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Pharmaceuticals After '1992'

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INTRODUCTION

The market for pharmaceuticals is probably the most strongly segmented and highly regulated market in the EC. Large price differences between countries are an indication for this segmentation. At the same time, the pharmaceutical industry in some countries such as Germany and the UK belongs to the most successful sectors of the economy on an international scale.

In studies of the internal market in 1992 the prospects for a unification of the markets for pharmaceuticals have been seen as not too bright (EUROPEAN ECONOMY, 1988). The expectations about the success of the planned directives of the Commission of the EC have been reserved, although some convergence of price levels was predicted. It remained unanswered what the potential path for prices could be in the process of unification and what welfare effects might be associated with this process (EAG, 1988). In "The Economics of 1992" a convergence of prices to a community average was assumed resulting in a fall of spending on pharmaceuticals of 720 mio. ECU or to some 3 percent in total expenditure.

In this paper a framework is developed within which the likely outcomes of measures taken towards an internal market can be analyzed. The first part of the paper introduces some features of pharmaceutical markets in terms of industry characteristics and demand regulations. In addition, the proposed measures by the Commission of the EC are summarized. In the second part a simple model of a price discriminating monopoly is presented which is exposed to price controls in one market and which faces limited arbitrage between the markets. Changes in regulations concerning arbitrage and price controls are then investigated and the impact of moves towards unified markets on welfare are discussed. The paper concludes with some speculations about the likely process of creating an internal market for pharmaceuticals as it is laid out by the directives of the EC and further planned directives.

INDUSTRY AND MARKET STRUCTURE

The European pharmaceutical industry can best be characterized by its dual structure. On the one hand, there are small companies which do not develop new drugs, have a small R&D budget, and sell mostly to local markets. They make up the bulk of the 2200 pharmaceutical companies in Europe. The European market is dominated, however, by around 60 internationally operating, large, research oriented companies of which about 30 are of European origin. They control about 70-80 percent of the market in France, Germany, Italy and the UK and most of the roughly 4-5 billion US-$ on R&D are allocated in these companies.

These large international firms rely to a considerable extent on intra-firm trade and production in local affiliates such that trade statistics reveal only a small proportion of the internationalization of the market for pharmaceuticals. It has been estimated that imports into the EC for 1984 amount to about 1.2 billion ECU, whereas sales of local affiliates of non-EC companies come to 7.7 billion ECU. This emphasis on local production has two reasons: It is often claimed that the national authorities involved in regulating pharmaceutical markets and in controlling demand discriminate against imports thus forcing foreign companies to establish local facilities. The other reason is based on the technology of producing pharmaceuticals.

Developing new drugs requires large investment in R&D which add up to, e.g., DM 2915 mio. (1980) in Germany, i.e. 14.6 percent of German industry turnover (BPI, 1990). This is about one third of total R&D spending in the EC (EAG, 1988). It is estimated that the development of one new pharmaceutical entity including unsuccessful search costs about DM 250 mio. Since R&D projects have a low probability of success large companies choose to work simultaneously on 8-10 projects in order to avoid the risk of being unsuccessful overall. In addition, research facilities require a minimum efficient scale for libraries, animal testing, laboratories, etc. such that the R&D facilities are in one centralized place, usually the headquarter of the company.

Once the chemical entity has been developed, the preparation of the active ingredients and their conversion into dosage form are the two other steps. Both involve some fixed costs but the optimum scale of operation

for the preparation of the ingredient is large enough to be located in the company headquarter whereas conversion into dosage form is largely decentralized. This decentralization has been reported to be forced by pressures of national authorities (EAG, 1988). The marketing of drugs then is a purely local activity. The production technology can therefore roughly be characterized as one which involves sizeable fix costs but otherwise constant marginal costs.

The decentralization of predominantly the last production step is therefore not necessarily forced by technological considerations. National policies forcing companies to set up local production sites seem to be more important. However, the cost savings of centralization are estimated to be rather low. If the most economical production sites are chosen unit costs of parmaceutical companies in the EC could fall by 0.19 to 0.61 percent or 65 to 208 mio. ECU (EAG, 1988). It is therefore not difficult for foreign firms to satisfy pressures by local authorities and to establish local production facilities.

The demand for pharmaceuticals is determined by complex interactions of patients, physicians, and different health insurance systems. The choice of the drug is largely made by the physician who is privileged to prescribe ethical drugs - the dominating market segment - but he does not pay for it. Patients who are the consumers of pharmaceuticals have in most countries little incentive to respond sensitively to price differences of drugs. Therefore national and local health institutions have tried to control the cost of pharmaceutical therapies in many different ways. Except for Germany, Ireland, the Netherlands, and the UK, all European countries use direct price controls. Additional measures include controls on total expenditure, positive or negative lists, and direct negotiations of health systems with the pharmaceutical industry which also try set limits on prices in general.

These national policies to control the costs of the health system in general and expenditures on pharmaceuticals in particular have put forward a number of studies which have tried to identify the degree of price dispersion within the EC. Table 1 which summarizes the results reveals drastic price differences between high price countries like Denmark, Germany, and the Netherlands - which incidently do not control prices - and low price countries like Italy and France which limit

prices. Also Spain and Portugal which are not included here have low prices.

These price comparisons are rather controversial since there is considerable confusion as to how the commodity baskets should be selected as there are thousands of pharmaceuticals supplied in European markets, but only a few are truly identical products with identical names, package

Table 1 - Estimation of Relative Drug Prices from Different Studies, UK=100

	COOPER 1974	PROGNOS 1981	HEALTH ECON. 1982	EEC 1983	DUKES 1984	EFPIA 1985
Belgium	143	73	66	103	69	70
Denmark	n.a.	n.a.	143	154	99	n.a.
France	80	69	57	76	52	77
FRG	288	128	159	164	124	120
Greece	n.a.	n.a.	n.a.	73	n.a.	n.a.
Italy	85	65	62	57	58	72
Netherlands	n.a.	n.a.	140	145	114	113

Source: Taken from EAG (1988), Table 4.2.

sizes etc. such that it becomes difficult to judge as to whether two products in two different countries are identical. This problem is aggravated by the fact that one important strategy of pharmaceutical producers is product differentiation such that a comparison of truly identical drugs underestimates the degree of price dispersion. These price differences may have been reduced somewhat in the meanwhile as the market share of generic products has increased and the price differences of newly introduced pharmaceuticals have turned out to be smaller.

A stylized picture of the pharmaceutical industry would therefore look as follows: An ethical drug which is patent-protected is usually the only product or one of very few products supplied in a specific therapeutical group if one considers only the most effective drugs and ignores older less effective ones. In many therapeutical groups there essentially exists a monopoly or anokgopoly of one company for some time but no

longer than the life of the patent. During that time market entry of competitors is difficult if not impossible. The production of the drug has high R & D costs and probably constant marginal costs of production.

