R&D expenditures in Canada and other countries

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DRAFT

AUTHORS: Ross Duncan, Intellectual Property Review Branch
Dave Blaker, Legislative Review Directorate
Consumer and Corporate Affairs

Working Group:
Ross Duncan, CCAC
Dave Blaker, CCAC
Roslyn Frankl, CCAC
George Michaliszyn, ISTC
Gerald Robertson, PMPRB
Brad Buxton, PMPRB

* The Inter-departmental Working Group provided both reference material and comments on drafts of this paper. The conclusions and any errors or omissions are solely attributed to the principal authors.

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EXECUTIVE SUMMARY

The changes to Canada's Patent Act in 1987 in respect of compulsory licensing of patented medicines were made, amongst other reasons, to bring about greater levels of pharmaceutical research and development (R&D). In response to this legislative change the Pharmaceutical Manufacturers Association of Canada (PMAC) made a public commitment to increase R&D expenditures as a percentage of sales to 8% by the end of 1991, and to 10% by the end of 1996 from the existing level of 4.9% (as established by a PMAC survey of its member companies).

Total R&D expenditures by reporting patentees have gone from $165.7 million in 1988 to $281.3 million in 1990. At the same time sales revenues increased from $2,718 million in 1988 to $3,203 million in 1990. This means that, for all patentees, the R&D to sales ratio has risen from 6.1% to 8.8% in this space of two years. For those companies which reported to the Board that were also members of the PMAC, the numbers are slightly different. The R&D to sales ratio for the PMAC patentees went from 6.5% in 1988 to 9.2% in 1990. This is ahead of the promised level of 8% by 1991 so it appears that the commitment to a 10% R&D to sales ratio by 1996 will also be met.

When compared to other manufacturing sectors the pharmaceutical sector is relatively R&D intensive. Throughout the 1980s the drug sector performed two to three times as much intramural R&D when compared with the manufacturing sector as a whole. This can also be seen when one studies the percentage of R&D performers by sector. Between 1982 and 1987 the pharmaceutical sector had 30.4% of its firms performing R&D. In contrast, the manufacturing sector only averaged 5.1% over the same time period.

Another good indicator of the relative importance of R&D across sectors is a comparison of rates of growth in R&D. Between 1981 and 1990 the total expenditures on intramural R&D (in constant dollars) in the pharmaceutical sector grew each year, on average, by 13.6%. For the entire manufacturing sector the equivalent figure is 5.4%. This result indicates that the pharmaceutical sector is ahead of the remainder of the manufacturing sector in both the level and growth of R&D.

This document also looked at some of the underlying factors which affect the R&D decision making processes of firms in the pharmaceutical industry. A survey of the location and research facilities of U.S., U.K., German and Swiss pharmaceutical multinationals shows that the largest share of research activity is performed in the home country and a large portion of the remaining R&D is done in another large developed country.

In general, R&D is conducted in the corporate headquarter's home country to foster closer linkages with overall corporate policies. Surveys of pharmaceutical companies indicate that the main factors influencing the location of R&D within a country include:

* proximity to the company's headquarters
* proximity to the main pharmaceutical production unit
* attractiveness of the location for research staff, and
* the availability of suitable premises and site.

This study illustrates that the most important factors determining the location of R&D are related to internal characteristics of the firm.

Finally, it is important to note that the world structure of the pharmaceutical industry has been changing and it will continue to do so throughout the 1990s. The world trend in R&D appears to be towards expansion. More and more companies are investing a greater percentage of their revenues into the R&D of new chemical entities. Evidence was presented which shows that the major countries conducting pharmaceutical R&D had reached an average level of R&D to sales ratio of 12.7% in 1987/88. Such evidence has led some commentators to suggest the possibity that Canada is only getting the share of an incresed R&D pot that it would have received in any event.

I. INTRODUCTION

The changes to Canada's Patent Act in 1987 in respect of compulsory licensing of patented medicines were made, amongst other reasons, to bring about greater levels of pharmaceutical research and development (R&D). In response to this legislative change the Pharmaceutical Manufacturers Association of Canada (PMAC) made a public commitment to increase R&D expenditures as a percentage of sales to 8% by the end of 1991, and to 10% by the end of 1996 from the existing level of 4.9% (as established by a PMAC survey of its member companies). The following analysis will make extensive use of data collected by the Patented Medicine Prices Review Board (PMPRB) as well as information from Statistics Canada and other foreign statistical agencies.

