

International Experience with Pharmaceutical Policy: Common Challenges and Lessons for Canada

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Executive Summary

Purpose

Pharmaceuticals are the focus of increased scrutiny by public insurers. Between 1985 and 1998, drug expenditure in Canada increased by 226% - approximately double the increase in total expenditure on health. Prescribed and non-prescribed drugs now comprise the second-largest share of health care expenditures after hospitals, surpassing physicians' services. The National Forum on Health called for common strategies across the provinces, to manage pharmaceuticals from a health policy perspective. At the same time, the federal government and several provinces are interested in promoting pharmaceutical research and development (R&D), as part of the advancement of a knowledge-based economy. In the past, debates about pharmaceutical policy centred on the balancing of cost-containment and access to needed pharmaceuticals. The creation of an environment more conducive to attracting pharmaceutical R&D introduces additional tensions that will, no doubt, require concessions in current policies to manage pharmaceutical expenditures. In addition, a significant R&D investment will have predictable "downstream" effects on other sectors, such as academic research.

In this study, we describe the experience of 7 Western industrialized countries in controlling pharmaceutical budgets while maintaining access to medically necessary prescription medications. In addition, we describe the potential impact of these policies on pharmaceutical R&D and the efforts of these countries to create a favourable climate for fostering R&D within their borders. We identify tensions that arise between health policy and industrial policy goals, and broad questions of directions and choices.

Target Audience

Government decision makers managing health and industrial policy around pharmaceuticals.

Synopsis of Methods

The study was carried out in three phases. Phase 1 consisted of a literature review of pharmaceutical utilization trends and methods to manage pharmaceutical budgets in OECD countries. This was followed by focused analyses, using a structured data collection tool, on 7 target countries: the United Kingdom, Sweden, Germany, the Netherlands, France, Australia, and New Zealand. Phase 2 consisted of semi-structured face-to-face interviews with key stakeholders and key informants in each of the selected countries. This included: government bureaucrats, insurance program administrators, representatives of industry associations, physicians' associations and colleges, pharmacists' associations and colleges, and consumers' associations, and individuals in academic and institutional settings who have studied pharmaceutical policy. In Phase 3, we synthesized the information gathered and conducted additional reviews of the literature to address emergent issues that were not covered in our initial analysis.

Main Findings

Health Policy Issues

- In all countries studied, expenditures on pharmaceuticals are growing at a greater rate than overall expenditures on health care.
- In all countries studied, except the Netherlands, there is no significant role for private insurance for pharmaceuticals.

- All countries studied use a mix of strategies to manage pharmaceutical expenditures.
- There has been little formal evaluation of the success of these strategies. The studies that do exist are primarily descriptive.
- All countries studied regulate prices either directly or indirectly. However, their ability to negotiate price concessions is diminishing. Like Canada, many other countries consider the prices in other countries when negotiating introductory prices with manufacturers. In recent years, manufacturers have been successful in negotiating higher introductory prices with countries that have historically had lower than average prices, so that new products are listed at prices closer to the world mean. In exchange, these countries have negotiated price-volume concessions. For example, Australia has reduced levels of remuneration for some products if volume exceeds a certain level. France has a global rebate system for expenditures beyond targeted growth in annual expenditures. Consequently, there is a convergence in the listed world prices.
- Recognizing that a major factor associated with increased expenditures is increased prescribing of newer more expensive medicines, insurers are placing increasing emphasis on restricting access to these medicines through measures well known to Canadian public insurers: positive and negative lists, reference-pricing, practice and practice guidelines.
- Especially contentious with industry are policies to restrict access to particular pharmaceuticals, through either positive or negative lists and attempts to induce price competition across therapeutically similar products through therapeutic reference-based pricing.
- Pharmacoeconomic evaluation is also being adopted more widely by public insurers across countries to evaluate the added benefit and costs of a new treatment. This has a mixed reception by industry. On the one hand, pharmacoeconomics is increasingly being adopted by firms in the drug development cycle to direct decisions about the economic viability of a new product. On the other hand, industry is concerned that this could effectively become a “fourth hurdle” for the marketing of new products.
- The introduction, in recent years, of a number of high-priced “lifestyle” drugs with large potential markets (e.g. sildenafil for impotence) has precipitated debate over just what *should* be an insurable benefit in a public insurance program. Public input has not been well addressed, to date, but is “on insurers’ radar screens” in several countries.
- All countries studied make use of consumer cost-sharing for pharmaceuticals. Concessions for low-income individuals are commonplace. Cost-sharing grew substantially in the 1990’s, in response to fiscal constraints, and currently averages 25% to 30% of prescription costs. Drug plan administrators believed that the level of cost sharing is unlikely to increase. Critics of cost sharing for health care services, including drugs, suggest that such policies can adversely affect health. We are unaware of any studies outside North America examining the effect of consumer cost sharing on health outcomes. However American and Canadian studies suggest that, among financially disadvantaged individuals, and those with mental disabilities, there is an adverse effect of even modest co-payments on utilization of essential medications and cost shifting to other health care budgets.
- Three of the countries studied – the United Kingdom, Germany, and New Zealand – negotiate or assign prescribing budgets with physician groups. The incentive structures of these policies differ. Evaluations of their effectiveness in managing costs are inconclusive, due to problems with evaluation methods.
- Risk sharing: Australia and New Zealand engage in price-volume contracting that renders the manufacturer liable for prescription drug expenditures in excess of forecasted levels. France uses a combination of (a) overall expenditure targets and rebates for over-expenditure, and (b)

individual contracts with firms, as a form of industry risk-sharing. In the United Kingdom, industry is financially liable for profits in excess of an agreed upon level.

Industrial Policy Issues

- The pharmaceutical industry is second only to aerospace in intensity of R&D globally. The high-risk nature of research has led to an evolution, through mergers and acquisitions, of a handful of large multinational firms that, collectively, cover between 40% and 60% of national markets in the more developed countries.
- The past 20 years has also witnessed the emergence of a large number of small to medium-sized research-intensive biotechnology firms that are developing new tools for drug discovery and development. It is unclear how the research-intensive biotechnology firms and the established multinationals will interact in the future.
- Patent protection is a cornerstone of pharmaceutical R&D. It provides a period of market exclusivity in return for full disclosure of the innovation. In recent years, there has been considerable harmonization of patent laws across countries. Several issues are identified around patents:
 - The patenting of gene sequences raises important questions regarding the terms on which scientific knowledge can be owned and has stirred debate on whether such liberal granting of patents will actually stifle (rather than promote) research, due to increased litigation.
 - Patent extension for new uses of products already marketed is likely to grow. In the absence of a written diagnosis or indication on the prescription, this creates problems with knowing when generic substitution is permissible.
 - In addition, recent disputes over intellectual property rights for pharmaceuticals and the prices of lifesaving drugs (e.g. for HIV/AIDS) in developing countries have raised ethical tensions, and a search for solutions that would allow for price discrimination without fear of parallel importation into the West.
- In the past decade, Europe has fallen behind the United States in terms of growth and productivity in pharmaceutical R&D. Several features of the American environment have been identified as contributing toward the American competitive advantage:
 - A high level of public funding of basic biomedical research, coordinated in a more centralized fashion, through the National Institutes of Health,
 - The ready availability of investment capital,
 - The ready flow of knowledge between university laboratories, start-up research firms, and large pharmaceutical firms, combined with a ready movement of an ample supply of scientists and technicians across firms and between university and private sector environments,
 - Strong patent laws, particularly in the area of biotechnology, and
 - An unregulated pricing environment.
- Conscious of migration of investment capital for pharmaceutical research and development to the United States, considerable efforts are being made at the level of the EC and in the United Kingdom and Germany to make the EU environment more conducive to attracting R&D funding, particularly in the area of biotechnology. This includes the encouragement of more market-based mechanisms for financing of pharmaceuticals and health care in general – i.e. deregulation.

Tensions between Health and Industrial Policy

- Every dollar in drug plan expenditures is a dollar of income for those who manufacture, deliver and distribute these drugs. Therefore, tensions naturally exist in the areas of price and utilization

control. Tensions are intensified when the few “blockbuster” drugs on which firms rely to recover R&D costs across all products and to garner profits are the very focus of public insurers’ attempts to contain pharmaceutical expenditures, through price or utilization management.

- In the European Union, the European Commission is responsible for industrial policy while Member States have purview over health and social insurance. To create a more industry-friendly environment, the European Commission is encouraging Member States to harmonize their prices and to remove barriers to market entry once marketing approval has been granted - either through the centralized or decentralized (mutual recognition) process. This is being resisted by Member States, as they are responsible for pharmaceutical budgets.
- The creation of an environment conducive to increased R&D investment on the part of the pharmaceutical industry is likely to constrain insurers’ ability to manage costs – e.g. through increasing access to newer more expensive pharmaceuticals. On the other hand, the inducement of aggressive price competition – particularly across therapeutically similar products – is likely to reduce the readiness of industry to invest locally in pharmaceutical research and development.
- The pharmaceutical industry generally acknowledges the need for public insurers to manage costs but aggressively opposes attempts to accomplish this through either exclusion of products from reimbursement or attempts to induce price competition across therapeutically similar products. This includes the use of restrictive formularies, reference-based pricing and recommendations from influential technology assessment bodies such as the National Institute for Clinical Excellence (NICE) in the UK and the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia. This has important implications for the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) and similar groups in Canada.

Implications and Recommendations for Canadian Policy

An integrated approach to policy making in the context of pharmaceuticals is particularly complex. Government has several roles – chiefly, as public insurer, in regulating marketing access, and as promoter of local industry investment, with competing objectives evident among these roles.

In the past, Canada has not been a serious contender globally in attracting substantial R&D funds from the pharmaceutical industry. Since the European Union is interested in recouping much of its lost R&D to the United States, competition for attracting these funds will be steep and industry will look to see which jurisdiction offers the best investment climate. Given the competition for R&D investment dollars, the kinds of concessions that the pharmaceutical industry will seek in exchange for greater investment will be substantial. These include:

- strengthening of patent laws,
- more rapid listing of products as insurable benefits and fewer restrictions on the subsidy of new products in public insurance programs, and
- freer pricing of these products.

These will have major implications for drug budgets and will have domino effects on other sectors. Many of the emerging tensions that will arise are ethical and political in nature. Therefore, attention needs to be given to priority setting, with opportunities for stakeholder representatives to come together to debate broad (and intersecting) questions around:

- Balancing public and private interests
- Defining the limits of insurability – particularly with regard to the medicalization of lifestyle issues
- What is the role for cost-sharing for pharmaceuticals in Canada? How do we reconcile its inconsistency with the Canada Health Act?

- What should be the role of the insurer *vis-à-vis* the medical profession with regard to managing appropriate utilization of pharmaceuticals?
- Strategies for creating an attractive market for pharmaceutical industry investment.
- Implications of commercialization in the academic sector
- Patents, parallel trade, and less developed countries – what are the moral responsibilities for Canada and other more developed countries in ensuring affordable access to life-saving medications?

It is beyond the scope of this paper to recommend the process for addressing these policy issues. However, given that promotion of pharmaceutical R&D investment will have a substantial impact on our ability to manage pharmaceutical budgets, cross-representation across portfolios in discussions is essential.

Globalization in the pharmaceutical industry, the ready movement of investment capital, and international trade agreements make it difficult for any one nation to create responses that reflect unique social or cultural values. The proposed solution common to many reports issued in recent years is to resolve tensions around pharmaceutical policy through deregulation of the market for pharmaceuticals. While this would make for an environment friendlier to research and development, in the United States – the country that most fully embraces this approach – the cost of pharmaceuticals has become a major public policy concern over the past two years, with the least equitable and most expensive system among developed countries.

Distinctly lacking from much of the current policy process is a systematic evaluation of the impact of policies introduced on desired and undesired shifts in health care expenditures and health outcomes. While recognizing that many other variables factor into policy-making, a more systematic approach to evaluation of policies can help inform future policy debates and is strongly encouraged. Such evaluation needs to be carried out at arm's length to both government and industry.

In addition, the policy environment around pharmaceuticals is rapidly evolving. Ongoing reconnaissance with regard to international developments would be a distinct asset for decision-makers.

While the requirements to create a more investment-friendly climate in Canada are predictable, given stiff global competition for investment dollars, our ability to attract substantial investment capital once those changes are implemented remains uncertain. These, however, may be forecast. As there are multiple approaches that can be taken to promote pharmaceutical and biotech R&D in Canada, several options should be carefully explored, forecasting both the costs and benefits to be accrued, before a course of action is pursued. As discussed above, there is more than a monetary cost to be considered. Thus, the information generated through the forecasting exercise would become a part of the grist for the priority setting process suggested above.

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International Experience with Pharmaceutical Policy

Common Challenges & Lessons for Canada

1. INTRODUCTION

Pharmaceuticals are the focus of increased scrutiny by public insurers. They constitute a significant and growing portion of health care budgets. Between 1985 and 1998, drug expenditure in Canada increased by 226% - approximately double the increase in total expenditure on health care services. Prescribed and non-prescribed drugs now comprise the second-largest share of health care expenditures after hospitals, surpassing physicians' services.(1) Because they consume an increasing proportion of healthcare expenditures, pharmaceuticals make an easy target for cost-containment efforts. To the extent that pharmaceuticals are cost-effective substitutes for other health care services, then policies to curb spending on pharmaceuticals may be short sighted. On the other hand, much of the growth in pharmaceutical expenditures has been attributed to the prescribing of new more expensive therapies instead of older equally safe and efficacious drugs that are much less expensive.(2;3) This would argue in favour of closer scrutiny of pharmaceutical expenditures and, in particular, on the prescribing behaviour of physicians.

Pharmaceuticals also figure prominently in industrial policy in many nations, including Canada. Canada has an interest in promoting a knowledge-based economy.(4-7) The pharmaceutical industry is considered to be a particularly desirable employer or contractor for an increasingly well-educated workforce – whether in research, manufacturing, or marketing. In addition, the industry is engaged in a great deal of interaction with public sector researchers at numerous stages in the drug development process, contributing substantial funds to biomedical and clinical research in the academic research sector.

An integrated approach to policy making in the context of pharmaceuticals is particularly complex.(8) Government has several roles – chiefly, as regulator, public insurer, and as promoter of local industry investment, with competing objectives evident among and within these roles. In addition to having competing objectives, these functions are usually performed out of different Ministries and often at different levels of government. Moreover, the pharmaceuticals environment is in the midst of radical change. Genomics and biotechnology are revolutionizing the pharmaceutical research and development landscape and are likely to do the same in the marketplace.

In this paper, we focus on the public insurer and industrial-promotion functions of government and the tensions between them, placing these in the context of government's role as regulator of market access, protector of intellectual property rights, and guardian against anti-competitive practices.

2. OBJECTIVES

This study describes (a) trends through time within countries, and (b) similarities and differences across 7 Western industrialized countries in balancing the management of publicly-funded pharmaceutical budgets with access to medically necessary prescription medications. In addition, we describe the potential impact of these policies on pharmaceutical research and development (R&D) and the efforts of these countries to create a favourable climate for fostering R&D within their borders. We identify tensions

that arise between the goals of health policy and industrial policy, and broad questions of directions and choices.

3. METHODS

The study was carried out in three phases.

Phase 1 consisted of a comprehensive literature review of pharmaceutical utilization trends in OECD countries, methods to manage pharmaceutical budgets, and focused analyses on the 7 target countries, using a structured data collection instrument (Appendix 1). Target countries were selected from among highly developed industrialized countries having pharmaceutical benefits that are covered as an integral part of their national health programs. These 7 countries were chosen, with the assistance of key informants in pharmaceutical policy^a, to provide a broad variation in approaches to cost containment and level of pharmaceutical industry investment.

Phase 2 consisted of semi-structured face-to-face interviews with key stakeholders and informants in each of the selected countries. This included:

- government bureaucrats and administrators of insurance programs,
- representatives of industry associations, physicians' associations and colleges, pharmacists' associations and colleges, and consumers' associations, and
- individuals in academic and institutional settings who have studied pharmaceutical policy.

During these interviews, we addressed issues and questions identified in Phase 1, discussed additional issues identified by the informant, explored what may be “on the horizon”, and followed up on issues identified by previous informants. Interviews were conducted between December 1999, and October 2000.

During **Phase 3**, we synthesized the information gathered and conducted additional reviews of the literature to address emergent issues that were not covered in our initial analysis.

