Stuck in the Middle: Welfare Effects of the European Pharmaceutical Markets' Incomplete Integration and a Possible Remedy

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Abstract

The paper focuses on the regulation and parallel trade for innovative in-patent medicines in the setting of a partially integrated EU-wide market for pharmaceuticals, the impact of different national and European level regulatory regimes, under which the prices for theses innovative medicines are set, on the strategic entry decisions of research oriented pharmaceutical enterprises (ROPEs), the consequences thereof for the innovative capacity of the European pharmaceutical industry and the overall welfare of the European citizens.

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1. Introduction and Background: the increasing role of the EU for national health care systems and the harmonization of the European pharmaceutical market

1.1. The EU's increasing role for national health care systems

The integration of health care, especially the realm of medical services is the background for the recent problems and developments in the pharmaceutical sector discussed in this paper. In spite of the member states exclusive role and competence for the organization of the national health care provision, which is granted in the EC treaty and has been made even more explicit in the last treaty updates, a series of ECJ judgments has – against the explicit resistance of the member states - opened a door, a window of opportunity for far reaching changes in the market for both medical services and medical products.

Differentiating between substantive and organizational health policy, one can see that despite the establishment of health as a theme on the European agenda in the seventies, the European and the EU's health policy (substantive – i.e. health measures to increase the health of the population) and measures with organizational impact (i.e. organizational health policy)- remained "a random addition of single measures" (Schwanenflügel (1996): 8), whereby the principle of subsidiarity and the principle of exclusive national competence resulted in the lack of an overall conception[1]. The driving force in the development is a classical *spill-over* from already integrated domains, especially from trade in services and goods, in the domain of health care, with the character of health as a service (in case of medical services) and a good (in the case of pharmaceuticals) as the underlying mechanism.

Important milestones in the legal development[2] of the EU's role in organizational health policy have been the regulations 1408/71 and 574/72 concerning the supply of medical services to migrant workers, which coordinated existing national regulations without any harmonization (see Kötter (1998): 238-239). Similarly the mutual recognition of national certificates of qualifications as well as the coordination of national regulations concerning medical practice were coordinated and harmonized by a series of directives[3] (Schwanenflügel (1996: 30/31) and Maydell (1992): 33)). For health insurances, the ECJ[4] approved of the national monopoly position of the mostly public and non-profit health insurance companies, a decision based explicitly on the special role of these institutions for the sustenance of the solidarity principle incorporated in these institutions (see Fuchs (1996): 342). Any direct form of influence of the EU on the organization of a national health care system is still explicitly

[1] See Randall (2001) for a short overview on the EU's developing role for organizational sectors of health care in the fields of organizational health policy (the impact of the EU on the organization of national health care systems), substantive health policy (like the establishment of common health standards, public health, etc.).

[2] See Van der Mei/Waddington (1998) and Schwanenflügel (1996) for an encompassing description of the development of the EU's role in health policy.

[3] See especially regulations 75/362 and 75/363, which were modified several times since their enactment.

excluded by the treaties. The interpretation of the respective formulation is that even the council can only enact measures under the exclusion of every form of harmonization of national organizational regulations (Hollmann/Schulz-Weidner 1998: 185). On the other hand, the EU obtained in the Amsterdam treaty competencies for substantive, i.e. public health measures, i.e. for programs like "Europe against cancer" or measures against the spread of BSE (see Van der Mei/Waddington (1998)).