As noted, prior to the enactment of Bill C-22 in 1987, research by the PMAC indicated that the R&D to sales ratio for the pharmaceutical industry as a whole, including non-patented R&D and sales, was 4.9%. Using this figure, in combination with the average sales of the pharmaceutical industry between 1983 and 1986 one can surmise that only $150 million was spent yearly on R&D during the early and mid 1980s. This result will be compared to the figures available from Statistics Canada in a later section of the paper.

II. DOMESTIC R&D LEVELS

A. Board Data

Companies with active Canadian patents pertaining to a medicine sold in Canada are required by the Patent Act to report R&D expenditures on medicines to the Board. It is important to note that reported R&D expenditures include only those expenditures that would have been eligible for an Investment Tax Credit in respect of scientific research and experimental development as allowed under the provisions of the Income Tax Act in effect as of December 1, 1987 plus an allowance for depreciation of new (post 1987) capital expenditures.

Each company must also report total revenues from the Canadian sales of all medicines. This data enables the Board's staff to determine the R&D expenditures to sales ratio for each company and the industry as a whole. The results of these calculations for 1988, 1989, and 1990 are presented in table 1 of Annex A. It should be noted that the definitions used by the Board and by the PMAC in its pre-1987 survey are similar. There are differences in definitions of sales and companies required to report but these are considered minor in impact.

As one can see, total R&D expenditures by reporting patentees have gone from $165.7 million in 1988 to $281.3 million in 1990. At the same time sales revenues increased from $2,718 million in 1988 to $3,203 million in 1990. This means that, for all patentees, the R&D to sales ratio has risen from 6.1% to 8.8% in this space of two years. The largest increase in R&D expenditures came in 1989 when the total amount spent by all patentees rose by 47.7%.

For those companies which reported to the Board that were also members of the PMAC, the numbers are slightly different. The R&D to sales ratio for the PMAC patentees went from 6.5% in 1988 to 9.2% in 1990. This is ahead of the promised level of 8% by 1991 so it appears that the commitment to a 10% R&D to sales ratio by 1996 will also be met. Individual company R&D to sales ratios are presented in Annex B.

The difference between the R&D levels reported currently by the Board and the PMAC may be indicative of the extent of the difference that would be determined if the PMPRB definition could be applied to the original PMAC survey that established the 4.9% level. If this is true, the 4.9% level would likely be an overestimate of what the Board would have reported. These differences will be explored with the PMAC and the Board, but given their likely small impact they are not important to this analysis.

The following table provides an indication of progress by the innovative sector to meeting the overall R&D commitment.

Table 2: PMAC R&D Commitment

YEAR	PRE-1987 R&D RATE	PRE-1987 AMOUNT	ACTUAL R&D RATE	ACTUAL AMOUNT	DIFFERENCE IN DOLLARS
1988	4.9%	$123.2m	6.1%	$165.7m	$42.5m
1989	4.9%	$145.7m	8.2%	$244.8m	$99.1m
1990	4.9%	$157.0m	8.8%	$281.3m	$124.3m
Total Increment					$265.9m

With regard to the type of research being conducted there is also evidence of improvement. Prior to any discussion of these results it is important to define what types of research are performed.

Basic Research - this consists of scientific investigations for which no immediate practical applications are envisaged (for instance intramural company and university laboratory research).

Applied Research - this work is directed towards some practical application and in most instances represents clinical trials.

In 1988 only 19% of all R&D reported to the Board was basic research. By 1990 this figure had risen to over 26% to represent an expenditure of approximately $70 million. Applied (clinical) research represents the remainder and the majority of all R&D done in Canada (almost two-thirds) with the balance being classified as other qualifying research.(See Table 2 in Annex A).

The groups performing this R&D can be seen in table 3 of the Annex. For the most part, as expected, patentees do the majority of the R&D. However, it seems that other research companies and universities/ hospitals are beginning to perform a greater percentage of the R&D which is conducted in Canada.

The funds for this research come, for the most part, from the patentees themselves. In all three years for which the Board has prepared an annual report, patentees have funded more than 97% of the R&D that has been performed domestically. The remaining funds come from federal and/or provincial governments and other sources.

