

**TRADE AND PRICE  
DIFFERENTIALS FOR  
PHARMACEUTICALS:  
POLICY OPTIONS**



# TRADE AND PRICE DIFFERENTIALS FOR PHARMACEUTICALS: POLICY OPTIONS<sup>1</sup>

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<sup>1</sup> This is a revised version of an earlier draft of January 1996. I have benefited from many comments, in particular, from Chris Bulpitt, Martin Buxton, Tony Culyer, Geoffrey Hulme and Adrian Towse.

© May 1997. Office of Health Economics.

ISBN 1 899040 00 5

Printed by BSC Print Ltd, London.

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## SUMMARY

Pharmaceutical prices have traditionally differed substantially across countries, reflecting differences in regulation and other factors. In recent years, governments in countries with relatively high prices are increasingly attempting to reduce their own pharmaceutical costs by taking advantage of the lower prices in other countries. Two policies are employed to this end. The first uses cross-national price comparisons as a benchmark for setting domestic price levels. Canada, Italy and the Netherlands already use international comparisons, and a similar approach has been proposed for Japan and the US. The second strategy permits parallel importing of pharmaceuticals from countries with lower prices into countries with higher prices.

Parallel importing has existed on a small scale in Europe for many years and has been upheld by the European Court of Justice, as consistent with standard principles of free trade. However, the potential impact of parallel trade has increased significantly with the launch of the European Medicines Agency in 1995, the accession to the European Union (EU) of low-price countries, such as Spain and the possible accession of Eastern European countries. The threat is particularly severe from potential exporting countries where newly launched products do not yet have patent protection, despite recent agreements under GATT to recognize intellectual property protection, because products already under development were exempted (the so-called pipeline exemption). Parallel trade in pharmaceuticals may become an issue in other trading blocks in the future.

This paper analyses the welfare economic arguments for price differences across countries for pharmaceuticals. It then examines the efficiency and distributive effects of current policies that promote price convergence, in particular, parallel trade and regulation based on international price comparisons.

The main conclusion is that uniform prices are generally not welfare enhancing for innovative pharmaceuticals because of the importance of 'global joint costs'. Global joint costs are costs that simultaneously provide benefits to consumers in all countries in which a product is sold. Such costs are invariant to the number of consumers served and hence cannot be attributed to specific users. Such global joint costs include R&D expenses and certain other production costs of research-based pharmaceuticals. R&D



accounts for roughly 30 per cent of total costs, if all costs are measured in discounted present value at the time of product launch.

Economic theory of optimal pricing when there are joint costs (Ramsey pricing) implies that charging different prices to different users or different countries is a (second best) optimal means of achieving the welfare-maximizing rate of R&D, given that the R&D serves multiple users worldwide who differ greatly in their ability and willingness to pay for innovative medicines. Such price differences do not imply cost-shifting, contrary to widely held beliefs. On the contrary, the prices required in high-price countries to support a given rate of pharmaceutical innovation are *lower* if low-price countries remain in the market, paying prices that are sufficient to cover their country-specific marginal cost and make some contribution to joint costs, rather than being priced out of the market by a uniform higher price.

R&D is not unique to pharmaceuticals. The standard mechanism for enabling innovators to obtain a return on their R&D investment is patent protection. However, for pharmaceuticals the value of patent protection is constrained in most countries by price regulation. The rationale for regulation of pharmaceutical prices derives from insurance coverage, which makes demand for medicines relatively inelastic, leading to higher price and volumes. Some control on insurance-induced overuse of services (moral hazard) and on price increases by providers and suppliers may be consistent with (second best) optimal insurance contracts. Ideally, such controls balance the benefits of controlling current expenditures against the need to preserve appropriate incentives for innovation for the future.

In practice, in social insurance programs where the government is a monopsony purchaser of medicines, each government faces a strong temptation to force prices down to the marginal cost of supplying that country, counting on others to pay for the joint costs of R&D. Such strategies are facilitated by the fact that the joint costs are largely sunk at the time of price negotiation. Companies are willing to supply existing products as long as prices cover the short run marginal cost of production and distribution. However, if each country pays only its country-specific marginal cost – either through direct regulation or by ‘importing’ low prices from other, lower-price countries through international price comparisons or parallel imports – then no one pays for the global joint costs of R&D. In the long run consumers will be worse off because they will not have access to some of the innovative

pharmaceuticals that they would have been willing to pay for, had price differentials been maintained closer to consumers' true willingness to pay. (Willingness to pay is defined here to include both private and altruistic (social solidarity) willingness to pay for others). At the limit, if prices are suppressed to the level of country-specific marginal cost in all countries, the revenue shortfall could be as high as 50-70 per cent of the total cost of bringing new pharmaceuticals to market.

The common presumption is that trade enhances consumer welfare, by shifting supply to the country that is the most efficient supplier, thereby permitting consumers in other countries to benefit from lower prices. However, in the case of parallel trade in pharmaceuticals, the necessary conditions for trade to enhance welfare are violated. The lower prices in the exporting country generally reflect greater regulatory leverage, not superior economic efficiency or lower real social cost of production. Second, the margin between prices in the importing and exporting countries typically accrues as profit to traders, wholesalers and retail pharmacists, not as lower prices to consumers, at least in the short run.

If parallel trade is – or is likely to become – a significant fraction of total sales in higher price countries, economic theory predicts that manufacturers will minimize their losses by implementing a uniform price in all connected markets, thereby eliminating the price arbitrage opportunity that induces parallel trade. Several multinational companies are adopting such a uniform price strategy for newly launched pharmaceuticals in all countries of the EU. The common price is likely to lie between the highest and the lowest prices that would have prevailed with separate markets. Since this implies higher prices for low income countries, they are likely to reduce their use or drop out of the market entirely for the most costly new medicines, with loss of health benefits for consumers in those countries. This is a net welfare loss if these low income consumers would have been willing to cover the marginal cost of serving them, although they are not willing to pay the higher, common price. Consumers in previously high-price countries may appear to benefit if the uniform price is lower than the price that they would have paid if market segmentation were possible. But in the long run they also lose. With the reduction in global revenues under the uniform price policy, some innovative medicines will not be developed that consumers would have been willing to pay for under differential pricing.

If parallel importing is permitted and companies move to uniform pricing

across markets, then the resulting welfare loss can be reduced if price differentiation remains feasible through the use of rebates that are paid directly to governments in countries with low willingness to pay, due to low income or other factors. Rebates that are paid directly to the purchaser permit price differentiation without inducing parallel trade. Such rebates are common in retailing in other consumer goods industries and have been used for pharmaceuticals. In the US, manufacturers grant rebates from list prices to managed care and other purchasers with highly price-elastic demand. Similar rebates were used temporarily in former East Germany to maintain ex post prices that were lower than those prevailing in former West Germany.

