USE AS NEEDED:

The mixed impact of reference pricing for prescription drugs

BRIAN FERGUSON

JULIA WITT

February 2009

Atlantic Institute for Market Studies

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EXECUTIVE SUMMARY

In any drug insurance system, public or private, a key issue is how to pay for the drugs the plan covers. One option is simply to have the plan pay the full cost of any covered prescription. However, unless accompanied by price ceilings and some tight restrictions on quantity, this approach can be counted on to run well over budget quickly.

The most common form of quantity restriction is the publication of a list of approved drugs — those for which the plan will pay. In the United Kingdom's National Health Service (NHS), for example, if the National Institute for Clinical Effectiveness approves a drug as cost effective, all NHS Trusts (which are really public sector corporations that provide many of the health services) are required to pay for it; if the drug does not pass the cost-effectiveness test, the NHS pays nothing toward its cost (though individuals may purchase it privately). The result has been that some Trusts have had to cover additional drugs regardless of the impact on their budgets, while some patients who might benefit from new, but not-yet-approved, drugs have had to bear the full cost of their purchase.

An alternative pricing system is the traditional co-insurance approach, in which the insured individual pays a certain percentage of the price of a drug and the plan pays the rest. Although this approach, which is common among private plans, sounds reasonable, it actually has contributed to rising drug prices over the years. In the long run, then, any such payment plan would have to be accompanied by a form of price ceiling.

Another approach, the focus of this paper, is *reference pricing*, which is used to set prices for clusters of similar pharmaceuticals for which there are substantial price differences.[1] Under this approach, pharmaceutical products are grouped into clusters using three different levels. The first level, and the one which most narrowly defines the clusters, is products that have the same active chemical ingredient — mostly brand-name drugs and their generic substitutes. The second level includes products with active ingredients that are chemically related but pharmacologically equivalent — for example, all ACE (angiotensin-converting enzyme) inhibitors. In the third level are products that are neither chemically identical nor pharmacologically equivalent but that have comparable therapeutic effects — for example, drugs that lower blood pressure.

Whatever approach is used to cluster drugs, the next step is to define the maximum price the plan will pay for a dose of any drug in a particular cluster and to determine the pricing structure that will be used. This could be either reference pricing, where drug companies are free to charge a price above the reference price but consumers must pay the excess out of pocket, or price ceilings, where drug companies face an upper limit to the price they can charge for their products.

[1] For details on the general structure of reference-pricing systems, see Danzon (2001).

International Experience with Reference Pricing

Variations on reference-pricing systems have been adopted in a number of countries — for example, Sweden (1993), Denmark (1993), Australia (1996), Italy (1996), and Spain (2000) (Danzon 2001). The literature on reference-pricing systems is growing, but slowly — a recent review (Aaserud et al. 2006) reports only ten evaluations of reference pricing.[2] The experiences of three countries — Germany, the Netherlands, and New Zealand — and that of British Columbia offer lessons about the implementation and operation of reference-pricing systems.

The German Experience

The first reference-pricing system for pharmaceuticals was implemented in Germany in 1989; it was not comprehensive. Manufacturers' price levels were used to set the reference price levels and pharmaceuticals were clustered in three phases: (1) products with the same active ingredient; (2) therapeutically and pharmacologically similar active ingredients; and (3) compounds with comparable therapeutic effects (Danzon 2001).

Despite the implementation of reference pricing, however, drug spending in Germany continued to grow. In 1993, in response to growing budgetary pressures, Germany increased patient co-payments, imposed a 5 percent price cut on non-reference-priced drugs, and implemented a national drug budget that limited outpatient drug expenditures. Responsibility for any spending over the limit was that of physicians for the first 280 million deutschmarks (DM) and that of the pharmaceutical industry for the next 280 million DM (Danzon and Ketcham 2003).

While Germany's reference-pricing system did not reduce expenditures on pharmaceuticals, the implementation of the national drug budget decreased such expenditures by 19 percent. The national drug budget was abolished in 2002.

The Dutch Experience

The Netherlands adopted reference pricing in 1991, and designed it to include all drugs, whether or not they are still under patent.