The most recent incident with the greatest potential for impact on the organization of national health care are the ECJs judgments in the cases Kohll and Decker from April 28., 1998 (non-stationary medical services and medical devices) and Smits/Peerbooms (C-157/99) and Vanbraekel (C-368/98) for stationary, in-patient medical services form July, 12. 2001, which are an application of the line of reasoning established by the ECJ in the Cassis de Dijon judgment[5]. The cases made a latent contradiction (free trade for goods and services but exclusion of medical goods and services form these principles) in the treaties visible, and the ECJ solved the contradiction by extending the principle of free trade to the medical sector, by arguing „that the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement. Consequently, the fact that the national rules at issue in the main proceedings fall within the sphere of social security cannot exclude the application of Articles 59 and 60 of the Treaty" (ECJ, judgment Kohll, Nr. 20/21). Furthermore, by organizing their national health care system, the "the Member States must nevertheless comply with Community law when exercising those powers" (ECJ, judgment Kohll, Nr. 19). The reaction of the states – who sided with the sued insurance companies in both cases – were fierce[6] and fueled the debate of the possibility of separated, national organized health care systems in an integrated EU anew (see Schmähl (2001), Lamping (2001) and Rabin (1993)).

The relevance of the recent ECJ judgments for the national regulation of pharmaceuticals follows form the argument, that the member states, in regulating their pharmaceutical markets, have to respect the EU/EC treaty especially the principle of free trade in products (see Kanavos (2000) for this question). Existing regulations for pharmaceuticals are - in their effects - a restriction of the free trade for pharmaceuticals in the EU, and are as such in need of a legitimization and justification, which might not be possible any more. Even there is no direct impact of the judgments towards a completion of the single pharmaceutical market, the door is open for developments – and one reason for the increased discussion was, that given the surprising judgments of the ECJ which clearly ignored the will of the member states, all actors feared that a solution by the ECJ could be worse for everybody than a political solution.

[4] ECJ, Case Duphar 238/82.
[5] ECJ Case C-120/78, Cassis de Dijon.
[6] See for the arguments and the expected consequences Palm (1999); Bundesministerium für Gesundheit (1999) and Verband der privaten Krankenversicherung e.V. (1999) for the positions of member states and insurance funds.

1.2. Europeanized and harmonized aspects of the pharmaceutical market

As an intensively regulated sector, pharmaceuticals have a lot of aspects which are potential candidates for various forms of centralization and harmonization. A decade ago, Abel-Smith (1985): 263/4) enumerated the following agenda for a European pharmaceutical policy: the establishment of a common list of medicines reimbursable by the health care systems throughout Europe, the harmonization of the regulation on sales promotion for pharmaceuticals and as a concluding point, the harmonization of regulations on price controls and other equivalent measures aiming at controlling the expenditure for pharmaceuticals used in the member states. Parts of this agenda have been implemented, in general in so far as there was a sufficient consensus among the states, who are interested retaining control over the organization of health care, whereas other themes remained untouched.

The reached Europeanization, defined as harmonization or centralization, started by defining what a medicine is (e.g. in contrast to borderline products like high dosage vitamin preparations, who do not need a authorization procedure) with directive 65/65, which still left considerable room for national differences in the decision and was substantially refined by ECJ case law (see Blasius/Cranz (1998: 45-50) and Thier (1990: 38)). The next steps concerned the regulation of the market authorization, the tests and trials necessary before getting market authorization for a new product and measures ensuring a common level of quality in the production of medical goods by introducing common/minimum standards (the common good medical practice started as guidelines and became law due to the coupling with EC directives[7], see also Blasius/Cranz 1998: 51-60). The development culminated in the establishment of a centralized market authorization procedure parallel to the remaining national procedures and a decentralized procedure as an instrument based on the mutual recognition doctrine (see the directives 93/39, 93/40, 93/41 and 93/2309 and Blasius/Cranz (1998: 68-74), Randall (2001: 85ff), Cuvillier (2000) and Collatz (1998) for a more detailed description of the procedures). Even product information and advertising for pharmaceuticals, as well as the labeling and the minimum information that must be contained in the instructions were harmonized in the 90s by directive 92/27, which combined existing national regulation to a common catalogue (see Blasius/Cranz (1998: 104-107)). Despite massive financial interest of the pharmaceutical industry as well as the impact of the situation of incomplete integration on the European pharmaceutical industry's competitiveness in comparison to the US firms, the transparency directive (89/105 EEC) is the first instance of European level action in the field of pharmaceutical pricing and reimbursement. Even if the transparency directive was evaluated as a success for the industry (at least in the sense that worse has been avoided) it did not have any noticeable impact in the sense that price regulation diminished or were abolished by the ECJ. Its main function was to establish a "foot in the door" for the commission in the question of national price regulations. The transparency committee, which should have institutionalized the treatment of the questions at EU level, although still existent, does not meet

[7] Directives 75/318, 75/319, 86/609, 87/18 and 88/320, see also directives 89/341, 91/356 and 91/412.

any more (see for the content and impact of this directive Thier (1990: 311-313) and Greenwood (1994: 188))[8].

