

International Trends in Managing Drug Plans: Lessons for Canada

Donald Willison, Sc.D.
Mary Wiktorowicz, Ph.D.
Paul Grootendorst, Ph.D.
Bernie O'Brien, Ph.D.
Mitchell Levine, MD, M.Sc., FRCPC
Raisa Deber, Ph.D.
Jeremiah Hurley, Ph.D.

1. Introduction

Pharmaceuticals constitute a significant and growing portion of health care budgets internationally. In Canada, between 1985 and 1999, drug expenditure increased by 250%, approximately double the rate in total health expenditure.(1) This trend has been observed in most major industrialized countries. In 2001, internationally, expenditures on pharmaceuticals increased by 12% over the previous year, with Canada and the USA witnessing the largest increases (17%).(2)

Analyses in Canada and the USA attribute expenditure growth to increased utilization and the introduction of new, more expensive, drugs.(3;4) Behind the increased utilization are a number of factors:

- (a) the increased prevalence of chronic illnesses such as diabetes, elevated cholesterol, and arthritis. It has been noted that these conditions are largely attributable to diet and sedentary lifestyle both of which are amenable to non-drug therapy.(5)
- (b) more aggressive medical treatment of these conditions using, for example lipid lowering agents, such as statins,
- (c) increased survival following formerly fatal conditions (e.g. AMI) with long-term treatment of chronic morbid and comorbid conditions, and
- (d) increased use of "lifestyle drugs" – e.g. sexual dysfunction, hirsutism.

Although most nations engage in some form of price control, the trans-national nature of the pharmaceutical industry has led it to seek a single global price for its new products. As public insurers recognize their reduced ability to moderate prices, they are turning toward a range of alternate mechanisms to prevent further increases in drug budgets. These include price-volume discounts, pre-negotiated price reductions for future years, reference-based pricing, and utilization management. In this paper we analyse the public drug plans of 7 Western industrialized countries, to compare their strategies for managing pharmaceutical budgets.

2. Methods

Most of the data for this paper were derived from a 7-country study conducted by the authors for the Health Transitions fund in 2001.(6) Countries included in the analysis were: The United Kingdom, Germany, France, the Netherlands, Sweden, Australia, and New Zealand. These countries were selected with the assistance of key informants in pharmaceutical policy¹, to provide a broad variation in approaches to cost containment and level of pharmaceutical industry investment. Data for the larger study were gathered

¹ Panos Kanavos and Elias Mossialos, London School of Economics, University of London, U.K.

through a combination of structured literature review, interviews with key informants, and follow-up analysis of literature provided by informants.

3. Structure and financing of health care and pharmaceuticals insurance

Before comparing public drug programs in these countries, it is helpful to situate these programs within the health care systems in those countries.

3.1 European Union countries

Among European Union countries, 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. Recently, though, the European Commission has entered into the health policy arena through its responsibility for public health.⁽⁷⁾

In the **United Kingdom**, the public health care system, which includes coverage for pharmaceuticals, is financed through taxes. General health and pharmaceutical policies are made at the national level, and price regulation occurs indirectly through pre-set levels for pharmaceutical company profits. There is no significant role for private insurance for pharmaceuticals. Until recently, budgets for pharmaceuticals were held by regional trusts. However, there has been a transition toward regional Primary Care Trusts, in which clusters of family physicians are given drug budgets to manage pharmaceutical expenditures.² There is only a very small negative list at the national level.

Sweden's system of public health insurance is also financed by tax revenues, generated at the local (County Council) level. Pharmaceutical policy-making is carried out both at the national level and through County Councils, with no significant role for private insurance for pharmaceuticals. 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 pharmaceuticals to take on this responsibility.

