A NATIONAL FORMULARY FOR CANADA

June 25 2004.

Abstract

This article analyzes the benefits and costs of replacing Canada's ten different provincial formularies with one single national formulary. The 2002 Romanow Commission on the Future of Health Care in Canada recommended that Canada should have a National Drug Agency which would maintain a national formulary, replacing the existing provincial formularies which balkanize drug markets across Canada. This recommendation has been in part incorporated into the "Common Drug Review" in which the provinces (excluding Québec) have agreed to undertake a single evaluation of all new drugs; provinces, however, retain their own formularies and decide which products to list. This balkanized approach to listing and insurance coverage of drugs substantially weakens the bargaining position of the provinces and leads to higher costs.

A NATIONAL FORMULARY FOR CANADA

1. Introduction

This article analyzes the benefits and costs of replacing Canada's ten different provincial formularies with one single national formulary. The 2002 Romanow Commission on the Future of Health Care in Canada recommended that Canada should have a National Drug Agency which would maintain a national formulary, replacing the existing provincial formularies which balkanize drug markets across Canada (Romanow Report, Recommendations 37 and 38, page 252). A national formulary would imply a single decision-making body to control access to drugs based on national considerations. This recommendation has been in part incorporated into the "Common Drug Review" in which the provinces (excluding Québec) have agreed to undertake a single evaluation of all new drugs; provinces, however, retain their own formularies and decide which products to list based on the information established under the drug review.

The provincial formularies are the lists of drugs that are approved as a benefit under provincial drug programs. Some private insurance plans base reimbursement on the provincial formularies. The formularies also indicate which products are interchangeable. The formularies do not list every drug a physician might prescribe, but unlisted drugs generally are ineligible under most insurance plans and typically obtain minimal sales if any. Obtaining a listing in the formulary is thus essential for sales, but is not a trivial matter. When a firm seeks a listing, it may be required to complete a series of forms and provide data on the medical/chemical properties of a drug as well as a pharmaco-economic evaluation and analysis of the drug's likely impact on the province's

insurance costs. The information requirements vary by province and type of drug, although in recent years there has been increasing harmonization. Formularies list different drugs, with wealthier provinces usually being more inclusive. The Common Drug Review process, while it may help to standardize the review process, will not result in a standardized set of drugs being included on formularies. Most likely it will lead to less diversity in listing, since all provinces will be working from the same information; but provinces will still make different choices on inclusion based on budgetary and other grounds. The provinces also have quite different pharmacare insurance plans, with different levels of insurance being provided in each province. Strikingly, even the maritime provinces, with reasonably similar fiscal capacity and relatively small populations, do not have a shared formulary.

Using data on formulary costs, evidence from court cases and arguments from economic theory, our analysis compares the financial and other costs of maintaining individual provincial formularies with the potential benefits of a national formulary. The benefits of the national formulary include increasing buyers power to reduce prices, eliminating redundancy, and improving decision-making. The main cost we identify is that provinces would lose the ability to tailor the formulary to their individual financial or social situation. There is a preponderance of benefits over costs, making for a strong case in favour of the proposed national formulary.

We begin by discussing the advantages of the national formulary system; then discuss its disadvantages; and finally comment on some implications for implementation of such a system.

2. Benefits of a National Formulary

2.1 Elimination of duplication

Annual costs of maintaining provincial formularies, as well as related federal institutions, include formulary management and drug review. Prior to the establishment of Common Drug Review (CDR) at the Canadian Coordinating Office of Health Technology Assessment (CCOHTA) all costs of drug review were borne independently by individual drug plans. A significant proportion of this cost must be duplicative across provinces. In addition, each province imposes administrative costs on the firms making submissions for new drugs to be listed. The requirements for new drugs to be listed are not always trivial – provincial formularies may require a variety of evidence, and the costs of meeting the administrative requirements of 10 or so different formularies must at least equal the direct government costs, and probably exceeds it substantially. Even with the creation of the CDR program, in the absence of a national formulary there remain potential expenditures for replications of secondary evaluations at the level of each province or plan (accepting or rejecting the results of CDR) plus costs for formulary management itself.

2.2 Cost savings from buying power

Having a single formulary negotiating prices and access to the entire Canadian market might help in providing bargaining power. In general, it is thought that single large buyers are able to obtain better prices than small, disparate buyers. Essentially, the idea is that the countervailing market power of the large buyer can force the seller to offer lower

prices. However, theoretical and empirical studies on this point are somewhat mixed in the conclusions they reach about the effectiveness of buyer power.