2. Causes and Consequences of national price differentials for pharmaceuticals

2.1. Legal and economic bases of parallel trade in pharmaceuticals

The causes of parallel trade are both of legal and economic nature: without the achieved integration, the possibility for trade in pharmaceuticals would not exist – and without the price differences among nationally regulated markets, no economic incentive to trade would exist.

Legal basis for trade in pharmaceuticals among different member states

Given the harmonization described in the introductory section, it is clear that trade in pharmaceuticals is legal, if certain legal conditions are fulfilled: the medicine must have market authorization be on the market in the import country, leaflet and re-packing must be adapted etc. requirements which can be managed by the importer at relatively low costs. A new market authorization for the imported medicine is not necessary[9] so the parallel trade can refer to the authorization of the original producer and only needs to demonstrate that the imported product is medically equivalent to the product already on the market[10] and obtains a "formal authorization". With the creation of the centralized authorization procedure, both the producer and the parallel importer can reach all national markets.

Seeing the economic losses inflicted by introduction of tradability and the persistence of differing national price levels which resulted in parallel trade, the RPOEs tried to tackle the economic and legal bases of parallel trade in order to create obstacles for parallel trade both on European and national level: e.g. the pharmaceutical industry lobbied at national level for regulations on minimal package sizes, which would make it necessary to repack the pharmaceuticals if they were imported into other countries, which would increases the costs arising for the importer and possibly make the trade no longer profitable. A further argument was, that repacking as such could damage the image of the firm and the product, if fake products were sold under the guise of the original product or the product would

[8] For a detailed description of the processes of development of the regulation and harmonization see the various studies on pharma-lobbying conduced by Shechter (1998), Greenwood (1994). For a more detailed description of the results, i.e. the existing regulatory framework for pharmaceuticals see Thier (1990) and Kröck (1998). With regard to the questions of this paper, the developments described here are completed steps, which define a given setting, in which all states, ROPEs and other involved actors act.

[9] The requirement of national authorization administration for parallel imported products, especially with the requirement of information accessible only to the original producer, was abolished by the commission (see Blasius/Cranz (1998: 90/91) for the legal details).

[10] See ECJ case de Peijper C-104/75, see also Kon/Schaeffer (1997: 140).

be damaged during the repacking procedure[11]. None of these arguments was accepted by the ECJ (see for the current legal situation on parallel trade Cranz (1998: 91); Kon/Schaeffer (1997: 142) and Forrester (2000)). Due to the lack of clear, politically created regulations, the case law developed by the ECJ is basically defines the current legal situation: as early as 1976 the ECJ[12] began to forbade national hindrances to parallel imports. In the key case Merck vs. Stephar, the ECJ argued that if a producer and patent holder enters a market, he has to bear the economic consequences – be that patent infringements or losses due to parallel trade[13]. The most recent decision was the case of Bayers' "Adalate" (T-41-96, from October 26., 2000), which concerned the new anti-parallel-trade-strategy employed by the ROPEs, not to sell the medicine to distributors who are known (or suspected) to be active in parallel trade. The judgment refuted a decision by the Commission (96/478/EC) which banned the strategy, but the judgment did not evaluate the practice as such but was based more or less on formal reasons. Whether the strategy will work effectively and will be refuted by the ECJ remains to be seen. In any case, parallel imports are seen positively and promoted wherever possible by the Commission which holds the position that parallel imports are a direct expression of the freedom of trade[14] and a essential feature of the common market.