BARRIERS TO TRADE

The major regulations for pharmaceuticals concern health aspects. Every pharmaceutical has to pass a registration procedure before it can be sold in national markets. Proof of safety, efficacy and quality have to be supplied by the producer. In addition, packages, labels, patient information leaflets and dosages must be approved. These characteristics together then define a pharmaceutical product in a national market. Strictly speaking this means that two products sold in two different countries with different patient information leaflets or different labels but identical chemical ingredients are treated as different products. Hence, the admission process of pharmaceuticals unintendedly produces perfect market segmentation if viewed from a legal standpoint.

In reality this view has been contested. Since the late 1970's companies appeared which tried to arbitrage pharmaceuticals from low priced countries to high priced countries, mostly to Germany, the Netherlands and the U.K. These companies bought, e.g., German pharmaceuticals in France or Italy and exported them to Germany or they bought Italian pharmaceuticals in Italy and they exported those parallel to the exports of the producers to Germany. These reimports and parallel imports are estimated to be rather small amounting to 150 mio. ECU in the EC in 1985 (EAG, 1988). For Germany a market share of one percent has been quoted (Sachverständigenrat für das Gesundheitswesen, 1987) which - according to industry representatives - has remained constant over the years up to today. Companies specializing in reimporting pharmaceuticals report that producers respond quickly to increased arbitrage by lowering prices in high priced markets. The model below also indicates that a low volume of reimports and parallel imports does not necessarily indicate little pressure on market segmentation.

In Germany, arbitrage is done by approximately 5 to 6 large firms and a larger number of smaller firms. Since these firms are required to be re-

gistered as pharmaceutical producers and since their reimported or parallel-imported products have to go through the national registration, arbitrage activities can not be performed on a hit-and-run basis. It is impossible to exactly assess the cost structure of arbitrage firms, but there seem to be some setup costs, whereas marginal costs are relatively flat until the producers of the arbitrage products actively try to prevent arbitrage. Then marginal costs may be very steep.

The European court has already ruled in 1976 that reimports and parallel imports do not need a separate admission procedure - which is time consuming and expensive - if the products are identical. If there are therapeutically relevant differences between the products, then a new admission is necessary. This statement is at the heart of the matter of many court rulings concerning reimports and parallel imports. National regulations differ substantially. In the Netherlands, a simplified registration procedure can be used by arbitrageurs if the pharmaceutical has the same chemical compounds and the same dosage. This procedure is frequently used (Hart/Reich (1990), pg. 250). Germany does not have a special admission procedure for reimported pharmaceuticals. It requires, however, that the reimporting firm is registered as a pharmaceutical producer with all the responsibilities for safety of the drugs which it sells. A recent court ruling in 1989 has strongly increased the barriers for arbitrage since it requires that in order to be identical products reimported pharmaceuticals need to have identical names with those sold in Germany. The federal court (Bundesverwaltungsgericht) decided that the products "Methorexat" sold in Germany and "Methorexate" sold in Italy which except for the last letter are otherwise identical cannot be treated as identical products. Arbitrage is therefore made very costly since the reimported product must go through the complete admission process which is time consuming and expensive. The UK has introduced a simplified admission procedure called PL (PI) - "product license - parallel import" - which is granted for pharmaceuticals coming from EC-countries which are identical in therapeutic quality to the product admitted in the UK by the principal producer. Since many British parallel imports have come from non-EC countries this ruling has limited the extent of arbitrage between UK and non-EC countries.

Taken together these regulations in countries with high prices for pharmaceuticals, it is fair to conclude that arbitrage inside the EC is still quite limited. It is costly since the imported products often have to be repackaged, or since wholesalers in the exporting countries do not deliver products to exporters, or since companies have reacted to court rulings by exploiting the possibilities of product differentiation in order to keep markets segmented as much as possible. Therefore national admission processes which undoubtedly are necessary for health and safety reasons provide the basis for market segmentation. The question is then as to whether the measures taken by the EC will attack this situation and will move pharmaceutical markets toward a unified internal market without segmentation.

This market segmentation is also a necessary condition for the sustainability of price control measures which are taken by the majority of countries. The measured price differences (see table 1) therefore represent a mixture of price discrimination imposed by profit maximizing firms and price controls imposed by national health institutions. An elimination of national price controls will therefore not necessarily lead to uniform prices within the EC. It is even an open question whether price differences would be larger with than without price controls. Whether European directives towards easier arbitrage opportunities under unchanged price control regimes will be sustainable is also unknown. The analysis below will shed some light on these issues.

INITIATIVES TOWARDS AN INTERNAL MARKET

The commission of the EC has in the past already introduced a number of measures to harmonize pharmaceutical markets. Their intended aim is to secure a safe supply of pharmaceuticals without limiting the development of the European pharmaceutical industry and the free movement of goods within Europe. Common criteria for the safety, efficacy and quality of drugs are determined in the directives. Whereas in the past a producer could register a drug only with the national authority of the country in which the product was sold, a multi-country registration procedure has been introduced.

The multi-country procedure gave pharmaceutical companies the option to obtain registration of a pharmaceutical product for the entire EC by supplying first five and since 1983 only two national registrations to the European Commission for Proprietary Medicinal Products (CPMP) which will then evaluate the documents supplied by the company and give a positive or negative recommendation to the member countries for accepting the national registrations in their countries without further delay. This procedure has not been used very much. The pharmaceutical industry accused it of being too time consuming. In 1987 the CPMP has been given more power through the rule requiring national authorities to include the CPMP in registration processes for high technology drugs such as drugs produced with biotechnology.

Despite these efforts to harmonize registration procedures, the final decision still remains within the national authorities. This also means that pharmaceutical firms still have the option to obtain only national admissions for their products. They can thus choose the degree of product differentiation and market segmentation through "spurious" product differentiation such as slight changes in the name of a drug, different packaging, different dosage or different patient information.

New initiatives towards a harmonized registration within the EC go in three directions (Hart/Reich, 1990): First, the establishing of the principle of mutual recognition of registration; secondly an expansion of the competence of the CPMP, yet without giving it registration authorities, and finally the creation of a pan-European admission agency, the "European Medicines Agency". The last proposal of the Commission of 1990 on a "Future System for the Free Movement of medicinal products within the European Community" envisages on obligatory pan-European registration for bio-technically produced drugs and an optional one for high-technology and new drugs. A decentralized procedure with mutual recognition of admissions is planned for drugs not in the two groups just mentioned but with European dimension. National authorities are therefore responsible only for drugs with only a local market.