Drug prices in Canada are determined through a variety of factors. Initially, drug companies will propose a price. The Patented Medicines Price Review Board (PMPRB), a federal body, reviews the price to ensure that meets certain criteria – mainly that it is not above the price for comparable medicines and not above the price for the same drug in other countries. At the same time, provincial governments consider whether to list the drug, using some cost-benefit criteria to determine whether the drug will contribute enough additional therapeutic value for the extra dollars it is expected to cost. For most drugs, the price proposed by the manufacturer obtains the approval of the PMPRB, implying that the PMPRB is not constraining prices very substantially. This suggests that it is provincial listing decisions which are chiefly constraining the prices that are charged, even though the provinces appear not to explicitly negotiate for price discounts (Barer, Morgan and Agnew, 2003, p. 52). However, it is not clear that provinces, in the current framework, can obtain the maximum benefits from their bargaining position.

Provinces have three principle methods of applying bargaining power: not listing a drug at all; delaying listing a drug; and giving a drug a "restricted" listing, which may require additional paperwork from the prescribing doctor. All of these could in principle be effective in bargaining for a lower price from the supplier. However, provinces are limited in their ability to strategically use these bargaining positions since with interprovincial trade, a price reduction in one province effectively implies the same price

reductions in the other provinces.[1] This makes the bargaining position of the sellers and buyers asymmetric: price reductions spread across the country, but listing decisions are specific to each province. Thus, manufacturers may prefer to get a restricted or delayed listing in one province rather than suffer a price reduction in ten provinces. The bargaining position of individual provinces is further weakened because not listing a product when it is listed in other provinces causes political difficulties, as patients then legitimately complain about the availability of the drug in their home province.

Borrell (2003) argues, using a theoretical model, that formularies can use buyer power to obtain lower prices. Ellison and Snyder (2001) examine the empirical importance of buyer size on wholesale pharmaceutical prices in the United States and find that larger buyers obtain price discounts on their purchases, but only when the buyers have some possibility of substitution. They do not find any evidence of price reductions for large buyers when the product has no therapeutic substitutes. Based on the findings of Ellison and Snyder, what is more important than the size of the buyer is whether the buyer has a credible policy of not listing drugs if the price is excessive. Thus, in the United States, HMOs and hospitals appear to be successful in obtaining considerable price discounts based on their willingness not to stock certain products. Presumably the same would apply to a national formulary – to achieve real price

[1] A 1994 PMPRB study noted that "for purposes of setting prices, patentees treat the Canadian market as one market and not ten different markets" and this conclusion was affirmed in a second PMPRB study (PMPRB 2002, page 21). The results of this second study "strongly attest to a high degree of price uniformity across the provinces. In no case does costing-out a given province's quantities at another province's prices yield an amount that differs from actual expenditures by more than 2.1 percent." (PMPRB 2002, Notes for Table 2-4, page 11.)

reductions, it would have to be willing to make hard choices in not listing overpriced products.

The fragmented situation of the formularies in Canada compares in an interesting way to the situation of Medicare in the US. The 2003 Medicare Modernization Act in the US explicitly and purposely prohibits the Department of Health and Human Services from negotiating on behalf of Medicare to obtain low prices, and fragments the consumers into smaller groups which have less bargaining power, in order to ensure that the US government would not use its buyer power in negotiating prices. The drug companies, at least, appear to have believed that they would be in a better position to charge higher prices than if they were facing negotiations with a single buyer for the approximately 41m Medicaid beneficiaries. In Canada, provincial control over formularies has resulted in a parallel situation, by accident.

2.3 Correct incentives for obtaining information

At present, each provincial formulary is not only duplicating administrative efforts, but each formulary is also only undertaking efforts in accordance with the size of its own market. Thus, Table 1 shows that Ontario and BC, the largest and third largest markets, have historically spent considerable resources on their formularies, much more than smaller markets. There is a rough proportionality to the spending, despite the fact that all formularies carry approximately the same number of drugs. Why should Ontario spend more than New Brunswick? Because spending more money on managing pharmaceutical expenditures is sensible for Ontario given the huge amounts of money it spends actually buying drugs. It should therefore be expected that a single national formulary should

optimally spend at least as much money as Ontario on managing the formulary, and probably much more. Based on Table 1, and simply extrapolating according to the size of the Canadian market, we might expect expenditures for a single national formulary to be somewhere between two and three million dollars. The total expenditures might end up being more or less than the sum of current federal provincial administrative expenditures, but at least there would be no duplication.