Under the Dutch plan, prices are defined using the World Health Organization's "defined daily dose" system.[3] Pharmacists may substitute generic drugs for brand-name drugs, but must inform the patient if they do so. For each prescription they fill, pharmacists receive a fixed dispensing fee and are allowed to keep one-third of the difference between the reference price and the list price of the cheaper substitute. This encourages pharmacists to substitute cheaper generic drugs for brand-name drugs. At the same time,

[2] For details, see Grootendorst et al. (2002a, 2002b); and Dolovich, Holbrook, and Woodruff (2002).
[3] For a detailed description of this system, see the World Health Organization's Web site: <http://www.whocc.no/atcddd/>.

pharmacists may retain any discount in the manufacturer's price below the list price, which encourages manufacturers to compete for market share by offering discounts off the list price, but not by reducing the list price (Danzon and Ketcham 2003).

Drug clusters were initially based on a set of five criteria, but by 1999 the only criterion was clinically relevant differences in effects that are influential in physicians' prescribing decisions. One problem was that new products would be reimbursed only if they joined an existing cluster, which led to an increase in the number of drugs that were approved for marketing but that could not be reimbursed. Since 1997, however, it has been possible to reimburse new products that do not fit into existing clusters if no other pharmaceutical treatment is available.

In 1996, the Netherlands introduced a law setting the maximum price for each dose molecule according to the average price in Belgium, France, Germany, and the United Kingdom. As a result, prices declined an average of 15 percent, and the maximum price of many products fell below their reference price. In 1999, the Netherlands reduced reference prices based on these maximum prices.

The New Zealand Experience

In New Zealand, which introduced reference pricing in 1993, the reference price is set at the lowest price in each cluster — defined as on- and off-patent pharmaceuticals with similar or equal therapeutic effects for similar or equal conditions. New products must join a cluster in order to be considered for reimbursement. The Pharmaceutical Management Agency (Pharmac), owned by the government's Health Funding Authority, exercises its monopoly power in negotiating the prices of new products. A new product is reimbursable within an existing cluster if it is priced well below the reference price of that group. Manufacturers can also negotiate a cross-therapeutic deal with Pharmac to reduce the price of an old product in order to launch a new product at a higher price. If the price of the old product is reduced substantially, this could mean a new reference price for that entire group. In 1996, for example, a cross-therapeutic deal reduced the price of one product — and the reference price of the whole group to which it belonged — by 40 percent in return for a listing on the reimbursement schedule for another product (Danzon and Ketcham 2003).

British Columbia's Plan

British Columbia adopted reference pricing in 1995 with the establishment of the Reference Drug Plan (RDP). The plan was meant to constrain pharmaceutical expenditure growth, and is based on the principle that people should pay for an evidence-based standard of drug therapy (British Columbia 2002). The plan initially had three drug categories (therapeutic classes), but two more were added in 1997. The RDP uses the lowest price in each cluster as the reference price, and includes patented products in its reference-pricing system (Kanavos and Reinhardt 2003). The program clusters drugs by therapeutic effect and encourages the use of closely related but chemically distinct products that are more cost effective. In order to have their drugs placed on the reimbursement list, manufacturers must prove their cost effectiveness.

Reference pricing is estimated to have saved British Columbia's health insurance plan approximately $35 million annually (Morgan, Bassett, and Mintzes 2004).

IMPLEMENTING A REFERENCE-PRICING SYSTEM

The implementation of a reference-pricing system requires consideration of some important issues, including how much centralization there should be, how to define therapeutic clusters, how to set the appropriate reference price, and how such a system might affect physicians and pharmacists (see Kanavos and Reinhardt 2003).

Determining the Degree of Centralization

One key issue is how to determine the degree of centralization. Highly centralized systems reduce administrative costs, but can also diffuse errors in categorizing pharmaceuticals or in setting reference prices throughout the entire system. A highly centralized system might also affect manufacturers' research and development (R&D) decisions, as future cash flows from new drug launches become more uncertain. In Germany, for example, on-patent (that is, new) drugs were removed from the reference-pricing system in 1996 on the argument that manufacturers could not recover R&D costs at the reference price and thus would lack incentives for further R&D. If a centralized system were introduced in a country with high R&D costs, other rewards would need to be found to encourage innovation outside the reference-pricing system.