The so called "Transparency Directive" addresses the question of price controls. The commission does not challenge price controls in general but aims at making price control measures more transparent for those in-

volved in the process by setting time limits on procedures or giving companies more rights to challenge price controls. Under these rules price controls can still be imposed, they may however be accompanied by higher political costs if the decision processes become transparent and the alleged discrimination of foreign firms can be documented. If the initiatives and plans by the Commission of the EC toward an internal market for pharmaceuticals are accepted and implemented a first step toward a unified market will be made. Through the pan-European registration of bio-technology products market segmentation will be ruled out. For other products companies may still use the option of segmenting markets through national registration. Whether the European court will challenge some of the national rules concerning arbitrage through reimports and parallel imports is hard to predict, but some harmonization between, e.g., German and Dutch rules will probably come about resulting in lower costs of arbitrage. Price controls, on the other hand, seem to prevail.

The question then is which impact such a development of regulatory measures will have on pharmaceutical markets in Europe. What will happen to price discrimination by firms? Will prices rise or fall? Will price controls persist as arbitrage becomes easier? Another issue coming up with a unified market with possibly uniform prices is the welfare issue. Consumer surplus in countries whose prices will increase will surely experience losses, but even on a community level it is not clear whether a move from the current system which is inefficient to a unified market which is also inefficient will increase or lower welfare. In order to clarify these questions and to answer some of them, in the following a simple model of a price discriminating firm faced with price controls in one market but not the other is developed.

A MODEL OF PRICE DISCRIMINATION, PRICE CONTROLS, AND ARBITRAGE

Market Segmentation

Suppose a firm produces an ethical drug which is protected by patents and serves a specific therapeutical group. There may be some substitutes in that market segment, but essentially the firm will have a monopoly

for its product - especially if it is the most advanced pharmaceutical for curing this specific illness. The pharmaceutical firm is assumed to produce just one pharmaceutical x and sells in two markets, 1 and 2. It has a cost function of producing x of the form

(1) $c(x) = F + c \cdot x$

where F = Fix cost (R&D, etc.)
c = marginal cost,

hence there are constant marginal costs and increasing returns to scale. According to the discussion above this is a plausible assumption.

The firm's profit if it can price discriminate between markets will then be given by

(2) $\pi(p_1, p_2) = x_1(p_1)p_1 + x_2(p_2)p_2 - c(x_1(p_1)+x_2(p_2))$

where $x_1(p_1)$ and $x_2(p_2)$ are the demand functions in market 1 and 2.

Profit maximization of the firm will yield the following first order conditions

(3) $$\frac{\bar{p}_2}{\bar{p}_1} = \frac{1 + \frac{1}{\epsilon_1}}{1 + \frac{1}{\epsilon_2}},$$

where ϵ_1 and ϵ_2 are the respective demand elasticities in the two markets. Equation shows that prices in the market with lower demand elasticities (in absolute terms) will be higher. For the following it is assumed without a loss of generality that $|\epsilon_2| > |\epsilon_1|$, hence $p_1 > p_2$.

Under a regime without market segmentation, the firm will set a uniform price p_o such that its marginal revenue in both markets together will equal its marginal cost, i.e.

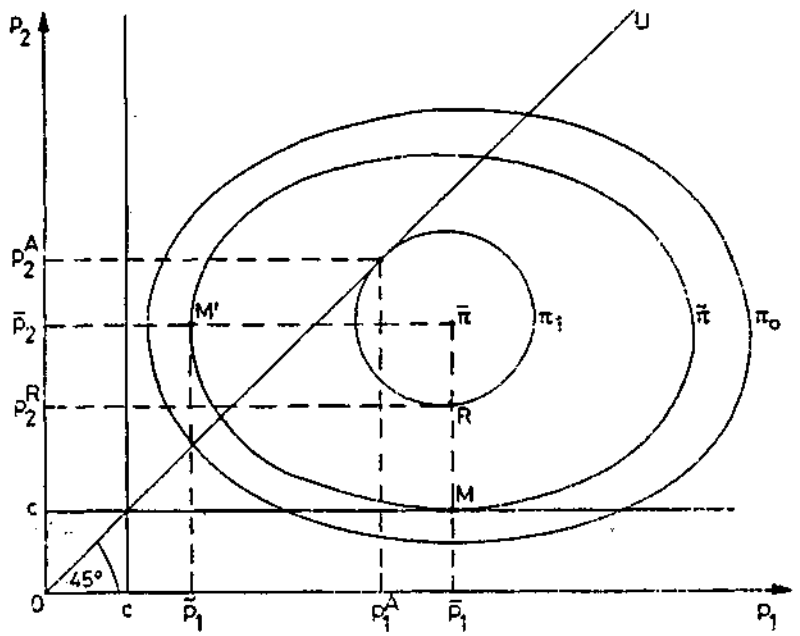
(4) $$p_U \left(1 + \frac{1}{\epsilon_U}\right) = c$$

where ϵ_U = price elasticity in both markets together.

Suppose now that prices are controlled by a regulatory agency in country 2 which fixes p_2 at p_2^R. Since the pharmaceutical producer faces constant marginal costs and the demand functions are independent the price in market 1 will remain at $\bar{p}_1$ whereas $p_2 = p_2^R$. This result is illustrated in Figure 1.

$\bar{\pi}$ represents the profit maximizing price combination $(\bar{p}_1, \bar{p}_2)$ under third degree price discrimination. The isoprofit line labled π^R goes through the price pair $(\bar{p}_1, p_2^R)$ when prices are controlled in market 2. The tangency point of the isoprofit line π_1 with the 45°-line, represents the equilibrium without market segmentation. π_o denotes price combinations

Figure 1



(p_1, p_2) where profits of the firm are zero. Under the demand constellation of the model prices in market 2 can be lowered to c through controls. Then the firm will cease to supply that market but will still

make profits in market 1. In market 1, however, prices cannot be regulated downward beyond π_o. Hence price controls have a higher chance of success in the low price markets.

Arbitrage

Suppose now that markets are only imperfectly segmented. Goods can be arbitraged between markets at some costs. There are arbitrageurs who supply parallel imports or reimports by buying in the low price market and selling in the high price market. In order to perform this activity they have additional costs of repackaging, of distribution, of sourcing, etc. which may parametrically depend on the institutional structure of the markets. Then the profit function of an arbitrageur would be where x_A

$$(5) \qquad \pi^A(x_A,\alpha) = (p_1-p_2)x_A - c_A(x_A,\alpha)$$

denotes the quantity which is bought, resp. sold, in the two markets and $c_A(\cdot)$ is the cost function of arbitrage parameterized with α. It is assumed that the cost function is convex, i.e.
$c'_A = \delta c_A/\delta x_A > 0$, $c''_A > 0$.

The profit maximizing arbitrage x_A will then be given by

$$(6) \qquad p_1-p_2 = c'(x_A,\alpha).$$

The supply function of the arbitrageur in market 1 will then be given as the inverse of (6),

$$(7) \qquad x_A = x_A(p_1-p_2,\alpha)$$

with $x'_{A1} > 0$, $x'_{A2} < 0$, $x'_A > 0$, where x'_{Ai} denotes the partial differential of the supply function with respect to p_i, and $x'_A = \delta x_A/\delta(p_1-p_2)$. The signs follow from the strict convexity of the cost function.