4. CONTEXT

4.1 Countries studied

We examined pharmaceutical policies in the United Kingdom (UK), Sweden, France, Germany, the Netherlands, Australia, and New Zealand. All these countries provide extensive public subsidies for prescription drugs to most of their residents. All have undergone substantial health care reform over the past decade. Below we briefly describe the countries, the organization of their health care systems, and some information on consumption of pharmaceuticals.

^a Panos Kanavos and Elias Mossialos, London School of Economics, University of London, U.K.

4.1.1 The countries and their health care systems

4.1.1.1 European Union Countries

The foundation of the European Union is liberalized trade – specifically the free movement of goods, labour, services, and capital across Member States, and the promotion of free competition.^b In the area of pharmaceutical policy, European Union (EU) countries have taken the following steps to harmonize regulation of markets:

- Efforts to establish a single market for pharmaceuticals, chiefly in the areas of marketing authorization, wholesale distribution, product classification, manufacturing practice, labelling and package inserts, and the establishment of a common European Pharmaceutical Databank.
- Freedom to purchase health goods and services across Member States (9;10)
- The establishment of laws prohibiting anti-competitive practices, and
- A common EU industrial policy (Fourth Framework and Fifth Framework programs, and patent protection).

Consistent with the subsidiarity principle,^c health insurance – and, therefore, questions of who is covered, what drugs are covered, and at what levels of subsidy – remains the sole purview of Member States.^d Recently, though, the European Commission has entered into health policy arena through its responsibility for public health.(11;12)

All the countries studied are characterized by heavy public subsidization of drug consumption amongst various beneficiary groups – more so than in Canada. Countries differ, though, in the financing and administration of their programs. The structure of the general and pharmaceutical insurance systems in countries under study is summarized in Table 1.

In the **United Kingdom**, the chief source of financing of the health care system is through taxes. General health and pharmaceutical policies are made at the national level. Until recently, budgets for pharmaceuticals were held by regional trusts. However, this is currently in a state of transition toward regional Primary Care Trusts.^e There is only a very small negative list at the national level. Under the public system, the entire population has coverage for pharmaceuticals. There is no significant role for private insurance for pharmaceuticals.

Sweden is also financed by tax revenues. These are generated at the local (County Council) level. Currently, pharmaceutical policy-making is carried out both at the national level and through County Councils. The national government has been attempting to devolve budget responsibility to County Councils since 1998. County Councils, however, have argued that they have been given insufficient control over the budget for

^b In the 1960's, there was a failed attempt to standardize social security systems.

^c Under the subsidiarity principle, government should not assume functions that individuals or private collectives address equally well or better. Similarly, government responsibilities should be devolved to the lowest level reasonable to accomplish the intended purpose.

^d Article 129 of the Treaty of Maastricht and Article 152 of the Treaty of Amsterdam

^e In theory, this gives physicians considerable prescribing latitude. However, locally, there is variation across Regional Trusts in the willingness to subsidize particularly expensive drugs. This phenomenon is known as “postcode prescribing”.(75)

pharmaceuticals to take on this responsibility. As in the United Kingdom, currently, there is no significant role for private insurance for pharmaceuticals.

Germany has a highly decentralized and complex system, financed chiefly through social insurance with contributions from employers and employees. Pharmaceutical policy making is carried out collectively through the federal Association of Sickness Funds. Local Sickness Funds – heavily regulated quasi-private insurers – manage revenues and budgets but ascribe to local physicians’ groups hard budgets with penalties for cost over-runs and to individual physicians indicative budgets.^f Below a certain income level, participation in the public social insurance system is mandatory. Approximately 9% of the population has opted for private insurance.

Currently, the **Netherlands** has a mixed public-private insurance system.^g In the public system, revenues are generated through social insurance contributions from employers and employees. Most policy making – e.g. development of a positive list, setting of price ceilings – is conducted at the national level through the National Health Insurance Council, with representation from professional associations, sickness fund associations, employers, and employees. Efforts are underway to encourage Sickness Funds to work with physicians and pharmacists to more actively manage benefits (e.g. through setting up of local formularies). Currently, approximately 2/3 of the population obtain their insurance through the public system.

In **France**, the health and social insurance system is in transition. Revenues are generated through either social insurance contributions by employer and employee or through employee taxes. Pharmaceutical policy is made at the national level. In contrast with the Netherlands, the local Sickness Funds have attempted in the past to take a more proactive initiative in managing pharmaceutical budgets but the government has chosen to maintain control at the national level. Therefore, local Sickness Funds function chiefly in a passive role as bill payers. While virtually 100% of the population are covered for pharmaceuticals under the public system, over 80% of the population subscribe to “Mutuelles”, a private insurance that covers the large co-payments charged in the public system.

4.1.1.2 Australia and New Zealand

Australia has a national health insurance system. Currently, the Commonwealth and the States have overlapping responsibilities in health care. The Commonwealth currently has a leadership role in policy making, particularly in national issues like public health, research, and national information management. It funds most medical services in the community setting, including subsidized pharmaceuticals through the Pharmaceutical Benefits Scheme. The states have jurisdiction over hospitals and in-hospital treatment. Funds are generated nationally, through general tax revenue and an income-related Medicare levy. Pharmaceutical policy is set at the national level, through the Pharmaceutical Benefits Scheme, which is also responsible for budgets for pharmaceuticals. While private insurance has been promoted by the Commonwealth^h, this is chiefly for private treatment in public or private hospitals. Currently, there is no significant role for private insurance for pharmaceuticals.

^f To date, there has been a failure to follow through on penalties for cost over-runs.

^g Between 1992 and 1995, all citizens were enrolled in the public plan.

^h Currently, approximately 1/3 of the population is covered by private insurance.

In **New Zealand**, funds for health care are generated nationally through income taxes. New Zealand has witnessed several waves of reform of its health care system in the past decade. Most recently, in January 1998, the national Health Funding Authority (HFA) was established, as an amalgam of the four Regional Health Authorities. Policies are set and programs and budgets are administered nationally. Pharmaceutical policy is set nationally, through the Pharmaceutical Management Agency Limited (PHARMAC). New Zealand has contracted with larger primary care organizations to manage either indicative or real pharmaceutical budgets, with different incentive schemes, depending on the nature of the fund-holding arrangement. While 40% of the population has private, non-tax deductible health insurance, there is very little private insurance for pharmaceuticals.

4.1.1.3 Comparison with Canada

Canada is unusual among Western nations with national health insurance programs, in that outpatient pharmaceuticals were not included in the publicly funded health insurance benefits package. As a result, during the 1970s, each province introduced its own prescription insurance program, outside medicare, with differing rules for eligibility, cost sharing, pharmaceuticals covered, and remuneration methods. In addition, private insurance coverage has grown, primarily as part of tax exempt employee benefit packages for full-time workers. The result is that Canada currently has a mix of public and private insurance for prescription drugs. Currently, the public sector provides coverage to approximately 25% of Canadians and accounts for 43% of all outpatient prescription expenditures. (13) Approximately 10% of the population has no prescription insurance coverage – either private or public.(14;15) Currently, the ten provinces and three territories account for approximately 88% of public expenditures on pharmaceuticals, primarily to senior citizens and those on social assistance.

4.1.2 Expenditures on health care and pharmaceuticals

Table 2 summarizes 1997 expenditures on health and on pharmaceuticals.ⁱ Figures 1 to 5 provide insights into trends in expenditures on pharmaceuticals between 1980 and 1997. The figures with the suffix “a” – e.g. Figure 1a – compare expenditures in Canada with: (1) average expenditures across the 7 countries studied, (2) average expenditures across European Union countries, and (3) consumption in the USA. The latter has been included in the figures as a comparator, as it is the extreme outlier internationally among highly developed countries. The figures with the suffix “b” – e.g. Figure 1b – provide individual country data.

Across countries studied, pharmaceuticals comprised between 10% (Netherlands) and 21% (France) of total expenditures on health in 1997. Per capita total expenditures varied two-fold from \$193 in New Zealand to \$418 in France (U.S. dollars, purchasing power parity). Canada ranked relatively high in total expenditures on pharmaceuticals, but ranked last compared with the 7 comparator countries with regard to public expenditures on pharmaceuticals as a percent of total expenditures. This reflects the high penetration of private third-party drug insurance in Canada.

Over time, both total and public per capita expenditures on drugs has been rising across all countries studied (Figures 1a, 1b, 2a, 2b). In the mid to late 1990's, there was a

ⁱ 1997 is the latest year in the OECD 2000 Health Data report (with the October, 2000 supplement) for which data were available across all countries.

levelling off in growth but, on the basis of our interviews, it appears that this may have been transient. Germany had a brief period of expenditure reductions commencing in 1993 (Figures 1b and 2b), due to price rollbacks and threats to make physicians financially accountable for expenditure over-runs. The levelling off of expenditures observed in France (Figures 1b and 2b) reflect the introduction, in 1996, of national spending targets (ONDAM) in which expenditure over-runs are “clawed back” at the end of the year and, thus, does not reflect actual utilization. In the Netherlands, the transient rise in public per capita expenditures between 1992 and 1995 reflect the short-lived universal public insurance (Figure 2b).

In most countries, over time, pharmaceuticals have consumed increasing proportions of total expenditures on health (Figures 3a and 3b). Exceptions are Germany, since 1993, and New Zealand, since 1995. The reductions in Germany are associated with the 1993 measures to reign in pharmaceutical expenditures to 1991 levels. The reductions in New Zealand reflect both the introduction of physician budget holding for pharmaceuticals and the aggressive price and utilization management tactics employed in that country.^j

4.2. Stakeholders and policy settings

A superficial analysis identifies two main stakeholders – government and industry – along with medicine, pharmacy, and the public. A closer examination, though, recognizes that each of these stakeholder groups represents several disparate groups, often acting in different policy settings, sometimes bickering, and aligning when necessary to address a common cause. In addition, any consideration of industrial policy must also take into account the academic research community, as there are very close links between industry and academia at all stages of the drug development process. In this section, we examine the dynamic between these stakeholders in the various policy settings. First, though, we briefly outline the many stakeholder groups represented under the umbrellas of “government” and “industry”.

4.2.1 Government and industry stakeholder groups

4.2.1.1 Government

Governments have three main roles in the context of pharmaceuticals: in regulating market access, as payer, and as promoter of local industry investment, with competing objectives evident among these roles.

Regulating market access: In all countries studied, for a pharmaceutical to receive market authorization, the manufacturer must demonstrate that the product is safe, efficacious for the intended purpose, and of high quality in manufacture. Regulatory processes to achieve this are described in Section 4.2.2.2.

Payer role: Among the 7 countries studied, public insurance was the sole or primary source of coverage for pharmaceuticals. The primary goal of public insurers is to reduce financial barriers to access for patients/consumers by subsidizing the cost of prescription drugs using public funds. Revenue constraints have dominated decision-making in the past decade, as governments have struggled to reduce deficits and to constrain

^j It should be noted that, until recently, prices in New Zealand were very high by comparison with the rest of the developed countries. Therefore, there was more room to negotiate prices down.

increases in taxes or premiums, in order to become globally competitive. The payer function will differ, depending upon whether budgets are administered directly by the government (or Sickness Fund) or indirectly, through the ascribing of fixed or indicative budgets to institutions (e.g. hospitals) or physicians.

Promoting industrial investment: The goal of industrial policy is to create an environment conducive to either pharmaceutical research and development (R&D) or manufacturing in their jurisdiction. Governments vary greatly in how they manage industrial policy. In the European Union, industrial policy generally is managed by the Directorate General (DG) for Enterprise. Much of pharmaceutical industrial policy is subsumed under this DG. Individual member states vary widely in efforts to promote industry investment. For example, in the U.K., pharmaceutical industrial policy is subsumed in the overall negotiations between brand-name manufacturers and the Department of Health through the Pharmaceutical Price Regulation Scheme (PPRS). In Germany, there appears to be no specific government department managing pharmaceutical industrial policy, though there is a clear strategy within the Industry portfolio to encourage the growth of the biotechnology industry. In Australia, the Commonwealth, through the Department of Industry, Science and Resources, has developed incentive programs to encourage pharmaceutical R&D. New Zealand appears to have little interest in promoting pharmaceutical industry investment, and therefore no structures to address this. Instead, it has concentrated its efforts on very aggressive measures to manage costs.

4.2.1.2 The pharmaceutical industry

The pharmaceutical industry is most often thought of in terms of brand-name and generic manufacturers. In Canada, each has its own association. However, in some countries (e.g. the U.K.), both generic and brand-name manufacturers may be represented by the same association and, in others (e.g. Germany) brand-name manufacturers may be represented by more than one association. While firms may turn to their associations to represent their political interests, ultimately, these firms are in competition with one another, so it is not uncommon for an individual firm (or collective of firms) to engage in independent lobbying efforts with government to meet specific interests. At the other extreme, with increased globalization of the industry, we are witnessing the emergence of the US Pharmaceutical Research and Manufacturers Association (PhRMA) as a global player in pharmaceutical politics.

The industry and individual firms have a long-term interest in promoting not only their products but also good will with those who may influence utilization and the policy agenda. This may be accomplished through a variety of means that may or may not be product-specific. These include: sponsoring of physician symposia and continuing education programs, assisting patient interest groups with lobbying insurers for coverage for particular medications, and general advertising of the benefits of pharmaceutical innovation.

Manufacturers of generic drugs are interested in drawing away market share of highly successful drugs from the brand-name firms once patents have expired. In recent years, the distinction between generic manufacturers and brand-name manufacturers has blurred. Some generic manufacturers are spin-off companies of brand-name manufacturers. These often get a "head start" by the brand-name manufacturer, in preparation for product launch, so as to corner the generics market for that product.

4.2.2 Policy environments

There are two main environments out of which policy issues arise: the research and development (R&D) process and the market. Bridging these is the product licensing process that oversees the transition of the product between these two environments. Below we describe these environments, the interactions among stakeholders, and issues that arise from these. In the case of the R&D environment, we are drawn into a discussion of the U.S. R&D environment, as developments in the United States have a strong influence on the R&D environment in other countries across the globe.

4.2.2.1 Pharmaceutical R&D

The pharmaceuticals industry is the second most R&D intensive industry in the world, second only to the aerospace industry and followed by computers and electronics. (16) It is characterized by long lead times and a high rate of failure to reach market. Among products that do make it to market, approximately 70% fail to repay their capitalized R&D investments.(17;18) Thus, a very limited number of successful products must repay the fixed R&D costs associated with the products that fail to reach market or to recover costs of development. To manage this high (though predictable) risk of failure, there has been an evolution, through mergers and acquisitions, toward a handful of large multinational firms that, collectively, cover between 40% and 60% of national markets in the more developed countries. One rationale for these mega-mergers is to increase the number of new chemical entities in the pipeline to replace the missing sales of those that will be going off-patent in the future and to manage the risks associated with a high product failure rate. However, this conventional wisdom has been called into question.(19)

The past 20 years has also witnessed the emergence of a large number of small to medium-sized research-intensive biotechnology firms that are developing new tools for drug discovery and development. By far, the leader in biotechnology is the United States, followed at a distance by the United Kingdom and Germany. Canada and Australia are still relatively new to this market.

Increasingly, to reduce the massive overhead of R&D, large pharmaceutical firms are either:

- contracting out research to smaller specialized research organizations,
- entering into collaborative agreements in which they trade financing and marketing support against research resources of dedicated biotechnology companies, or
- licensing of successful products from biotechnology firms or acquiring biotechnology firms with very promising products in the pipeline.

The net result is that the risks associated with R&D are being transferred from the large pharmaceutical firm to smaller research organizations and their shareholders.

In the past decade, Europe has fallen behind the United States in terms of growth and productivity in pharmaceutical R&D. Whereas R&D investment has doubled in Europe, it has tripled in the United States.(20) European-based firms are investing in US scientific bases, and the recent mergers among European and American multinational firms have resulted in the net migration of head offices to America. Several features of the American environment have been identified as contributing toward this competitive advantage(20):

- A high level of public funding of basic biomedical research, coordinated in a more centralized fashion, through the National Institutes of Health,

- The ready availability of investment capital,
- The ready flow of knowledge between university laboratories, start-up research firms, and large pharmaceutical firms, combined with a ready movement of an ample supply of scientists and technicians across firms and between university and private sector environments,
- Stronger and more liberal patent laws, particularly in the area of biotechnology, and
- An unregulated pricing environment.

