of dollars)								
Year of ntroduction	**Category**	**1992/93**	**1993/94**	**1994/95**	**1995/96**	**1996/97**	**1997/98**	**1998/99**
1992/93	1	1,018	2,088	2,513	3,016	2,206	269	156
1992/93	2	107	57	52	19	17	7	5
1992/93	NC	426	332	331	294	181	114	69
1993/94	3	0	5	4	8	12	5	6
1995/96	1	0	0	0	45	415	748	702
1995/96	3	0	0	0	287	4,074	6,702	6,942
1995/96	NC	0	0	0	0	0	0	0
1996/97		0	0	0	0	164	397	139
1996/97	2	0	0	0	0	4,886	10,892	10,721
1996/97	3	0	0	0	0	1,067	4,647	5,681
1996/97	NC	0	0	0	0	2	5	13
1997/98		0	0	0	0	0	416	427
1997/98	1	0	0	0	0	0	1	6
1998/99		0	0	0	0	0	0	68
1998/99	1	0	0	0	0	0	0	19
1998/99	3	0	0	0	0	0	0	1,708
Total Expenditure		**1,551**	**2,483**	**2,900**	**3,670**	**13,023**	**24,202**	**26,664**
Patented Expenditure		**1,551**	**2,483**	**2,900**	**3,395**	**4,483**	**23,390**	**23,520**
Non-Patented Expenditure		**0**	**0**	**0**	**275**	**8,540**	**812**	**3,144**


Expenditures on Antivirals for Systemic Use
Ontario: 1992/93 - 1998/99
$30,000,000
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

Impact of Existing and Newer Products Ophthalmologicals Ontario: 1992/93 -1998/99 (thousands of dollars)								
Year of ntroduction	**Category**	**1992/93**	**1993/94**	**1994/95**	**1995/96**	**1996/97**	**1997/98**	**1998/99**
1992/93		7,989	8,557	7,742	6,439	6,242	5,388	5,133
1992/93	1	2	1	3	2	2	1	0
1992/93	3	345	576	762	984	1,385	1,849	1,988
1992/93	NC	7,681	9,548	10,776	11,215	5,428	2,638	2,057
1994/95		0	0	203	337	316	329	333
1994/95	2	0	0	0	0	0	0	0
1994/95	3	0	0	107	231	290	371	488
1994/95	NC	0	0	286	1,078	1,709	1,984	1,930
1995/96		0	0	0	684	5	20	9
1995/96	1	0	0	0	93	948	2,750	2,752
1995/96	3	0	0	0	7	52	75	90
1996/97		0	0	0	0	3,174	3,977	3,739
1996/97	1	0	0	0	0	176	771	1,312
1996/97	3	0	0	0	0	338	2,716	3,583
1997/98		0	0	0	0	0	88	401
1997/98	3	0	0	0	0	0	5	59
1997/98	NC	0	0	0	0	0	0	0
1998/99		0	0	0	0	0	0	22
Total Expenditure		**16,017**	**18,682**	**19,879**	**21,070**	**20,066**	**22,963**	**23,896**
Patented Expenditure		**3,680**	**3,460**	**1,948**	**2,350**	**4,414**	**8,540**	**10,182**
Non-Patented Expenditure		**12,336**	**15,222**	**17,931**	**18,719**	**15,652**	**14,423**	**13,714**


Expenditures on Ophthalmologicals
Ontario: 1992/93 - 1998/99
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
1992/93
1993/94
1994/95
1995/96
1996/97
1997/98
1998/99
Category 1
Category 2
Category 3
Non Categorized
Non Patented

Appendix 5

Glossary

Beneficiary
Someone who has made a claim to the Ontario Drug Benefit Plan Program.

Category 1 Drugs
PMPRB din categorization - a new DIN of an existing or comparable dosage form of an existing medicines, usually a new strength of an existing drug (line extension).

Category 2 Drugs
PMPRB DIN categorization - the first drug product to treat effectively a particular illness or which provides a substantial improvement over existing drug products, often referred to as "breakthrough" or "substantial improvement".

Category 3 Drugs
PMPRB DIN categorization - a new drug or new dosage form of an existing medicine that provides moderate, little or no improvement over existing medicines.

Exiting Drug Effect
Exiting Drug Effect shows the amount by which expenditures decrease as a result of de-listing drugs from the Drug Benefit Formulary, discontinuation of the products by the manufacturer, or lack of claims during follow-up periods.

Existing Drug Products
In this Study, Existing Drug Products are defined as drug products that were already listed in the Ontario Drug Benefit Formulary before 1991, or were listed in 1991.

New Drug Effect
New Drug Effect shows the amount by which expenditures increase as a result of listing new drugs in the Drug Benefit Formulary.

Newer Drug Products
In this Study, new drug products are defined as drug products that were listed in the Ontario Drug Benefit Formulary in 1992 or during subsequent years.

Price Effect
Price effect shows the impact of prices on expenditures by holding volume consumed constant. In other words, it is the amount by which expenditures would change if volume consumed did not change from the previous year.

Total Pharmaceutical Expenditures
Total Pharmaceutical Expenditures in this study include expenditures made by the Ontario Drug Benefit Program and any deductibles and co-payments made by its beneficiaries. Expenditures also include wholesale mark ups but do not include dispensing fees.

Volume Effect
Volume effect shows the impact of volume consumed on expenditures by holding prices constant. In other words, it is the amount by which expenditures would change if prices did not change from the previous year.