Germany has a highly decentralized and complex system, financed chiefly through social insurance with contributions from employers and employees. Below a certain income level, participation in the public social insurance system is mandatory. Approximately 9% of the population has opted for private insurance. 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. Until 2002, local physicians' groups were ascribed hard budgets with penalties for cost over-runs and to individual physicians indicative budgets.³

Currently, the **Netherlands** has a mixed public-private insurance system.⁴ In the public system, revenues are generated through social insurance contributions from employers and employees. Currently, approximately 2/3 of the population obtain their insurance through the public system. Most pharmaceutical 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,

² 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”.⁽²⁵⁾

³ To date, there has been a failure to follow through on penalties for cost over-runs.

⁴ Between 1992 and 1995, all citizens were enrolled in the public plan.

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).

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 to take a more proactive initiative in managing pharmaceutical budgets in the past, 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 all the population is insured for pharmaceuticals under the public system, over 80% of subscribe to "Mutuelles", a private insurance that covers the large co-payments charged in the public system.

3.2 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. While private insurance has been promoted by the Commonwealth⁵, this is chiefly for private treatment in public or private hospitals. Currently, there is no significant role for private insurance for pharmaceuticals. Pharmaceutical policy is set at the national level, through the Pharmaceutical Benefits Scheme, which is also responsible for budgets for pharmaceuticals.

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. While 40% of the population has private, non-tax deductible health insurance, there is very little private insurance for pharmaceuticals. 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.

3.3 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. As a result, Canada 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. (8) Approximately 10% of the population has no prescription

⁵ Currently, approximately 1/3 of the population is covered by private insurance.

insurance coverage – either private or public.(9;10) 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. Expenditures on health care and pharmaceuticals

Across countries studied, pharmaceuticals comprised between 10% (Netherlands) and 21% (France) of total expenditures on health in 1997. ⁶ Per capita total expenditures varied two-fold from \$193 in New Zealand to \$418 in France (U.S. dollars, purchasing power parity). Canada ranked second, after France, in total *per capita* expenditures on pharmaceuticals (Figure), but ranked last compared with the 7 comparator countries with regard to public expenditures on pharmaceuticals (Figures 2 and 3). 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. In the mid 1990's, there was a transient levelling off in growth, as expenditures appear to be rising once again. The levelling off of expenditures observed in France (Figures 1 and 2) reflect the introduction, in 1996, of national spending targets (ONDAM) in which expenditure over-runs are "clawed back" from pharmaceutical firms 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 2).

In most countries, over time, pharmaceuticals have consumed increasing proportions of total expenditures on health. 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.⁷

5. MANAGING PHARMACEUTICAL BUDGETS

A wide assortment of policy tools is available to public insurers to manage pharmaceutical budgets. Typically, 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.

The measures the 7 countries used to manage pharmaceutical budgets include (a) direct or indirect price regulation, (b) 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 (c) inducing price competition through a combination of promotion of generic drugs and therapeutic reference-based pricing (d) pharmaco-economic evaluation (e) physician budgets, and (f) consumer cost sharing,

We examine these policy tools below, considering what is known about their effects and side-effects and what may be on the horizon. Most published reports describe policies that have been implemented with little to no evaluation of their effectiveness. Evaluating the impact of these policies on drug expenditures,

⁶ 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.

⁷ 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.

cost-shifting to other budget silos, and on health outcomes is extremely difficult. There are 3 chief reasons behind this.

First, 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. Second, 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. Finally, 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.(11-13)

5.1 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. While, officially, there are no price controls in the United Kingdom or Germany, there have been price roll-backs in both countries in the 1990's and early 21st century. In the United Kingdom, manufacturers were given the opportunity to modulate prices of individual products to achieve the overall desired rollback, so that certain products could maintain higher list prices. In Germany, negotiations are underway to substitute price roll-backs with discounts, again to maintain higher list prices.

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.

As in Canada, **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.(14) In making considerations about reimbursement levels, Australia takes into consideration the prices of drugs in “reasonably comparable overseas countries”.(15)

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.(16)

Diminishing ability to negotiate prices: By virtue of the growing awareness of prices in public insurance markets in other countries, the ease of parallel importation of pharmaceuticals from neighbouring countries,

and the upcoming expansion of the European Union, the pharmaceutical industry is moving toward a single global price for its products. This leaves less and less room for public insurers to negotiate price concessions. Also, 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.