Conscious of this growing gap, considerable efforts are being made at the level of the European Commission and in the United Kingdom and Germany to make the European Union environment more conducive to attracting R&D funding, particularly in the area of biotechnology. This includes the encouragement of more market-based mechanisms of financing of pharmaceuticals and health care in general.(11;12;21)

Patents

In recognition of the high risk of failure associated with drug development, the pharmaceutical industry commands a high rate of return on investment. Because fixed R&D costs are so much greater than manufacturing costs, patent protection is a key incentive for manufacturers to engage in R&D. By granting market exclusivity for a set period of time, they allow inventors to profit from their research in return for a complete description of the invention, so that others may build on that invention.

In the majority of patent legislation across countries, there are five statutory classes of inventions that are patentable (22):

- processes,
- machines,
- products – i.e. objects made by machines or humans,
- compositions of matter (including chemicals, and combinations of chemicals, and
- new uses of any of the above

The pharmaceutical industry tends to use composition claims most often, but may also apply for a process, product, or new use claim.

In addition, the five classes of invention must be:

- useful – i.e. not a theoretical phenomenon or idea
- novel – something that no one has done before
- unobvious to a person having ordinary skill in the art to which the subject matter pertains, and
- nothing that is contrary to public morality.

Emergent issues

Challenges to compulsory licensure: The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), established at the Uruguay Round of negotiations, sets out, as a requirement for membership in the World Trade Organization (WTO), the obligation to grant patent protection. Under this agreement, countries must grant patents, for a minimum of 20 years from the date of filing of an application for approval, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness. Less developed nations have been granted until 2005 to come into compliance with TRIPS. Though compulsory licensing is not specifically mentioned in TRIPS, Article 31 sets out circumstances that would allow

for compulsory licensing of products for public health emergencies (e.g. the devastating consequences of the HIV/AIDS virus in some less developed countries).(22) Despite these provisions, the brand-name pharmaceutical industry has challenged in court South Africa's application of these provisions and its importation of generic antiretroviral therapy for HIV/AIDS.(23)

Patent extension through new uses: In the past, patent extension was often sought through the development of new dosage forms for existing products – e.g. in sustained-release formulations. The “new uses” claim for patents may come into greater use in the future. A current example is that of sertraline (Zoloft). The initial approved indication for the drug was depression. However, it has recently been approved for two new indications – obsessive compulsive disorder and panic disorder. As the patent for the original indication expired in Canada in 1999, a generic can be substituted, but only for the indication of depression.(24) To avoid patent violation, the pharmacist must have either a written diagnosis of depression on the prescription, or equivalent verbal information from the physician or patient before the pharmacist can dispense the generic product. This issue of patent extension for new uses is likely to grow in the future, as the “statins” (currently indicated for hypercholesterolemia) appear to be effective in treatment of osteoporosis and COX-2 inhibitors may have a role in prevention of colon polyps and in the treatment of Alzheimer's disease. The budgetary implications for insurers is potentially enormous.

Genomics and the limits of patentability: Developments in genomics and biotechnology have redefined the limits of what is considered patentable and what is knowledge in the public domain. While there is general agreement that the human genome itself is not patentable, there remains controversy over gene sequences – i.e. subsets of the genome. In both Europe and America, a patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. According to the 1998 European Biotechnology Directive, simple discovery and isolation of gene sequences is not patentable, on the grounds that the invention must demonstrate real world utility. Until the draft utility guidelines were issued in December 1999, the U.S. Patent and Trademark Office (PTO) was much more liberal in granting patents, resulting in the patenting of gene sequences for which no purpose was known. For example, Human Genome Sciences, a private American firm, was awarded a patent for a protein that turned out to serve as the entryway for the AIDS virus to infect cells – even though the company did not know the actual function of the gene at the time of patent application. Nevertheless, the firm is now entitled to royalties on any drug that targets this protein.(25) The American guidelines on utility, finalized in January 2001, tighten substantially the utility criteria. Even with the tightened utility requirements, the patenting of gene sequences continues to generate considerable controversy in the scientific community and among politicians in both North America and in Europe, on both practical and philosophical grounds. Critics have argued:

- That nobody should own or control something so basic to nature as the genome.
- That mere discovery of gene sequences – even if their utility is known – is not equivalent to inventing,
- That patents should be limited to methods of using DNA rather than to DNA itself, and
- That patenting of the genome could actually inhibit rather than speed up the development of applications, due to increased incidence of court disputes.

Patenting of the genome has been likened to a “land grab” and to patenting of the alphabet or a page ripped out of a book rather than the book itself.(25) This liberalization

of the patent environment has prompted at least one serious suggestion that applied clinical knowledge and pathologic diagnoses be patented.(26)

Time pressures induced by patents: Because a patent application is filed at the beginning of the product development cycle, innovator-firms have a strong interest in minimizing the time to market. This puts intense pressures on the R&D cycle and the marketing approval process. In the R&D cycle, the time required to complete Phase 3 clinical trials has increased steadily.(27) One way in which industry has managed this – particularly in the United States – is by outsourcing of clinical trials management to private contract research organizations.(28) Another approach has been to combine Phase 2 (dosing) and Phase 3 (efficacy) trials, by incorporating multiple dosing schedules into Phase 3 clinical trials. In recent years, industry has managed to expedite the marketing approval process in several countries through financing (in whole or in part) the costs of the process (Table 3).

Industry and academia

Pharmaceutical discovery involves a complex reciprocal interaction between industry and academia.(29) While this can create a very fertile environment for discovery, increasing concern is being voiced in the United States over the side-effects of commercialization of the academic research enterprise from wet lab to clinical studies.

In the wet lab environment, for example, the University of Rochester was granted a broad patent for its discovery of the gene in humans that is responsible for producing the COX-2 enzyme. (30;31) This entitles the university to royalties on the sales of any drugs using that enzyme. Since COX-2 inhibitors are the next “blockbuster” drugs for inflammatory diseases, Rochester University anticipates revenues in the hundreds of millions of dollars from this discovery. With decreasing revenues from public sources, the reliance on income streams from basic discovery raises many concerns, not the least of which is the future of “open science” in universities. Some have argued that such liberal granting of patents may actually slow down research progress, as increasing resources go into resolving patent disputes in court.(32-34)

In the area of clinical research, concerns have been voiced over increased competition between clinical investigators and private contract research organizations for the business of running clinical trials, and the increased incidence of clinical trials being run by investigators with financial conflicts of interest. They argue that this greatly increases the potential for conflict of interest in the recruitment of research subjects and in the reporting of adverse events associated with an investigational therapy.(28;35-38) Some have questioned the impartiality of academic experts’ judgments, if substantial portions of their work has been funded by the private sector.(39) As a result, in the Fall of 2000, the Department of Health and Human Services in the United States announced broad reforms to increase scrutiny over clinical research in the United States.(38) and a call for the establishment of a national policy on conflicts of interest for academic medical faculties.(37)

4.2.2.2 Product licensing – the bridge between R&D and the market

Decisions to license a pharmaceutical for marketing are based on evidence of safety, efficacy, and quality of manufacture. Currently, there is no need to prove “value added”^k

^k Beyond proof of safety, efficacy, and quality of manufacturer – current requirements for product licensing – insurers are increasingly looking for additional product benefits, such as lesser costs

over existing products on the market in order to receive marketing approval.¹ Through the International Conference on Harmonization (ICH), technical requirements for demonstrating quality, safety, and efficacy of new medicines have been almost fully harmonized throughout the European Union, United States, and Japan.(40) However, some differences in regulatory criteria remain.(41)

In Australia and New Zealand, this function is carried out at the national level. In the EU, since 1995, marketing authorization may occur through either a centralized body, the European Medicines Evaluation Authority (EMA), or through a decentralized process among Member States known as “mutual recognition”.(40) The centralized process is required for all biotechnology-related innovations and for significant new chemical entities. A comprehensive evaluation of this new European marketing approval process has recently been published.(42) Overall, the parallel processes were favourably reviewed, though concerns were voiced over transparency in the centralized process and compliance among Member States in the mutual recognition process.

The trend, in recent years, toward financing of the review process in whole or in part through manufacturer levies (Table 3) increases the pressure on government regulators to produce timely decisions. This pressure is compounded through the bidding process that occurs among EU Member States, should a manufacturer decide to pursue marketing authorization through the mutual recognition process. This bidding process has raised concerns among many regulators in EU Member States with respect to potential safety implications.(43)

4.2.2.3 The market for pharmaceuticals

In the industrialized world, there is a relatively small number of global firms dominating the market for pharmaceuticals, and a large number of small firms producing mostly for local or national markets. While no one firm holds a large share of the total pharmaceutical market, sub-markets tend to be dominated by a handful of firms. Because of this, regulators (i.e. European courts, the U.S. Federal Trade Commission) watch closely the mergers and acquisitions among the large pharmaceutical firms, and have intervened in circumstances where mergers would create monopolies in therapeutic sub-classes. For example, Smith, Kline & Beecham sold off three anti-emetic and antiviral products to Roche and Novartis to satisfy antitrust requirements in its merger with Glaxo-Wellcome.(44)

Historically, the competition induced by the introduction of additional chemical entities within a therapeutic class has been based not on price but on “quality” issues, such as side-effect profile and ease of use. There are several reasons for this. Insurance may render both consumers and prescribers price insensitive. This price insensitivity was perpetuated when insurers (whether private or public sector) acted as passive “bill payers”, passing on increasing costs through either increased taxes or premiums, or through deficit financing.

for the same outcome (cost minimization) or some tangible additional therapeutic benefit or outcome for the additional costs incurred, before that product will be subsidized. These additional benefits are often referred to as “value added”. This is usually a separate consideration from marketing authorization requirements, but not always. (See next footnote.)

¹ Prior to joining the European Union, marketing approval in Sweden could be conditional upon demonstrating added therapeutic or economic value over existing products on the market.

Over the past decade, insurers have become increasingly price sensitive. With this increased price sensitivity have come important shifts in the marketplace for pharmaceuticals. These include:

- Active efforts by insurers to induce price sensitivity on the part of both consumers and prescribers. For consumers, this has been achieved chiefly through cost sharing. For physicians, multiple methods have been employed, particularly feedback and budget holding.
- Attempts by insurers to become more active in influencing the prescribing process through:
 - Use of clinical practice guidelines, and
 - Developing more stringent criteria for inclusion of pharmaceuticals in the benefits package. This may include requiring more rigorous evidence on which to base claims of superior quality or outcomes, or justification of the additional benefits to be accrued for the additional costs.

These events have led to a decline in the decision making sovereignty of individual physicians, and also of the medical profession generally, as the consensus opinion of medical “experts” is challenged by demands for more evidence-based decision-making, based on average therapeutic effectiveness in a population. Consequently, tensions have grown between (a) insurers and prescribers and (b) insurers and industry.

In the EU, consistent with the subsidiarity principle, product pricing and determining the reimbursement status of a particular pharmaceutical are the sole purview of individual Member States. Historically, some of the Member States had used marketing approval and/or approval for reimbursement/subsidy within the public insurance program as a means of managing expenditures through either exclusion of products from market or as a lever for price negotiation.^m In addition, delays in bringing new products to local market defers the economic consequences on pharmaceutical budgets. Therefore, the “Europeanized” marketing authorization process, which stipulates that all Member States comply with approval decisions, has been a matter of contention within the EU, and compliance with marketing authorization decisions – whether centralized or decentralized – varies substantially across Member States.(12;42) This tension is compounded by the introduction a number of “lifestyle” drugs – e.g. for impotence, obesity, and alopecia.

From industry’s perspective, pressures in the marketplace are intense and growing. Despite reduced mean time for drug approval, the overall time to bring a product to market is increasing.(27) Since the time-limited patent protection period commences at the beginning of the product development cycle, this reduces the period of market exclusivity for products that do reach market. As discussed above, firms rely upon a limited number of highly successful drugs to repay their capitalized R&D investment. These “blockbuster” drugs are subject to intense competition from therapeutically similar products produced by other firms. They are also the focus of public insurers’ attempts to contain pharmaceutical expenditures – through price and/or utilization management. Sales distributions of these drugs are becoming increasingly skewed, with more rapid rates of growth after launch (due to heavy marketing) and in expected decline after patent expiry (because of increasingly vigorous promotion of generics). The net result is

^m For example, in Sweden, prior to joining the EU in 1995, a new pharmaceutical was not licensed for marketing if the manufacturer could not demonstrate superiority of the product over those currently on the market.

an increase in volatility in sales performance (18) and huge tensions between industry and public insurers regarding the speed and terms under which products are included as insurable benefits.

Direct-to-consumer advertising

In recent years, full direct-to-consumer (DTC) advertising by manufacturers has been permitted in the United States and in New Zealand. In the EU, currently, advertising of a particular pharmaceutical directly to the consumer is illegal. However, it is legal for manufacturers to provide information to patients that would raise awareness about management of a particular disease in general. DTC advertising of products is being studied in the EU, and is facing strong opposition by physicians and pharmacists.(45)

The internet, however, knows no national barriers. Consequently, DTC advertising available on American web sites is now freely available globally, subject only to local market penetration of the internet. By comparison with the funds infused by the industry in DTC advertising, public sector efforts to provide arm's length information have been very limited.

4.3 Summary of context

The environment that shapes policy-making around pharmaceuticals is complex and rapidly evolving. On the one hand, in recent years, the industry has witnessed mergers of unprecedented magnitude. On the other hand, there has been a proliferation of small and medium-sized enterprises, particularly in the area of biotechnology. Increasingly, research at all stages is being contracted-out. The evolving relationship between industry and academia and liberalized patent laws are changing the nature of academic research – particularly as it relates to commercialization of the research enterprise.

The two central policy actors are government and industry. Government performs 3 main roles: as regulator, as public insurer and (in some countries) as promoter of pharmaceutical industry investment. Public insurers are the most conflicted of actors in the pharmaceutical policy arena. Within their own portfolio, they must balance cost-containment and access to needed medications. In addition, public insurers may find themselves at cross-purposes with those in other government departments who are promoting industrial investment, particularly when accommodations are sought during negotiations with pharmaceutical firms or industry associations. In their attempts to manage budgets, insurers frequently come into conflict with both physicians and consumers, as restrictions are placed on what can be prescribed under the public insurance system (loss of autonomy for physicians and loss of choice for consumers) and consumers face increased cost-sharing.

The research-based pharmaceutical industry has a very focused interest in expediting the drug development and market authorization processes, to maximize the period of market exclusivity. The marketplace is becoming increasingly competitive, with intense pressures on a limited number of “blockbuster” drugs to recover R&D costs and earn profits. These very blockbuster drugs that draw manufacturers' profits are the focus of public insurers' attempts to contain pharmaceutical expenditures.

5. MANAGING PHARMACEUTICAL BUDGETS

A wide assortment of policy tools is available to public insurers to manage pharmaceutical budgets. Ham has likened these to a golfer's clubs – a specific club used for a particular purpose.⁽⁴⁶⁾ Typically, though, several of these tools are used simultaneously. Like pharmaceuticals, themselves, the combination of policies can produce additive or synergistic effects, or they can work at cross-purposes with unanticipated deleterious effects.

There are several ways in which these tools could be categorized – e.g. supply-side vs. demand-side⁽⁴⁷⁾ or stakeholder-focused (industry, physicians, and consumers).⁽⁴⁸⁻⁵⁰⁾ Each of these classification systems has its limitations, particularly when a policy tool has both supply-side and demand-side characteristics or when it affects more than one stakeholder. Table 4 summarizes the measures that the 7 countries in this study have used to manage pharmaceutical budgets. We take a slightly different approach, organizing policy tools into direct and indirect approaches.

Below, we examine these policy tools, considering what is known about their effects and side-effects and what may be on the horizon. We emphasize, though, the dearth of reports available that do anything more than describe events that have occurred. Evaluating the impact of these policies on drug expenditures, cost-shifting to other budget silos, and on health outcomes is extremely difficult. There are 3 chief reasons behind this.

1. Reforms – particularly in the 1990's – have tended to be multi-pronged, often occurring in rapid sequence. Thus, the effect of a particular policy may be confounded by another policy introduced at the same time or shortly thereafter.
2. Reforms have usually been introduced across the country at the same time, removing the opportunity for a concurrent control group with which to compare trends.
3. Several of the countries studied lacked the data to conduct evaluations of anything beyond crude drug expenditures. In Sweden, for example, data were de-identified early on, rendering it impossible to get any more than aggregate data for analysis. In Germany, the Netherlands, and France, prescribing information was kept on hundreds of databases.

We provide an overview across countries, drawing upon common trends and pointing out important exceptions. A systematic country-by-country analysis may be found in recently published reports.^(47;51;52)

5.1 Direct Approaches

From the supply side, there are 3 approaches commonly used by insurers:

- direct or indirect price regulation,
- limiting the products that are selected for reimbursement through positive lists (i.e. formularies that list products that are subsidized) and negative lists (i.e. lists of products that are not subsidized), and
- inducing price competition through a combination of promotion of generic drugs and therapeutic reference-based pricing.