The pharmaceutical firm will now recognize the behavior of arbitrageurs which itself depends on the extent of the firm's own price discrimination among the two markets. Profits of the pharmaceutical firm then become

$$(8) \quad \pi(p_1,p_2,\alpha) = p_1\,[x_1(p_1) - x_A(p_1-p_2,\alpha)] + p_2\,[x_2(p_2) + x_A(p_1-p_2,\alpha)] - c\,[x_1(p_1) + x_2(p_2)] - F.$$

Maximization with respect to p_1 and p_2 then yields first order conditions

$$(9) \quad 0 = p_1 \left[1 - \frac{1}{|\epsilon_1|}\left[1 - \frac{x_A}{x_1}(1+\epsilon_A)\right]\right] - c$$

$$(10) \quad 0 = p_2 \left[1 - \frac{1}{|\epsilon_2|}\left[1 + \frac{x_A}{x_2}(1+\epsilon_A)\right]\right] - c.$$

The familiar condition on third degree price discrimination given in (3) is then transformed into

$$(11) \quad \frac{p_1}{p_2} = \frac{1 - \frac{1}{|\epsilon_2|}\left[1 + \frac{x_A}{x_2}(1+\epsilon_A(\alpha))\right]}{1 - \frac{1}{|\epsilon_1|}\left[1 - \frac{x_A}{x_1}(1+\epsilon_A(\alpha))\right]}$$

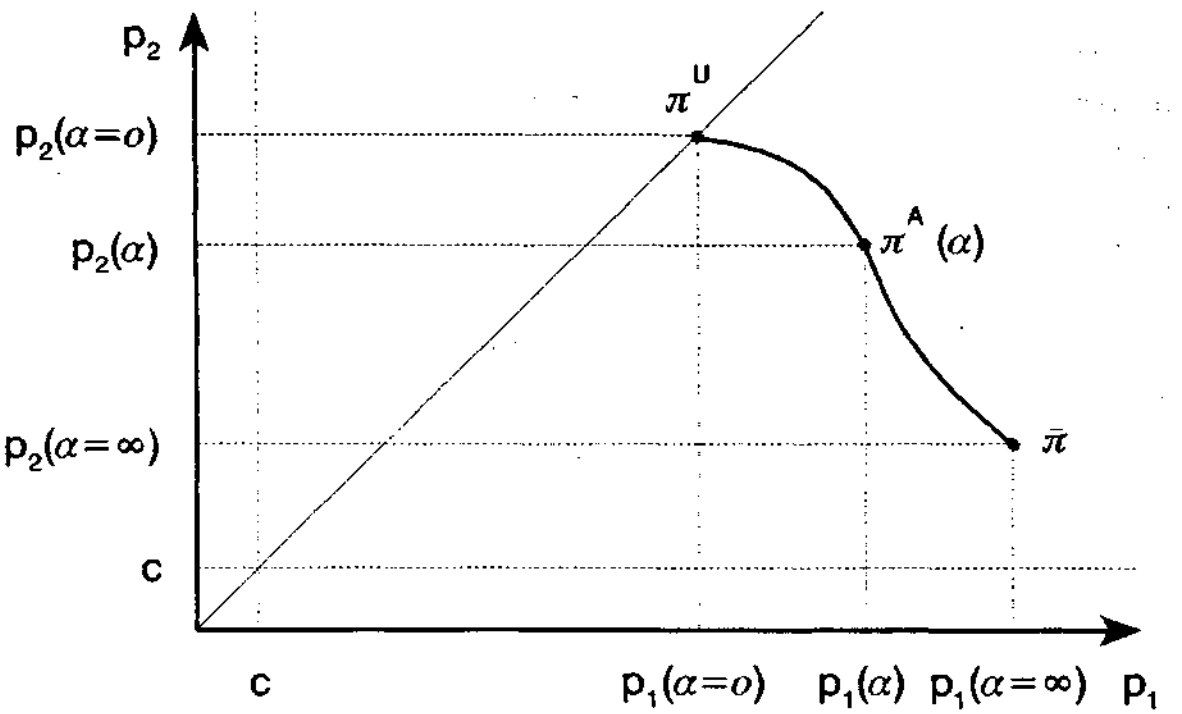
$|\epsilon_1|$ and $|\epsilon_2|$ are defined as the market demand elasticities net of arbitrage. ϵ_A denotes the reaction elasticity of arbitrage with respect to the price dispersion, i.e.

$$(12) \quad \epsilon_A(\alpha) = \frac{\delta x_A(p_1-p_2,\alpha)\cdot(p_1-p_2)}{\delta(p_1-p_2)\cdot x_A(p_1-p_2,\alpha)} \quad .$$

A comparison of the first order conditions under price discrimination without arbitrage (equation 3) and with arbitrage (equation 11) shows that arbitrage reduces the wedge between the two prices. The degree of reduction then is determined by the two brackets on the right-hand side of equation (11).

The degree of price discrimination by the pharmaceutical firm depends on the extent to which arbitrage is made costly by the regulation of marketing drugs in a country and of barriers to reimports or parallel imports. This effect is captured by the parameter α. Suppose a high α represents strict regulations such that the cost of arbitrage increase. Then the extent of arbitrage will fall as α increases, $\delta x_A/\delta\alpha < 0$ and consequently $\delta\epsilon_A/\delta\alpha < 0$. Hence, with falling α, i.e. low cost of arbitrage, the bracket in the numerator if equation (11) increases and it falls in the denominator. In other words, the perceived price elasticity of the pharmaceutical firm in market 2 falls and it rises in market 1. Since $|\epsilon_2| > |\epsilon_1|$, the perceived elasticities will eventually equalize as α falls and price discrimination will cease to exist. Conversely, as α increases the perceived elasticities will deviate and price discrimination will increase.

Figure 2



In Figure 2 the line $\pi^{U}\bar{\pi}$ indicates the optimal price discrimination under alternative costs of arbitrage. The comparative static results for alternative costs of arbitrage are

$$(13)\qquad \frac{dp_1}{d\alpha} \begin{cases} \geq 0 & \text{if } 2x_2' + (p_2-c)x_2'' \leq 0 \\ < 0 & \text{if } 2x_2' + (p_2-c)x_2'' > 0 \end{cases}$$

and

$$(14)\qquad \frac{dp_2}{d\alpha} \begin{cases} \leq 0 & \text{if } 2x_1' + (p_1-c)x''_1 \leq 0 \\ > 0 & \text{if } 2x_1' + (p_1-c)x_1'' > 0 \end{cases}$$

The path of profit maximizing allocations under different arbitrage opportunities has a negative slope like in Figure 2 if both demand functions are not too convex. It is also apparent that the sign of the slope of the path $\pi^{U}\bar{\pi}$ is independent of the cost structure of arbitrage.