In response, those countries, such as Australia and France, that have traditionally negotiated prices substantially lower than world average are now agreeing to diminished price concessions in exchange for other concessions. For example,

- France has agreed to “higher” initial list prices for new anti-inflammatory drugs (coxibs) in exchange for **pre-negotiated price reductions** in future years.
- Australia, N.Z., and other countries have entered into **price-volume agreements** on selected products such that, above a certain volume of sales, prices at the margin drop to reflect the reduced cost-effectiveness of that product as overall usage moves into other indications for which there are more cost-effective therapies.

5.2 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. 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.⁸

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. (17) 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.

Currently, all but two countries studied – Sweden and the U.K. – have some form of positive list at the national level.⁹ However, lists of recommended drugs proliferate at the level of the County Council in Sweden and discussions are underway to establish a positive list at the national level, based on economic evaluations. In the UK, there is discussion that local formularies will be developed as Primary Care Groups in the U.K. evolve into Primary Care Trusts.

⁸ 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.

⁹ After years of on-again off-again attempts at introducing a positive list in Germany, a draft positive list has been introduced but not yet implemented.

5.3 Generics and therapeutic reference-based pricing

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”.(18) 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. In this paper, we will refer to *therapeutic* reference-based pricing to denote the subsidizing of therapeutically similar products at a common level.

5.3.1 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. 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.(19) This suggests that a free-market environment for generics may result in lower prices. However, in the United Kingdom, when the market for generics was not regulated, prices for many generic products rose by as much as 765% in 1999.(20) Consequently, in July 2000, the UK government introduced a statutory maximum pricing scheme.

Most countries studied actively promote the prescribing and/or dispensing of generic substitutes of off-patent products. 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.(18;20) 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.(18) 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 the United Kingdom manage budgets for pharmaceuticals. Therefore, they have a directive incentive to prescribe generics. In the case of France, prices on brand-name products are already relatively low, so there is less incentive for generic prescribing or substitution. Moreover, 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.

5.3.2 Therapeutic reference-based pricing

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 where the reference price 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.

5.3.3 Pharmacoeconomic evaluation

A growing trend across countries is to employ some form of technology assessment to gauge the cost-effectiveness of new therapies. Pharmacoeconomics applies principles of cost-benefit, cost-effectiveness, and cost-utility analysis to the use of pharmaceuticals.(21) 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.

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).

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 Sub-committee 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. As of 2002, NICE recommendations are now binding. The **Netherlands** now make regular use of pharmacoeconomics in evaluating new pharmaceuticals, using its own guidelines. In **Sweden**, The Committee on Reimbursement of Medicines recommended, in the Fall of 2000, that the government restrict reimbursement to those drugs that are cost-effective and at least as suited to its purpose as other comparable treatment alternatives currently subsidized. , in order to be an insurable benefit. 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.

5.4 Physician budgets

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

In 1997, the **United Kingdom** undertook major health care reforms under which a new purchasing model was formed based on primary care groups or trusts. 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.(22) Savings realized in one budget envelope may be reallocated to other services. As they take on more responsibility, Primary Care Groups are

evolving toward Primary Care Trusts that manage their budgets directly.(23) 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.(24) 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.(24) A major concern that has arisen is regional variation in the reimbursement of particularly expensive drug therapies. This has been referred to as "postcode prescribing".(25-27) Binding recommendations from NICE were intended to obviate post code prescribing. However, it has been argued that this cannot occur without central funding to implement NICE's recommendations on expensive drugs such as taxanes.(28;29) The ability of physicians collectively (through Primary Care Groups or Trusts) to manage individual physicians' prescribing behaviour is unknown at this time.