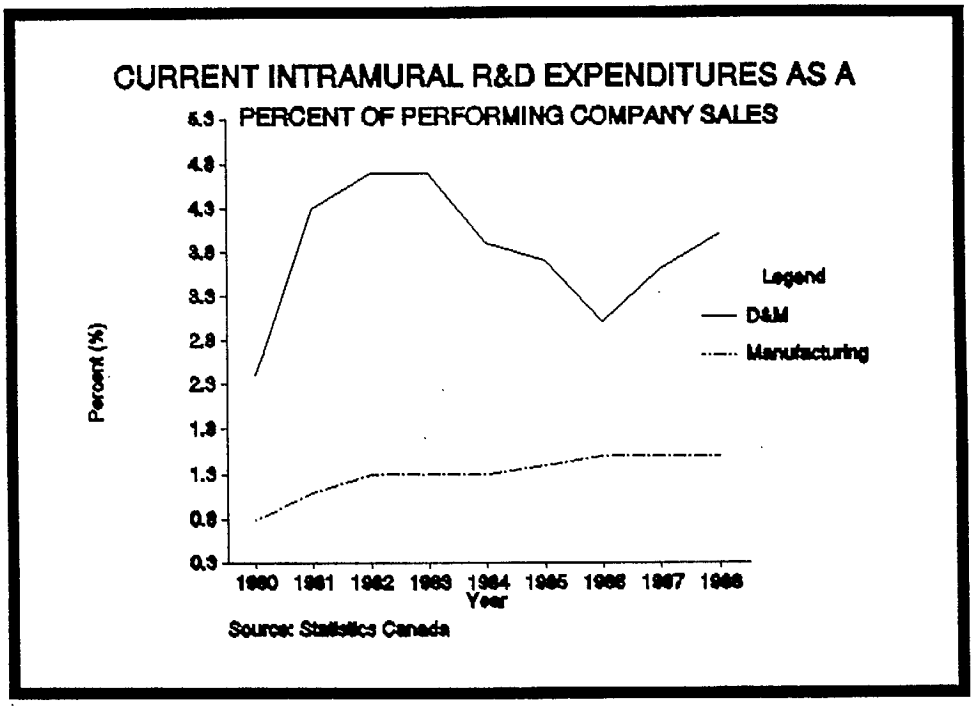
The most striking, but not surprising, aspect of pharmaceutical R&D performed in Canada is the location of this research. Table 4 in the Annex shows that Quebec and Ontario consistently attract the greatest amount of R&D. This makes sense because the large population base these two provinces have, together with the associated and very necessary university/research hospital structures, provide the infrastructure needed to carry out both basic and applied R&D.

B. Statistics Canada Data

Since the Board has its own unique definition of the pharmaceutical industry, it is not valid to use it's data to compare and contrast the pharmaceutical industry with other domestic manufacturing sectors. As an example of the variation in results between the Board and Statistics Canada consider the information available for 1988. In that year, Statistics Canada calculated an R&D to sales ratio for the pharmaceutical sector of only 4.4 per cent, while the Board found this ratio to be 6.1 per cent. In any event, the Statistics Canada data is considered adequate to illustrate intersector differences.

The difference in this figure arises out of three variations in the methodology used by these two agencies. First, they do not report on R&D expenditures for the same group of firms: the Board does not include firms without active Canadian pharmaceutical patents in its definition of the "drug industry". Second, the definitions of these expenditures on R&D, and sales, differ slightly between the two sources. Third, and related to the second reason, the Board, unlike Statistics Canada, includes extramural research as part of the total R&D expenditures for this sector.[1] For these reasons the following analysis makes use of Statistcs Canada data only.

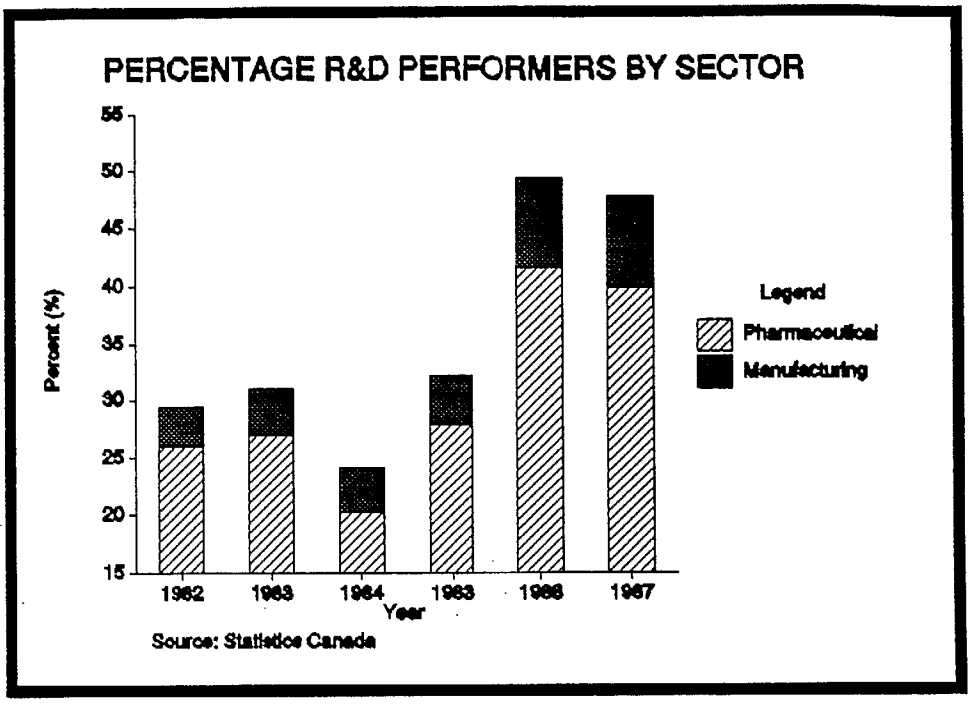
When compared to other manufacturing sectors the pharmaceutical sector is relatively R&D intensive. Throughout the 1980s the drug sector performed two to three times as much intramural R&D[2] when compared with the manufacturing sector as a whole. This is clearly seen in the graph presented below.