Table 1. Cost of Drug Reviews (2001)

Alberta	$335 000
British Columbia	$350 000
Manitoba	$21 600
Ontario	$400 000
New Brunswick	$37 700
Nova Scotia	$195 000
Prince Edward Island	$20 000
Newfoundland	$18 000
NIHB/Federal P&T	$89 011
Total	$1 529 311

Notes: The cost of drug reviews is extremely difficult to estimate as they are currently produced to different standards by both internal drug plan staff as well as by contractors. As these costs are not directly and independently tracked, various methods were applied to roughly estimate them. It should be noted that some jurisdictions included the costs for pharmaco-economic reviews, while others did not. This may account for some of the variability in the expenses reported.
Source: Nakagawa (2002).

2.4 Strategic Behaviour

The rules governing drug pricing in the provincial formularies vary widely. Most striking is the rule in Québec (*Loi sur l'assurance medicaments*, *S. III*, *Annexe II* (*Engagement du fabricant*)) requiring that the price charged for any drug in Québec should be no higher than that charged in any other province. How does this affect the national price, and the price charged in different provinces? Suppose that the optimal price by province for different drugs varies. (For example, it could be that there are lower costs of distribution in some provinces; or doctors in some provinces may be more inclined to write no-substitution prescriptions for brand-name drugs in place of generics.) If the optimal price in Québec is lower than in other provinces, then the law will have no effect. However, if the optimal price in other provinces is lower than in Québec, then the effect of the regulation will be to cause the firm to set a price which is intermediate between the optimal price in other provinces and the optimal Québec price, harming consumers in other provinces, and benefitting them in Québec. In economic terminology, the Québec regulations prevent firms from price discriminating across the country in certain drug markets. As is well known, price discrimination may be good or bad for welfare in total. However, assuming that both locations would be served in either case, preventing price discrimination will definitely harm consumers in the lower priced market.

The strategic behaviour principally affects generic drugs, not patented ones, because it is more possible to obtain generic price differentiation across provinces. The effects of the Québec regulation appear at least to harm Saskatchewan, where the provincial formulary employs a "standing offer" system which ensures that the lowest bidding firm for a given market obtains market exclusivity for a given period as well as

guaranteed payment within 30 days. For generic drugs facing market-splitting from several competitors, this system reduces the costs of serving a market and provides an incentive for aggressive pricing, typically resulting in lower prices. (F/P/T Task Force on Pharmaceutical Prices, 1999, Table 4.) During the 1990s, this policy in Saskatchewan appears to have led to generic prices which were substantially lower than in other provinces. In 1993, Saskatchewan generic prices jumped by around 10%, which, as the Federal/Provincial/Territorial Task Force on Pharmaceutical Prices noted, "coincided with the introduction of Quebec's lowest price policy" (p. 10).

While it is possible for firms in some cases to minimize the effect of this regulation by setting up a shell company to offer the same drug under a different name and different price in Québec, this procedure is costly, and firms that have not complied with the regulations have been penalized. For example, Nu-Pharm Inc., which is the largest selling generic supplier in Saskatchewan (PMPRB 2002b), was recently found to have offered a lower price for certain products in Saskatchewan. The Ministry of Health in Québec, in response, removed thirty-seven Nu-Pharm products from its formulary. Nu-Pharm successfully sued the province to re-list its products, but at the appellate level the decision was reversed on the grounds that the Minister was not acting unreasonably beyond his discretion. In a dissenting opinion, Beauregard J. noted that "The minister cannot have the best of both systems without equally accepting the disadvantages. He cannot obtain the Saskatchewan price of the manufacturer without assuring him, when he sells in Québec, an exclusivity period of six months, a guarantee of payment of invoices, and payment of invoices thirty days after delivery." (*Nu-pharm Inc. c. Québec (Ministre de la santé et des services sociaux*), (2000-09018) *QCCA* 500-09-004994-976, our

translation) The case has been appealed to the Supreme Court. In the meantime, the Québec regulations must cause Saskatchewan prices to be higher than they otherwise would be.