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, PCOs 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.(30) 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 than it has on high cost prescribers. In addition, budgets have not reduced the wide variation across practices in per capita volume of prescribing.(31)

In 2001, the system of physician budgets in **Germany** was abandoned. This follows several occasions in the 1990's where budgets were exceeded without any invocation of penalties.

5.5 Consumer cost sharing

The rationale commonly put forward 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. 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 cost sharing.

All countries studied employ consumer cost sharing for pharmaceuticals. 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. Until 2000, Sweden used a stepped approach, wherein the consumer shouldered 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. This has now been replaced by an initial deductible followed by a fixed co-payment until an annual cap on out-of-pocket expenditures (equal to 25 prescriptions) is reached. In Germany, co-payments are tiered according to package size.¹⁰ 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.(17;32;33) 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.(34)

6. Summary and Conclusions

While all countries in this study engage in some form of price control, the pharmaceutical industry is moving toward a single global price among industrialized countries for its new products. Therefore, the ability of public insurers to exact concessions in the list price has diminished greatly. In its place, some countries are negotiating either price-volume discounts or pre-negotiated reductions in prices in future years. Recognizing their reduced ability to negotiate price concessions, public insurers are increasingly turning toward utilization management.

Positive or negative prescribing lists are widely used to restrict the products available for subsidy. The trend, in recent years, has been toward positive lists (i.e. formularies), requiring new products to offer either cost-savings for equivalent outcomes (cost-minimization) or pricing deemed “cost-effective” over products currently subsidized.

All countries examined actively encourage the use of generic products where available. Sweden is perhaps the most conservative of the countries studied. In Canada, sales of generics by volume are approximately equivalent to those in Germany and the UK, the highest generic users among countries studied. Therapeutic reference-based pricing is employed in one form or another in four of the seven countries studied. New Zealand is perhaps the most aggressive in its use of therapeutic reference-pricing while Australia is the most selective. The best evidence to date, from British Columbia, found little evidence of discontinuation of treatment for hypertension, cost shifting to other sectors, or long-term adverse health events when therapeutic RBP was introduced for ACE inhibitors.

Physician budgets for prescription drug expenditures are currently employed in only 2 of the 7 countries studied – the UK and New Zealand. Germany has recently abandoned its experiment with drug budgets, following several failed attempts to enforce these. Evaluations of the effects of drug budgets on drug expenditures are limited by selection biases associated with non-experimental design. Physician fund-

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

holding runs the risk of physicians' denying patients more costly medications. In the UK, the recommendations issued by NICE are meant to circumvent this. However, in practicality, "post-code" prescribing remains. Variation in access to medicines also exists in New Zealand, but this pre-dates the introduction of physician budgets. The physician practice environments are substantially different from that in Canada, making it difficult to generalize the experience in those countries to Canada.

Consumer cost sharing is practised in all countries studied, though concessions for various groups exempt the majority of prescriptions in the UK and the Netherlands. Also, in France, for the majority of patients, price sensitization from co-payments is obviated through the widespread use of private third-party coverage to underwrite these costs.

As debate ensues in Canada concerning the introduction of a national pharmacare plan, the experience of the seven countries can offer insights, given that they face similar pressures on their drug budgets. Although each country may have some unique feature to their cost / utilization management strategy, for the most part, there is considerable convergence in strategies taken. The chief differences occur in the UK, where the main policy tool is physician drug budgets with binding guidance on those products reviewed by NICE, and where there is no positive drug list.

Shift from price to utilization management is wise, not only because of the reduced ability to negotiate price concessions but also because the upcoming wave of new therapies (products of genomics) are expected to be particularly effective in targeted patient groups but, because of cost, it will be particularly important to ensure that use be confined to those who are most likely to benefit from the therapy.