Defining Therapeutic Clusters

A second implementation issue concerns how to define therapeutic clusters and what to include in them. On-patent drugs can be included in groups of products that are pharmacologically equivalent or therapeutically comparable, but doing so can affect innovation, making it difficult to recover costs when generic versions become available in the same class. Moreover, patients might be unwilling to pay for the added value of patented drugs, making consumer-driven health care less feasible. As well, how physicians form their opinions of new drugs and their generic substitutes is important before and after clustering into therapeutic groups because they are the ones prescribing the medications. Finally, larger clusters increase equity concerns since, as higher-priced and lower-priced drugs are grouped together, they make higher-priced drugs more difficult for low-income patients to afford (Danzon 2001). Since larger clusters would include products that differ in effectiveness and side-effects, patients that cannot tolerate the lower-priced drugs in such a large cluster are then faced with a higher co-payment to purchase the higher-priced drug that is better for their health, but not because they choose to purchase the more expensive drug. Indeed, the lack of interchangeability is considered the most controversial aspect of reference pricing (see López-Casasnovas and Puig-Junoy 2000).

The degree of both interchangeability and heterogeneity of pharmaceuticals that are grouped together in one cluster raises further important issues. First, without interchangeability, reference pricing might discriminate against patients who cannot avoid co-payment, because they cannot tolerate lower-priced drugs in a cluster and therefore have no choice but to make the extra out-of-pocket payment. Second, there could be adverse health effects if drugs are chosen simply to avoid co-payments. And third, a lack of interchangeability might discriminate against some manufacturers if patients choose not to purchase

pharmaceuticals that are potentially more beneficial due to their higher price. The problems associated with heterogeneity can even lead to increases in other health care costs, lower health outcomes, and distorted competition in the pharmaceutical market (López-Casasnovas and Puig-Junoy 2000).

Setting the Reference Price

A third implementation issue is how to set the reference price. This includes deciding, among other things, whether to use the market price or the cost to manufacturers and where to set the reference price in that distribution. But this decision is complicated by other factors. For example, if on-patent products are to be included in the reference-pricing system, then setting the price at marginal cost is insufficient because it does not encourage R&D, which represents approximately 30 percent of total cost. However, "generic referencing" (off-patent products only) is potentially consistent with efficient incentives for R&D (Danzon 2001).

Defining "one dose" is another complication in establishing a reference price. For example, while a stronger dose of a particular medication that needs to be taken only once a day could be twice as expensive as a weaker dose of the same medication that needs to be taken twice a day, evidence suggests that patients are more compliant when they have to take fewer doses, making once-daily medication more effective and potentially less expensive in the longer run.

Another problem with setting a reference price is the frequency of necessary revisions (Danzon 2001). Adjusting therapeutic reference prices is costly to manufacturers, physicians, and patients alike. For example, changing the reference price because a new drug has been added to the cluster affects all products in that cluster. Since the products are not as closely related as generic substitutes, a new lower reference price makes some products relatively more expensive for patients. This, in turn, might affect physicians' prescribing behaviour, if they have to take the time to explain to the patient why they now have to pay more. It might also affect manufacturers, who see their market share fall as physicians and patients increasingly switch to a cheaper substitute. When clusters are narrow, as in generic referencing, however, a change in the reference price entails no significant costs (Danzon 2001).

Implications for Physicians and Pharmacists

The requirements that a reference-pricing system imposes on physicians are also important to consider. In Germany, for example, physicians are required by law to explain to their patients why an additional payment (the difference between the reference price and the manufacturer's price, if higher) is necessary. Since appointment times are relatively short in Germany, however, physicians may have an incentive to prescribe the cheapest medication routinely in order to avoid spending time justifying their choice to the patient. But requiring physicians to spend additional time explaining the choice of a higher-priced or new substitute drug would add extra costs in the form of longer physician visits, possibly additional tests, and return visits if the drugs prove ineffective, with the possible transfer of costs to other sectors of the health care system.

The difference in reimbursement and acquisition costs to pharmacists should also be considered when setting reference prices. In the Netherlands, for example, pharmacists have an incentive to encourage the use of cheaper drugs because they are allowed to keep the difference between the list price and the reference price. Moreover, this means manufacturers have an incentive to offer discounts to pharmacists, but not to reduce their list prices to consumers in order to gain market share without affecting the reference price.

THE EVIDENCE ON REFERENCE PRICING

In evaluating the success of reference pricing, it is sometimes difficult to disentangle the effects of such a scheme from those of other policy measures targeted at pharmaceutical spending. Reference pricing has distinct advantages for consumers, insurers, and pharmaceutical manufacturers, but it must be properly implemented, well managed, and fair.