The latter two approaches are usually used in combination. In addition, we discuss the special complementary role of pharmacoeconomic evaluation, which may be applied in price negotiations and as a criterion for product inclusion in formularies.

5.1.1 Direct and indirect management of price

All countries studied engage in price management of one form or another. Three of the countries – Sweden, the Netherlands, and France – actively negotiate or set drug prices that reflect prices in both public and private sector transactions. Australia and New Zealand both negotiate reimbursement amounts. In the United Kingdom, profits are regulated. In Germany, the reimbursement price of off-patent prescription drugs is reference priced.

New Zealand is the most aggressive of countries studied in pursuing price competition among manufacturers, leveraging a combination of: formulary inclusion, therapeutic reference-based pricing and exclusive tendering of products to bring prices down. However, this has created a climate that is not conducive to R&D investment. Australia, historically, has been the next most aggressive in pursuing lower prices, but the entry prices of products introduced in recent years are closer to world average. France has also had low prices historically. In return for higher entry prices for newer pharmaceuticals, both France and Australia have negotiated agreements with manufacturers that compensate for reduced concessions. These are discussed under “Risk Sharing” in Section 5.2.3.

International price comparisons are conducted as a formal part of pricing negotiations in Sweden and the Netherlands. France does not formally reference other countries in setting prices. However, it has become sensitive to the fact that prices were often much lower than other OECD countries and they are currently setting launch prices closer to the average European price. Although the United Kingdom does not regulate price, it conducts periodic reviews of comparative drug prices.⁽⁵³⁾ In making considerations about reimbursement levels, Australia takes into consideration the prices of drugs in “reasonably comparable overseas countries”.⁽⁵⁴⁾

Parallel trade in pharmaceuticals exists because of differences in pricing for the same drug in different countries. Among EU Member States, it comprises only 1% of sales but has become a major point of contention among the industry. The EC supports parallel trade within the EU, as it promotes price competition, but does not support the principle of “international exhaustion”, in which parallel trade extends beyond the borders of the European Union.⁽⁵⁵⁾

Diminishing ability to negotiate prices: By virtue of the growing awareness of prices in public insurance markets in other countries and the ease of parallel importation of pharmaceuticals from neighbouring countries, the pricing corridor for prescription pharmaceuticals – i.e. the difference between highest and lowest available prices – is steadily narrowing, leaving less and less room for public insurers to negotiate price concessions.

When a significant “breakthrough” product is introduced in the market, with rare exceptions, follow-up (“me too”) products tend to price very closely to that of the breakthrough product. This places heightened importance on the initial setting of the price of the first innovator product. With increasing numbers of countries engaged in international comparisons of prices, manufacturers are inclined to first introduce their product in a country that allows them to set relatively high prices.

5.1.2 Limiting the benefits package – positive & negative lists

An important cause of rising expenditures on pharmaceuticals is the shift in mix of pharmaceuticals prescribed – where more expensive, second line drugs are being prescribed in place of less expensive older first-choice medications.ⁿ In light of this, public insurers are increasingly turning to policies restricting the conditions under which these drugs may be reimbursed. The main policy instrument for restricting access to these second-line drugs is the use of positive or negative lists.^o

While a potent method of managing costs, there is also a high risk of creating unintended consequences, such as prescribing of less desirable substitutes and/or cost-shifting into budget silos for other health or social services, or onto the consumer. Thus, the net effect of restricted access to a particular drug may be to increase total systems costs. (56) Therefore, care must be taken to ensure that the results of utilization management efforts are consistent with good clinical practice. Achieving this balance requires a considerable investment in information infrastructure and human resources – an investment that insurers have generally been reluctant to make in the past.

All countries studied have some form of positive or negative list. (See Table 4.) Three countries rely upon negative lists at the national level – the United Kingdom, Germany, and Sweden. The negative lists in the U.K. and Sweden are quite small. However, lists of recommended drugs proliferate at the level of the County Council in Sweden and there is discussion that local formularies will be developed as Primary Care Groups in the U.K. evolve into Primary Care Trusts.

For several years, Germany has attempted to expand its negative list and to introduce a positive list. These efforts have met with stiff resistance on the part of manufacturers in Germany, largely through challenges in the European courts.(57-59) In part, this may be due to the proliferation of pharmaceuticals on the German market of unproven benefit, according to current requirements for evidence of efficacy.

Sweden represents a particularly interesting case study. Prior to joining the European Union in 1995, subsidy of pharmaceuticals in the public insurance program was closely tied to market approval. A product was not approved for marketing if it did not add value over existing products on the market. The close linking of market approval and subsidy continued after joining the EU. However, compliance with EU policies re: mutual recognition and centralized authorization of medications resulted in a large influx of medications under public subsidy. Currently, sildenafil (Viagra) for male impotence and orlistat (Xenical) for the treatment of obesity are the two largest budget items in Sweden's pharmaceuticals budget. In the Fall of 2000, the Edhag commission recommended that restrictions be introduced such that a drug be subsidized only if it is "cost-effective and at least as suited to its purpose as other comparable treatment alternatives".(60)

ⁿ For example, in the treatment of hypertension, a diuretic or beta-blocker may be considered to be a first-line treatment, while an ACE-inhibitor would be considered second-line.

^o A positive list is a written compendium of products that are insurable benefits under the insurance plan. In North America, they are usually referred to as formularies. A negative list delineates those products that are not insurable benefits under the insurance plan. Negative lists are usually used when there are relatively few products that are not covered.

5.1.3 Generics and therapeutic reference-based pricing

In the use of generic medications and reference-pricing, there is considerable potential for confusion over terminology. A generic medicine refers to “a prescription medication based on an active substance that is out of patent and which is marketed under a different name from that of the original branded medicine”.(61) Some generics use their own brand name. These are often referred to as “branded generics”. Others use only the generic or international non-proprietary name (sometimes referred to INN-generics). Some authors differentiate generics from “copy products”, the latter referring to replicas of drugs for which there is still patent protection. The term “reference-pricing” is used in some countries to denote subsidizing of therapeutically similar products at a common (reference) price and in others subsidizing of chemically identical products (i.e. generic equivalents) at the level of the least expensive product. For this report, we will refer to *therapeutic* reference-based pricing to denote the subsidizing of therapeutically similar products at a common level.

5.1.3.1 Generics

There is little controversy over the role of generic products. Because the active ingredient and bioavailability are the same as the brand-name product, generics compete head-to-head on the basis of price. The question then arises whether free-market competition or regulating minimum price differentials results is more successful in driving down price. Most countries studied regulate either the price or the reimbursement level of generics (Table 6). In our interviews, informants indicated that there was little price competition below the regulated price. In the USA, in a free-market environment, price was found to be inversely correlated with number of generic manufacturers.(62) This would suggest that a free-market environment for generics may result in lower prices. However, in the United Kingdom, where the market for generics is not regulated, prices for many generic products have risen by as much as 765% in 1999.(63) While this has been attributed, in part, to plant closures & relocation, and to the switching from bulk packs to individual patient packs in accordance with EU regulations, the Department of Health is investigating possible anticompetitive practices, and is examining price control options for generics.(64)

Most countries studied actively promote the prescribing and dispensing of generic substitutes of off-patent products. (See Tables 5 and 6.) However, use of generics varies widely across countries. Germany and the United Kingdom have been particularly successful at promoting the use of generics, at approximately 40% and 62% of volume, respectively.(61;63) France and Sweden have had relatively low market penetration for generics (under 10%). Among OECD countries, Senior and colleagues found no association between the number of policy instruments in place promoting use of generics and level of generic penetration in the market.(61) They conclude that the individual instruments themselves and how they are applied are the drivers of generic penetration in individual countries rather than the total number of such instruments. For example, physicians in Germany and the United Kingdom both manage budgets for pharmaceuticals. In the case of France, prices on brand-name products are already relatively low. Until recently, physicians were not constrained in their prescribing and pharmacies received larger mark-ups for dispensing higher-priced products. In Sweden, the attitude toward generics seems to be somewhat conservative. For example, while there may be local agreements between physicians and pharmacists allowing generic substitution, currently, the laws require that a physician actively authorize generic substitution on the prescription for substitution to occur.

Some countries – including: Canada, the USA, and Australia – permit the registration and limited production of generic products before patent expiry (Roche-Bolar provisions). This provision provides a speedier entry to market for generics, once a product's patent has expired.^p European generics manufacturers have expressed concern over the lack of similar provisions and the competitive disadvantage at which this places them. (65;66)

5.1.3.2 Therapeutic reference-based pricing

As mentioned above, therapeutic reference-based pricing (RBP) refers to the subsidizing of therapeutically similar products at a common level. Therapeutically similar products may include: all beta-blockers, all nitrates, all statin lipid-lowering agents, etc. Insurers defend the use of therapeutic RBP on the basis that there are essentially “class-effects” within these therapeutic categories or that these products are sufficiently therapeutically similar that selection of a product for reimbursement should be on the basis of price. Therapeutic RBP is practised in four of the seven countries studied. Therapeutic RBP is most vigorously pursued in New Zealand where patented products may compete with generics in the same therapeutic class and the reference price is the lowest in the category. In addition, agreements may be sought with manufacturers to cross-subsidize products, to reduce the reference price listed. Therapeutic RBP is applied quite broadly in Germany and the Netherlands. In Germany, the reference price is determined through a complicated statistical formula to fall near the mean price of the products available and, in the latter. A proposed new formula will place a ceiling reference price at the top of the lower 1/3 of products. In the Netherlands, it falls at approximately the mean price. In 1996, in Germany, the brand-name manufacturers won the concession to exclude from therapeutic RBP patented products introduced after January 1, 1997. By contrast, in the Netherlands, a product may be excluded from RBP not on the basis of patent but its degree of innovation. In Australia, therapeutic RBP is practised on a very limited set of therapeutic classes, with no exclusions for patented products and referencing at the lowest price. Where therapeutic RBP has been applied, prices of competing products have dropped substantially.

Therapeutic RBP is particularly contentious with brand-name manufacturers. They generally regard this as an infringement on patent protection and chilling to investment interests in a particular country. As mentioned above, Germany's concession was to remove patented products from reference pricing. While concern has been raised about possible adverse consequences to health or cost-shifting to other health care sectors, to date there has been no evidence to this effect.

5.1.4 Determining added value of new therapies

In all countries studied, public insurers expressed an interest in encouraging the introduction of new products that added a “significant” value over existing insured benefits. They were also concerned over the increasing blur between pharmaceuticals that are medically necessary and those that meet “lifestyle” purposes. A growing trend across countries is to employ some form of technology assessment to gauge the cost-effectiveness of new therapies. Below, we describe pharmacoeconomics and other

^p In March of 2000, the European Union successfully challenged Canada's practice of allowing generic companies to amass large stockpiles of medicines prior to patent expiry. Now, generic manufacturers will be able to stockpile sufficient product to develop the formula and have appropriate tests completed prior to patent expiry.

endeavours in these countries to address the difficult issue of added value of new therapies.

5.1.4.1 Pharmacoeconomic evaluation

General: Pharmacoeconomics applies principles of cost-benefit, cost-effectiveness, and cost-utility analysis to the use of pharmaceuticals.(67) Principles and methods for the economic evaluation of pharmaceuticals were pioneered in Australia and Canada. Pharmacoeconomics is a useful tool to help decision makers ascertain the most efficient approach to maximizing benefits under resource constraint. Its application does not necessarily result in reduced budgets for pharmaceuticals. The end result may be increased expenditures on pharmaceuticals with or without savings in other budget envelopes. With increased use, there is a growing sense of what are reasonable costs to expect to pay for marginal additional benefits (e.g. quality-adjusted life-years gained) offered by new therapies. Economic analysis of pharmaceuticals may be used by insurers in negotiations over price or reimbursement levels, as it facilitates comparisons across products based on firmer evidence of potential system-wide costs.

Limitations: While a useful instrument to help inform decision making, pharmacoeconomics has a number of limitations. It should not be regarded as a prescription for decision-making. Rather, it is only one input among many for determining what *types* of products to fund.(68) It is based on the philosophical perspective of utilitarianism, which is not always consistent with demonstrated societal preferences (e.g. the importance placed on life-saving technologies, as compared with preventative measures). Because the substitute and complementary health care services vary across countries, generalizability of findings across countries is severely limited. Also, over time, as the limits of an insurer's willingness to pay for set marginal benefits become revealed, there is the potential for manufacturers to price the product close to the limit of what the insurer considers to be the upper limit of an acceptable marginal additional benefit for the additional cost.

While formal economic evaluation of pharmaceuticals is on the increase, countries appear to be developing their own guidelines, rather than adopting those of the innovators (Australia and Canada). This may reflect the need for "re-invention"⁹ of this policy tool, a well-recognized step in the diffusion of innovation.

Use in countries studied: Australia and New Zealand make routine use of pharmacoeconomic evaluations in assessing new products for subsidy. In Australia, submissions prepared by manufacturers and adjudicated by the Economics Subcommittee of the Pharmaceutical Benefits Advisory Committee. Rules for submissions are very explicit and posted on the PBAC's web site. In New Zealand, economic analyses are conducted in-house, using cost-utility analysis. The degree of rigour of the analysis is contingent on the budgetary implications to PHARMAC, the insurance plan – a point of contention with manufacturers. In the United Kingdom, the National Institute for Clinical Excellence (NICE) reviews a limited selection of technologies annually (pharmaceutical or otherwise). An economic evaluation of the technology is included as part of the evaluation. At the time of interviews, the Netherlands was in an early stage of adoption of pharmacoeconomics in evaluating new pharmaceuticals and had just issued draft guidelines. In Sweden, the National Insurance Board made some limited use of pharmacoeconomic studies in the process of negotiating prices with manufacturers, but

⁹ Reinvention refers to the practice of taking an innovation and customizing it to meet local needs.

no official guidelines were in place at the time of interview. Officially, in France, there is currently minimal interest in formal pharmacoeconomic evaluation in decision-making over new pharmaceuticals, although this was being studied. However, in reviewing submissions from manufacturers, the Economic Committee for Medicines often had access to such studies and prices were often negotiated to an equivalent daily costs of treatment as products currently on the market. In Germany, there is no official use of pharmacoeconomic data in insurance decisions.

Pharmacoeconomic evaluation as a proprietary secret? A common practice across countries is for the manufacturer to stipulate that pharmacoeconomic data be treated as a proprietary secret and that the reason for rejection of a product from reimbursement also not be revealed. NICE in the U.K. is a notable exception. It is committed to transparency in its decisions, although some of the data included in manufacturers' submissions may still be deemed proprietary and not publicly available.

Industry response: In general, the pharmaceutical industry is ambivalent towards pharmacoeconomic evaluation. The chief concern is that this could become a routine "fourth hurdle" to overcome to become an insurable benefit, after satisfying market authorization requirements for safety, efficacy, and quality of manufacture. Despite continued resistance to economic evaluation being incorporated into subsidy decisions, there is now growing recognition that early incorporation of pharmacoeconomics into a firm's drug development lifecycle can be useful to help direct decisions as to the most likely products to produce a positive return on R&D investments and on competitive pricing of these products.(69) Consequently, there have been cases in recent years where Phase 3 clinical trials have been discontinued prematurely out of concerns over the economic viability of the product.(70)

5.1.4.2 Other Approaches

Apart from formal pharmacoeconomic evaluation, countries have used a variety of approaches to recognize innovativeness of pharmaceuticals, through pricing and formulary structures.

In **France**, prices for new medicines included on the positive list are negotiated between the manufacturer and the State, through the pharmaceutical economic committee (CEM). The CEM relies upon the decision of the Transparency Commission as to the added therapeutic value afforded by the new drug (Amélioration du Service Médical Rendu or ASMR), as compared with drugs currently being reimbursed. The Transparency Commission assigns a rating between 1 and 6. Products assigned a rating between 1 and 4 are considered for public reimbursement:

- Rating 1 – An innovative product with significant added therapeutic benefit
- Rating 2 – The product is a therapeutic benefit from an economic point of view
- Rating 3 – An equivalent pharmaceutical exists
- Rating 4 – The product is more economical but has a less significant effect than existing equivalents

Superior products (Rating 1) are allowed to command a higher price than products currently reimbursed. They are also exempted from the rebate system described in 5.2.3 below. Products receiving a rating of 2 are exempted from rebates for one year. Equivalent products (Rating 3) must not be priced above products currently reimbursed, and are subject to rebates. While pharmacoeconomic evaluations may be considered when negotiating price, the CEM does not officially recognize these.