Economic basis of parallel imports

The economic basis for parallel trade are price differences for the same products in among the member states. The relevant prices are the producer prices, at which a medicine can be obtained in a country and the price, at which a medicine is bought by the retailers (pharmacies). These differences create an incentive to buy medicines in countries with low producer prices (low price countries, LPC), export them to countries with a higher price level (high price countries, HPC) and sell them to the retailers, i.e. the pharmacies and the distributors in this country. The retailers themselves afterwards sell the medicine at the same or a marginally lower retail price as the product sold by the producer at the price in the import country.

Situation: price differentials in the European Union

Although the fact that prices for pharmaceuticals differ among the national markets of the member states is a kind of common knowledge, detailed and most of all systematic information is hard to come by. Ignoring the impact of different regulations for trade margins and taxation, the focus here is set on the producer prices. The prices at this level usually do not differ to a degree as dramatic as the retail prices and are sometimes higher in countries in which the retail price at the end of the distribution

[11] See the judgements July 11., 1996: Bristol-Myers Squibb vs. Paranova A/S C-427/93, C.H. Boehringer Sohn, Boehringer Ingelheim KG und Boehringer Ingelheim A/S vs. Paranova A/S C-429/93; Bayer AG und Bayer Danmark A/S vs. Paranova A/S C-436/ 93.

[12] Case de PeijperC-104/75. In the ECJ's argumentation obstacles for parallel imports are inadmissible, if they factual make any imports impossible - the import state may regulate parallel imports for reasons of health security, but in doing so he must respect the EU Treaty Art. 30 und 36 see for the argumentation the judgements in the cases Merck& Co. Inc. vs. Stephar BV and Petrus Stephanus Exler; case C-187/80, ECJ Judgement from July 14. 1981 and Blasius/Cranz (1998: 90).

[13] see ECJ Merck vs. Stephar; case C-187/80; especially Nr. 11 and 13).

[14] See Blasius/Cranz (1998: 91) as well as the statements by the Commission during the Round-Table.

chain, including the profit spans guaranteed by the state and the taxes is lower than in a country where the state grants higher profits to the actors in the distribution chain and does tax pharmaceuticals more heavily. For instance, the price levels across the EU Member states range at the level of producer prices form 85 in Greece to 135 in the UK – at the level of retail/pharmacy prices from 69 in Greece to 126 in Ireland. While the UK grants the highest prices to producers, the pharmacy price level is only in the medium range (see the price indices in Schneider et al. (1999: 51 and 57)). The available data on price differentials only allows for a crude estimation about the flows of parallel trade among the countries. According to the literature, subject to parallel trades are especially in-patent medicines, where the price differences are more significant (Burstall 1990: 69; Arnold (2000)).

Causes of price differences at the producer level

In contrast to the retail/pharmacy price level[15], differences in the producer price levels result from at least three possible sources:

a) At national level, various forms of **price controls** are a common measure to curb health expenditure in a politically convenient way with a maximum of public support and a minimum of opposition compared to other measures aiming at the patients, hospitals or doctors (Oberender 1984: 246) and is therefore spreading in times of rapidly growing expenditure[16]. Although the existence of price regulations is seen as incompatible with a free European market[17], regulations are legal, and have as such never been questioned by the ECJ or the commission. The price controls have to be non-discriminatory, that is applicable to both, imported products and products produced in the country. Differently to the question of market authorization, the regulation of prices can be justified with the argument, that the supply of the patients with the indispensable medicine couldn't be paid for otherwise (see Randall (2001: 79/80) and Kon/Schaeffer (1997)). The methods of regulation employed differ largely among the member states (see Mehnert (1998: 195-199) and Mossialos/Le Grand (1999: 40) for an overview). The regulations and the resulting price level in each state represents a decision made by the government among different interest groups and different political targets – the price level

[15] The price, at which a medicine is sold to the patient/health insurance consists of the amount going to the producer plus taxes and profit rates for trades and retailers, the later often regulated – i.e. granted – by law. The profit rates may be up to fifty percent of the retail price: e.g. the profit rate for the pharmacy reaches from 18 % in Portugal to 36% in Austria, the tax rate reaches from zero in Great Britain and Ireland to 20 % in Denmark (see Schneider et al. (1999: 39) for details). Both rates are the result of decisions made by the government on a distributional question: How much should the distribution chain obtain in exchange for keeping up a infrastructure for the distribution of medicines – and should medicines, the and therefore Health care system, be subsidized by granting tax exemption to pharmaceuticals?

