

Competition in the Off-patent Sector: The US Experience

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In pharmaceutical policy, the European Union (EU) faces a conflict between three basic principles or objectives. The principle of member state autonomy in healthcare results in different prices for medicines in different countries. However, the principle of free trade has been interpreted to include parallel trade, which "exports" low prices from countries with stringent regulation to higher-price countries, thereby undermining these price differences. The resulting downward pressure on prices and manufacturer revenues tends to undermine the industrial policy objective of promoting innovative R&D in the EU.

The **Bangemann** process was established to address this conflict of principles. The December 1997 meeting (see *PPR* January 1998, pp 4-6) suggested a possible compromise solution, founded on the idea of differentiating policies for on-patent and patent-expired products. The idea is to stimulate competition – including permitting parallel trade – in the off-patent sector that includes generics and OTC medications, in order to free-up budgetary "headroom" for on-patent, innovative products, which **might** be protected from parallel trade to **preserve** incentives for innovation.

Details of such a **two-prong** strategy remain to be worked out and agreed upon. However, the basic principle, that competition policy should **distinguish** between the on-patent and off-patent sectors, is sound economic policy and is consistent with the fundamental purpose of patents as a necessary protection for **innovation**. Patents intentionally restrict competition from generically equivalent compounds, in order to **give** the innovator firm an **opportunity** to recover its investment in R&D. Since patents are of limited duration and do not bar competition from therapeutic substitutes, recovery of R&D costs is possible although not assured. Parallel trade reduces the likelihood that innovator firms can recoup R&D expense, but provides no efficiency gain for consumers in return, because low prices generally reflect stringent price regulation, currency fluctuations **and/or** weak patent protection, not superior efficiency in low-price countries. By contrast, once the patent term **has** expired, there is no economic rationale for restricting competition from generically equivalent products, including parallel **imports** – indeed, there is a presumption that post-patent competition generally increases consumer welfare for pharmaceuticals as

for other industries.

Benefits of Off-Patent Competition

This combination of policies – stimulus to competition in the patent-expired sector combined with protection from unreasonable competition for patent-protected products – could offer a win-win **compromise** that is budget **neutral** for payers, while **strengthening** incentives for **innovation**. **Assume** that there is a **shift** of budgetary spending from the off-patent sector to the on-patent sector, **through** some combination of lower manufacturer prices, lower distribution **margins**, reduced volume or increased patient **co-payment** on **generics** and **OTCs**, and either **higher** prices or broader patient access to on-patent products. Even if such a budget **neutral** reallocation of funds were also revenue neutral to a **research-based** firm – for example if the revenue reduction on its **off-patent** generic and OTC products just offset a revenue **increase** for its newer on-patent products – this could nevertheless provide a **significant** stimulus to R&D. The reason is that revenue is shifted from the later years to the earlier years of the product life cycle. The incentives for R&D depend on the discounted present value of expected revenue flows **over** the life-cycle of a drug. Early revenues are more valuable to the firm than the **same** revenues received later in the life-cycle, because later revenues are discounted. The **higher** the **discount** rate, the lower the discounted present value of post-patent revenues. Thus shifting the same revenue from the post-patent phase to the on-patent phase **increases** the discounted present value and increases incentives to invest. Since the real cost of capital for research-based pharmaceutical firms is 10-11 percent (Myers and **Shyam-Sunder**, 1996), revenue received after the tenth year (a **rough** estimate of patent expiration) is discounted by over 60% in a present value calculation.

¹ The opinions expressed here are entirely those of the author. They do not necessarily reflect the views of other **members** of the **Bangemann** Working Group 1, in which the author participated.