Since joining the EU, **Sweden** has automatically subsidized all new products for which a selling price could be negotiated. The Committee on Reimbursement of Medicines recommended, in the Fall of 2000, that the government revert to its former system in which a drug must be cost-effective and at least as suited to its purpose as other comparable treatment alternatives currently subsidized, in order to be an insurable benefit. The Committee also recommended that a new independent government authority - the Pharmaceuticals Reimbursement Board - be appointed to assess whether or not a new medicine should be included in the reimbursement system and that existing medicines be scrutinized by the Board for suitability for reimbursement.

In **Germany**, patented products were granted an exemption from reference pricing, thus acknowledging innovations, independent of added therapeutic value. This was a negotiated policy, after initially including patented products in the referencing system. In the **Netherlands**, the reference pricing system has been tailored to discourage new products that are duplicative. In particular, products are exempted from reference pricing not on the basis of their patent status but the added therapeutic value they offer relative to products already subsidized.

5.1.4.3 Ascertaining the values of the public

As discussed above, the advent of “lifestyle” drugs such as orlistat for treatment of obesity and sildenafil for impotence have raised important questions about how to determine funding priorities. These two products were routinely available only in Sweden, and they were consuming a large proportion of the budget for pharmaceuticals. Moreover, in Sweden, the Committee on Reimbursement of Medicines has recommended that this practice be reconsidered.

Governments are only beginning to experiment with approaches to explicitly defining values. For example NICE in the United Kingdom plans to assemble a “citizens’ council” early in 2001 to determine public priorities.⁽⁷¹⁾ There are numerous challenges, not the least of which are: (a) how to identify individuals who are truly “representative” of the public and (b) how to present options in such a way as to avoid biasing respondents toward a particular endpoint. In the United Kingdom, there have been experiments with “citizens’ juries” and in Denmark with citizens’ consensus conferences.

5.2 Indirect Approaches

5.2.1 Physician-directed strategies

5.2.1.1 Physician budgets

Three of the seven countries studied - the United Kingdom, Germany, and New Zealand – have allocated drug budgets for physicians. Unfortunately, the effects of these budgets on overall health care spending and on health outcomes has not been well evaluated.

In the **United Kingdom**, the system of fund holding is in transition. In 1990, those physician practices with fundholding status (based on large practice size) were allocated prescribing budgets separate from other funds. Among other physician practices, indicative budgets were introduced at the level of the regional independent medical advisers, and attention was focused on high prescribers. As of April 1999, prescribing budgets have been merged with community and hospital service budgets at the level of the newly created Primary Care Groups (PCGs). These are formula-based and cash-

limited.(72) Savings realized in one budget envelope may be reallocated to other services. In addition, Primary Care Groups are evolving toward Primary Care Trusts that manage their budgets directly.(73) While this will allow physicians greater control (and accountability) for prescribing within budget, the 1999 reforms have shifted financial accountability from individual fundholding physicians to collectives of physicians through the Primary Care Groups. While it appears that fundholding practices initially experienced slower growth in prescription drug expenditures between 1991 and 1995, in the longer run, the growth in pharmaceutical expenditures in fundholding practices appears to run parallel to that in non-fundholding practices. Also, there appear to have been selection biases in the earlier waves of fundholders.(74) These early savings were accrued through a combination of: increased generic prescribing, limitations on prescription volume, the use of practice formularies, and improved prescribing information.(74) A concern that has arisen is regional variation in the reimbursement of particularly expensive drug therapies. This has been referred to as “postcode prescribing”.(75-77) The intention was that recommendations from NICE would obviate postcode prescribing. However, it has been argued that this cannot occur without central funding to implement NICE’s recommendations on expensive drugs such as taxanes.(78;79) The ability of physicians collectively (through Primary Care Groups or Trusts) to manage individual physicians’ prescribing behaviour is unknown at this time.

Drug budgets were first introduced in **Germany** in 1993, at the level of the federal physicians’ association, as part of a package of reforms aimed at reducing expenditures on pharmaceuticals. Under these reforms, the federal physicians’ association (as well as industry) was held financially accountable for over-spending. Were the 1993 drug budget exceeded, the physicians’ association would be responsible for repayment to a maximum liability of DM 280 million, after which the pharmaceutical industry was then liable up to a maximum of DM 560 million. The initial result was a precipitous drop of 30% in expenditures on prescriptions issued by office-based physicians. On closer examination, this drop could be attributed, at least in part, to shifting of treatment to specialists and in-hospital care.(80) In subsequent years, expenditures on pharmaceuticals continued to increase at the same rate as in the past. Currently, regional collectives are assigned fixed budgets and individual physicians are assigned indicative budgets. It is the responsibility of the regional physicians’ association to monitor and provide feedback to individual physicians on their prescribing behaviour. On paper, under fixed collective budgets, there is no reward for coming under budget but there are financial penalties for over-spending. Although budgets have been exceeded on several occasions, penalties have never been invoked. Clearly, such a policy that is not enforced will be ineffectual at containing costs.

In **New Zealand**, 80% of general practitioners are now members of primary care organizations (PCOs). There are four types of PCOs, the most predominant of which are the Independent Practitioner Associations (IPAs) that are coordinated over multiple sites and practices. Many of the PCOs have entered into agreements with the government to hold prescribing budgets. Most hold indicative budgets. Under indicative budgets, PDOs are advised of any cost over-runs but are not held financially liable. However, if the PCO spends less on pharmaceuticals than budgeted, it must share 50% of the savings with the government. Under fixed budgets, the PCO accepts 100% of the liability of cost over-runs and retains 100% of any savings from coming under budget. In the cases of both fixed and indicative budgets, surplus funds retained must be re-invested in the services provided by the PCO. In the past, budgets were based on historical prescribing trends. In 2000, the government signed a contract with IPAs to move to population based equitable funding for laboratory and pharmaceutical services for all GPs. In

addition, IPAs must now account for variation within and between associations.(81) The limited evidence available suggests that budget holding is associated with reductions of 5-10% in overall expenditures, and that it has had a greater effect on low-cost prescribers to a greater extent than it has on high cost prescribers. In addition, budgets have not reduced the wide variation across practices in per capita volume of prescribing.(82)

5.2.1.2 Role of information systems, feedback on prescribing, and practice guidelines

Whether or not physicians are responsible for drug budgets, feedback on prescribing behaviour – particular feedback on individual behaviour compared against either peer behaviour or best practice – is an important element in changing prescribing practices.(83) No country studied had an operational system of feedback for individual physicians on their prescribing behaviour. The challenge was especially great in Germany, the Netherlands, and France, where even collective physicians' profiles had to be compiled from the records of multiple sickness funds. There were promising pilot studies of computerized information systems for use in physicians' practices, but not in routine use.

All countries studied were engaged in the development of practice guidelines – either for the management of specific diseases or guidelines for appropriate use of specific drugs. In many countries, these guidelines were very sophisticated. However, consistent with the published evidence, dissemination and uptake into the practices of office-based physicians was uniformly weak. Practice guidelines alone are generally ineffective at changing physician behaviour. It is best if they are combined with feedback on one's own practice and/or delivered in a timely fashion in relation to prescribing decisions.(83;84)

5.2.2 Consumer cost sharing

The theoretical rationale for cost sharing is to counteract the market distortion that comes about through price insensitivity and consequent "moral hazard" on the part of the consumer and the prescriber. That is to say, an individual will consume more medicine if s/he does not have to face the cost of the prescription. Likewise, a physician may prescribe more (or more expensive) medicine if s/he knows that the individual has insurance coverage. Thus, one goal of cost-sharing is to increase patient awareness and accountability for the cost of pharmaceuticals and, thus, reduce the amount of "unnecessary" use of prescription medications. Another goal is to reduce total expenditures on pharmaceuticals through shifting some of that cost onto the consumer. Reduced total expenditures, then, are realized through (a) reduced overall utilization, as a result of price sensitivity on the part of the consumer, and (b) the transferring of part of the costs of the medication to the consumer, through either fixed or variable co-payments.

All countries studied employ consumer cost sharing for pharmaceuticals (summarized in Table 7.) In all countries, cost sharing is reduced or waived for individuals with low income or who are otherwise financially vulnerable to high drug costs. The reliance on consumer cost sharing grew in the 1990's in response to pressures to contain expenditures. Our informants felt that the amount of cost sharing (as a proportion of total prescription cost) was likely at or near its maximum. In fact, co-payments were actually reduced in Sweden and Germany in the late 1990's. In four of the seven countries studied – the United Kingdom, the Netherlands, Australia, and New Zealand – cost

sharing is through a flat fee, regardless of the cost or size of the prescription. Sweden uses a stepped approach, wherein the consumer shoulders 100% of the cost up to a limit, then 50% of the cost up to the next limit, then 25%, 10% and finally no co-payment beyond total expenditures over SKr 4300. In Germany, co-payments are tiered according to package size.[†] In France, co-payment varies with the nature of disease being treated: 100% reimbursement for drugs for serious and disabling or long lasting diseases, 65% for serious diseases, and 35% for diseases which are “not serious”.

We are unaware of any studies outside North America examining the effect of consumer cost sharing on health outcomes. However American and Canadian studies suggest that, among low income individuals, and those with mental disabilities, there is an adverse effect of even modest co-payments on utilization of essential medications and cost shifting to other health care budgets, and that consumers discontinue both essential and non-essential medications.(56;85;86) This is consistent with a Swedish survey that found the young, those with poor health status, low education and low income to be most price sensitive.(87)

5.2.3 Industry risk sharing

France, Australia, and New Zealand all engage in price-volume contracting that renders the manufacturer vulnerable to financial risk should higher-than-anticipated expenditures be incurred. In France, since 1996, the federal government has set targets for growth in expenditure in different health care sectors, including pharmaceuticals. Above this target (“ONDAM”), health care service providers/suppliers and the pharmaceutical manufacturers begin to pay rebates. For 2001, the target is 3%, after which the rebates are applied. Industry will have to pay back 50% of the value of any sales rise between 3% and 3.5%, 60% for 3.5 to 4%, and 70% for any increase of more than 4%. Given that overall spending rose by 12% in the first 8 months of 2000, substantial rebates are anticipated. Because this across-the-board rebate system is so unpalatable, most manufacturers have opted for individual contracts with government to globally negotiate the entire firm’s portfolio, allowing firms to make trade-offs, update prices on old products (which was not previously possible) develop generic policies, and discontinue some older products.

In Australia, reimbursement levels are negotiated, in part, on the basis of pharmacoeconomic evaluations. In some cases, a product may be deemed “cost-effective” at one price for a limited set of indications, but not across the board. Calculations are made to determine what that overall target level of utilization is expected to be. Above a certain level of utilization, the additional sales at the margin are deemed to be less cost-effective and reimbursement amounts drop. New Zealand negotiates similar price-volume contracts.

It is not clear for how long the low French global caps on spending targets may be sustained. Approaches like those taken by Australia and New Zealand – where subsidies are tied to price-volume agreements, based on estimated cost-benefit ratios – hold promise.

[†] There are three package sizes – small, medium, and large – for which there are three tiered co-payments of DM 8, 9, and 10, respectively.

6. TENSIONS BETWEEN HEALTH & INDUSTRIAL POLICY

6.1 Conflicting goals

Every dollar in drug expenditures is a dollar of income for those who manufacture and distribute the drugs. Therefore, price and utilization control naturally induce tensions with industry. Tensions are intensified when the few “blockbuster” drugs on which firms rely to recover R&D costs of other products and to garner large profits are the very focus of public insurers’ attempts to contain pharmaceutical expenditures through price or utilization management.

The US Office of Technology Assessment has identified that efforts to induce price competition among manufacturers – particularly through therapeutic reference-based pricing and tendering – are likely to reduce the overall amount of money invested locally in pharmaceutical R&D. However, they state:

“Whether this decrease in R&D would be good or bad for the public interest is hard to judge. It is impossible to know whether today’s level of pharmaceutical R&D is unquestionably worth its costs to society.” (88)

Out of the next wave of therapies – products of genomics and proteomics – may come very significant advances in treatment with large potential public health benefit. For example, researchers in the U.S. & Japan have discovered how to trigger the body’s natural defences against cancer.(89) Most discoveries, however, will have a much more modest public health benefit, and the probability of a product clearing pre-clinical and clinical trials and achieving market success will likely be no greater than for existing pharmaceuticals. This wave of innovations will likely come at unprecedented costs to the health care system. Billions of dollars of investment capital have been invested in the many biotechnology firms that have gone public with little to no return on investment yielded to date. Investors will expect to see high returns commensurate with the risk taken. Challenges associated with developing generics for biotech products after their patents have expired also suggests that these products will remain expensive items for public and private insurers.

6.2 Examples of recent industry responses to cost-containment efforts

Recently, industry has sent very clear signals in response to countries’ attempts to manage expenditures on pharmaceuticals. As discussed in Section 4.2.2.1, there has been a general shift in R&D investment toward the United States where patent laws are stronger and more liberal, and pricing is unregulated. Virtually all the recent mega-mergers involving European and North American based firms have resulted in decisions to locate head office in the United States.

The pharmaceutical industry generally acknowledges the need for public insurers to manage costs but aggressively opposes any mechanism that accomplishes this through either exclusion of products from reimbursement (e.g. through restrictive formularies) or attempts to induce price competition across therapeutically similar products. This includes the use of restrictive formularies and recommendations from influential technology assessment bodies such as the National Institute for Clinical Excellence (NICE) in the UK, the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia.

NICE in the United Kingdom is being followed closely by both proponents and detractors. While there is talk of the development of a “Euro-NICE”, NICE has faced considerable pressure to not create a “fourth hurdle” – both at home (from industry and Invest-UK) and from abroad (the US Pharmaceutical Research and Manufacturers Association).(90) It is unclear whether the recent controversial reversal of NICE’s advice against the prescribing of zanamivir for flu was at all related to threats by GlaxoSmithKline to withdraw R&D investment in the United Kingdom.(91)

Australia’s PBAC has had a long history of tough bargaining with industry, using pharmacoeconomic evaluation as an important component in justifying decisions whether to subsidize a product and at what level. Recently, most of the members of the PBAC and its Economic Sub-committee were removed from office. Among those nominated to the PBAC is the former Executive Director of the Australian Pharmaceutical Manufacturers’ Association.(92) Accusations of industry involvement in this decision may well be borne out. It appears that this action closely followed meetings between the Prime Minister and representatives of pharmaceutical firms in his riding. (93;94) Actions such as these send strong signals to technology assessment bodies worldwide.

The pharmaceutical industry is also generally opposed to attempts by public insurers to increase their monopsony purchase power either through harmonized efforts across insurers (as among Sickness Funds in Germany) or through the consolidation of public insurers in Canada into a National Pharmacare program. In Germany, the industry continues to contest in the European courts reference-based pricing, practice guidelines, and the introduction of a positive list, citing these as anti-competitive practices.(57;57;95;96)

6.3 Balancing cost-containment and promoting research & development

All insurers interviewed in this study were interested in promoting the development of innovative new therapies while discouraging the 15th “me-too” product in a particular therapeutic class. While this goal is simple to articulate, creating incentive structures to promote this orientation in innovation is challenging.

The high-risk environment of pharmaceutical R&D strongly influences industry’s target – to develop the next “blockbuster” drug. Once a new biochemical pathway is elucidated, several firms may race to bring the first product to market – witness the race to develop statins, bisphosphonates, leukotriene inhibitors, and COX-2 inhibitors. The first product to market, though, may not be the most appropriate. Initial diversity of products is good to the extent that it leads to the discovery of the drug with the best combination of therapeutic profile and price.

The best tools we have to date to encourage the “right” balance between innovative and “me-too” products are the techniques employed in the application of economic evaluation of new pharmaceuticals. Using these tools, the focus of discussions between payers and providers can be based on marginal value added as compared with existing therapies. Thus, competition could be on the basis of either better price for equal therapeutic effect or some marginal additional value accrued (e.g. additional fractures averted) for additional dollars spent on a new product over existing products.

6.4 The “costs” of promoting pharmaceutical R&D investment in Canada

Canada is not alone in its interest in encouraging the pharmaceutical industry to invest within its borders. Conscious of the migration of investment capital for pharmaceutical R&D to the United States, the European Union is actively pursuing strategies to create a more investment-friendly environment. Given the competition for R&D investment dollars, the kinds of concessions that the pharmaceutical industry will seek in exchange for greater investment include:

- strengthening of patent laws,
- more rapid listing of products as insurable benefits and fewer restrictions on the subsidy of new products in public insurance programs, and
- freer pricing of these products.