International price comparisons are an even more potent force of cross-national diffusion of low prices than parallel trade, because a regulated low price prevails marketwide and then may be copied in other countries. If international comparisons are to form the basis for regulating pharmaceutical prices, then the objective of such comparisons should be to achieve price differentials that are roughly consistent with appropriate contributions to the global joint costs of R&D, based on Ramsey pricing principles. This suggests several methodological principles that should be applied in conducting international price comparisons. Comparisons should be applied to broad, representative samples or to the full portfolio of a specific manufacturer's products, not to individual products. Standard index number methods should be used and, to the extent possible, the entire life-cycle trends of prices should be taken into account, not just prices at launch. Currencies should be converted at exchange rates, not purchasing power parities (PPPs). Exchange rates determine the net revenues to manufacturers, hence relative contributions to R&D. Moreover, if price regulation attempts to stabilize prices cross-nationally based on PPPs, this creates an opportunity for parallel trade and hence puts downward pressure on prices in all connected countries whenever exchange rates deviate from PPPs. The volatility of exchange rates can be addressed by using an average of monthly forward exchange rates over several years. This assures price stability for consumers and payers, while enabling manufacturers to hedge against revenue fluctuations.

With comprehensive insurance coverage of pharmaceuticals, there is a legitimate need to devise systems of incentives or reasonable controls to reduce insurance-induced tendencies for overuse. The ideal system balances the need to provide reasonable financial protection and access to care for consumers, with reasonable control over expenditures, while preserving



incentives for future innovation. A full analysis of alternative systems of cost control is a high priority but beyond the scope of this paper. However, the analysis here does imply that regulation that attempts to set prices based on costs is particularly inappropriate for the pharmaceutical industry. Such cost-based regulation induces well-known distortions. In addition, in the case of the pharmaceutical industry, cost-based regulation is likely to be arbitrary at best, at worst systematically downward biased because the costs of R&D are a global cost, rather than a marginal cost of serving a specific country.

# 1 INTRODUCTION

Pharmaceutical prices have traditionally differed substantially across countries, reflecting differences in regulation and other factors. In recent years, governments are increasingly attempting to take advantage of lower prices abroad to control pharmaceutical expenditures under their own national health and social insurance programmes. Two policies are used to these ends. The first uses cross-national price comparisons as a benchmark for setting domestic price levels. For example, Canada and Italy use prices in a specified set of foreign countries to cap the prices permitted in their own countries. A similar approach was proposed for the US in President Clinton's Health Security Act (1993), and has recently been proposed for Japan. The second strategy permits parallel importing of pharmaceuticals. Traders are granted a license to import products purchased in lower price countries, such as France, Spain or Greece, into countries with higher prices, such as Germany, the UK or the Netherlands. The European Court of Justice has upheld parallel importing, as consistent with the free movement of goods. In 1996, in *Merck v. Primecrown*, the free movement of goods was affirmed even though the exporting country did not grant patent protection and the practical effect was to undermine the patent value in the importing country.

Parallel trade and regulatory use of international price comparisons both have the effect of exporting low pharmaceutical prices in one country to other countries that have traditionally paid higher prices. Actual parallel trade flows were only 5 per cent of total EEC value of sales in 1992 (SNIP, 1993), but may be 20 per cent or more in traditionally higher price countries such as the UK and Germany. However, actual trade flows greatly understate the potential impact of parallel imports. For a manufacturer faced with the threat of significant parallel imports, the loss minimizing strategy is to reduce the price differentials, in order to eliminate the arbitrage opportunity. Thus the mere threat of parallel trade may suffice to make the lowest price within a trading area the effective maximum price, even in markets that would otherwise pay higher prices.

The potential for parallel importing to reduce the revenues of pharmaceutical companies has increased with the admission to the European Union of traditionally low price countries such as Spain and, in the future, the

countries of Eastern Europe.<sup>2</sup> In addition, since 1995 new medicines that are approved by the European Medicines Agency are automatically approved in all EU countries. The resulting harmonization of registration and labelling requirements is likely to reduce the costs of parallel importing and hence reduce the price differentials that can be sustained without inducing parallel trade. Previously, a 15-20 per cent price difference was necessary to cover the costs of complying with different regulations and other importing costs.

Trade normally increases consumer welfare and it is on this basis that the European Commission has upheld parallel imports. The economic rationale for international trade is the same as for any other exchange. Trade occurs when the value to the purchaser exceeds the marginal cost to the supplier. In well-functioning competitive markets, the supplier's marginal cost reflects the social opportunity cost of resources used in production, and the buyer's demand price reflects the marginal value to consumers. Trade occurs where marginal value exceeds marginal cost and is therefore generally welfare-enhancing. Consumers benefit through either lower prices or a wider range of products.

The purpose of this paper is to examine the welfare arguments for international price differences for pharmaceuticals and the welfare effects of policies that have the effect of eliminating such differences, in particular, parallel trade and regulation based on foreign prices.

The main conclusion is that uniform prices are generally not welfare enhancing for innovative pharmaceuticals because of their unusual cost structure, in particular, the importance of global joint costs. Joint costs are costs that jointly benefit many consumers and are the same, regardless of the number of consumers served. These costs are 'global joint costs' when the benefits accrue to consumers in different countries. R&D expenditure for innovative pharmaceuticals is largely a global joint cost. Economic theory (Ramsey pricing) implies that charging different prices to different users (in this case, different countries) is a (second best) optimal means to achieve the welfare-maximizing rate of R&D, given its 'jointness' for users worldwide who differ in income, preferences for medical care and other factors that affect price elasticity of demand.

In practice charging to cover these global joint costs of R&D and other shared functions is made more difficult because these costs are sunk at the

2 In the case of Spain, a three year transition was adopted.

time of price negotiation. In most countries governments have monopsony power as purchasers for national health and social insurance programmes. Each government faces the temptation to exploit this bargaining leverage, attempting to force prices down to its country-specific marginal cost, free-riding on others to pay for the joint costs. However, if every country pays only its marginal costs – either by direct regulation or by the spillover of low prices in one country to others through international price comparisons or parallel imports – then no one pays for the global joint costs of R&D. In the long run, consumers will be worse off because they will have access to fewer innovative medicines. The lower level of pharmaceutical revenues will not support the development of some innovative medicines that would have been developed, had price differentials that reflect true willingness to pay been maintained, thereby generating greater revenues.

In this paper, Section 2 describes the cost structure of the innovative pharmaceutical industry, and the role of patents and regulation in constraining pricing to cover these costs. Section 3 outlines the economic approach to determining optimal price differences in the presence of joint costs. Section 4 identifies the winners and losers from parallel trade. Sections 5 and 6 discuss policy options to minimize the adverse impact of parallel trade and regulation based on foreign prices, if these policies are to be permitted. Section 7 sets out concluding comments.