Price Controls with Arbitrage

The introduction of price controls in a model with perfectly segmented markets leads to lower prices in the market in which the controls are imposed but prices in the unconstrained market are not affected. This follows immediately from the first order conditions of profit maximization and is illustrated in Figure 1. Under arbitrage this independence disappears since price controls increase the price dispersion between the two markets such that arbitrage will increase in order to exploit the new profit opportunities. Consequently, the producers will adjust prices in the market without price controls such that their profits are maximized given the behaviour of the arbitrageurs.

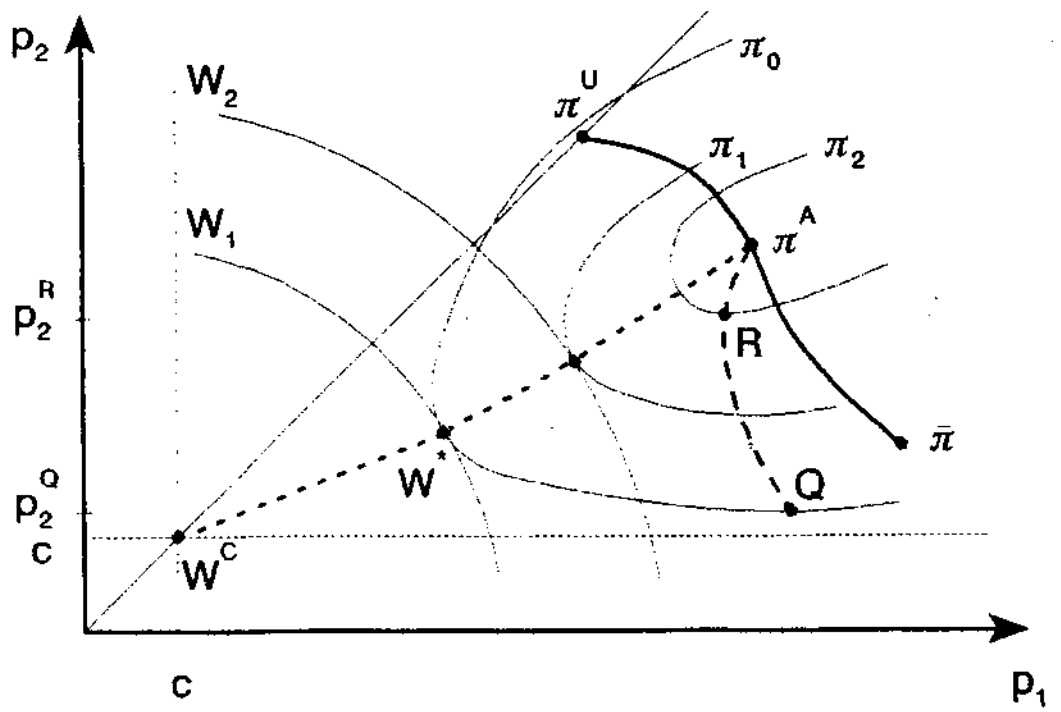
If prices in market 2 are controlled by the authorities of that country, the pharmaceutical producer will adjust p_1 such that

$$(15) \qquad \frac{dp_1}{dp_2^R} = - \frac{(p_1-p_2)x_A'' + 2x_A'}{2x_1' + (p_1-c)x_1'' - 2x_A' - (p_1-p_2)x_A''}$$

The denominator is identical to the first diagonal term of the second-order condition and is negative. The sign of the numerator depends on the sign of x_A'' which is ambivalent and which represents the shape of the marginal cost curve of arbitrage.

If the arbitrage supply function, i.e. the marginal cost curve is concave, then the sign of equation (15) is uniquely positive, hence a reduction of the price in market 2 through administered price ceilings will be accompanied by a reduction in the price in the uncontrolled market. If however $x_A'' < 0$ and $(p_1-p_2)x_A'' < -2x_A'$ then prices may be raised in market 1 as a response to lower prices in market 2. This could happen, if the marginal cost curves of the arbitrageurs is sufficiently convex.

Figure 3



In Figure 3 an example is given where price controls at p_2^R initially induce a reduction of the price p_1 in market 1 such that R is the optimal allocation. If the price in market 2 is further reduced to p_2^Q, then the optimal decision by the producer will be to raise the price of good 1 in order to compensate for the losses in market 2. The reason for such a result comes from the fact that as p_2 falls arbitrage will increase c.p. resulting in a lower p_1. If, however, the marginal cost curves of the arbitrageurs are sufficiently steep then it becomes profitable for the producer to reduce the supply in market 1 since this reduction is not matched by increased arbitrage.

The introduction of arbitrage and price controls will therefore lead to either a fall of prices in both markets or in a rising price in the uncontrolled and a lower price in the controlled market. The question which case will occur is essentially an empirical one which is determined by the shape of the marginal cost curve of arbitrage[1]. Since arbitrage involves the buying of large amounts of the commodity in the low price market, it will not go unnoticed by the producer if the market share of reimported goods or parallel imports increase. Companies specializing in the reimport of pharmaceuticals report increasing difficulties of buying large quantities from one wholesaler and have often to rely on a large number of smaller suppliers. Such evidence suggests that a convex marginal cost curve for arbitrage is more likely than a concave one. This, in turn, would indicate that increasing arbitrage going hand in hand with stricter price controls could be accompanied by rising prices in market 1. Or, vice versa, a more towards a unified European market may lower prices in the high priced market if arbitrage was at its capacity limits. It would result in rising prices in both markets if the reduced arbitrage would result in only marginally lower marginal costs.

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[1] E.g. for a quadratic cost function, the line $\pi^A RQ$ has a positive slope, hence stricter price controls in market 2 go hand in hand with lower prices in market 1.

OLIGOPOLISTIC MARKETS

Pharmaceutical companies usually supply many different products in market segments which are divided among therapeutic groups. Sometimes there is only one producer supplying a dominating drug, in other cases there are very few; very rarely, however, here is a larger number of suppliers. The question is therefore whether the result which has been derived for a monopoly in a market segment also holds for an oligopolistic market structure. One can show that the same results can also be derived in a Cournot-Nash framework.

Suppose there are two producers K, and L, which both sell in the two markets 1 and 2 which have the same characteristics as before. The supply of the two oligopolists is (x_{K1}, x_{K2}) and (x_{L1}, x_{L2}). Under Cournot-behaviour each producer will choose those quantities which maximize his profits given the output of the other producer and given the arbitrage which takes place between the two markets.