Canada is in the process of amending its patent laws to conform more closely with the TRIPS agreement and is currently reviewing its biotechnology patent policy.(97)

The relaxing of restrictions on the subsidy of new products and on pricing of products will have major implications for growth in pharmaceutical expenditures. In many ways, Canada is in a very similar position as the European Union. While the European Commission is favourably disposed toward liberalizing markets for pharmaceuticals, Member States are quite resistant, as they must pay the bills.

7. DISCUSSION AND CONCLUSIONS

7.1 Points of similarity and distinctiveness

Among the countries studied, there is considerable convergence or harmonization around principles guiding the management of pharmaceutical insurance programs and the policy tools to achieve those principles. These include: the promotion of generic products, the use of positive lists, and the move toward scientific evidence and pharmacoeconomics as bases for decision making regarding reimbursement of new pharmaceuticals.

While the use of pharmacoeconomic evaluation in subsidy decisions is becoming more widespread, most of the countries appear to be developing their own evaluation guidelines, rather than adopting the criteria developed by the leaders in this field – Australia & Canada – or developing common European criteria. With the exception of NICE in the United Kingdom, grounds for accepting or rejecting products for subsidy are not in the public domain.

Internationally, there is convergence with regard to the requirements for attaining market approval. There is also a convergence in the funding of the market approval process through user fees covering 50-100% of the operating budget.

Countries remain distinctive with regard to fundamental policies that affect their abilities to raise revenues for their insurance programs. Germany and the Netherlands have maintained the use of employer-based Sickness Funds, as opposed to the primarily tax-

base funded programs in the UK, Sweden, Australia, and New Zealand.^s Likewise, co-payments for prescriptions vary greatly from one country to the next.

The United Kingdom, Germany, and New Zealand have taken the distinctive approach of giving to collectives of physicians drug budgets – either for drugs alone or unified with other budget envelopes. The three countries have taken considerably different approaches. While short-term efficiencies have been gained, there appears to be no effect in the long run on the slope of the growth in expenditures on pharmaceuticals.

Therapeutic reference-based pricing continues to attract the interest of many countries but, sound evaluation of the impact of RBP on outcomes is lacking in these countries. Like physician budgets, RBP takes many different forms. In Germany, the innovator in reference-based pricing, brand-name manufacturers negotiated concessions to exempt patented medicines from reference-pricing.

7.2 From price to utilization management

In all countries studied, there was the recognition that there were diminishing returns to focusing on price and a need to address utilization. While tools are available to manage utilization, they are intensive in both information needs (e.g. prescribing profiles) and human resources, if the results are to reflect the balance between good clinical practice and efficient utilization of limited resources. If public insurers wish to manage utilization directly (e.g. through: use of formularies, prior authorization requirements for expensive new pharmaceuticals, and the issuing of clinical practice guidelines), then it will be necessary to make the appropriate investment in support systems. Otherwise, consideration needs to be given to physician prescribing budgets and risk-sharing arrangements with industry. Neither of these latter strategies, though, has been well evaluated, to date.

7.3 Need for priority setting

In the past, Canada has not been a serious contender globally in attracting substantial R&D funds from the pharmaceutical industry. Competition for attracting these funds is steep. Therefore, creation of a competitive environment will introduce tensions with existing health policy goals, and will have domino effects on other sectors that may not be anticipated. Many of the emerging tensions that arise are ethical and political in nature, and not amenable to technical “fixes”. Therefore, attention needs to be given to priority setting, with opportunities for stakeholder representatives to come together to debate broad (and intersecting) questions around:

- Balancing public and private interests
 - Promoting pharmaceutical R&D vs. managing costs.
 - Limits of patentability in genomics
 - Industry-academic interface
- Defining the limits of insurability
 - On what grounds do we exclude a drug from public insurance or limit its access – particularly with regard to the medicalization of lifestyle issues through the introduction of new drug therapies?

^s France is in transition toward a tax-based system.

- What is the role for cost-sharing for pharmaceuticals in Canada? How do we reconcile its inconsistency with the Canada Health Act?
- What should be the role of the insurer *vis-à-vis* the medical profession with regard to managing appropriate utilization of pharmaceuticals?
- How best to invest to create an attractive market for pharmaceutical industry investment?
 - Public sector (e.g. through strengthening university infrastructure, targeted funding for priority areas)
 - Private sector (e.g. through tax incentives, strengthening patent laws)
 - Promoting public-private networks
 - Relaxing of formulary restrictions
- Implications of commercialization in the academic sector
 - Intellectual property and patents
 - The combined pressures of the technologic imperative and the profit imperative
 - Potential conflicts of interest on the part of investigators
- Patents, parallel trade, and less developed countries – the role for Canada and other more developed countries.

It is beyond the scope of this paper to recommend the process for addressing these policy issues. However, given that promotion of pharmaceutical R&D investment will have a substantial impact on our ability to manage pharmaceutical budgets, cross-representation across portfolios in discussions is essential.

In setting priorities, transparency of process and accountability to the public cannot be ignored. Important lessons have been learned from prior experience with public resistance to genetically modified food and the backlash of public opinion regarding industry's challenge of South Africa's compulsory licensing legislation.

7.4 Impact of globalization

Globalization in the pharmaceutical industry, the ready movement of investment capital, and international trade agreements make it difficult for any one nation to create responses that reflect unique social or cultural values. The proposed solution common to many reports issued in recent years is to resolve tensions around pharmaceutical policy through deregulation of the market for pharmaceuticals. While this would make for an environment friendlier to research and development, in the United States – the country that most fully embraces this approach – the cost of pharmaceuticals has become a major public policy concern over the past two years, with the least equitable and most expensive system among developed countries. Currently, in the United States, the elderly without coverage face higher drug costs than those with insurance and employer coverage is eroding.⁽⁹⁸⁾

7.5 Need for independent forecasting and evaluation of policies

Distinctly lacking from much of the current policy process is a systematic evaluation of the impact of policies introduced on desired and undesired shifts in health care expenditures and health outcomes. While recognizing that many other variables factor into policy-making, a more systematic approach to evaluation of policies can help inform future policy debates and is strongly encouraged. Such evaluation needs to be carried

out at arm's length to both government and industry. In addition, the policy environment around pharmaceuticals is rapidly evolving. Ongoing reconnaissance with regard to international developments would be a distinct asset for decision-makers.

Canada is not alone in its desire to attract R&D investment within its borders. The European Commission is particularly interested in drawing back much of the investment capital that it has lost to the United States in recent years. While the requirements to create a more investment-friendly climate in Canada are predictable, our ability to attract substantial investment capital once those changes are implemented remains uncertain. These, however, may be forecast. As there are multiple approaches that can be taken to promote pharmaceutical and biotech R&D in Canada, several options should be carefully explored, forecasting both the costs and benefits to be accrued, before a course of action is pursued. As discussed above, there is more than a monetary cost to be considered. Thus, the information generated through the forecasting exercise would become a part of the grist for the priority setting process suggested above.

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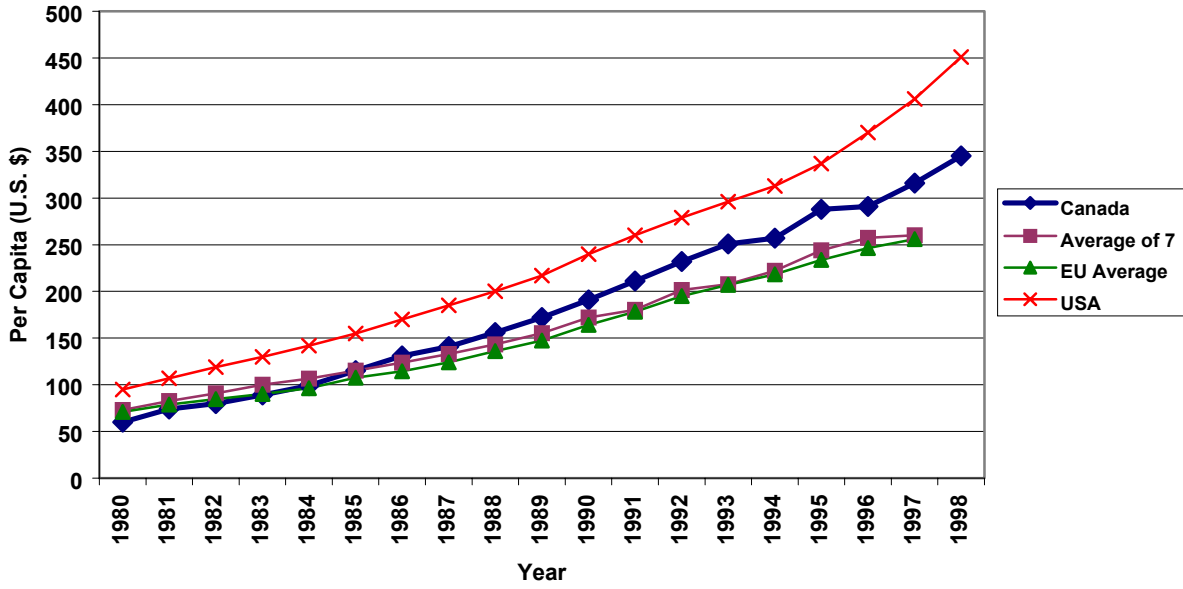
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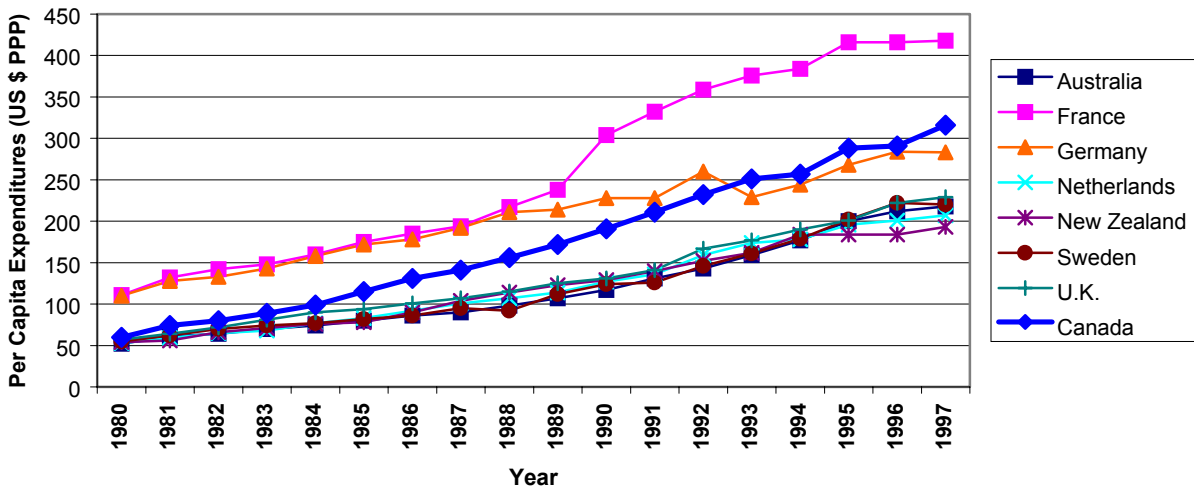
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Figures

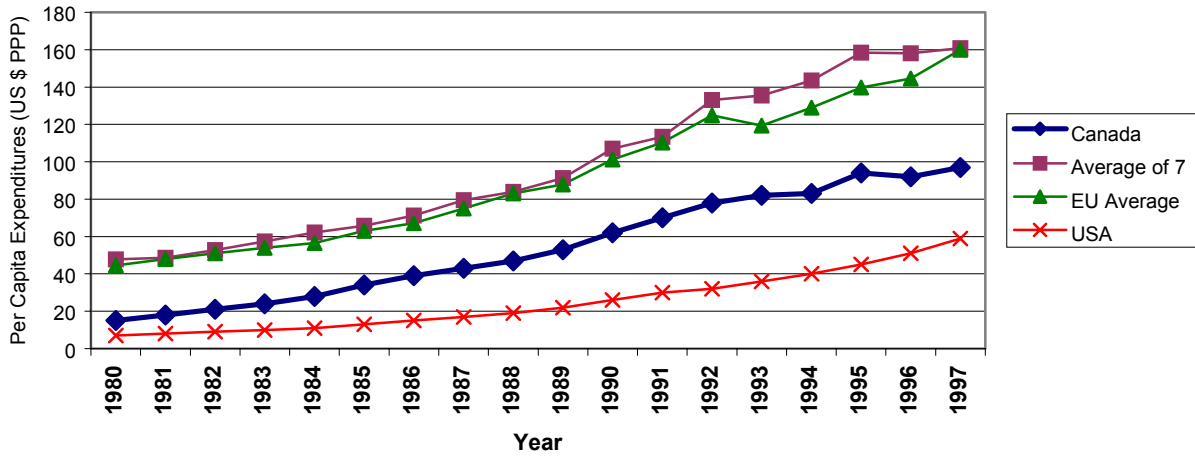
**Figure 1a. Total Per Capita Expenditure on Drugs
(U.S. Dollars, PPP)**



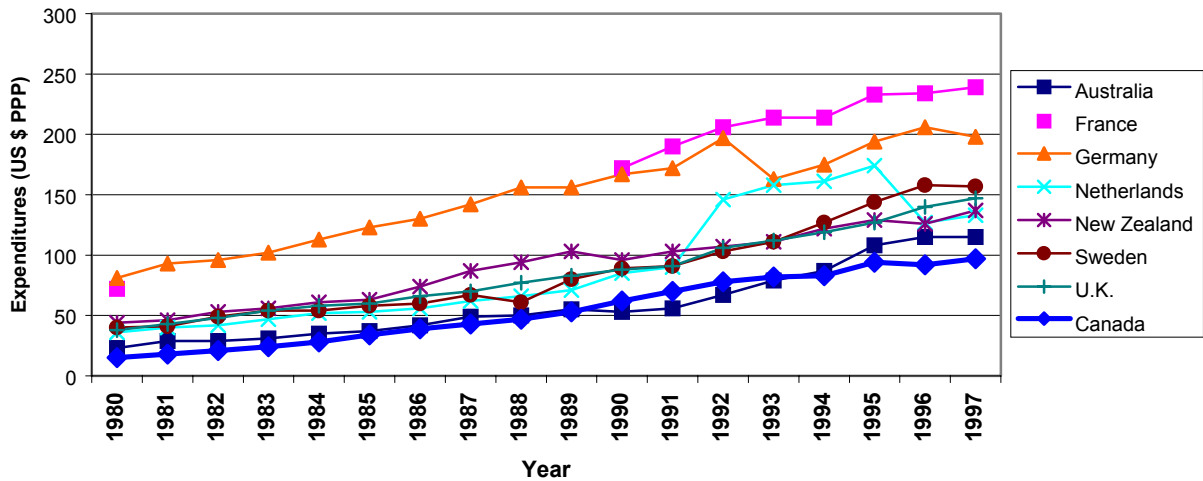
**Figure 1b. Total Per Capita Expenditures on Drugs
by Country (U.S. Dollars PPP)**



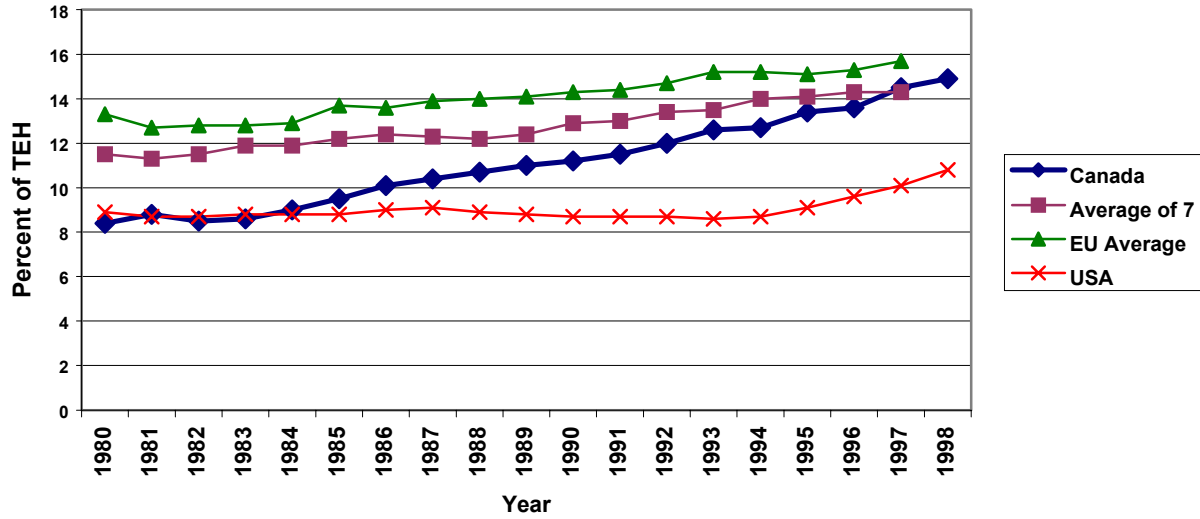
**Figure 2a. Public Per Capita Expenditures on Drugs
(US Dollars-PPP)**