## 2 THE ECONOMICS OF COSTS AND PRICING FOR INNOVATIVE PHARMACEUTICALS

### 2.1 The cost structure of innovative pharmaceuticals

The pharmaceutical industry is among the most research-intensive industries (CBO, 1994), with R&D accounting for roughly 17 per cent of sales.<sup>3</sup> The fraction of sales spent on R&D, although widely-cited, seriously understates the R&D share of the real economic cost of developing and marketing new pharmaceuticals because the numerator and denominator do not refer to the same products. The numerator of the sales-based ratio is current R&D, which pertains to future products, whereas the sales value in the denominator pertains to products that were developed many years previously. The economic measure of the R&D cost share that is relevant to pricing and profitability expresses all costs for a given cohort of drugs as a discounted present value at point of launch. This measure includes in the cost of R&D the opportunity cost of funds that are invested many years prior to realization of returns. When all costs are expressed as discounted present value at the time of product launch, R&D accounts for roughly 31 per cent of total cost, manufacturing and distribution are 28 per cent, marketing is 24 per cent, and other administrative costs are 12 per cent.<sup>4</sup>

The large R&D share of total cost raises problems for pricing because R&D is a global joint cost, that is, the cost is the same, regardless of the number of users served worldwide. Such joint costs cannot be attributed to particular users. Production and distribution also entail significant costs that jointly serve several countries. Primary production of bulk chemicals is typically concentrated in two or three plants worldwide, each of which serves

3 The R&D cost per new chemical entity (NCE) brought to market in the US was estimated in 1993 at \$359 million before tax, \$194 million after tax (see DiMasi et al., 1991; OTA, 1993).

4 These are after-tax estimates, based on estimates of R&D and other costs from OTA (1993) and assuming a 46 per cent corporate tax rate (see Danzon, 1994, 1997). The pre-tax figure for R&D is 32 per cent. I would like to thank Dan Zhang for assistance in developing these estimates.

all countries in an entire region, producing multiple compounds for many years. The capital costs of such plants cannot be attributed to specific packs of a particular product sold in a particular country in a particular year, for example, France or Italy in 1995. Distribution networks and other overhead may be country-specific but often cannot be attributed precisely to specific products sold in that country.

The problems of pricing to cover joint costs are exacerbated by the fact that most of these joint expenditures are committed ('sunk') at the time of negotiation over price. Most expenditures on R&D and some costs of production, promotion and other overhead are committed by the time the initial price negotiations take place.

This high percentage of sunk, joint costs creates a potential for extortionary regulation. The profit-maximizing strategy for a firm in any industry is to supply a product in the short run as long as the price covers the short run marginal cost of production and distribution, even if that price is less than average total cost including the sunk costs. Any amount greater than the marginal cost contributes to paying off the sunk costs. In the long run, the average price across all markets must cover the average total cost, including the joint costs, if the firm is to stay in business and continue to develop new products. But in the short run, the supply of existing pharmaceuticals will not dry up as long as prices cover short run marginal costs.

## 2.2 Patents as a means of recouping R&D costs

R&D expenditure is not unique to pharmaceuticals, although it is a higher percentage of total cost for pharmaceuticals than for other industries. Most industrialized countries grant patent protection as a means of recognizing the legitimate claim of innovators to receive a reasonable return on their R&D investments.<sup>5</sup> By permitting the innovator to bar imitators, patent protection conveys potential monopoly power for the duration of the patent. If imitators could immediately copy a new invention, competition would force prices down to marginal production cost and the innovator could not recover the

<sup>5</sup> Some current EU members first granted protection for pharmaceuticals under the 1992 Uruguay Round of the General Agreement on Tariffs and Trade (GATT). Products already in the pipeline were not included.

costs of R&D. Thus the purpose of patent protection is to enable the innovator firm to charge a price above marginal cost for the duration of the patent.

In practice, effective market power even while on patent may be undermined by competition from close substitute products. Whether or not actual patent duration is adequate, excessive or insufficient to encourage an optimal rate of innovation is theoretically indeterminate and varies across industries and products, depending in part on the speed of entry and extent of competition from substitute products. In the case of innovative pharmaceuticals, the value of patent protection in most countries is further constrained by regulation.

## 2.5 The economics and politics of pharmaceutical price regulation

Pharmaceutical price regulation constrains through one branch of government the value of the patents and pricing power that are explicitly granted through another branch of government. Regulation of pharmaceutical prices cannot be justified on arguments of natural monopoly, as have traditionally been applied to industries such as power generation and telecommunications. Any monopoly power enjoyed by pharmaceuticals derives primarily from the patent protection that is granted by the state to encourage innovation.

The primary rationale for regulation of pharmaceutical prices derives from government's role in funding national health and social insurance programmes that typically cover pharmaceuticals, often with minimal co-payments. Insurance of pharmaceuticals, like other medical services, tends to make consumers indifferent to costs, because 'someone else is paying'. Similarly, medical providers have financial incentives to prescribe medicines without regard to cost if patients are thereby encouraged to make more visits and visits are reimbursed fee-for-service. Moreover, because insurance with a fixed or percentage co-payment tends to make demand inelastic, insurance raises the profit-maximizing price that suppliers of insured services would seek to charge. This 'moral hazard effect' – that insurance tends to encourage overuse and higher prices for covered services – implies that insurance without constraints entails a deadweight loss or excess burden, reflecting the distortion in resource allocation.



Economic theory concludes that, given imperfect information that leads to moral hazard, insurance contracts should optimally include some well-designed constraints. If well-designed, such constraints are in the long run interests of consumers, who ultimately pay for overuse through higher insurance premiums or higher taxes.<sup>6</sup> These constraints may include consumer incentives such as co-payments, and provider incentives such as capitation and other risk-sharing forms of reimbursement. In a static environment, the optimal strategies to control moral hazard should balance the savings from controlling overuse against the welfare loss to patients due to limited choice of services or, in the case of co-payments, exposure to financial risk. In a dynamic environment, the challenge for insurers, including governments, is to design constraints to promote the optimal trade-off between controlling current expenditures and preserving efficient incentives for investments in innovative R&D.<sup>7</sup>

In national health and social insurance systems the government, as the monopsony purchaser of pharmaceuticals, has a strong incentive to focus on its own, country-specific, short run interests of controlling costs, assuming that its contribution is a negligible fraction of global revenues and hence will have a negligible effect on manufacturers' incentives for R&D. Consumers in each country prefer low co-payments and low prices, since this reduces their out-of-pocket costs and premium or tax contributions. Thus each country is tempted to pursue policies to drive prices down to the marginal cost of supplying that country, free-riding on others to pay for joint costs.

Such policies designed to minimize country-specific budget cost may have negligible impact on the supply of future medicines if confined to small countries with no spillovers to other markets. But if the US or Japan, which together account for roughly 60 per cent of the global sales of pharmaceuticals, regulate their prices based on comparisons with such small countries, then aggressive regulatory policies in a tiny market such as New Zealand can have a dramatic effect on global pharmaceutical revenues. Similarly, permitting parallel trade without restriction in the EU expands the impact of low prices from a few member countries to the entire trading area. Thus in a world with parallel trade or regulation based on foreign prices,

6 Zeckhauser (1971) describes optimal patient co-payment; Ellis and McGuire (1993) consider optimal provider cost-sharing.

7 See Danzon (1995b).



forcing prices down to marginal cost in a only a few small countries can suffice to make average prices worldwide inadequate to cover the joint costs of R&D.