2.5 Elimination of differential standards

As has been observed by Anis *et al* (2001), the provincial formularies have quite different inclusion of various drugs. The variations are particularly pronounced for newer drugs, which may be included in some but not other provincial formularies. Two implications may be drawn from this. First, patients who move from one province to the next may find their treatment interrupted because of different drug lists in the different provinces. This may compromise their treatment and will almost certainly lead to some discomfort. Second, different levels of pharmaceutical availability must lead to different levels of care, so that there will be variation of the standards of medical care available in different provinces which is clearly undesirable, from both the policy and the equity perspectives. Consistency of service levels across provinces is a recommendation of the Romanow Report (Recommendation 5, page 248).

2.6 Streamline drug approval

A further benefit to be obtained from a national formulary is that it could work hand-in-glove with the PMPRB and Health Canada. At the moment, there are considerable periods of delay for the approval of many new and generic drugs at the provincial formulary level even after all the necessary federal approvals have been granted. Anderson and Parent (2001, page 32) show that the number of days required for approval

of new generic drugs varied substantially across provinces. The median number of days from submission to approval in their study ranged from 23 in BC to 254 in PEI and 232 in Ontario, and averaged around 164 days. There is clearly room for improvement here – if all drugs were approved as quickly as in BC, there would be very substantial savings.

As the common drug review is now set up, it is not clear that there will be any reductions in waiting time at all, since the process of getting drugs onto the formulary listing will now require first submission to the common drug review process and then separate evaluation by each province for inclusion on its formulary. For most drugs, the second step should be relatively quick.

3. Disadvantages

3.1 One size fits all?

There are some disadvantages to setting up a national formulary. First, provincial formularies might be thought to cater to each province's distinct needs. For example, poorer provinces might choose not to list certain expensive drugs. Some provinces might alternatively have a preference for certain drugs over others. While it is not objectively obvious why this should be the case, different provincial preferences could lead to different sets of drugs being listed. A national formulary would either have to list a larger set of drugs to meet the needs of all provinces, or it would have to limit the drugs, possibly compromising along the way.

Anis *et al* (2001), based on their study of new drug listings, conclude that the variations between provincial drug listings are so large that if the listings were combined,

the set of available drugs would increase substantially, leading to "unaffordable" costs. However, they appear to assume that increasing the set of available drugs increases total health costs. To the extent that drugs not listed in some provinces tend to offer a relatively low benefit/cost ratio, this may be true. However, the right drug in any given case may decrease total health expenditures and improve outcomes, and so having a larger set of drugs available might actually decrease health care costs while improving outcomes. Some new pharmaceutical products reduce overall health care costs so a narrow-minded (or myopic) exclusion of these products (based only on a consideration of the "silo" of drug costs) might raise health care costs. Aspirin-equivalents may be expensive to include without carefully imposed listing requirements and restrictions, especially the specification of extra paperwork on the part of the prescribing physician. However, other excluded drugs may improve outcomes but also increase costs to the province. In this case, coordinating the formularies by making them inclusive could increase costs.

There is some evidence to support the contention that some provinces have opted for lower cost formularies. For example, some of the most expensive drugs have taken a long time to obtain formulary approval. This is part of a wider pattern of variation in drug purchases observed by Morgan (2004): "Quebec residents purchased prescriptions for relatively more costly classes of drug within given broad therapeutic categories than did residents of other provinces. Residents of Saskatchewan, British Columbia and the Atlantic Provinces tended to purchase from the least costly classes of drug within treatment categories."

On average across the provinces, price appears to be one important determinant of the decision to include drugs on provincial formularies: "Among the accepted drugs, those with a price ratio above the median were 8% less likely to be included. Among the rejected drugs, those with a price ratio above the median were 10% more likely to be excluded. Price ratio showed a significant association with the coverage decision (P = 0.001)." (Anis, *et al.*, 2001, p. 322)

3.2 Loss of experimentation

A second possible disadvantage to the national formulary system we are proposing is that it would limit the scope for experimenting with different formulary programs. The provinces currently use different drug management systems and regulations. For example, Saskatchewan makes firms bid to be sole supplier to the province for some drugs; British Columbia has been aggressive about identifying drugs in therapeutic categories and then imposing substitution to the lowest cost drug within a therapeutic class; while Ontario has developed its own rules for generic pricing. This experimentation is potentially valuable, since successful experiments can provide a good model for other provinces to learn from.

However, it appears that the value of this experimentation is limited. There are formulary systems in use all over the world run by governments (as in Canada) and by private insurance companies, so the experimenting in Canada is a relatively small set of possible experiments. Even more seriously, there appears to have been relatively little adoption of successful experiments from one province to another. Perhaps this is because demonstrating that an experiment is successful is not always straightforward – it is

usually argued, for example, that lower costs may come with lower quality, or that anything that harms the pharmaceutical companies will reduce R&D in new drugs. Or perhaps provinces are simply loath to imitate each other. In any case, experiments initiated a decade ago show little sign of being adopted by other provinces.