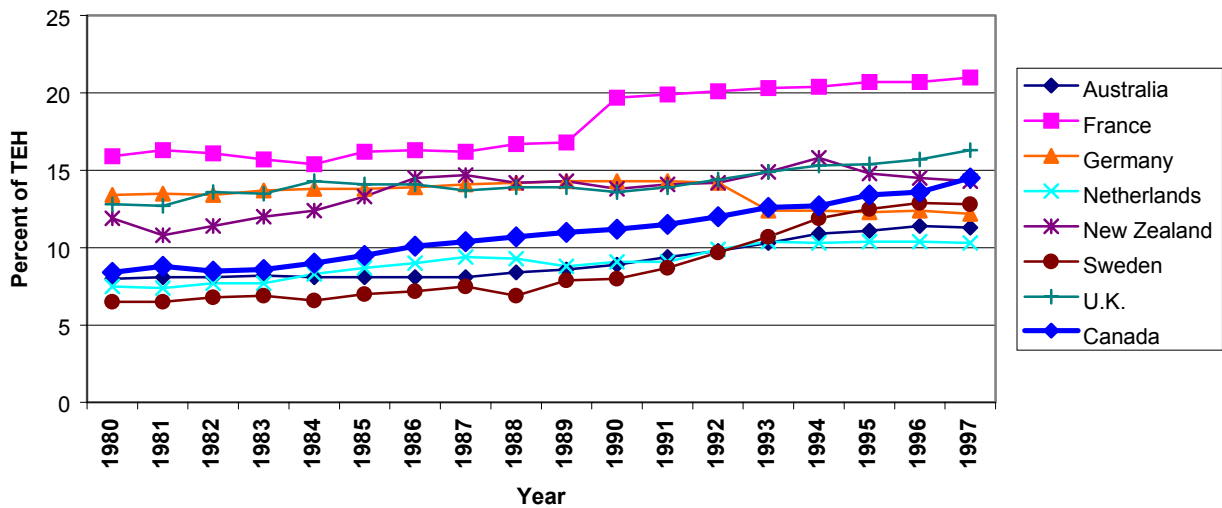
**Figure 2b. Public Per Capita Expenditures on Drugs
(U.S. \$ PPP)**



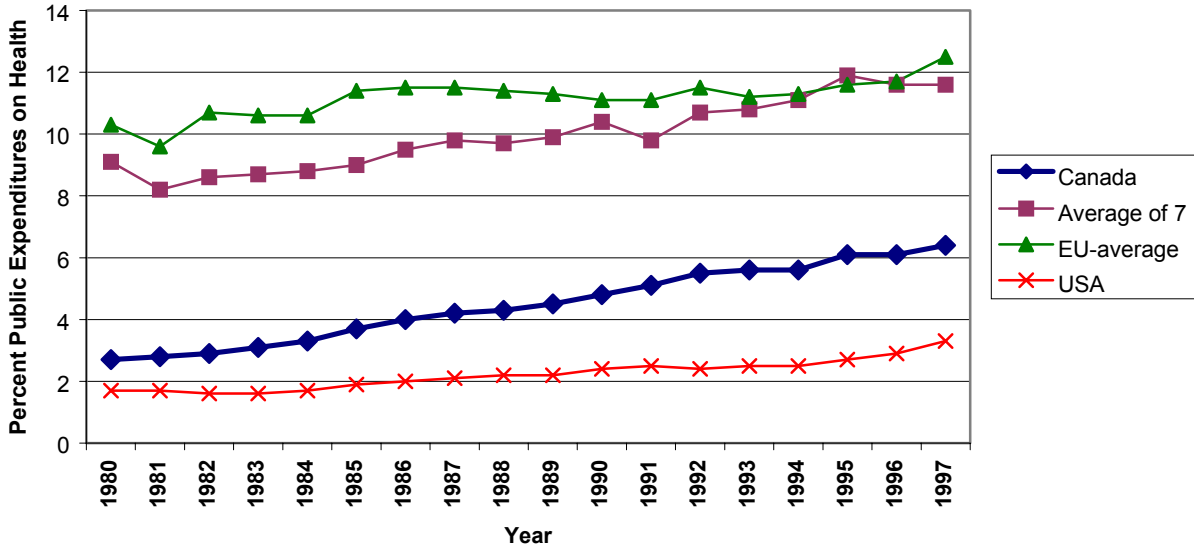
**Figure 3a. Total Expenditure on Drugs
(Percent of Total Expenditures on Health)**



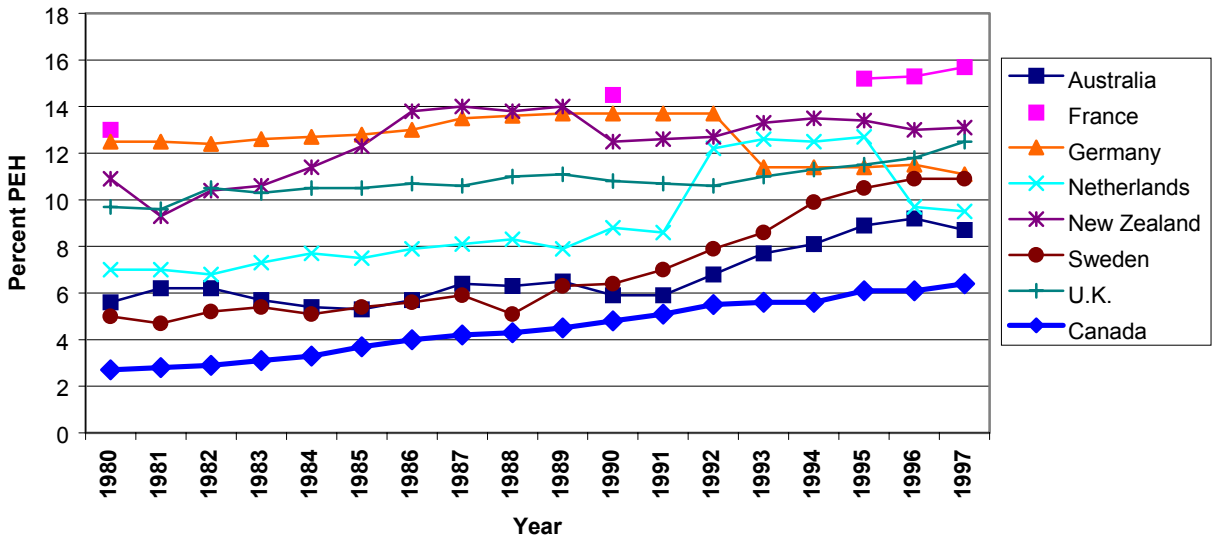
**Figure 3b. Total Expenditure on Drugs by Country
(Percent of Total Expenditure on Health)**



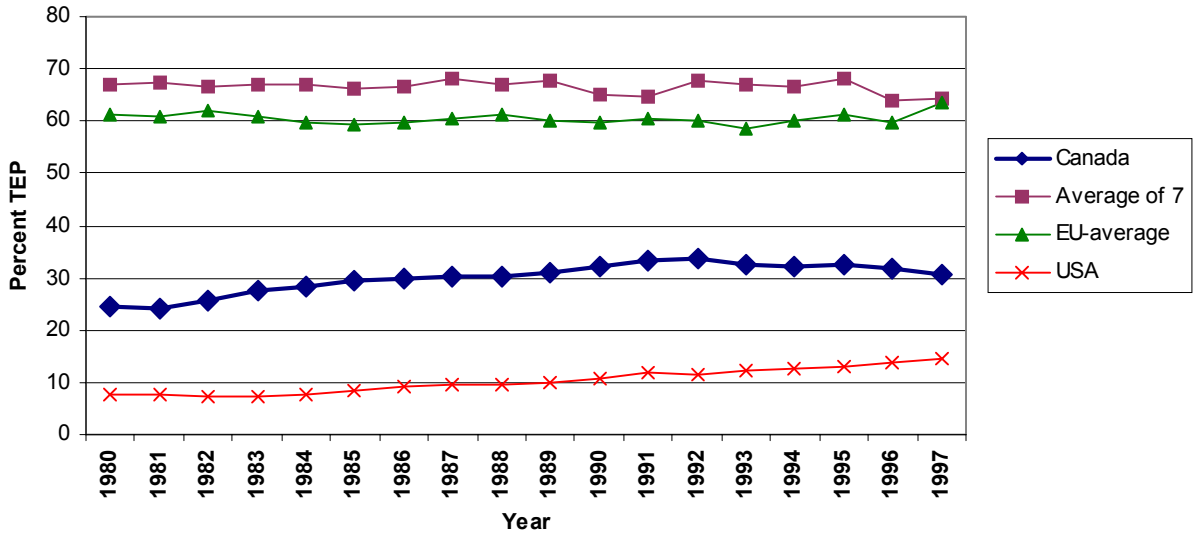
**Figure 4a. Public Expenditures on Drugs
(Pct. Public Expenditures on Health)**



**Figure 4b. Public Expenditures on Drugs
(Percent Public Expenditure on Health)**



**Figure 5a. Public Expenditures on Drugs
(Percent of Total Expenditures on Drugs)**



**Figure 5b Public Expenditure on Drugs by Country
(Percent of Total Expenditures on Drugs)**

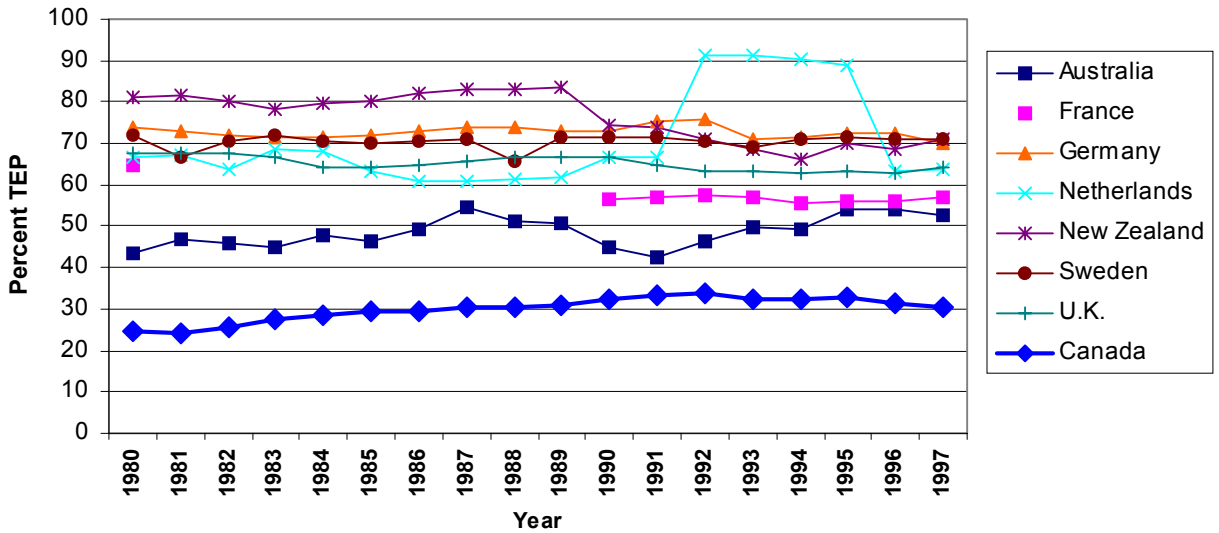


Figure 6a. Public Expenditures on Drugs (PPP)

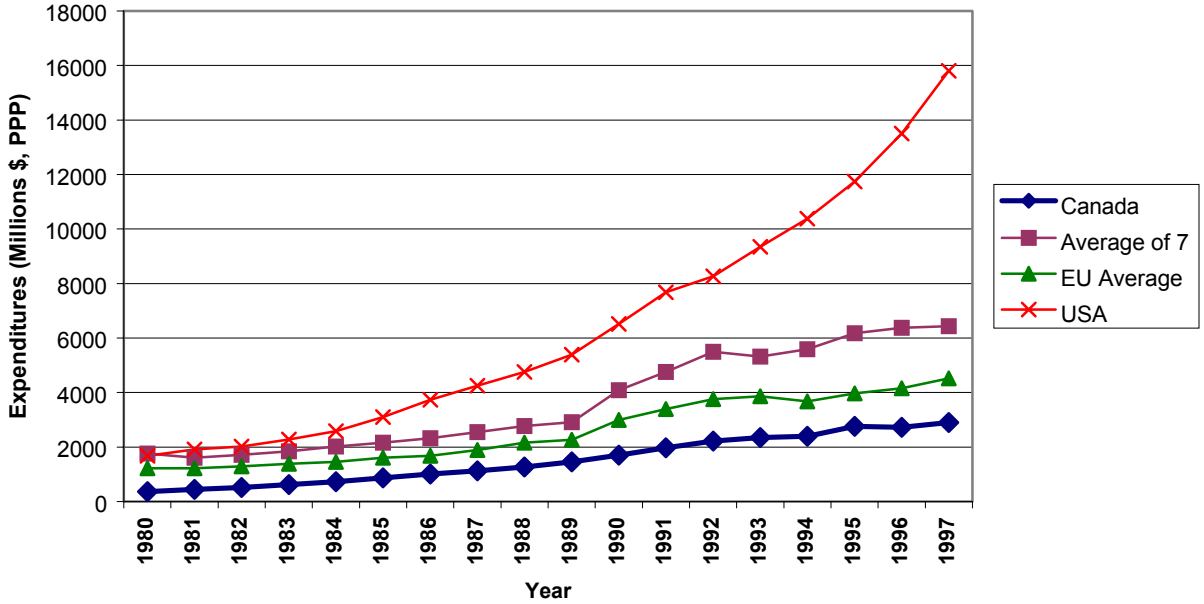
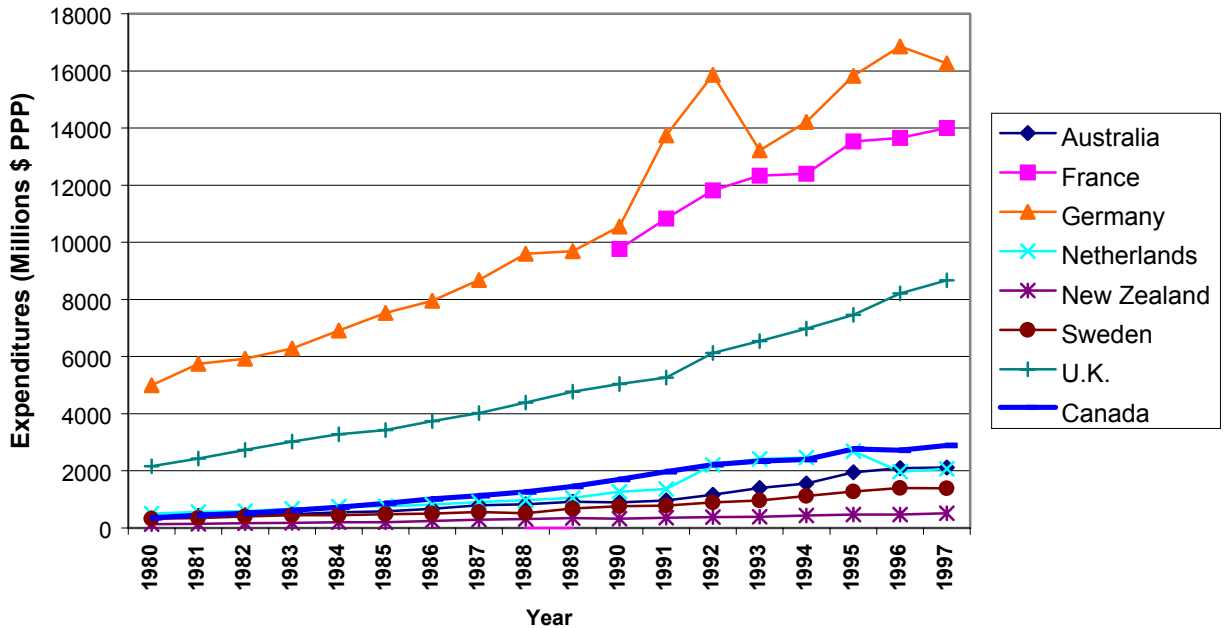