An obvious question is, if there are large potential savings from increased competition in the off-patent sector, why have they not already been realised? One factor of course is that a reallocation of funds that is budget neutral to the government and revenue neutral to industry overall would still result in winners and losers among individual firms, because not all participate equally in the on-patent and off-patent sectors, and possibly also to intermediaries, depending on how the off-patent savings are achieved. Thus achieving consensus will not be easy. Nevertheless, the relatively large size of the off-patent sector compared to the on-patent sector in many EU countries (see PPR December 1997, p 225) provides leverage such that a modest cut in off-patent prices could yield a significant gain in the on-patent sector. To illustrate, if on-patent drugs account for only 25% of total reimbursed spending while the remaining 75% is spent on off-patent drugs (roughly the EU average), then a 10% price (or volume) reduction in the off-patent sector would fund a 30% increase in average price (or volume) for the on-patent sector because the latter is only one third as large, while remaining budget neutral to government

Of course, some countries in the EU do already realize significant savings in the off-patent sector. Multisource generics have a significant market share in several countries and are often reimbursed using relatively low reference prices. Most EU countries have deregulated manufacturer prices for OTCs (exceptions are Austria, Belgium and Greece (PPR January 1998, p6)). However, the US experience suggests that significant additional savings remain to be realized in the off-patent sector in most EU countries.

Relevance of the US Experience

In the field of health policy the US is often viewed as a model of pitfalls to be avoided, not strategies to be emulated, because of its high per capita spending and gaps in universal coverage. However, it is important to distinguish between the macro, financing policies, which are primarily responsible for high costs and gaps in coverage, and the micro experience at the level of healthcare delivery, which provides useful experience on innovative strategies in cost control and consumers' preferences between them. In the case of pharmaceuticals, US per capita spending is comparable to the EU average. Nevertheless, US-based companies are undisputed leaders in innovation (Barrall, 1995), and many non-US companies are seeking to increase their presence in the US market, either through acquisition or shifting components of their R&D activities to the US. Many factors no doubt contribute to the R&D-friendly environment of the US. The size of the US market might appear to be an advantage but in terms of total sales the EU market is larger. More important probably is the free pricing environment, constrained primarily by competition rather than regulation

The conventional wisdom is that free pricing of pharmaceuticals results in US prices that are significantly higher than European prices. However, such conclusions are based on comparisons that use small samples of leading on-patent branded products, ignoring the off-patent generic and OTC sectors where US prices are relatively low because of aggressive price competition. We have calculated cross-country comparisons of average prices applying standard index

number methods to the full market basket of matching compounds between the US and eight other major markets (Danzon, 1996). Compounds that are available in only a single country cannot be included, but many generics and OTCs are included, appropriately weighted to reflect their market shares. With this more fully representative market basket, US prices on average are comparable to or lower than those in Germany, Canada, Switzerland and Sweden. Not surprisingly, since the multisource generic and OTC sectors tend to be larger and have lower prices in countries with relatively free pricing, omitting these important sectors from international price comparisons tends to bias upward the estimates of price levels in countries with freer pricing compared to countries with more strictly regulated prices that typically have smaller and/or less price-competitive generic sectors. Thus when generics and OTCs are included in international price comparisons, the US is in line with several other countries and the UK, which also has a large, competitive generic market, has second from the lowest average price levels of the nine countries compared, after France.

Competition in Pharmaceuticals in the US

Although access for new drugs to the US market is strictly regulated by the FDA, to assure safety, efficacy and quality, pricing and distribution are largely unregulated. Competition occurs at all levels, from the health plan down through dispensing to the manufacturer level. Indeed, an important lesson from the US experience is that to realize the full benefits of competition requires competition at all levels. For example, if wholesale margins are competitively determined while retail margins remain controlled, competition is stunted and some of the benefits of the partial deregulation may accrue to the remaining regulated participants, rather than to payers or consumers.