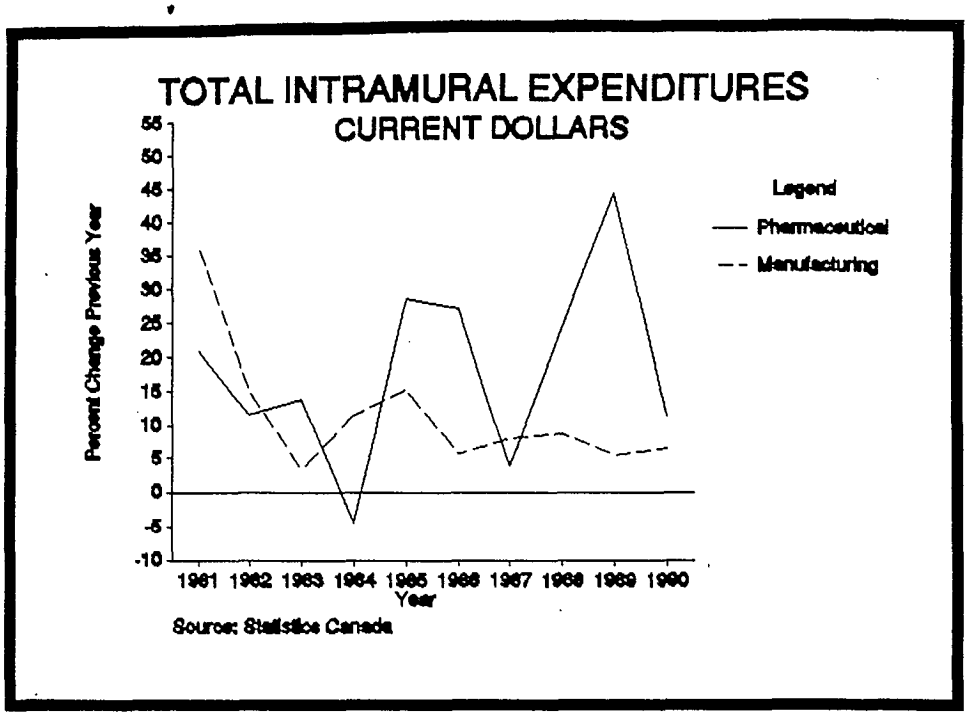
[1]Extramural R&D expenditures are, as defined by Statistics Canada, funds expended by one statistical unit for R&D which was performed by another unit.

[2]Current Intramural R&D expenditures include labour costs and other current costs for R&D, such as non-capital purchases of materials, supplies and equipment.

This can also be seen when one studies the percentage of R&D performers by sector. Between 1982 and 1987 the pharmaceutical sector had 30.4% of its firms performing R&D. In contrast, the manufacturing sector only averaged 5.1% over the same time period. These differences would be enhanced of course, if the Statistics Canada definition were such that the extensive clinical trials conducted by the highly regulated pharmaceutical sector could be included.



Another good indicator of the relative importance of R&D across sectors is a comparison of rates of growth in R&D. Between 1981 and 1987 the total expenditures on intramural R&D (in current dollars) in the pharmaceutical sector grew, on average, by 14.48%. For the entire manufacturing sector the equivalent figure is 13.61%. This result indicates that the pharmaceutical sector is ahead of the remainder of the manufacturing sector in both the level and growth of R&D expenditures. The figures after the passage of Bill C-22 show an even starker comparison. Pharmaceutical R&D has increased to a yearly average of 26.71% from 1988-1990, whereas manufacturing intramural R&D has decline to an annual average of 6.96% over the same time span. Overall it seems apparent that the pharmaceutical sector is achieving excellent returns from its R&D efforts and firms will continue, if at all possible, to expand their efforts to develop new chemical entities.