[16] See Mossialos/Le Grand (1999: 36ff) and ÖBIG (2001) for an overview over the most recent developments. Even though price regulations are widespread, their appropriateness to reduce costs in the long run is seen critical in the academic literature, because the reduce competition and can even lead, via an increase in consumption, to even higher expenditures: „In this light, the enormous French consumption of drugs (...) is not caused by low French prices, rather, low prices are necessary to limit expenditure on a demand which is determined by non-economic factors" (Burstall (1990: 38), see also Abbott (1995), Zweifel/Crivelli (1996), Berndt (2001) and Danzon/Chao (2000b)).

[17] See Abel-Smith (1985): 262) for this argument.

represents a willingness-to-pay – and while some states want to pay a little as possible, others are willing to pay more and would like to see higher price levels throughout Europe.

b) Differences in the **production efficiency**, wages and other production costs as well as the competition by other products can have an impact on the prices that a pharmaceutical enterprise charges for its products.

c) A third reasons for price differences is a **voluntary price discrimination** by the producer of a medicine among different markets: the ROPE acts like a discriminating monopolist and charges a different price, the maximum it can charge in the respective market and maximizes its overall profit by extracting whatever the consumers are willing to pay for the product[18]. This price discrimination by a pharmaceutical enterprise is not to be seen negative: according to the argumentation of the *Ramsey pricing*[19]*,* price discrimination, especially in an industry like pharmaceuticals, may increase the overall welfare. The argument runs as follows: innovation in the pharmaceutical industry incurs substantial expenditures during the process of R&D, which are sunk costs at the time, when the product is introduced into the market. The actual production costs are comparatively low. Nevertheless, the consumers must contribute to the costs that already accrued, that is the consumers as a group must pay for the costs of innovation. *Ramsey pricing* would be an optimal mechanism to divide the costs among the consumers, this mechanism is oriented at the willingness-to-pay of each consumer and extracts this willingness-to-pay completely: consumers who value the medicine higher, should pay higher prices for it, since the derive greater utility from the medicine. Usually, the willingness-to-pay increases with the income and wealth of the consumer. The argument is similar to the price discrimination for airline tickets (where people who need to travel during the "business/rush hour" are willing to pay more in comparison to people who are more flexible and would therefore accept a standby ticket at a lower price) and electricity (where electricity is more expensive during the day, when the demand is high, than during the night - see for the application of the argument on pharmaceuticals Danzon (1997a: 11ff), Arnold (2000: 49) and Hausman/MacKie-Mason (1988: 255)). Compared to the situation of a monopoly, in which the monopolist charges a uniform price at which some people buy the new medicine whereas others can't afford and are therefore excluded form access to the medicine, the welfare gain of the *Ramsey pricing* mechanism stems from two sources: first, even people (or states) with a lower willingness-to-pay contribute to the sunk costs of innovation and have in exchange access to the innovative medicine. People (or states) who are willing to pay a higher price still obtain the medicine at a price which is acceptable for them, but there is an additional amount that is contributed to the overall R&D-fund, which can either be used to lower the prices in general (which would be unrealistic) or to increase the innovative activities of the ROPE. This situation

[18] See Varian (1989) for an economic theory and the welfare implications of price discrimination. Price differentials exists even if the consumer could save himself substantial amounts by buying a product abroad (e.g. cars – see McLaughlin/Jordan (1993)). Further, price differentials for pharmaceuticals exist even within a national market (see Schweitzer (1997: 104) and Sorensen (2000)).