1. Competition Between Plans

In the US, the public programmes Medicare and Medicaid, respectively, target the elderly (over 65) and the poor. Over 80% of the population not covered by these public programmes obtains private insurance. Of the privately insured population, over 70% is now in some managed care organization (MCO), including HMOs and PPOs. These plans compete for consumers on the basis of breadth of coverage, cost (premiums and out-of-pocket payments) and quality. Since the early 1980s, many plans have added coverage of outpatient drugs as a competitive strategy. These recently added drug benefits are typically "managed", either by the plan itself or by specialized pharmacy benefit managers (PBMs) that contract with all types of health plans, from HMOs to traditional indemnity plans, to manage the pharmacy benefit. The fact that very few plans now offer traditional unmanaged pharmacy benefits, which simply reimburse the patient for the cost of the drug after a co-payment (typically 20%) suggests that most consumers prefer the managed plans that offer lower premiums in return for modest restrictions on choice of drugs and pharmacies.

A managed prescription drug benefit usually includes the following components:

- a contracted pharmacy network that agrees to discounted fees,
- electronic, point-of-service claims adjudication and

processing that eliminates paperwork and invalid claims;

- a formulary of preferred, "cost-effective" drugs;
- an aggressive generic substitution programme;
- negotiated discounts from manufacturers for incremental market share; and
- utilization review and management

As we review the competitive purpose of these different components, two key points emerge. First, competition between health plans, to offer broad coverage to consumers at reasonable cost, forces competition down to the retail pharmacy and manufacturer pricing levels, passing on the benefits of competition at each of these levels to consumers. Second, this can occur because the necessary legislative and regulatory structure is in place in the US, in contrast to many European countries.

2. Competition in Retail Pharmacy

2.1 Regulatory Structure

Although individual pharmacists are subject to strict licensure requirements in the US as in other countries, the business of retail pharmacy is largely unregulated in the US, in contrast to many other countries. Pharmacies may be owned by non-pharmacists, although a licensed pharmacist is always in charge of dispensing. Free entry – including by mail order and supermarket outlets that are operated but not necessarily owned by licensed pharmacists – is a further stimulus to competition. Branching and chains are permitted and can take advantage of economies of scale to reduce prices and increase convenience for consumers. These scale economies include spreading the fixed costs of information systems for electronic claims processing and inventory control; ability to offer consumers a broader range of products and longer hours, hence greater convenience; and volume discounts in purchasing. The chain pharmacies compete aggressively on price, particularly for OTC medicines and dispensing fees. Thus although the number of pharmacy outlets has remained essentially constant over the last decade, the number of independents has declined while the number affiliated with chains has increased. This shift towards more concentrated ownership of geographically diffuse retail outlets is a familiar feature in many countries for other retail and service industries, such as banking. Many of the same economic forces that lead to branching in other industries apply in pharmacy and have led to chain pharmacies in countries where regulations permit. The evidence from the US suggests that permitting pharmacy ownership by non-pharmacists, including branching, reduces costs, increases competition and lowers prices to consumers without loss of service quality which is protected by requirements for dispensing by licensed pharmacists.

2.2 Competitive Contracts

PBMs take advantage of the competitive environment in retail pharmacy to reduce dispensing margins. PBMs contract with a select network of pharmacies that agree to accept discounted dispensing fees in return for the higher volume that flows from participation in the network. The dispensing fee is usually a fixed fee per script (roughly \$2-3), rather than

the traditional percentage of price. In addition, the participating pharmacist agrees to accept reimbursement for ingredient cost at a pre-agreed discount off the average wholesale price (AWP) of drugs purchased. AWP is a list price used primarily as a benchmark for reimbursement purposes. Competition between wholesalers faced with price sensitive retailers results in significant discounts, such that AWP is not necessarily the average of actual wholesale prices. Competitive pressures thus result in pharmacists accepting reimbursement at prospectively determined discounts off AWP in the 10-18% range for branded products, 40-60% for generics or sometimes even lower effective prices if a MAC (see below) rather than a discounted AWP rate is used for generics (Kongstvedt, 1996).

This reimbursement structure creates incentives for pharmacies to be highly price sensitive purchasers from wholesalers, which in turn stimulates price competition in manufacturer pricing, particularly in the off-patent sector where pharmacists are most price sensitive as a result of the structure of generic substitution programmes.