The profit of producer K is

$$(16) \quad p_1(x_{K1}+x_{L1}+x_A)x_{K1} + p_2 (x_{K2}+x_{L2}-x_A)x_{K2} - c(x_{K1}+x_{K2})$$

and correspondingly for producer L. Arbitrage is determined corresponding to (6) by

$$(17) \quad p_1(x_{K1}+x_{L1}+x_A) - p_2(x_{K2}+x_{L2}-x_A) = c'(x_A, \alpha)$$

Under Cournot-behaviour each producer maximizes profits subject to the constraint of the arbitrage between the two markets. The resulting reaction functions are illustrated in Figures 4 and 5. Figure 4 represents the market with the high prices. Without arbitrage the Nash-equilibrium is $\bar{\pi}_1$ where the reaction functions K_1, K_1' and L_1', L_1 intersect. In the presence of arbitrage, the reaction functions can not be uniquely determined in terms of the supply of the two producers in market 1, i.e. x_{K1}

Figure 4

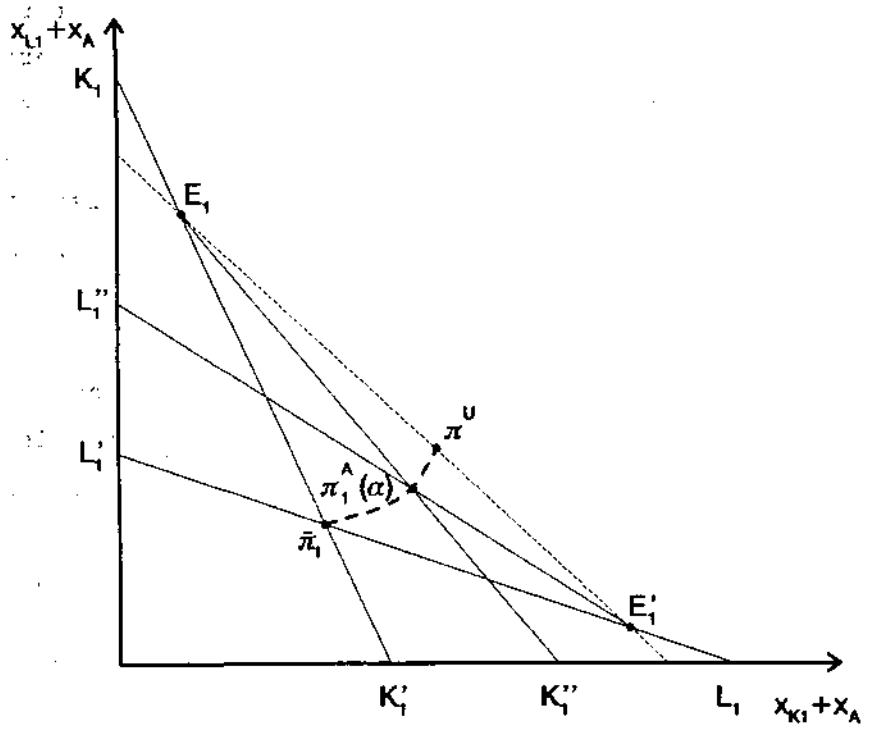
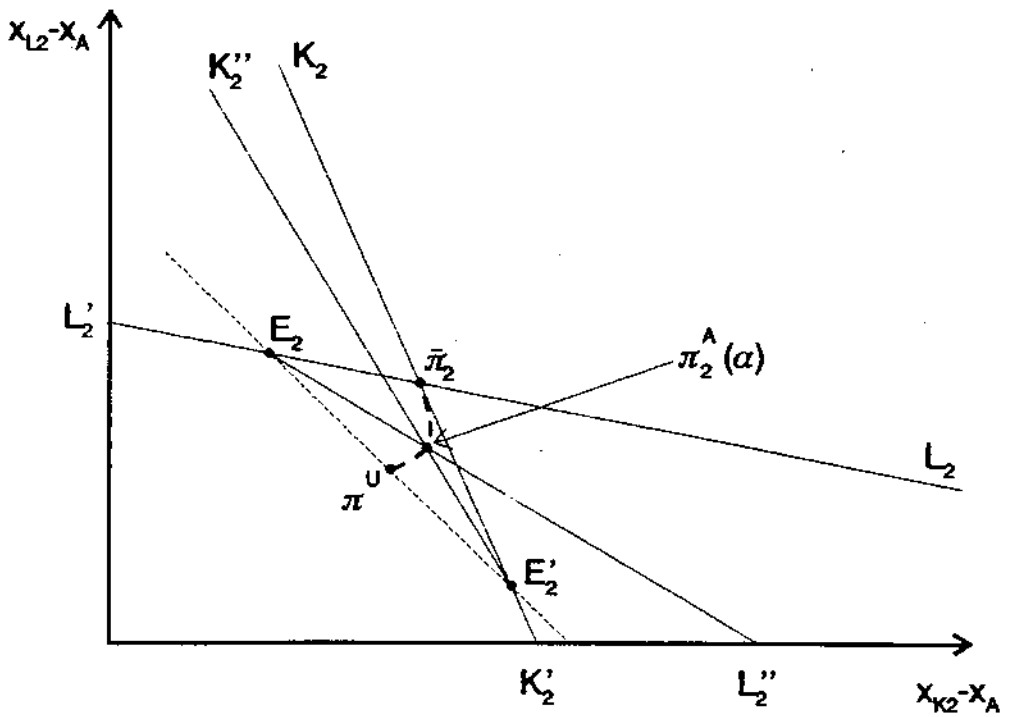


Figure 5



and x_{L1}, but only as total market supply, i.e. $x_{K1}+x_A$ or $x_{L1}+x_A$. For a specific arbitrage opportunity parameterized by α, the resulting equilibrium market supplies are represented by $\pi_1^A(\alpha)$ and the corresponding supply in market 2 is $\pi_2^A(\alpha)$ in Figure 5.

As in the monopoly case one can not predict which quantities are supplied by the producers directly and which are supplied by arbitrageurs. Yet, the comparative static results are the same as in the monopoly. If arbitrage becomes more costly, i.e. $d\alpha>0$, then

$$\frac{dx_A}{d\alpha} = \frac{\pi_{11}\,\pi_{22}}{\Delta} \cdot \frac{\delta c''(x_A, \alpha)}{\delta \alpha} < 0 \tag{18}$$

where π_{11} and π_{22} are the second derivatives of the profit function (16) and Δ is the determinant of the constraint maximization (16) and (17).

For each producer the sum of arbitrage supply and his own supply is also negative, i.e.

$$\frac{dx_A}{d\alpha} + \frac{dx_{K1}}{d\alpha} = \frac{\Pi_{22}}{\Delta} \frac{\delta c''(x_A, \alpha)}{\delta \alpha} \cdot p_1' < 0 \tag{19}$$

where p_1' is the first derivative of the demand function in market 1.