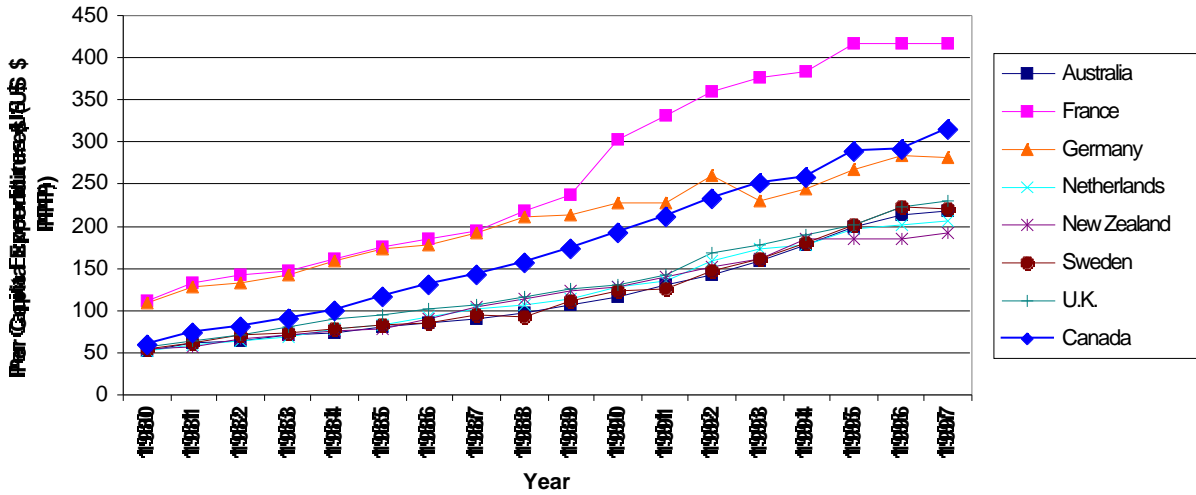
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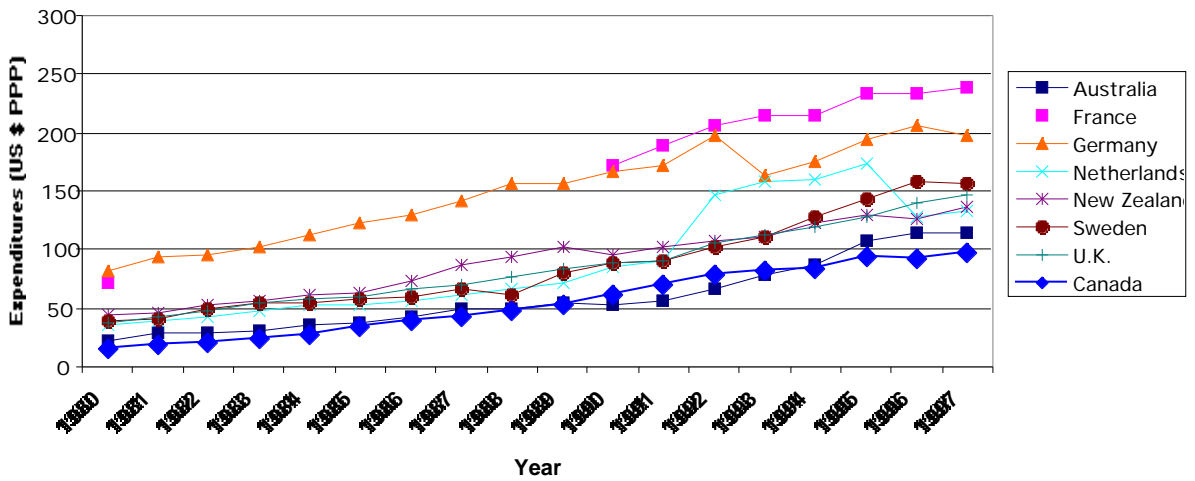
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**Figure 1. Total Per Capita Expenditures on Drugs
by Country (U.S. Dollars PPP)**



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



**Figure 3. Public Expenditures on Drugs
(Percent Public Expenditure on Health)**