It is this combination of global, sunk, joint costs and country-specific price regulation by budget-conscious governments that makes regulation of pharmaceutical prices potentially more distortionary than regulation in other industries such as utilities.<sup>8</sup> Utilities such as telephone, gas and electricity, are also characterized by a high ratio of sunk costs to user-specific marginal costs. However, the regulatory formulae for setting utility prices have explicitly recognized the need to provide a reasonable return on capital, because the capital is country-specific and hence clearly must be paid for if service is to continue.<sup>9</sup>

In pharmaceuticals, by contrast, the sunk costs are either truly global (R&D) or are joint to several countries (primary production). Thus regulators in each country face incentives to free-ride, setting prices to cover the marginal costs of serving their country in the hope that others will pay for the joint costs. In pricing specific products, short-sighted regulators may also ignore country-specific joint costs that contribute to all the products sold by a firm in that country, including the overhead of administrative offices, secondary production facilities and intangible investments in brand name capital and good will. The regulator correctly reasons that prices may be inadequate to cover the quasi-rents on these sunk investments for several years before a company will close down its operations and totally withdraw from that country, particularly if there are significant costs of re-entering in the future if the pricing environment improves. In the long run these costs must be covered if the firm is to maintain its operations. But the regulator can correctly argue that these costs are not attributable to the specific product whose price is under negotiation.

An important implication of the high proportion of joint costs relative to user-specific, product-specific marginal costs, is that any attempt to regulate pharmaceutical prices on the basis of individual product costs – as attempted in Italy prior to 1993 and as proposed by President Clinton's Health Security Act – is necessarily imprecise and arbitrary. Cost-based regulation always creates the potential for creative accounting and even distortion of true economic costs. In

8 Within the EU, the threat of low prices and their export has become more acute as countries attempt to reduce their budget deficits in order to meet the Maastricht criteria for membership of the European Monetary Union.

9 As these utilities expand across national boundaries, allocating joint costs between countries may become more problematic, and problems may arise similar to those already experienced by pharmaceuticals.

the case of pharmaceuticals, the existence of significant global joint costs adds further potential for distortion if countries attempt to set product prices based on cost. The fraction of the joint costs that should be paid by Italians or Americans cannot be determined by accounting rules; rather, the appropriate sharing rule depends on demand conditions in different countries. But true demand is at best not readily verifiable; at worst, it may be concealed in order to free-ride on the contributions of other countries. Thus in the case of pharmaceuticals, individual product 'costs' do not provide an objective benchmark for setting prices.<sup>10</sup> Moreover to the extent that such regulation is based on verifiable, attributable costs, it will lead to inadequate prices.

A further important implication of the global joint costs is that the distortion that arises from abuse of monopsony power is different for pharmaceuticals than for a standard product without joint costs. The standard monopsony problem is that the single purchaser faces rising marginal cost and therefore buys a suboptimal quantity. The price paid covers average cost; however consumers suffer a welfare loss because the quantity bought is too low: at the margin, the value to consumers exceeds the social opportunity cost. By contrast, the monopsony purchaser of pharmaceuticals probably faces a flat or declining supply function for products that are already on the market. The problem is not suboptimal consumption of pharmaceuticals that are already developed – indeed it is often argued that prices must be regulated because volumes are so high. Rather, the welfare loss occurs because the monopsonist force prices down to the supplier's *short run, country-specific* marginal cost. Since this price does not cover the sunk, joint costs of R&D, the long run supply of new products will be suboptimal.

How inadequate could prices be, if all users pay only marginal cost? The estimates above suggest a rough answer to this question. If all purchasers pay only their short run, country-specific marginal cost, including the costs of secondary production, packaging and distribution, the shortfall between revenues and total costs could be as high as 70 per cent.<sup>11</sup> If prices cover all

10 Following a major corruption scandal in 1993, Italy replaced its cost-based formula with a system that sets prices based on international comparisons.

11 This estimate, that the marginal cost of production and distribution may be no more than 30 per cent of total costs, is consistent with the evidence that prices of generics, which incur minimal cost of R&D and promotion, ultimately fall to roughly 25 per cent of the price of the originator product in highly competitive markets in the US (Grabowski and Vernon, 1991).

costs except R&D, the shortfall would be roughly 30 per cent. One implication of the low ratio of user-specific marginal cost to total cost is that prices that are adequate to cover the joint costs, will appear to yield abnormally high accounting profits. This further fuels the arguments for lower prices.

## 3 OPTIMAL PRICING TO SHARE JOINT COSTS

### 3.1 The theory of pricing to cover joint costs

The theory of efficient pricing to recoup joint costs was first developed by economist Frank Ramsey (1927) and is widely referred to as Ramsey pricing. This theory concludes that in order to achieve optimal resource allocation, including optimal investment in the joint inputs, users who are less price sensitive should pay higher prices than users who are more price sensitive, such that prices in aggregate cover total costs including the joint costs.<sup>12</sup> Thus the common presumption, that all consumers should pay the same price, is only optimal if there are no joint costs and the marginal cost of serving each user is the same.

These principles may be applied to the problem of paying for the joint costs of pharmaceutical R&D. The implication is that consumers who value innovative pharmaceuticals more highly and hence have more inelastic demand should pay higher prices and contribute more to the joint costs than consumers with lower valuation and more price-sensitive demand. Intuitively, the reason is that if all users are charged the same price, the price-insensitive users will reduce their consumption by less and hence experience a smaller loss in welfare than the price-sensitive users, who will reduce their consumption by more or drop out of the market entirely, although they might have been willing to pay a price sufficient to cover the marginal costs of serving them and, by definition, their use adds nothing to the joint costs. Thus consumer welfare in aggregate is maximized by charging different prices that take into account these differences in price sensitivity.

The level of R&D that can be sustained is lower under uniform pricing than with price differentials that reflect true willingness to pay for innovation. With differential pricing, those with high valuation pay more, those with low

<sup>12</sup> Ramsey prices are only second best optimal if setting price above marginal cost reduces consumption. An alternative strategy for paying for R&D, while setting price equal to marginal cost, is through a system of taxes and subsidies. However, such a system is likely to be inferior to Ramsey pricing. In addition to tax-generated distortions in other markets, political pressure may distort the distribution of subsidies to R&D.



valuation are charged less and now stay in the market. Total revenues are sufficient to support a higher level of innovation than with uniform prices. Uniform prices, and hence lower global revenues, will deprive consumers of some innovative pharmaceuticals that would have had positive net social benefit, that is, consumers in aggregate would have been willing to pay their costs of development, had differential pricing been feasible.

Ramsey pricing principles are commonly applied in public utilities and airlines, where joint costs are also very significant relative to user-specific marginal costs. Peaktime users pay higher prices for electricity than do off-peak users; travelers with inelastic demand pay higher airfares than travelers who are willing to accept the inconvenience of advanced booking and minimum stay requirements. Although those who pay more may grumble, their prices can be lower than they would have to be to cover the cost of the same level of service in the absence of the discount fares. This is true as long as those who pay discounted fares cover their own marginal cost and make some contribution to the joint costs.