2.3 Generic Substitution Programmes

Since the 1970s and 1980s, all states have abolished anti-substitution laws and have authorized pharmacists to substitute between approved, generically equivalent products, unless the physician explicitly prescribes the brand and notes "dispense as prescribed"

Over 80% of managed care plans have generic substitution programmes for off-patent, multi-source products. A common format is to set a "maximum allowable cost" (MAC) as the maximum reimbursement. The MAC is based on actual generic prices, taking into account discounts from AWP. If a manufacturer's price exceeds the MAC – as is likely for branded products – the patient must usually pay the difference. Thus from the patient's perspective, managed care generic substitution programmes are similar to the German reference pricing system for multisource products from 1996, when patent-protected products were first exempted.

However, a critical difference for purposes of competition is that the US pharmacist is authorized to decide which generic product to dispense and retains the difference between the reimbursement price and the acquisition cost or manufacturer's price. Not surprisingly, pharmacists are highly price sensitive in their choice between multi-source products and this in turn creates strong incentives for generic manufacturers to compete on price.

3. Competition in Manufacturer Pricing

3.1 Generics

Faced with very price sensitive pharmacy customers, generic manufacturers compete aggressively on price. This results in absolute pharmacy margins on generics that are on average higher than on branded products (Grabowski and Vernon, 1996). For major products such as Tagamet (cimetidine) and Capoten (captopril), following patent expiry and generic entry, generic erosion of the originator brand's market share is usually almost complete within a few months, while generic prices fall to as low as 10% of the brand price before patent expiration. The saving from this rapid and widespread shift to very low-priced generics is passed on to consumers and payers

as managed care plans revise the MAC downward to reflect falling manufacturer prices on generics.

A further result of aggressive price competition and easy substitution between generically equivalent drugs is that as patent expiry approaches, promotion effort by brand manufacturers often declines, because much of the market-expanding effect of promotion would accrue to generics (Caves and Winston, 1991). Generics compete primarily on price, not brand image; indeed, most generics invest little in promotion of brand image because generic prices are too low to cover significant promotional expense.

3.2 On-Patent Products

PBMs and other MCOs use formularies of "preferred" drugs that are selected by a pharmacy and therapeutics committee, which includes pharmacists and doctors who participate in the plan. In selecting between drugs that are close therapeutic substitutes, price and cost-effectiveness relative to alternatives are important factors. Physicians are encouraged to use preferred drugs, although non-preferred drugs may be prescribed. In some cases (closed formularies) the patient may face a higher co-payment. This ability of PBMs to shift market share towards preferred drugs enables them to negotiate manufacturer discounts from list prices. Because these discounts are not reflected in list prices, cross-country price comparisons between the US and other countries usually overstate the prices received, net of discounts, by manufacturers in the US.

These discounts might be even greater were it not for the requirement, since 1989, that manufacturers offer Medicaid and other public programmes the "best" (lowest) price given to any private purchaser. Whereas a discount is negotiated with a private plan in return for gain in market share, no such volume gain results when the "best price" is automatically extended to another programme. Consequently, the "best price" requirement increases the revenue loss to a manufacturer from offering deep discounts to private payers. Economic theory suggests and anecdotal evidence confirms that this best price requirement has tended to reduce discounts given to private payers. Comprehensive data are not available because these discounts are proprietary.

This "best price" experience in the US demonstrates more generally the effect of tying prices paid by one purchaser to the lower prices paid by other, more price sensitive buyers. Faced with such a spill over of prices between market segments, manufacturers rationally are less willing to offer low prices to the previously low price buyers. This is simple economics and occurs in any market where market segmentation breaks down, not just pharmaceuticals. There is a parallel between the US experience with the Medicaid "best price" programme and the EU experience as relatively high price countries attempt to hold down their prices by tying them to lower foreign prices, either through regulation based on foreign prices or parallel trade. Theory predicts that this will lead manufacturers to raise prices in the previously low price countries and move towards a single price policy. Consistent with this, major manufacturers now attempt to maintain launch prices within quite narrow bands in all major markets.