For market 2 we get symmetrically

$$\frac{dx_{K2}}{d\alpha} - \frac{dx_A}{d\alpha} = - \frac{\Pi_{11}}{\Delta} \frac{\delta c''(x_A, \alpha)}{\delta \alpha} p_2' > 0. \tag{20}$$

From equation (19) one can immediately see that with increased costs of arbitrage the price in market 1 rises. Whether the price in market 2 rises or falls depends on how the demand of the arbitrageurs changes relative to the change in the supply of the producers. This is not uniquely determined as in the monopoly case. Hence, the price discrimination equilibria as illustrated in Figure 2 carry over to the oligopoly.

In the case of price controls the profit maximization of each firm as given by equation (16) and the constraint (17) has the additional constraint that the price in market 2 must remain below p_2^R:

$$p_2(x_{K2}+x_{L2}-x_A) \leq p_2^R. \tag{21}$$

The comparative static results of this maximization also reveal that as the price controls are loosened, i.e. $dp_2^R > 0$, the price difference will be reduced. Whether the price in market 1 falls or rises, again depends on the slopes of the demand functions in the two markets.

WELFARE EFFECTS

The welfare effect of third-degree price discrimination has been investigated by SCHMALENSEE (1981) and VARIAN (1985). Varian derives bounds an the welfare change of different degrees of price discrimination and on the difference in welfare between uniform pricing and profit-maximizing price. discrimination. The basic necessary condition for an increase in welfare when firm is moving from uniform pricing to price discrimination is that output in both markets together must increase. This result depends on profits of the firm as well as on consumer surplus. In analyzing the welfare effects of price controls at some given regulation of arbitrage the results of Schmalensee and Varian can be used. One has only to use the additional assumption that arbitrage takes place in a perfectly competitive environment with zero profits. Then the welfare of the overall region - assuming quasi-linear utility - is given by

$$W(p_1,p_2,\alpha) = \int_{p_1}^{\infty} x_1(v)dv + \int_{p_2}^{\infty} x_2(v)dv + \pi(p_1,p_2,\alpha) \tag{22}$$

where $\pi(p_1,p_2,\alpha)$ is defined by (8).

Figure 3 illustrates the results. W^C represents the welfare maximum although at negative profits. W^* is the welfare optimum under a zero profit restriction illustrated by the iso-profit contour π_0. The dotted line $W^*\pi^A$ contains the welfare optima under alternative profit

constraints and given arbitrage opportunities α. These optima all involve some degree of price discrimination. They do not, however, correspond to equilibria given by price controls in either one market. The line $\pi^A RQ$ corresponds to equilibria under alternative price control measures in market 2. One can show that the iso-welfare contours W_1 and W_2 have negative slope for prices above marginal costs and therefore the tangency points with the iso-profit contours have a negative slope as well. The points along $\overline{\pi^A RQ}$, however, are defined by zero slopes of the iso-profit contours such that the line of price-control equilibria $\overline{\pi^A RQ}$ lies always below the profit constrained welfare maxima $\overline{W^* \pi^A}$. It is also apparent that - as it is likely for the pharmaceutical market - with increasing price controls overall welfare will first increase as long as prices in both markets fall, i.e. consumer surplus rises faster than profits fall. But after equation (15) has turned negative, i.e. the producer reacts to price controls with higher prices in market 1 because of high costs of arbitrage, then welfare can fall as price controls become tighter. From the arguments about the likely slope of the line $\overline{\pi^A RQ}$ above one can conclude that small price controls increase welfare but large price controls probably lower welfare.

The welfare analysis of changes in the regulatory framework which determines the costs of arbitrage as it is represented by the parameter α are more difficult to analyse. Changes in α without price controls move π^A along the line $\pi^U \bar{\pi}$. Such movements are accompanied by new iso-profit contours and by new iso-welfare contours which contain the profits of the producing firm. It is therefore impossible to compare the welfare of two equilibria determined by alternative α, i.e. alternative regulatory regimes. One can, however, illustrate the impact of α on consumer surplus alone.

In a situation without price controls anything can happen to consumer surplus for both countries together when α is varied. The shape of the line $\pi^U \bar{\pi}$ determines the welfare effect. In Figure 6 easier arbitrage first goes hand in hand with an increase in consumer surplus and beyond π_2^A consumer surplus begins to fall. Uniform prices then may or may not yield higher consumer surplus then perfect price discrimination for which the bound on welfare are given by VARIAN (1985).

The sign of consumer surplus changes can be predicted when price controls are imposed. If the price in market 2 is restricted to p_2^R (see Figure 6) and this control is not lifted as arbitrage becomes liberalized, then consumer surplus will unambiguously increase. Total differentiation of the first order condition for profit maximization with respect to p_1 yields

$$(23)\quad \frac{dp_1}{d\alpha} = \left[\frac{\delta F_1(p_1,p_2^R,\alpha)}{\delta p_1} \right]^{-1} \left[\frac{\delta x_A}{\delta \alpha} + (p_1-p_2)\frac{\delta^2 x_A}{\delta(p_1-p_2)\delta\alpha} \right] > 0$$

with

$$F_1(p_1,p_2^R,\alpha) = x_1(p_1) + (p_1-c)\frac{\delta x_1}{\delta p_1} - x_A - (p_1-p_2^R)\frac{\delta x_A}{\delta(p_1-p_2^R)} = 0$$

being the first order condition $\delta\pi/\delta p_1$.