To be successful, any reference-pricing system must balance patient care and the promotion of the R&D that provides new — though perhaps more expensive — treatments. Patients must be prepared to absorb out-of-pocket costs for some drugs, insurers must monitor the effectiveness of the reference-pricing system, and manufacturers must find ways to get their products to market at a competitive price. The resulting system would offer access to more drugs on at least a cost-shared basis, broaden markets for a wider variety of products, and allow insurers to improve cost control and predictability. Even the most perfect system, however, faces persistent challenges that would need to be addressed.

Most reference-pricing exercises have shown that patients are sensitive to out-of-pocket drug expenses — indeed, that poor patients will even stop taking medication to avoid such expenses. This is in contrast to conventional wisdom, which suggests that patients are impervious to price increases for the drugs they need. In reality, consumers make a conscious economic choice between different drugs for the same condition. Graham (2002) argues, however, that reference pricing distorts the marginal cost of various drugs, which creates a bias in favour of less-effective drugs that are priced below the reference price. According to his analysis, under reference pricing the patient has to pay out of pocket the full difference between the more expensive and the less expensive drug, whereas under a co-insurance system the patient pays the same percentage of the full price of each drug.

While Graham has a point, it is important to note that reference pricing forces both the patient and the physician to weigh the incremental cost of a new drug against its incremental benefit. A co-insurance scheme does not increase the incremental benefit of a new drug; it simply allows the patient to pass on some (or all) of the incremental cost of the treatment. This is the essence of the moral-hazard problem, which has led many economists to argue that the structure of most health insurance plans is a major reason for the high cost of health care.

More important, though, are the implications of co-insurance and reference pricing for the market price of drugs. Many health policy commentators neglect the basic principle that, just as consumer demand responds to prices, so prices must respond to consumer demand. While the demand for health care as a whole is not very responsive to demand, the demand for the product of individual suppliers — in this case, individual drug companies — is quite responsive. The empirical evidence shows that, when faced with a reference-pricing system, consumers quickly shift away from the higher-priced drug toward a lower-priced one, and the supplier of the higher-priced drug would face a considerable loss of market share unless it responded by lowering the price. In the Netherlands, for example, after a reduction in the reference price, drug companies slashed prices in response to increased customer sensitivity to prices (Windmeijer et al. 2004). In Germany, when reference pricing reduced a flat prescription fee (a fixed

price that consumers were required to pay for each prescription) and consumers were exposed to greater costs for higher-priced drugs, manufacturers responded by lowering prices (Pavcnik 2000). Furthermore, the price cuts were greatest where there was the most competition. Apparently, drug companies thought it was more important to hold on to market share at a lower price than to charge a high price and have virtually no market. In short, the market functioned as it was meant to.

When it comes to government-funded programs, however, the evidence is mixed due, as noted above, to the difficulty of differentiating the effects of reference pricing and those of other policy measures. Government-funded schemes also must be designed and adapted properly to correspond with market realities. For example, in the Dutch case, where pharmacists were allowed to keep the difference between list and reference prices, the Dutch health care system did not benefit from lower prices, and funds were being diverted from future research activities by brand-name drug companies (which could not afford to give discounts on their drugs because they had to recover their R&D costs). Instead, it seems that these funds were being split between generic manufacturers and pharmacists.

CONCLUSION

A study by the Competition Bureau Canada (2007) found that drug manufacturers and pharmacies were given little incentive to offer public plans low competitive prices on generic drugs, but that instead, pharmacies received incentive payments through off-list rebates that were not reflected in the price that provincial plans had to reimburse.

As a result, in a more recent report (Competition Bureau, 2008), the Competition Bureau suggested that in order to obtain the benefits from generic drug competition, which could lead to substantial savings on drug expenditures, public plans should, among other things, put in place mechanisms that would allow generic drugs to be reimbursed based on their competitive prices. Three approaches were suggested, all of which aim to put in place mechanisms that reveal the true competitive prices. Reference pricing is another approach that would ensure that drugs get reimbursed at competitive prices.

Despite its complexities, reference pricing appeals to consumers because it allows them a degree of choice, while permitting better access to treatment for those who might not otherwise afford it. For suppliers, reference pricing encourages competition and makes it easier to recover the costs of investment in R&D. Perhaps most important, since reference pricing does not exclude certain drugs from coverage, it does not limit physicians' choice of treatment for their patients. Regardless of the price of the necessary treatment, patients pay less than they would if the prescribed drug were not reimbursable at all.

Ultimately, however, reference pricing works well only if it is used appropriately.

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