Figure 6b. Public Expenditures on Drugs by Country (PPP)



Tables

Table 1. General and Pharmaceutical Insurance Systems ^a

	Sweden	UK	Germany	Netherlands	France	New Zealand	Australia
Chief source of financing	Taxation	Taxation	Social Insurance	Social and private insurance	Social insurance	Taxation	Taxation
General health policy making body	National	National (NHS)	Federal	National Ministry of Public Health, Welfare & Sport	National	National	National (Dept. of Health and Aged Care)
Pharmaceutical policy making	mixed National and County Council (CC)	National	Federal Association of Sickness Funds	National Health Insurance Council (ZFR) – check CVZ	National	National (PHARMAC)	National – Pharmaceutical Benefits Scheme
Who holds drug budget?	In transition from National to CCs	Region / Primary Care Trusts	Regional physician groups	In transition from National to SFs	National	Primary Care Organizations	National (PBS)
Administration of programs	CCs	Regional & Primary care trusts	Local Sickness Funds (SFs)	Local Sickness Funds	Local Sickness Funds	National (PHARMAC)	National
Pharmaceutical insurance							
% of patients covered by public plan	100%	100%	88% (SF system)	67%	99%	100%	100%
Role of Private Insurance	Each CC handles private insurance differently and it may cover drug expenses not covered by public plans. Extent of private insurance is not known but is thought to be insignificant.	No significant role, About 11% of the population have private insurance which is used primarily for acute health care and for jumping queues.	About 9% of the population have private insurance	Private insurance runs parallel to the public system.	About 90% of population has Mutuelle coverage, chiefly to defray the high co-payments.	Covers only what is subsidised by the public plan. Assists with co-payments; 40% of the population have private insurance, covering 7.1% of total health care expenditures	Encouraged by government (30% subsidy to those who obtain private insurance)

^a Source: author's notes

Table 2. Health Care and Pharmaceuticals Expenditure

	Canada	Sweden	UK	Germany	Nether-lands	France	New Zealand	Australia
Total expenditures on health (TEH)^a								
Percent of GDP (rank)	9.3 (3)	8.5 (5)	6.7 (8)	10.5 (1)	8.6 (4)	9.5 (2)	7.6 (7)	8.3 (6)
Per capita expenditures (US\$ PPP) (rank)	2,185 (2)	1,712 (6)	1,406 (7)	2,325 (1)	2,004 (3)	1,987 (4)	1,347 (8)	1,923 (5)
Per capita expenditures (rank) (US\$ exchange rate)	1,884 (5)	2,196 (3)	1,498 (7)	2,701 (1)	2,086 (4)	2,291 (2)	1,312 (8)	1,881 (6)
Pharmaceutical expenditures^{a, b}								
Percent of TEH (rank)	14.5 (3)	12.8 (5)	16.3 (2)	12.2 (6)	10.3 (8)	21.0 (1)	14.3 (4)	11.3 (7)
Percent of GDP (rank)	1.3 (2)	1.1 (3)	1.1 (3)	1.3 (2)	0.9 (4)	2.0 (1)	1.1 (3)	0.9 (4)
Per capita expenditures (US\$ PPP)	316 (2)	220 (5)	229 (4)	283 (3)	207 (7)	418 (1)	193 (8)	218 (6)
Per capita expenditures (US\$ exchange rate)	272 (4)	282 (3)	244 (5)	329 (2)	216 (6)	482 (1)	188 (8)	213 (7)
Public expenditures as a percent of total expenditures on pharmaceuticals	30.6 (8)	71.2(1)	64.2 (4)	70.0 (3)	64.0 (5)	57.1 (6)	70.8 (2)	52.5 (7)

^a 1997 data, source: OECD 2000

^b The OECD defines a category “pharmaceutical and other medical non-durables” which measures final consumption, outside an institutional setting, of prescription medicines and over-the-counter products. Pharmacists’ fees, where separate from the price of medicines, are included. This includes drugs purchased directly by consumers or by third-party payers.

Table 3. Manufacturers' funding of drug approval process ^a

	Percent of costs covered through fees
EMEA	60%
U.K.	100%
Germany	50%
Netherlands	Unknown
France	68% of operating budget in 1997 and 1998
Sweden	100%
Australia	100% of Therapeutic Goods Administration costs
New Zealand	50% of MEDSAFE's operating budget

^a Source: author's notes

Table 4. Measures to manage pharmaceutical budgets

	Sweden	UK	Germany	Nether-lands	France	New Zealand	Australia
1. DIRECT APPROACHES							
1.1 Price Regulation – direct & indirect							
Direct price regulation	√ ^a	(√) ^b	(√) ^b	√	√ ^a		
International price comparisons	√			√	√		
Profit regulation		√					
Price-volume agreements					√	√	√
Advertising expenditure restrictions					√		
Tendering						√	
1.2 Limiting products for reimbursement							
Positive lists	(√) ^c			√	√	√	√
Negative lists	√	√	√				
1.3 Inducing price competition							
Generics							
Automatic substitution	(√) ^d	√		(√) ^d	(√) ^e		√
Promotion of generic prescribing		√√	√	√√	(√√) ^f		
Therapeutic reference-based pricing			√	√√		√√√	√
1.4 Use of formal pharmacoeconomic analysis	√	√ ^g		√		√	√
2. INDIRECT APPROACHES							
2.1 Prescriber-focused							
Budgets for pharmaceuticals							
Collective level		Fixed ^h	Fixed ⁱ			Mixed ^j	
Individual level		Indicative	Indicative ⁱ				
Educational programs							
Clinical practice guidelines	√	√	√	√	√	√	√
Audit and feedback	aggregate	√	√				√
Electronic medical record	√	√		√			
Academic detailing		(√)		√		(√)	
2.2 Consumer focused							
Cost sharing	√	(√) ^k	√	√	(√) ^l	√	√
Rx to OTC & drop from public reimbursement	√	√	√	√		√	√
2.3 Industry focused							
Risk sharing					√	√	√

Legend:

A check-mark – ✓ – is provided if the policy instrument is used in the country. If the check-mark is placed in parentheses, there is some condition or exception, which is explained in the footnote. For “promotion of generic prescribing”, two checks means that generic prescribing is very heavily promoted. For “therapeutic reference-based pricing”, one check indicates limited use, 2 checks mean moderate use, and 3 checks means very heavy use of

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- ^a Manufacturers are free to set their own prices. However, if the product is to be reimbursed in the public insurance program, the reimbursement price must be negotiated with the government. The same price must be used in both the public and private sector transactions.
- ^b Officially, the U.K. and Germany have free pricing of patented pharmaceuticals. However, they have implemented price cut-backs in the 1990's.
- ^c There is no positive list at the national level. However, many County Councils have developed their own positive lists.
- ^d No formal legislation or regulations authorizing automatic substitution, but physicians and pharmacists frequently have informal agreements for auto-substitution.
- ^e Although automatic substitution laws are in place, generics occupy less than 10% of prescription sales.
- ^f Generic prescribing is heavily promoted but generics occupy less than 10% of prescription sales.
- ^g Pharmacoeconomic analysis limited to subset of products reviewed by National Institute for Clinical Excellence (NICE)
- ^h Primary Care Groups (PCGOs) now hold fixed unified budgets from which hospital, community health services, community prescribing costs, and general medical services are funded. This allows for the cross-subsidization across budget envelopes which, formerly, had been disallowed. The degree of control over funds will depend on which of the 4 levels of responsibility they have achieved in the transition to Primary Care Trusts. Majeed A, Malcolm L. Unified budgets for primary care groups. *BMJ* 1999; 318:772-776.
- ⁱ In Germany, regional collectives are assigned fixed budgets and individual physicians are assigned indicative budgets. Under fixed budgets, there is no reward for coming under budget but there are financial penalties for over-spending. However, efforts to recover costs resulting from exceeding the budget have never been realized, to date.
- ^j Not all primary care organizations (PCOs) have entered into agreements for prescribing budgets. Of those that have entered into contracts, one large PCO has a fixed budget. The remainder have indicative budgets. Under fixed budgets, the PCO accepts 100% of the liability and retains 100% of any under-spending. Under indicative budgets, PCOs are advised of the cost over-run but are not held financially liable. However, if the PCO comes in under-budget, it must share 50% of the savings with the government. In the cases of both fixed and indicative budgets, surplus funds retained must be re-invested in the services provided by the PCO.
- ^k 85% of prescriptions dispensed are exempted from co-payments.
- ^l Although the copayments in the public insurance scheme are quite large, the intended effect of inducing price sensitivity are lost, because most of the population purchase private supplemental insurance (Mutuelles) that pays for the copayment. In January, 2000, concessions for low income residents were introduced but there may still be a financial barrier for the working poor, as there is a fixed cut-point for eligibility for subsidy, as opposed to a sliding scale.

Table 5. Overview of Selected National Policies Towards Promoting the Use of Generics (1996/97)

	EU					Other OECD		
	Fr	Ge	Ne	Sw	UK	Au	Ca	NZ
Generic substitution permitted	0	1	1	0	0	1	1	0
Consumer permitted to refuse generic substitute		0	1			1	1	
Financial incentives to doctors		0	0	0	1	0	0	
Non financial influences on doctors	1	0	1	1	1	1	1	
Financial incentive to pharmacies	0	0	1	0	1	1	1	
Non-financial influences on pharmacists	0	0	1	1	0	1	1	
Roche-Bolar type regimes in place	0	0	0	0	0	1	1	0
Reimbursement systems specific to generic products	0	0	0	0	0	0	1	1
Official publicity in favour of generic products	0	0	1	1	0	1	0	0
Number of yes responses	1	1	6	3	3	7	8	1

1=Yes 0=no Blank=no information

Source: Adapted from Senior I, Whitaker D, Cameron J, Ribbert J. Policy relating to generic medicines in the OECD. Table 5.1. 1998. London, National Economic Research Associates.

Table 6. Generic-Specific Methods of Price Control and Reimbursement in the OECD (1996/97)

	EU					Other OECD		
Country	Fr	Ge	Ne	Sw	UK	Au	Ca	NZ
Control of ex-manufacturer generic prices	1	0	0	1	0	0	1	
Control of reimbursement prices	0	1	1	1	1	0	1	
Generic manufacturer free to increase or decrease price at will?	0	1	1	1	1	0	1	1 ^a
Do authorities have the power to increase or decrease reimbursement price at will?	1	1	1	0	0	0	0	1
Do authorities reduce the reimbursement price of an original when generics enter the market?	0	1	0	1	0	0	0	1

1=Yes 0=no Blank=no information

Notes:

^a Only in some cases

Source: Adapted from Senior I, Whitaker D, Cameron J, Ribbert J. Policy relating to generic medicines in the OECD. Table 11.1. 1998. London, National Economic Research Associates.

Table 7. Consumer cost sharing		
Country	Co-payment / Coinsurance	Provisions for elderly, social assistance, children
Australia	Co-payments were introduced in the 1960's, and have gradually increased, doubling in 1986. General beneficiaries, which is everyone except concessional beneficiaries, pay \$20.60, or less if the prescription costs less, for each prescription item up to a maximum level of \$631.20. Once the maximum is reached individuals pay the concessional rate, which is \$3.30 per prescription. In addition to the co-payment the patient may be required to pay a brand premium or a therapeutic group premium if they wish a brand or type of medication which is more expensive than the lowest price listed. These additional costs do not count when calculating the \$631.20 maximum.	<p>Concessional beneficiaries include:</p> <ul style="list-style-type: none"> \$ pensioners \$ part pensioners \$ veterans \$ sickness and long term allowees \$ low income earners \$ anyone over 65 years of age (since 1998) <p>These groups pay the concessional rate of \$3.30 per prescription and once they reach a maximum of \$171.40 per year the co-payment is removed. As co-payments were increased, pensions and payments to other concessional beneficiaries were also increased. A pharmaceutical allowance of \$2.70 per week, paid fortnightly or \$140.40 per year, is received from the department of family and community care to assist in defraying these out of pocket drug costs. As with general beneficiary patients, additional costs for brand or therapeutic group premium products are covered by the patient.</p>
New Zealand	The co-payment for fully subsidized products currently is \$15 for each prescription or the cost of the medication whichever is less. A manufacturers= surcharge is paid by all patients, if the patient insists on a brand name product or a more expensive therapeutic agent, regardless of whether they have a community service card or pay a reduced co-payment.	<p>There are three types of exemptions in New Zealand. A community service card (CSC), a high use health card (HUHC) and a prescription subsidy card (PSC).</p> <p>A community service card is issued to:</p> <ul style="list-style-type: none"> \$ pensioners receiving superannuation \$ individuals on income support \$ low income earners with dependents <p>Also, a community service card is issued to an individual after they have purchased 20 prescriptions as they are then considered a >high user= (then called a high use health card, HUHC). Patients with a CSC or HUHC pay a \$3.00 co-payment per prescription.</p> <p>A Prescription Subsidy card may also be supplied to those with financial need. If the patient has a subsidy card then the co-payment they pay is as follows:</p> <ul style="list-style-type: none"> \$ PSC only They pay \$2.00 per prescription

		§ PSC and HUHC They pay \$2.00 per prescription § PSC and CSC They pay \$0 per prescription
UK	Prescription co-payments have been paid in the UK since 1952 (except for 1965 to 1968). Currently the co-payment is , 5.90 (1998) which is approximately 57% of an average prescription price.	Seniors, low income earners, children under 16 years, individuals with chronic conditions and drugs for specific uses (eg. oral contraceptives) are exempt from co-payments. In 1995/6, 84% of prescriptions dispensed were for patients claiming exemptions.
France	In France the patient pays a co-payment (ticket modérateur) which is dependent on the nature of the medication. The reimbursement levels are as follows: § 100% reimbursement for drugs for serious and disabling or long lasting diseases § 65% for serious diseases § 35% for diseases which are not serious	All Sickness Funds require a small (or no) co-payment for drugs and ambulatory care associated with illnesses such as AIDS, cancer, diabetes, end stage renal disease, transplants, heart attacks, maternal care from 6th month of pregnancy, maternal and neonate care to 3 months, veteran care, handicap care etc. There are 30 disease states altogether that have no co-payments. It is also possible to apply for exemptions for diseases not listed or in cases where the individual has multiple disorders.
Sweden	Co-payments have been common in Sweden and in 1999, it was believed they had become too high and they were subsequently reduced. The patient currently pays the following step wise co-payments: § total cost of prescriptions up to 900 SKr (=900) § then 50 % of cost between 900 and 1700 SKr (=400) § then 25 % of the cost between 1700 and 3300 SKr (=400) § then 10 % of the cost between 3300 and 4300 SKr (=100) § and 0 % over 4300 SKr. Therefore in total the individual has to pay a maximum 1800 SKr per year. Patients are allowed to pay these co-payments in instalments and the RFV has recently reported that it is owed SKr 23 million by individuals who have defaulted on these instalment payment.	Patients with diabetes receive their medications free and children under 18 pay a smaller deductible if they are part of a family. All other patients pay the co-payments when they receive their medications, however for patients who find this a financial burden, they may go to the Social Security office and obtain reimbursement for these co-payments. Few people take advantage of this system as culturally it is associated with a strong social stigma.
Germany	Co-payments have been a common part of the German system. Since 1997, a patient co-payment is required for drugs reimbursed by the GKV which are not subject to the fixed price regulation (About 40% of total expenditure of the GKV in 1997). The co-payment, based on package size, has recently been	Patients who are chronically ill are exempted from co-payments if, in the preceding year, they spent 1% of their income on treating the same disease.

	<p>reduced as follows: \$ 13 DEM to 10 for large size \$ 11 to 9 DEM for medium \$ 9 to 8 DEM for small packages</p>	
The Netherlands	<p>Starting in Jan. 1997 co-payments began for those covered by ABWZ and ZFW. Patients pay a fixed prescription fee of FI 10.80 (1998) up to a yearly maximum amount of FI 200. (This FI 200 is for total health care expenditures not just medications). After the maximum is reached, prescriptions are paid entirely by the government. In the fixed price system the patient also pays the difference between the fixed price of a drug and its actual retail price. If the patient has private insurance then co-payments vary with the plan.</p>	<p>Low income and retired individuals pay a maximum of 100 NLG per year.</p>