### 3.2 Price differences do not imply cost shifting

It is often argued that price differences between countries or between users within a country reflect cost shifting:

'A pharmaceutical company may only be willing to sell in a low price country because it can recoup any losses it makes there from sales in higher priced countries.' (Sir Leon Brittan, 'Brittan Speech on Pharmaceutical Pricing' European Commission Press Release, 2 December 1992).

This argument either ignores the problem of joint costs or mistakenly assumes that they should be allocated equally to all users.<sup>13</sup>

From the long run perspective of the firm trying to estimate whether prices on average will be sufficient to justify the costs of developing a new pharmaceutical, if low price countries cover at least their marginal costs and make some contribution to the joint costs, prices in high price countries can actually be *lower* than they would have to be to cover joint costs in the absence

13 The cost shifting argument as stated here is correct only if a company is forced to sell at a price less than marginal cost, due to political or other factors. In that case it does sell at a loss; however, whether or not it is willing to do this may depend on several factors in addition to the possibility of covering the loss from other countries. In any case, the profit-maximising price in other countries is not affected.

of contributions from the low price market. Thus from a long run perspective the cost shifting argument is backwards.

Similarly, from the short run perspective of pricing products that are already on the market, the cost shifting argument is also mistaken. A firm that can set prices in separate markets will attempt to charge the profit-maximising price in each market. This profit-maximising price is lower in more price sensitive (elastic) markets than in less price sensitive markets. If demand conditions change, such that the profit maximising price in the price sensitive market is now lower, this does not affect the price in the other market. If this other price is already at the profit maximising level, to increase it in an attempt to 'recoup losses' from the lower price in the other market would actually reduce net revenues. Thus viewing pricing from either a long run perspective (deciding which products to develop) or a short run perspective (pricing existing products) the cost-shifting argument assumes behavior that is inconsistent with profit-maximisation by firms.<sup>14</sup>

### 3.3 Implications for price regulation

Applying these principles to pharmaceuticals implies that policies that force prices to converge to a common level – including parallel trade and international price comparisons – violate optimal pricing principles and are likely to reduce consumer welfare in the long run. Those who argue for uniform prices on the basis of standard international trade principles fail to address the issue of paying for global joint costs and differences in true willingness to pay for innovative medicines. Given the joint costs, consumers who place a higher value on having access to newer therapies should appropriately contribute more to their costs of development than consumers who are willing to make do with existing therapies.

Unfortunately, true willingness to pay is unobservable in practice. It may depend not only on income, but also on willingness to trade-off income for convenience, on attitudes towards risk, preferences for medical care and other factors. Consumers and governments, acting as surrogates for consumers, may rationally seek to conceal their own willingness to pay, as long as others are willing to cover the common costs. But in the long run everyone is worse off from this free rider strategy.

14 For a similar analysis applied to the allegation of cost shifting by hospitals, see Phelps (1986), Dranove (1988). For discussion of price differentials in pharmaceuticals more generally, see Berndt (1994), Danzon (1995a).

## 4 WELFARE IMPLICATIONS OF PARALLEL TRADE

### 4.1 Why standard gains from trade do not occur

The EEC Court of Justice has repeatedly upheld parallel trade based on the principle of free movement of goods. The manufacturer's control and rights over a product terminate when it is released in one country. In *Merck v. Primecrown*, this was interpreted to include foregoing the value of patent protection in one country, as a result of parallel imports from another country that did not recognize intellectual property rights. Strategies designed to deter parallel imports, such as differences in labeling intended solely to impede the free circulation of products, are not allowed.

The 'naive' welfare argument in support of parallel trade is simply the standard argument for free trade. Trade increases economic well-being when (a) it permits consumers in the importing country to benefit from lower prices in the exporting country, and (b) these lower prices reflect the full social opportunity cost of production in the exporting country and are due to either superior efficiency or lower input costs.

In the case of parallel importing of pharmaceuticals, these necessary conditions for trade to be efficient are usually violated. The savings from lower foreign prices often accrue mainly to the intermediaries – parallel traders, wholesalers and retail pharmacists – not to consumers or payers in the importing country who continue to pay the (higher) regulated price, at least in the short run.<sup>15</sup> How the margin between the lower foreign supply price and the higher domestic retail price is split between the middlemen depends on the extent of competition in the wholesale market and on details of the regulatory system. The Netherlands reference price system specifically permits the retail pharmacist to keep 20 per cent (initially 30 per cent) of any savings, as an incentive to encourage pharmacists to seek out cheaper sources of supply. In the UK, Department of Health payments to pharmacists assume a

<sup>15</sup> Consumers may actually suffer a utility loss due to confusion and possible noncompliance, if the parallel import is in a different form, colour and shape than the product to which they are accustomed, and the labelling is literally in Greek.



clawback for sales of cheaper pharmaceuticals, including parallel imports. Since this clawback is uniform for all pharmacists and is based on a national average import share, not the actual import share of the individual pharmacy, each individual pharmacist still maximizes his or her net revenues by using the cheapest source of supply. The level of the clawback still leaves much of the profit to the intermediaries.

The second condition for efficiency gain, that the lower foreign price should reflect lower social cost of production, is also often violated. Countries achieve low pharmaceutical prices and become parallel exporters usually through denial of intellectual property protection or through stringent regulation, not through superior efficiency. Indeed, regulation may actually reduce efficiency.<sup>16</sup> Governments with successful domestic research-based pharmaceutical firms – including the UK, Germany, Switzerland, Sweden – have traditionally been more willing to grant higher prices, recognizing the need to cover R&D. Conversely, companies have accepted lower prices in countries with relatively low per capita income, hence low ability to pay, and in some countries with high per capita volume, such as France and Italy.<sup>17</sup> High volume to some extent makes up for low prices in contributing to joint costs, as long as the price still exceeds marginal cost. However none of these factors that lead to relatively low prices provide a welfare case for expanding exports from these countries.

Moreover, because parallel trade is designed to arbitrage price differences that do not reflect real cost differences, it can actually increase real social costs because of additional labeling, transportation and other administrative costs, but still be profitable for the trader. For example some parallel trade is fully circular. 'Parallel trade has become so great that eight in ten High Street chemists in Britain regularly dispense pharmaceuticals made in Britain, exported to France, say, and re-imported for sale to NHS patients (in Britain).'<sup>18</sup>

16 See Danzon and Percy (1996) for effects of regulation on productivity; Thomas (1996) for effects on innovation.

17 For evidence on prices in eight countries relative to the US, see Danzon and Kim (1995).

18 Pallor (1992). Even if the magnitude of circular trade is less than asserted here, the point remains valid.



## 4.2 Price and quality effects of parallel trade

If a multinational pharmaceutical manufacturer cannot prevent parallel imports, economic theory predicts that the firm will minimize its losses by attempting to obtain a sufficiently uniform price in all connected markets to deter parallel trade. The implications are somewhat different for launch prices and for price adjustments for medicines already on the market. For medicines already on the market in several countries, this optimal pricing strategy may require reducing price in the relatively high price, potential importing countries, say the UK, because prices for established pharmaceuticals in low price countries, say France, are heavily regulated and cannot be increased. If a manufacturer cuts price in the UK, such that the margin between prices in the UK and France is insufficient to support parallel trade, it loses some revenue on sales that would otherwise have been sourced from the UK at the previously higher price; but there is no additional revenue loss on the sales that would have been imported from France. This revenue loss may be worth incurring in order to maintain control of production and distribution, as discussed further below. The lower the parallel trader's costs and the larger the potential parallel import share, the smaller the sustainable price gap and the greater the downward pressure on prices for established pharmaceuticals to the lowest level in a trading block.