III. INTERNATIONAL R&D LEVELS

A. Evidence On The Level Of R&D Across Countries

The Board is currently conducting a survey on the level of R&D in those countries listed in the Patented Medicine Regulations. These countries are: France; Germany; Italy; Sweden; Switzerland; the United Kingdom; and the United States.

The preliminary indication is that differences in definitions, methodology, and the definitions of the universe used between the various international data sources prohibit any statistically meaningful direct comparisons of figures to either Statistics Canada or Board data. Instead, any comparisons should be restricted to examining the changes in each country's levels of R&D to sales ratio over time, and not comparing Canadian with foreign data from any given year.

Furthermore, in any comparison of international data, Statistics Canada and not the Board figures are more pertinent. This is because Statistics Canada base their R&D definitions on the "Frascati Manual" (OECD) as do most other foreign statistical agencies. The Board definition, in contrast, is based on the Revenue Canada definitions of R&D expenses.

R&D data are presently being collected directly from the foreign counterparts of Statistics Canada. Results should be available some time this fall.

While the above-noted definitional and methodological differences cannot be dismissed, the claims of higher R&D levels in other countries necessitate that the data reported for those countries at least be examined. Such data for 1987/88 was reported by SCRIP, an international periodical on the industry, in one of its publications and referred to by the Canadian Drug Manufacturers Association in a presentation to the National Advisory Council on Pharmaceutical Research (see below for additional information on the Council). The following table, extracted from the CDMA presentation, indicates where some countries were believed to be in terms of R&D to sales ratios for 1987/88.

Table 2: International R&D-to-Sales Ratios

Country	Average R&D to Sales %
U.S.	12.4%
Japan	10.4%
EEC	14.4%
West Germany	12.5%
U.K.	10.7%
Switzerland	15.4%
France	14.4%
Italy	11.4%

As noted, these numbers cannot be compared directly to reported Canadian levels for several reasons. It will be necessary to conduct further detailed analyses of the structural differences between these data and that reported for Canada before comments can be provided.

B. Factors Affecting The Location Of R&D Activities

At this point it is useful to consider some of the underlying factors which affect the R&D decision making processes of firms in the pharmaceutical industry. R&D is highly centralized in order to achieve the synergies of creating multidisciplinary teams and economies of managing such teams. A survey of the location and research facilities of U.S., U.K., German and Swiss pharmaceutical multinationals shows that the largest share of research activity is performed in the home country and a large portion of the remaining R&D is done in another large developed country (Burstall et al, 1981).

In general, R&D is conducted in the corporate headquarter's home country to foster closer linkages with overall corporate policies. It may also be performed at home because of its orientation on basic or applied research which is not directly related to individual product lines. Surveys of pharmaceutical companies indicate that the main factors influencing the location of R&D within a country include:

* proximity to the company's headquarters
* proximity to the main pharmaceutical production unit
* attractiveness of the location for research staff, and
* the availability of suitable premises and site (Howells, 1983).

This study illustrates that the most important factors determining the location of R&D are related to internal characteristics of the firm.

Usually, the original function of an affiliate R&D facility is adaptive research design of dosage forms, supply of analytical methods and standards, and technical support to manufacturing facilities. The functional progression from adaptive research to creation of new technology of a pharmaceutical product is predetermined by the scope of the research activity in the home country. The past profitability of research conducted by affiliates, demonstrated ability to undertake research and its self-financing capabilities are crucial in accessing corporate funds for basic and applied research.

Clinical research is the most widely distributed form of R&D internationally. The location of this work is determined by such factors as relative costs, regulatory approval regimes and legal requirements in certain countries that tests be conducted locally (Pazderka, 1985).

Canada has a number of positive features to attract investments in the pharmaceutical sector but it must be emphasized that these features are not all unique or superior to what is offered in other important locations. In addition there are a number of limitations in Canada that reduce the possibility for innovative potential in the Canadian pharmaceutical sector. Two of these factors are the small size of the Canadian market and the absence of firms with minimum efficient size of laboratories. Furthermore, the extent of foreign ownership in Canada's pharmaceutical sector affects the amount of R&D done in the following ways:

* Invisible imports of technology via the multinational corporation that displaces domestic innovation

* Multinationals react to unfavourable domestic policy (ie. compulsory licensing) by reducing the share of their global R&D done in Canada (Pazderka, 1985).

Two other studies point out the possible limited gains that may be acheived from the use of public funds to support pharmaceutical R&D in Canada. First, McFetridge and Warda(1983) suggest that it may not be rational to support R&D with taxpayers money when the technology can be developed in one location and used without compensation in many others. Second, an OECD study(1984) stated in its summary on the Canadian pharmaceutical industry that " the results of innovation from parent corporations have been so readily available and so economically attractive in the short term that the growth of national innovative technological capacity has been severely inhibited".