OTCs and Sole Source Generics

OTC products are generally not covered by insurance in the

US, thereby freeing up insurance funds for other purposes, whereas reimbursed OTCs are a significant fraction of public spending on drugs in some other countries. It is often argued that eliminating reimbursement of OTCs and other non-essential drugs through a negative list would actually increase total insurance costs because patients (or physicians on their behalf) would switch to more expensive, reimbursed alternatives. This could result in higher outlays not only on drugs but also on physician visits to get the prescription.

The validity of this argument, that reimbursement for relatively inexpensive OTCs saves money, depends critically on the level of patient co-payment. If patients make a rational calculation based only on their out-of-pocket costs, they would make the physician visit to obtain a reimbursed Rx drug, rather than buy a cheaper OTC drug if the co-payment (c) on the Rx product (P_{Rx}) plus the co-payment on the physician visit (V) is less than the price of the OTC (P_{OTC}):

$$cP_{Rx} + cV \leq P_{OTC} \text{ although } P_{Rx} \geq P_{OTC}$$

This condition – that the patient faces an incentive to prefer a more costly but reimbursed prescription drug over a less costly OTC – occurs if the co-payment on Rx drugs and physician visits is low and prices of OTCs are relatively high.

In the US the opposite is more likely: co-payments on Rx drugs and physician visits are higher than in many European countries, whereas OTC prices are relatively low. In this environment, excluding OTCs from reimbursement saves money to the health plan and avoids the perverse switching to higher priced but reimbursed Rx products when cheaper and adequate OTCs are available. The implication is that if budget savings are to be realized from delisting OTCs from reimbursement, significant co-payments on reimbursed Rx products may be necessary in order to deter inefficient substitution. In order to protect patients from excessive out-of-pocket cost, these co-payments can be capped by an annual limit on the patient's out-of-pocket expense, as exists for example in Japan. However, if the co-payments are incorporated in the basic social insurance plan but are then covered by supplementary insurance, as commonly occurs with mutual insurance in France, this nullifies the effect of the co-payment, making substitution towards higher-priced, reimbursed Rx drugs likely.

The second feature that makes OTCs an more important source of savings in the US is their low prices. This results from two factors. First, because OTCs are not reimbursed, consumers are more price sensitive, which avoids the cost-increasing effects of insurance. Second, because pharmacies can and do compete on price to consumers, they are highly price sensitive purchasers and this creates incentives for price competition by manufacturers. In our on-going analysis of cross-national price differences for pharmaceuticals, we find that US prices for products that are OTC in the US are significantly lower than prices for the same compounds in other major markets of Europe or Japan.

Comparison with Other Countries

In countries such as France, Italy and Japan the market share of generic producers of off-patent, multi-source products is small. Although generic market shares of off-patent molecules are significant in other countries such as Germany, the UK and Canada, generic prices do not appear to fall as low or as

quickly as in the US. Several factors appear to contribute to the more aggressive nature of generic competition in the US. First, the average number of generic competitors per molecule is greater in the US. This is not simply a matter of greater market size – the US pharmaceutical market actually includes a smaller total number of molecules than the smaller markets of Germany, France or Japan (Daruon, 1996). The fact that brand prices at the time of patent expiry are relatively high in the US compared to other countries that drive prices down more sharply over the life-cycle, such as France, Italy, and Japan, may encourage entry by multiple generic producers. The speed of generic price decline in the US is directly related to the number of generic competitors (Grabowski and Vernon, 1992). Nevertheless, multiple generic suppliers may be necessary but is not a sufficient condition for aggressive price competition. For any given number of suppliers, the extent of competition between them depends on the price sensitivity of purchasers. Giving pharmacists a large financial stake in making price sensitive choices proves to be highly effective in stimulating price competition between generic suppliers.