In launching new products, a manufacturer's optimal strategy in response to the threat of parallel trade and the resulting downward pressure on prices after launch, is to attempt to set a relatively high, uniform launch price in all countries in the trading block. If the problem were a single period pricing problem, the common price would lie between the price that would have been charged in the low and high price markets, had these markets been separable. Given the multiperiod economic life of pharmaceuticals, the optimal launch price also depends on post-launch pricing pressures. If aggressive regulation drives down prices after launch in some markets and these low prices spill over through parallel trade to become the EU norm, then the optimal common launch price will be higher than without this postlaunch spillover effect. It may appear that consumers in the initially high price country ultimately do benefit from lower prices as manufacturers respond to the threat of parallel trade by lowering prices in potentially high price markets. However, in the long run consumers who would have been willing to pay higher prices are worse off if these lower prices result in lower investments in R&D and hence

fewer new medicines than they would have been willing to pay for.

Conversely, a uniform pricing policy implies an increase in prices in traditionally low price countries, because these low prices constrain the price that can be realized in other markets that are linked through parallel trade or international price comparisons. If governments in traditionally low price countries are unwilling to pay higher prices, this can lead to long delay in price negotiations, which implies foregone revenues for companies because the patent term continues to run despite delays in launch, and foregone benefits for consumers whose access to the new medicine is delayed. Even if the product is finally launched at the high price, access may be restricted to a very small number of users, in order to stay within a limited budget.

At the limit, some countries may refuse to pay the higher price that is required by the uniform price policy and hence may lose access entirely to the innovative medicine, even though they would have been willing to pay a price sufficient to cover marginal cost. For a company, the profit-maximizing strategy (ignoring good-will, reputation and non-financial concerns), is to withhold launch in a low price country if the expected net revenue from that country is less than the revenue loss that its low price would cause through parallel trade or international price comparisons in other markets that are willing to pay more. This implies, in particular, that companies may rationally choose to abandon smaller markets that contribute minimally to global revenues, rather than accept prices that would erode the prices and revenues that can be achieved in other, larger markets.

These predictions of economic theory are borne out by recent empirical evidence. Several of the major multinational companies now attempt to pursue a uniform launch price strategy for new pharmaceuticals, in order to deter parallel trade and to reduce the revenue losses that would result if low prices spillover through regulation based on international price comparisons. Glaxo Wellcome's refusal to accept a relatively low price for its migraine product Imigran has delayed launch in the social insurance system in France for several years, despite marketing approval. In 1996, Merck launched its protease inhibitor Crixivan at a common price, denominated in ecus, throughout the EU.

The welfare loss from uniform prices is greater, the greater the true difference in willingness to pay between consumers who now face a common price. The welfare loss from parallel trade is greater, the broader the trading block within which trade is permitted and the more stringent the regulation

in any one country in that block. Similarly, the welfare loss from international price comparisons is likely to be greater, the broader the comparison group of countries and the lower the benchmark price in the comparison group. For example, the use of lowest rather than mean or median price in the comparison group accelerates the downward price spiral.

Because parallel trade is concentrated in the high volume, 'blockbuster' products, this might lead some observers to erroneously conclude that parallel trade merely siphons off 'excess' profits without significant adverse effect on incentives for R&D, for which only a normal rate of return is necessary. However, roughly two thirds of new chemical entities yield insufficient lifetime revenues to cover their costs of development (Grabowski and Vernon, 1994, 1996). It is the profit on the most successful one third that makes up for losses on the majority of new medicines, such that overall the firm earns a normal rate of return on R&D. Thus even if only the high revenue products are subject to parallel trade, the effect on incentives for R&D will be far-reaching.

Parallel trade may also distort relative prices of different pharmaceuticals and create unfair advantage between pharmaceutical manufacturers. Companies with a relatively large market share have broader opportunities and leverage to deter parallel trade without resorting to price cuts, compared to smaller companies. For example, in the UK Glaxo Wellcome has adopted a form of agency contract with wholesalers who are paid a management fee, replacing the traditional intermediary contract whereby wholesalers buy and sell products. As agents, wholesalers have no legal title to Glaxo Wellcome goods and hence cannot legally export them. The agency contract may reduce profits to wholesalers and retail pharmacists and, at least initially, was unpopular with them. It is feasible only for a manufacturer that has a sufficiently large market share in leading pharmaceuticals that distributors cannot afford not to carry its products.<sup>19</sup>

In addition to price effects, parallel trade undermines the incentives of pharmaceutical distributors to provide information and support services to physicians, which may ultimately reduce the quality of care to consumers. If

19 For Glaxo Wellcome, the adoption of this agency relationship with wholesalers has other benefits besides any preemption of parallel export by wholesalers, including access to data and better control over price.



pharmaceuticals for the UK market can be parallel imported from abroad, the UK subsidiary or licensee of a multinational company receives no return on investments in sales force support, providing information and other services to physicians, and promoting the company's products and reputation for reliability. Such investments in information and reputation benefit consumers, to the extent that they improve the efficiency of physicians' prescribing decisions or patients' compliance. The economic literature on retail price maintenance and exclusive dealerships demonstrates that there may be welfare gains from stabilizing demand among different distributors of a manufacturer's products, in order to create appropriate incentives for each distributor to invest in such services.<sup>20</sup> The value to manufacturers from maintaining distributors' incentives to service their products is an additional reason why manufacturers may adopt a uniform price policy in order to preempt parallel trade, even if this reduces revenue in the short run due to the lower price in the previously higher price markets.

Parallel trade may also undermine safety and efficacy regulation and hence affect risks to consumers, by making it easier for counterfeit manufacturers to enter the supply chain. Although parallel importers are required to obtain a license, chemical testing for equivalence is not performed. Such threats to safety from counterfeit products have occurred, although infrequently. Nevertheless, a single instance can be extremely costly to the original manufacturer's brand image and reputation. Consumers are unlikely to understand fully that the unsafe pharmaceuticals that bore the originator's name were in fact supplied by a counterfeit manufacturer.

20 See also Rozek and Rapp (1992).



## 5 POLICY OPTIONS FOR PARALLEL TRADE

The analysis so far concludes that, if parallel trade is permitted, pharmaceutical manufacturers will attempt to minimize their losses by setting a uniform price in all connected markets. Such uniform prices are not optimal for consumers. Moreover, the attempt to implement a common launch price is likely to lead to delays in launch into previously low price countries and, in the extreme, to withdrawal of innovative pharmaceuticals from small, low price countries, even though these countries may be willing to pay prices sufficient to cover their country-specific marginal costs. It is therefore worthwhile to explore other strategies that might be used to achieve the desired price differentials to end users, while preserving the uniformity in ex-manufacturer prices to wholesalers that is necessary to preempt parallel trade.