These comments must be considered in the light of the level of intellectual property protection provided to pharmaceuticals in Canada and the value of promoting domestic innovative capacity.

IV. NATIONAL ADVISORY COUNCIL ON PHARMACEUTICAL RESEARCH

This Council, which was formed by the Minister of National Health and Welfare for the purpose of advising him on methods to stimulate pharmaceutical research in Canada, has made note of a number of deficiencies in the infrastructure available for purposes of training researchers and for conducting research. Among these is the inability of universities to update existing facilities or to build new ones that are claimed as needed to create a satisfactory future climate for pharmaceutical R&D in Canada.

Discussion by the Council has examined the balance between basic and clinical R&D in the pharmaceutical sector and noted that basic research has not increased as much as the university community desired under the 1987 amendments. In part the Council acknowledges that absorption of a significantly greater part of the R&D increase of the last four years would be difficult. However, the Council has also noted that this occurs because of the very problem outlined above.

The Council is scheduled to report to the Minister of Health and Welfare in late 1991 or early 1992. Its recommendations are expected to touch upon the direct subject under consideration in this analysis, the impact of the 1987 amendments to the Patent Act on the current level of R&D, and also upon infrastructure and definitional failures of the current legislative system that impact on Canada's future as an attractive R&D site. The analysis in this paper, together with the Council's recommendations are expected to contribute significantly to the debate on Canadian competitiveness.

V. CONCLUSION

The world structure of the pharmaceutical industry has been changing and it will continue to do so throughout the 1990s. The world trend in R&D appears to be towards expansion. More and more companies are investing a greater percentage of their revenues into the R&D of new chemical entities. The table presented earlier in the paper shows that the major countries conducting pharmaceutical R&D had reached an average level of R&D to sales ratio of 12.7% in 1987/88. Such evidence has led some commentators to suggest the possibity that Canada is only getting the share of an incresed R&D pot that it would have received in any event.

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ANNEX A: PMPRB R&D Data

TABLE 1: TOTAL R&D EXPENDITURES AND R&D TO SALES RATIOS

Year	Companies Reporting	Total R&D Expenditures	% Change from Previous Year	Total Sales Revenues ($M)	% Change from Previous Year	R&D to Sales Ratio	
						All Patentees	PMAC Patentees
1990	63	281.3	14.9	3,203.6	7.7	8.8%	9.2%
1989	66	244.8	47.7	2,973.0	9.4	8.2%	8.1%
1988	66	165.7	NA	2,718.0	NA	6.1%	6.5%

Note: Total expenditures include capital equipment expenditures and allowanble depreciation expenses.
Source: Patented Medicine Prices Review Board, first, second and third annual report.

TABLE 2: CURRENT R&D EXPENDITURES* BY TYPE OF RESEARCH

Type of Research	1990		1989		1988		% Change 1990/1989	% Change 1989/1988
	($M)	(%)	($M)	(%)	($M)	(%)		
Basic Research	70.1	26.3	53.5	23.4	30.3	19.1	30.9	76.6
Applied Research	161.1	60.6	143.3	62.7	106.6	67.2	10.9	34.4
Other Qualifying Research	34.7	13.1	31.8	13.9	21.7	13.7	7.5	46.5
Total	265.9	100.0	228.6	100.0	158.6	100.0	16.3	44.1

Source: Patented Medicine Prices Review Board, second and third annual report.
Note *: Current expenditures exclude capital and depreciation expenses

TABLE 3: CURRENT R&D EXPENDITURES* BY R&D PERFORMERS

Number of Performers	1990		1989		1988		% Change 1990/1989	% Change 1989/1988
	($M)	(%)	($M)	(%)	($M)	(%)		
Patentees	134.3	50.5	134.0	58.6	95.8	60.4	0.2	39.9
Universities & Hospitals	67.5	25.4	55.1	24.1	37.4	23.6	22.5	47.3
Other Companies	47.5	17.8	21.8	9.6	NA	NA	117.9	NA
Others	16.6	6.3	17.7	7.7	25.4	16.0	(6.2)	55.5**
Total	265.9	100.0	228.6	100.0	158.6	100.0	16.3	44.1

Source: Patented Medicine Prices Review Board, second and third annual report.
Note *: Current expenditures exclude capital and depreciation expenses.
Note **: Numbers form "Other Companies" and "Others" were added from 1989 (21.7 + 17.7) to get this ratio
Number in parentheses represent negative values.