Figure 6

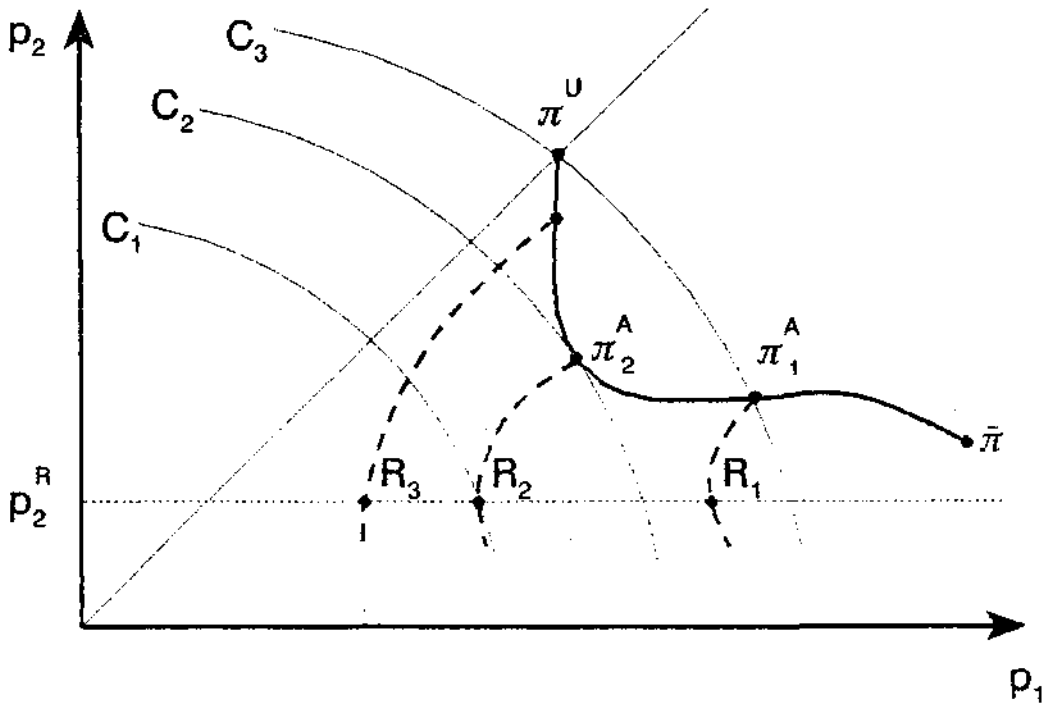


Figure 6 illustrates this case. Without price controls easier arbitrage would move the price discriminating prices from π_1^A to π_2^A and finally to π^U. Whereas these movements are accompanied first by a rise in consumer surplus and later by a fall, the equilibria under prices controlled at p_2^R which are represented by the intersection of the p_2^R-line with the dotted lines yield increasing consumer surplus throughout. It should be mentioned, however, that the profits of the pharmaceutical firm fall and eventually it will make negative profits. Before such a situation arises the firm may also stop supplying market 2 and set the price in market 1 as in the unconstrained case. This situation has recently occurred when a German pharmaceutical company has stopped to supply the Greek market because the price controls and the induced arbitrage opportunities were unacceptable for that firm.

THE LIKELY IMPACT OF HARMONIZATION

The commission of the EC has addressed in the directives on market transparency and on the authorization of medicinal products the two eminent issues, namely market segmentation and price controls. The directives in both issues will surely not create an internal market for pharmaceuticals; they will rather induce some slight moves towards an unified European market. Two immediate questions then arise: What will happen to prices in the national markets and what might be the likely welfare effects of moves towards unification?

The transparency directive requires national authorities to lay open their procedures and guidelines in controlling and authorizing prices of pharmaceuticals. Although it is not a ban on price controls, it is hoped that the new regulations will pressure national authorities to end discriminatory practices and will therefore lead to less restrictive price setting for products from foreign countries. According to market insiders, companies already get more freedom to price their newly introduced products according to their interests. Arbitrageurs also report that new products exhibit lower price differences than in the past.

The model presented here does not uniquely predict the likely outcome of an easing of price controls. One can, however, expect that in cases where arbitrage is very costly, price differences are large, and the cost function is strongly convex, a reduction in price controls is accompanied by falling prices in the unrestricted market as it is commonly expected. If, on the other hand, arbitrage is relatively easy then it is more likely that the optimal response of pharmaceutical companies to less price controls will be to raise prices in the unrestricted market. The outcome of the transparency directive would then be falling consumption accompanied by rising prices in both markets.

Statistical information about the shape of the cost curve of arbitrageurs is not available. According to company officials arbitrage involves some set up costs for the registration of the products which are to be reimported, but otherwise the marginal cost of arbitrage seem to be rather flat. If this is generally the case, then it is less likely that less restrictive price controls are accompanied by falling prices in the unrestricted market.

The welfare impacts of the transparency directive depend on price responses as well. The welfare of the EC overall may slightly increase through movements from, e.g., Q to R in Figure 3 if the path $\overset{A}{\pi}$ RQ has a sufficiently negative slope between R and Q. It is more likely, however, that welfare declines because the losses of consumer surplus in the price controlled market and possibly the unrestricted market will not be outweighed by increasing profits of the pharmaceutical companies.

The existing procedures for the authorization of pharmaceuticals and the proposed procedures leave open alternative ways for pharmaceutical companies to introduce new products. With the exception of biotechnology products they can still choose national authorization. These options have been demanded by the industry organization in order to have the choice of the most cost effective and fastest admission system. Yet, this option still entails the choice to segment markets by obtaining different national admissions for the same chemical entity, e.g. under different names. One can therefore predict that as long as price dis-

crimination is sufficiently profitable - e.g. because of price controls or because of different demand elasticities - the community procedures such as multistate registration will not be used extensively. Still, arbitrage will become alleviated somewhat in the future.

It has been shown in the model that institutional changes which facilitate arbitrage represent movements along the path between perfect price discrimination and uniform pricing such as $\bar{\pi}\pi^U$ in Figure 6. Since the present situation also entails price controls the starting point would be an allocation like R_1 (Figure 6). If price controls remain in place the new admission procedures will move prices from R_1 to R_2, i.e. only prices in unrestricted markets fall. In that case profits will fall and consumer surplus will increase. If, on the other hand, price controls are partially lifted as well this would be represented by a move from R_1 towards some point along the line $R_2\pi_2^A$. The impact on consumer surplus would be ambivalent and would among others depend on the shape of the line $\pi^U\bar{\pi}$.

If the goal is to reach uniform pricing in European markets it is clear that facilitating arbitrage is the most powerful policy since it moves pharmaceutical firms at unchanged price controls quickly towards their zero profit contour. This puts pressure on national authorities to lift price controls or to risk having their market not supplied by the company in question as it has been the case in Greece where a German firm has ceased to supply the Greek market. Lifting price controls alone could not eliminate market segmentation since, given the existing income differences within the EC and different demand structures, it would still be profitable to exploit the different price elasticities.

A welfare analysis in segmented markets raises the general question to which situation one wants to compare the current situation. Since the welfare maximum with marginal cost pricing is not achievable one could use a constrained welfare maximum, e.g. with a zero profit constraint as shown by W* in Figure 3. Yet, this second best optimum also leads to some degree of price discrimination, hence the equilibrium with uniform prices π^U is not even second best. The problem then is that the publicly announced goal of creating an internal market by eliminating market seg-

mentation does not lead to a second best situation as described by points along $W^{*}\pi^{A}$ in Figure 3, not to speak of the first best W^{C} which includes subsidies to firms. It is therefore not surprising that the policy initiatives by the Commission which are discussed here lead to welfare losses or at best to ambivalent results.

The question whether market segmentation should be eliminated at all is not discussed in detail here, only a few remarks should be made. If one believes that pharmaceutical markets are competitive markets then this competition without price controls will lead to price discriminating equilibria $\bar{\pi}$ which are close to the constrained welfare maximum W^{*} since competition through entry in the different pharmaceutical markets will drive down profits. But then only distributional judgements could determine whether such price discrimination should be maintained or eliminated. The fact that pharmaceutical companies are international and import penetration is high in all markets suggest a rather competitive environment. Hence, the possible argument for a unification of markets because of limited competition does not seem too convincing.

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