### 5.1 An exemption for patented products

The simplest approach is to prohibit parallel trade for products or industries that meet the following conditions:

- (a) patents are essential to the industry;
- (b) the same or very similar patents are registered in many countries;
- (c) product prices are regulated in one or more countries of the trading bloc.

An essential role for patents indicates that the industry invests significantly in R&D and hence that it requires some period of pricing above marginal cost. If the same or similar patents are registered in many countries, this indicates that the R&D is a global, joint cost, as opposed to an investment that serves only one country. Price regulation creates the risk that regulators constrain prices to cover only their country-specific marginal cost, free-riding on other countries to pay for the common global costs. If these low prices diffuse to other countries, through parallel trade, this prevents innovator firms from recouping R&D costs, contrary to the intent of patent protection.<sup>21</sup>

Patent protection is normally defined to include the right of the patent holder to enjoin unauthorized distribution, including unauthorized imports.

<sup>21</sup> Mansfield (1986) develops methods of measuring patent dependency. By his measures, the pharmaceutical industry is highly patent dependent compared to other industries.

The preservation of this right under the North American Free Trade Agreement (NAFTA) prevents parallel trade between NAFTA countries. The EU recognizes a similar right of patent holders to enjoin unauthorized imports from countries outside the EU, but within the EU this right has been curtailed to permit parallel imports. The proposed exemption would restore traditional patent rights within the EU, in the case of products that are heavily patent dependent *and* are subject to price regulation.

## 5.2 Country-specific rebates

If parallel trade is not pre-empted by a block exemption, then one possible strategy to reduce the welfare loss that would result from uniform pricing is to permit companies to pay rebates directly to governments in the countries where lower prices are desired, while maintaining a uniform supply price to wholesalers in all connected countries in order to preempt the opportunity for parallel trade. Because price differentials are achieved through rebates paid directly to the ultimate payer, rather than through lower supply prices to wholesalers in different countries, the intermediaries' opportunity for price arbitrage is eliminated, but the price differentials to the end users are preserved.

A rebate system would extend to international pharmaceutical prices a strategy for achieving price differentials to consumers that is common in other industries. For example, consumer products are often sold with a coupon that the buyer must submit to the manufacturer for a rebate. Since only the price-sensitive buyers take the time to send in the coupon, this achieves an ex post price discount to price sensitive buyers, although all buyers face a common ex ante price. Similarly, pharmaceutical manufacturers in the US have given ex post discounts to price sensitive managed care purchasers, including pharmaceutical benefit managers, by means of rebates that are delivered directly to the purchaser (usually an insurer, employer or managed care company), not to the wholesaler, retail pharmacist or other intermediary.<sup>22</sup>

22 Managed care purchasers use formularies and other strategies to channel demand towards products for which they are able to negotiate relatively low prices compared to other close substitutes. From the perspective of the manufacturer, this makes managed care demand more elastic. In essence, consumers in these plans accept some channelling of their use of pharmaceuticals in return for lower prices. Retail pharmacists have challenged such discounting through antitrust litigation and legislation. The antitrust litigation is analysed in Scherer (1996). The anti-discount pricing legislation is analysed in Danzon (1995a).

If rebates are permitted, economic theory predicts that companies would set the common list price at a higher level than in the absence of rebates.<sup>23</sup> Governments that receive rebates would receive lower prices than in the absence of rebates; with no constraints on rebating, they could receive the same low prices as they did before the threat of parallel trade induced companies to adopt a uniform price policy. Consumers and payers in countries that pay the undiscounted list price might appear to lose compared to the situation of uniform pricing and no rebates. By permitting manufacturers to separate markets, the rebating scheme reduces the ability of the less price sensitive buyers to free-ride on the price sensitivity of other buyers. But in the long run these consumers also benefit because the higher prices permit a higher rate of supply of innovative new pharmaceuticals than would a uniform price policy with no rebates. In the absence of rebates, the uniform price that is the best compromise price for countries that differ greatly in their willingness to pay will significantly reduce revenues and hence incentives for innovation relative to a system that permits rebates to achieve price differentials.

Under uniform pricing, with or without rebates, middlemen lose their profits from parallel trade, because uniform pricing eliminates the differentials which they arbitrage into profit. However, since such trade is primarily a transfer that entails real resource costs but no net benefits and, as argued above, probably real welfare loss, from a social policy perspective the elimination of parallel trade is a net gain.

23 For a profit-maximizing seller, the optimal uniform price with no rebates depends on a weighted average of demand elasticities in the different markets. With rebates, the most price sensitive markets are removed from the average, so the price based on the average of the remaining, less price-sensitive markets is higher.



## 6 POLICY OPTIONS FOR INTERNATIONAL PRICE COMPARISONS

It has been argued that regulation based on prices in other countries tends to force prices to converge on the lowest price in the comparison group. Uniform prices across countries that differ in their true willingness to pay for innovation will lead to suboptimal rates of innovation. The shortfall is greater, the broader the comparison group and hence the lower the common price. The downward pressure on prices and revenues is even greater from regulation based on foreign prices than from parallel trade because regulation applies immediately and marketwide, whereas parallel trade typically has more limited scope. There is no economic welfare rationale for foreign prices as a basis of regulation, once it is recognized that there is no welfare basis for uniform prices.

If international price comparisons are to serve as a criterion for setting domestic prices, then the objective of such comparisons should be to determine whether price differences are roughly consistent with appropriate Ramsey price differences and appropriate relative contributions to the joint costs of R&D. Unfortunately, readily observable data provide at best a rough indication of appropriate Ramsey prices. These optimal prices depend on the true price sensitivity of demand for innovative medicines, which depends on income, tastes and other factors. In practice, actual demand also reflects the effects of insurance, provider incentives, supplier promotion, regulation and other factors. Nevertheless, approaching the problem of international price comparisons from the perspective of optimal price differentials does imply certain useful methodological guidelines that are quite different from those commonly used.

### 6.1 Comparison countries

Comparisons should be limited to countries that are similar with regard to the factors that are likely to affect willingness to pay for innovative pharmaceuticals. These include not only per capita income and pharmaceutical use but also preferences for innovative medical care more generally. The presence of a domestic research-based pharmaceutical industry



might also be an indicator of greater willingness to pay, because of the employment and other industrial policy benefits of having such an industry. On the other hand, to the extent that countries that lack an innovative domestic pharmaceutical industry are simply more prone to free ride, there is no theoretical basis for differentiation based on local industry structure.