TABLE 4: CURRENT R&D EXPENDITURES* BY LOCATION OF R&D

Location of R&D	1990		1989		1988		% Change 1990/1989	% Change 1989/1988
	($M)	(%)	($M)	(%)	($M)	(%)		
Atlantic Provinces	3.4	1.2	3.1	1.4	1.9	1.2	9.6	63.2
Quebec	126.0	47.3	98.3	43.0	71.8	45.3	28.2	36.9
Ontario	114.6	43.3	106.7	46.7	72.2	45.5	7.4	47.8
Western Provinces	21.9	8.2	20.5	9.0	12.7	8.0	6.8	61.4
Canada	265.9	100.0	228.6	100.0	158.6	100.0	16.3	44.1

Source: Patented Medicine Prices Review Board, second and third annual.
Note *: Curent expenditures exclude capital and depreciation expenses.

ANNEX B: Company R&D to Sales Ratios

Table 1: International R&D-to-Sales Ratios

Country	Average R&D to Sales %
U.S.	12.4%
Japan	10.4%
EEC	14.4%
West Germany	12.5%
U.K.	10.7%
Switzerland	15.4%
France	14.4%
Italy	11.4%

Table 2: Canadian Generic R&D-to-Sales Ratios

YEAR	R&D Spending	R&D-to-sales Ratio
1980	$2.2 million	per cent
1981	$2.7 million	per cent
1982	$3.4 million	per cent
1990	$ million	11 per cent

Table 3: Progress on PMAC R&D Commitment

YEAR	PRE-1987 R&D RATE	PRE-1987 AMOUNT	ACTUAL R&D RATE	ACTUAL AMOUNT	DIFFERENCE IN DOLLARS
1988	4.9%	$123.2m	6.1%	$165.7m	$42.5m
1989	4.9%	$145.7m	8.2%	$244.8m	$99.1m
1990	4.9%	$157.0m	8.8%	$281.3m	$124.3m
Total Increment					$265.9m