3.3 Mismatch between decision making authority and expense

Perhaps the most important single benefit from the current system is that provinces have appropriate incentives regarding listing of drugs in the formulary since they have to pay for prescriptions for them. Provincial government programs pay for about 40% of all pharmaceuticals prescribed, meaning that provinces have strong incentives to list only products they believe will be valuable. Transferring control of the listing process would limit the control of the province over its own expenditures; and it is not obvious that a negotiated list would necessarily be the most desirable list. There are possible solutions to this problem. For example, a national formulary could include two categories – one for drugs which only some provinces would pay for, and the other category for drugs eligible for insurance everywhere. This would, of course, require provinces to decide which type of province they wanted to be, and would highlight the disparities between provinces in their willingness to finance drug expenditures, but it wouldn't require provinces themselves to maintain a staff to decide which expensive drugs they would include as benefits under provincial insurance programs.

4. Conclusions

The discussion of advantages and disadvantages above can help in thinking about what would be required to implement a national formulary. There are potentially quite substantial cost savings to be obtained from coordinating on a single national formulary which could apply bargaining power effectively through its listing decisions. The most important disadvantage is that the decision to list a drug is made nationally, while the responsibility of paying for it is provincial. This disconnect between authorizing an expenditure and receiving the bill is obviously problematic and is likely the reason that provinces, having mostly approved of the common drug review, have opted to retain control of their own formularies. If all the provinces that participated could jointly control the national formulary, each province would be in a position to have some impact on listing decisions and expenditures.

A national formulary, would, we believe, be one of the necessary steps towards developing a national pharmacare-type program, as has been proposed by some parties in the 2004 federal election campaign. As pharmaceuticals eat up an increasing share of health care budgets, it becomes more and more attractive to consider how the principal payers (the provinces) can use pharmaceuticals more effectively and at lower prices. It is also notable that there is nothing to stop provinces that have similar drug programs from immediately coordinating to share a single formulary.

References

Anderson, Malcolm and Karen Parent (2001) "Timely Access to Generic Drugs" Research paper prepared for the Canadian Drug Manufacturers Association, (Kingston: Queen's University).

Anis, Aslam H., Daphne Guh, and Xiao-Hua Wang (2001) "A Dog's Breakfast: Prescription Drug Coverage Varies Widely Across Canada" *Medical Care*, Volume 39, Number 4, pages 315-326.

Commission on the Future of Health Care in Canada (2002) *Building on Values: The Future of Health Care in Canada – Final Report* ["The Romanow Report"]

Ellison, Sara F. and Christopher M. Snyder(2001) "Countervailing Power in Wholesale Pharmaceuticals" MIT Working Paper, 01-27, July 2001.

Federal/Provincial/Territorial Task Force on Pharmaceutical Prices (1999) *Price and Expenditure Trend Analysis of Prescription Drug in Six Provincial Plans, 1990-1997*, April 1999.

Morgan, Steve (2004) "Sources of Variation in Provincial Drug Spending" *Canadian Medical Association Journal*, Volume 170, Number 3, February 2004, page 329-330.

Morgan, Steven G., Morris L. Barer and Jonathan D. Agnew (2003) "Whither Senors' Pharmacare: Lessons From (And For) Canada" *Health Affairs*, Volume 22, Number 3, pages 49-59

Nakagawa, R. (2002) "The Development of a Single Common Drug Review for Coverage of New Drugs in Canada: A Business Case Analysis." mimeo

Patented Medicines Price Review Board (1994) *Interprovincial Price Comparisons (1988 - 1993).*

Patented Medicines Price Review Board (2002a) *Inter-Provincial Prescription Drug Price Comparison 1995/6 - 1999/00*, prepared by the PMPRB for the Federal/Provincial/Territorial Working Group on Drug Prices

Patented Medicines Price Review Board (2002b) *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*

Cases and Statutes

Federal: *Canada Health Act*

Province of Québec: *Nu-pharm, Inc. c. Québec (Ministre de la santé et des services sociaux*), (2000-09018) *QCCA* 500-09-004994-976

Province of Québec: *Loi sur l'assurance medicaments*, *S. III*, *Annexe II* (*Engagement du fabricant*),.