## 6.2 Sample and methods

Even within a relatively homogeneous comparison group of countries, the measurement of price differences necessarily entails judgment about sample, criteria for matching products across countries, unit of price, volume weights, etc.<sup>24</sup> The range of medicines available differs significantly across countries. Even for global products that are widely available, the range of dosage forms, strengths, packsizes and manufacturers differs across countries, reflecting different medical norms, dispensing restrictions and other factors including regulation. Comparisons that are confined to products that are identical in all respects – chemical composition, manufacturer, dosage form, strength and packsize – are extremely unrepresentative because only a small fraction of the full product range available in each country can be included. To compare the costs of pharmaceutical therapy to consumers in different countries requires broader matching criteria, to permit a more representative sample of pharmaceuticals, including generics and some over-the-counter medicines.

In practice regulation often compares the price of an individual product in different countries. A preferred approach, if comparisons are to be made, is to apply the comparison to the full portfolio of all products sold by that manufacturer in the sample countries, rather than to perform product-specific comparisons. Since many costs are joint costs for a portfolio of products, optimal Ramsey pricing might allocate these joint costs differently to different products in different countries, if their price elasticities differ across countries.

## 6.5 Launch price vs. average life cycle price

Price comparisons should ideally reflect the full trend of prices over the product's economic life, not just the price at launch or at some other point in time. The post-launch trend in prices differs greatly across countries. For

24 Danzon and Kim (1995, 1996).

example, the Japanese price regulatory system leads to a much sharper decline in real, inflation-adjusted prices over the life-cycle than in other countries.<sup>25</sup> The more negative the post-launch price trend, the higher the launch price required to yield a given life-cycle revenue. The speed of post-patent generic entry and market penetration also differs significantly across countries, which implies variation in length of economic life for the originator product. For example, recent experience in the US is that generics take over 50 per cent of the market within the first year of post-patent sales. The shorter the economic life, the higher prices must be while on patent to yield a given life-cycle revenue.

Of course at any point in time, the future revenues of products currently being launched can only be estimated. The most reliable basis for projecting future revenues may be the current experience of established products at later stages of their economic life. This argues for using a broad sample of products of different ages for cross-national price comparisons, as a rough proxy for expected life-cycle revenues, even if the immediate concern is the level of launch prices for new drugs.

## 6.4 Currency conversion

Since prices are expressed in national currencies, the issue arises whether currencies should be converted at market exchange rates or using some measure of purchasing power parity (PPP). Assuming that the benchmark for evaluating price differences is the appropriate sharing of the global joint costs, then exchange rates are the appropriate basis for currency conversion. Exchange rates determine the innovator firm's actual net revenues from foreign sales in terms of domestic currency, hence the relative country contributions to financing R&D.

A common objection to use of exchange rates is their volatility. If the price comparison and hence the regulated price were to fluctuate with every change in the exchange rate, this would impose costly instability on consumers and manufacturers. A simple solution is to use an average of forward exchange rates over the time period for which prices are to remain in effect. This yields a stable price for payers and consumers for the relevant period. Manufacturers also benefit from the stabilization of prices in local currency units. Although

25 Danzon and Kim (1996).

the manufacturer's revenues in its domestic currency units still fluctuate with exchange rates, this can be hedged if desired.

The alternative that has been proposed in Italy is to base international price comparisons on purchasing power parities (PPPs). The rationale is that PPPs are more stable than exchange rates and that PPPs provide a more accurate comparison of prices relative to purchasing power of consumers. However an alignment of prices based on PPPs would provide a very different alignment in terms of real contribution to joint costs, because PPPs may diverge significantly from exchange rates. It is exchange rates that determine net revenues to manufacturers, hence contributions to joint costs.

A further disadvantage of regulation based on foreign prices converted at PPPs is that this would generate incentives for parallel trade whenever exchange rates fall relative to PPPs. Even if manufacturers set prices uniformly at current exchange rates, in order to deter parallel trade, this may be undermined if regulators set prices based PPP comparisons. Thus international price comparisons based on PPPs further undermine the ability of manufacturers to control their revenue loss from parallel trade.



## 7 CONCLUDING COMMENTS

The EU is founded on the principle of free movement of goods. At the same time, the subsidiarity principle authorizes individual countries to establish their own regulatory systems for health care, including pharmaceuticals. These two principles, as currently applied, undermine the ability of pharmaceutical companies to set prices to cover the costs of R&D in the most efficient manner. The welfare maximizing set of prices to cover joint costs requires charging different prices to different users, based on their differing price sensitivity of demand and willingness to pay for innovative medicines. There is no assertion here that actual or traditional price differences are optimal. However, current policies – in particular, parallel trade and regulation based on foreign price comparisons – tend to force prices to converge throughout the trading area, which is clearly not optimal.

In response to such policies, theory predicts and evidence confirms that manufacturers will attempt to set a common launch price in all countries and postlaunch prices will converge on the lowest price in the trading block. A low price in this context usually reflects regulatory leverage or disregard for intellectual property, not superior efficiency. If price is forced down to short run marginal cost in one country, through use of these strategies, and this proliferates to other, potentially higher price countries, revenues may be insufficient to cover the joint costs of R&D. Incentives for development of new medicines will depend on other countries continuing to pay for the joint costs. However, the incentive to free-ride is infectious, as evidenced by the fact that both Japan and the US have recently considered reducing their prices to levels paid in other countries.

If incentives for innovative R&D are to be preserved, there is a strong case for exempting from parallel trade pharmaceuticals and other products that are both patented and subject to price regulation. An alternative is to permit manufacturers to pay rebates selectively to final users, while selling at a common list price to wholesalers. Such a rebate system preserves differentials in final prices without generating opportunities for parallel trade.

While some strategies to constrain spending on pharmaceuticals may be justified because of the moral hazard effect of insurance, price regulation based on foreign prices lacks any efficiency rationale. On the contrary, by



inducing downward spillover pressures on prices, such regulation tends to undermine optimal price differentials and undermine the adequacy of revenues to pay for R&D.

In theory, the methodology of price comparisons and target prices could be designed to achieve price differentials that yield optimal contributions to the joint costs of R&D. In practice, the data requirements and political pressures for cost control make this a risky and unattractive approach, both for use across countries within a trading area such as the EU and more broadly to include other major markets. Other cost control strategies may well offer a more appropriate trade-off between control of current budget costs and preservation of incentives for R&D. Consideration of such alternatives is clearly a high priority.

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## GLOSSARY

<b>Cost shifting</b>	Cost shifting occurs when the price to one group of consumers is less than the marginal cost of serving that group and, as a consequence, the price to another group of consumers is increased.
<b>Parallel import</b>	Parallel importing occurs when a branded product is shipped by a wholesaler or other intermediary from one country to into another country in which the manufacturer has a local source of supply.
<b>Purchasing power parity</b>	A purchasing power parity (PPP) is a measure of the relative value of one currency in terms of a base currency, calculated such that the cost of purchasing a specified basket of products is the same in the comparison countries.
<b>Monopsony</b>	A single purchaser in a given market.
<b>Quasi-rent</b>	A quasi-rent occurs when the price of a good exceeds its marginal cost by an amount that is just sufficient to cover the fixed costs that are incurred to produce the product in the long run.