The UK incentive structure comes closest to that of the US. UK pharmacists can select between multisource products if the script is generically written and 60% of scripts written by English GPs are generically written. Moreover, in the short run, the UK pharmacist retains the savings from choosing lower priced products. In the longer run, the government claws back the average saving by reducing the retail margin. However, since the claw-back is based on average savings across all pharmacies, the individual pharmacist still has a strong incentive to purchase at the lowest price. Thus the UK incentive system for pharmacists creates incentives for generic manufacturers to compete on price that are similar to those in the US.

By contrast, the German pharmacist is only authorized to choose between generics if the prescription is generically written, which occurs in only 5% of scripts (Schoffski, 1996). Prescribing is often by brand or company name as well as compound, and many generic products are promoted as branded generics. The pharmacist is paid a regulated margin and pharmacists do not compete on price (Schoffski, 1996). Degressive margins that vary inversely with product price may avoid incentives to substitute towards more expensive products but create weak incentives to dispense less expensive products. Consequently, although Germany has a large and vital generic sector and reference pricing for multi-source products, the savings from generic substitution on multi-source products are unlikely to be as great as in the US. One important difference is the nature of competition at the retail pharmacy level.

The price pressure on generic prices that derives from price conscious dispensing pharmacists in the US resembles in some respects the downward pressure on all drug prices that derives from price conscious dispensing physicians in Japan. In both cases, the person who selects the drug has a financial stake in making price-conscious choices between therapeutically acceptable alternative products. However, the similarity ends there and other features of the Japanese incentive system tend to be cost increasing. In particular, since the Japanese physician both prescribes and dispenses, there may be a financial incentive for the Japanese physician to

increase number of scripts whereas the dispensing pharmacist in the US only decides which generically equivalent drug to dispense, given the physician's prescription. Second, the Japanese system for setting initial reimbursement prices for new products has traditionally permitted minor extensions of old products to obtain relatively high prices, whereas in the competitive environment in the US, minor new versions of old molecules gain market share only if they compete on price. Hence in the US the only viable strategy for a new producer of an old molecule is to compete on price and generic entry reduces average prices, whereas in some price regulated systems such as Japan, modifying old molecules has traditionally been a strategy to raise price.

Conclusions

The US experience suggests that there may be significant unrealized savings in the off-patent sector in most EU countries, from lower manufacturer prices, lower retail mark-ups and in some cases higher consumer co-payments, particularly on OTCs and other low essential drugs. A critical component of competition in the US off-patent sector is both greater authority for retail pharmacy, in undertaking generic substitution for multisource products, and greater competition in setting margins and retail prices. Competitive pressure has been facilitated by permitting branching, which has enabled chains to take advantage of economies of scale to reduce unit costs. Competition at the retail level forces competition at the manufacturer level in pricing generics and OTCs. Thus competition throughout the value chain is necessary if the maximum savings are to be realized.

References

- Barrall, P.E. 1995. "Twenty Years of Pharmaceutical Research Results Throughout the World." Rhône Poulenc Rorer Foundation, Antony, France.
- Daruon, P.M. 1996. "Uses and Abuses of International Price Comparisons for Pharmaceuticals" in *Competitive Strategies in the Pharmaceutical Industry* RB. Helms ed. Washington D.C. American Enterprise Institute Press: 85-106.
- Grabowski, H. and J. Vernon. 1992. "Brand Loyalty, Entry and Price Competition in Pharmaceuticals after the 1984 Act." *Journal of Law and Economics* 35(2): 331-50.
- Grabowski, H. and J. Vernon. 1996. "Prospects for Returns to Pharmaceuticals Under Health Care Reform." in *Competitive Strategies in the Pharmaceutical Industry* RB. Helms ed. Washington D.C. American Enterprise Institute Press: 194-207.
- Kongstvedt, P.R. 1996. *The Managed Health Care Handbook Third Ed.* Gaithersburg MD: Aspen Publications.
- Myers, S. and L. Shyam-Sunder. 1996. "Measuring Pharmaceutical Industry Risk and the Cost of Capital" in *Competitive Strategies in the Pharmaceutical Industry* RB.