ANNEX C: Statistics Canada Data on R&D

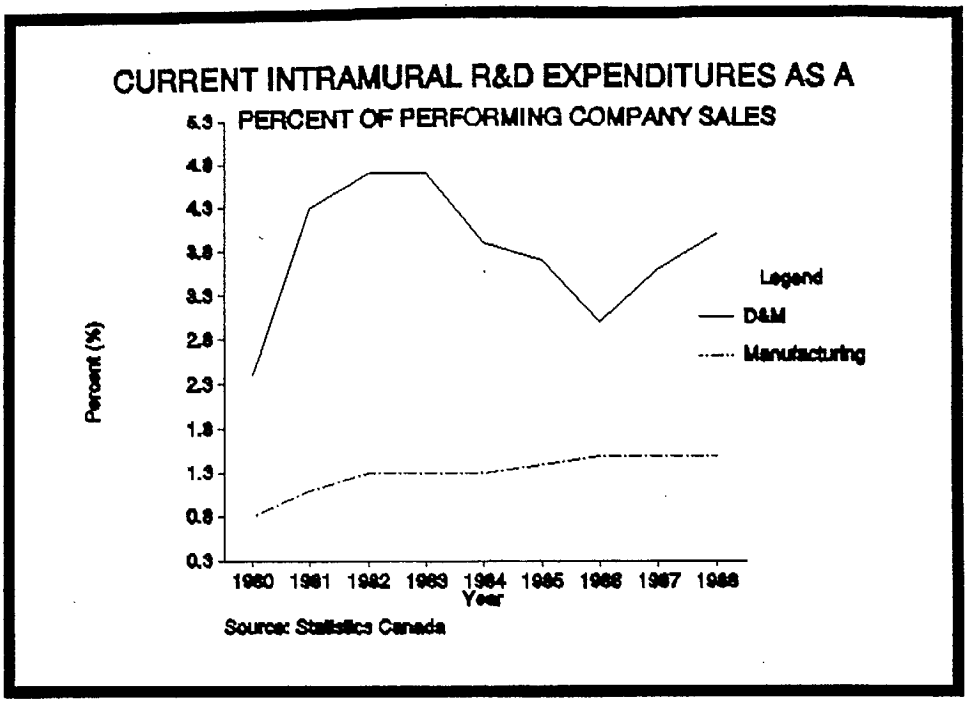

Figure 1

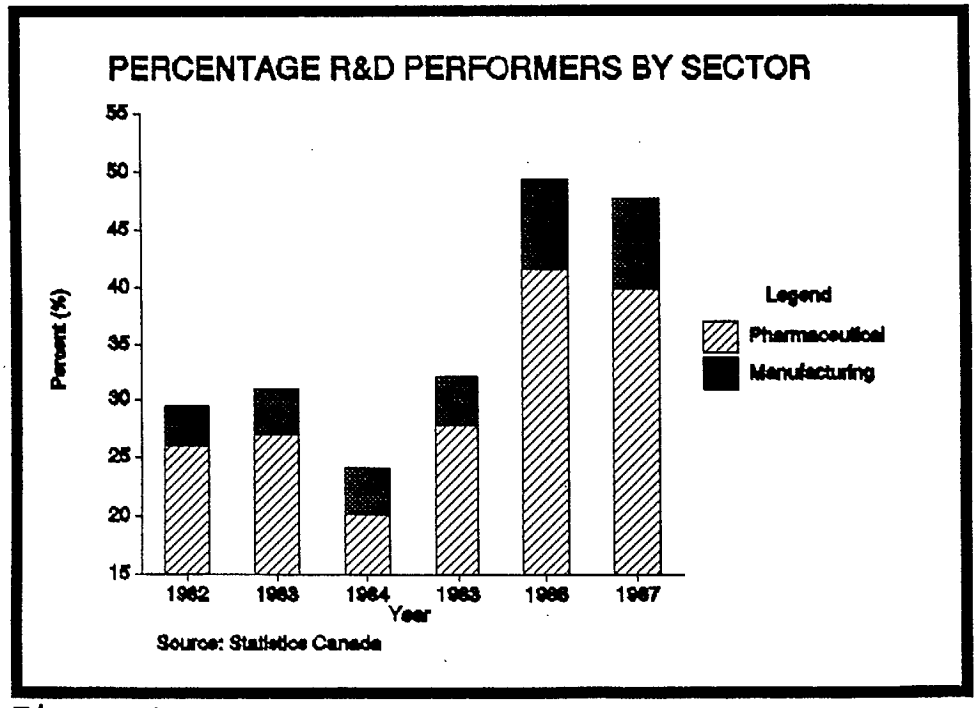

Figure 2

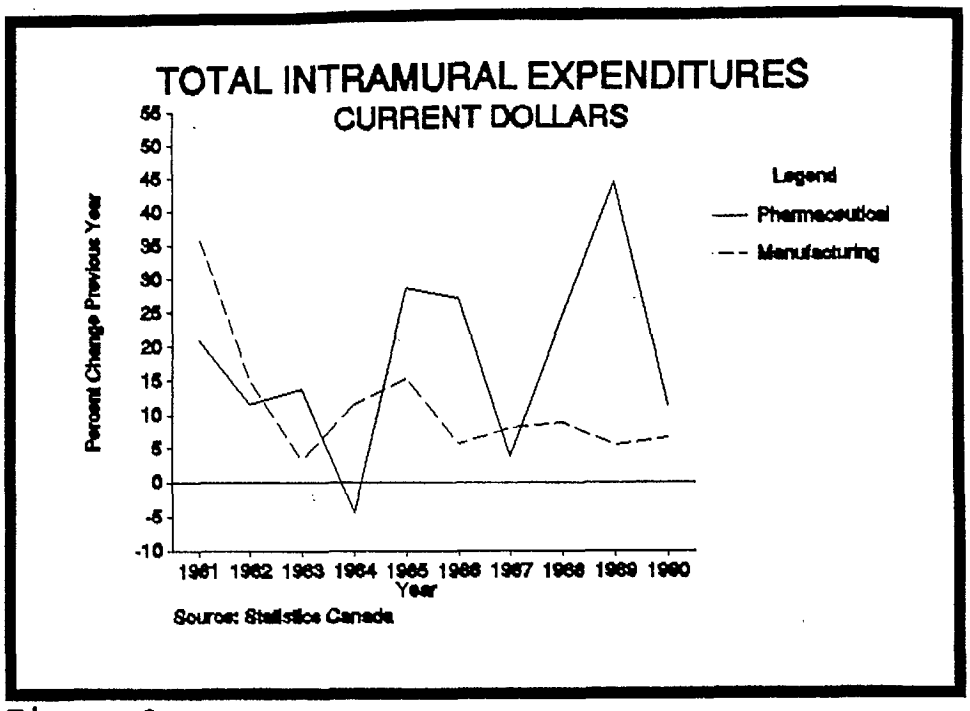

Figure 3

ANNEX D: Glossary of acronyms and abreviations

CDMA	:	Canadian Drug Manufacturers Association
D & M	:	Drugs & Medicine
OECD	:	Organization for Economic Cooperation and Development
PMPRB	:	Patented Medicine Prices Review Board
PMAC	:	Pharmaceutical Manufacturers Association of Canada
R & D	:	Research and Development
U.K.	:	United Kingdom
U.S. (USA)	:	United States (of America)

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