[19] See for the basic idea Ramsey (1927); Baumol/Bradford (1970); Danzon (1997a: 12) and for the question, whether the mechanism is fair Baumol (1986: 4 and 143ff).

is equivalent to a discriminating monopolist and is an pareto-improvement compared to the situation of a non-discriminating monopolist.

Evaluation: the main reasons for price differentials

Which of the three reasons mentioned above is the main source of price differentials? For in-patent products, which are the focus of this paper, production costs do not vary since with the patent holder, there is only one producer. As said above, a voluntary price discrimination form the side of the ROPE would only make sense, if the national markets where separated and no trade would take place. Only in this setting, the price differentials could increase systematically the profit the ROPE can realize with his innovation. Furthermore, the ROPE, when introducing its innovation, does not set the price unilaterally at its own choosing, but the price is negotiated with – or unilaterally set by – the national administration. Even though in reality – due to imperfect substitution of the original sold at the (higher) original price with the parallel imported product – a certain price discrimination still makes sense, national price regulation is seen as the main reason for price differentials among the EU member states (see for an evaluation of the different reasons Hart/Reich (1990: 265); Darbá/Rovira (1998: 132), Arnold (2000: 54ff) and Danzon/Chao (2000a)).

The effect hereof is, that at the producer price level, that is when the product is fed into the distribution chain, substantial price differences exist among different markets for a product that can easily be traded. The price differentials themselves differ in degree among the market segments and are highest in the prescription in-patent segment (where the state is involved in the financing and has the highest interest in price control and the ROPE tries to charge the highest prices in order to recover the R&D investments as quick as possible) and lowest in the OTC segment (where the state is not involved in the financing and therefore has no interest in regulating the prices) (see Darbà/Rovira 1998: 130).

2.2. Parallel imports and their immediate effects

In the case of parallel imports, medicines are – due to whatever reasons – on the market in different member states at different price levels. They are bought by parallel traders, repacked if necessary, exported to the HPCs where they are fed into the distribution chain at a marginally lower price than the original offered by the original producer (see Darbà/Rovira (1998: 130) and Blasius/Cranz (1998: 90)). Parallel imports create the situation of an intensive price competition during a period for which the patent holder and original producer is granted a monopoly position and monopoly prices as a reward for his innovation. If parallel trades works perfect, all national markets are supplied with medicines bought by parallel trades in the country with the lowest price throughout the single market. Since the price in the country with the lowest price is regulated, it cannot increase if the demand in this country increases. For the quantity of the medicine consumed in all markets on which the producer sells the new medicine, the producer only obtains the price of the country which granted the lowest price. In theory, the producer should be expected to know this and charge only the same price everywhere.

However, in reality, the parallel imports do not work perfectly, because transaction costs - for instance repacking and the transportation costs - make parallel trade attractive only if the price differentials exceed theses costs. Therefore it does not pay for the producer to set the lowest price voluntary throughout Europe as long as he can sell at least a part of the quantity consumed in a HPC at the higher price. With regard to the fact that some states want the ROPE to receive a certain remuneration and therefore grant higher prices, it has to bee seen that, since the imported product is fed into the distribution chain, the state can not guarantee that the patent holder receives the price the state is willing to pay. Further, the retail price may be the same or only slightly lower for the imported product, which means that only little money is saved for the financing organizations (state or insurance funds) and the price difference is appropriated as profit by the distribution chain and the parallel traders[20] (see Cranz (1985): 353/4) and Abel-Smith (1985: 263) for the mechanisms of parallel trade, Freisler (1998), OECD (2001: 53) and Commission (1998: 4) for the distribution of the price differences among the states and the distributors). The same effects arise due to re-imports, where a product is first exported by the original producer to another country, where it is sold at a lower price, bought by parallel traders and is then re-imported in the home market where it is introduced in the distribution chain and substitutes the product offered by the producer for the higher price (see Darbà/Rovira 1998: 130). By a narrow definition, re-imports only exist for in-patent products, where one producer, the patent-holder, sells the product at home and aboard at different prices

2.3. Magnitude of financial impact of price regulation and parallel trade

The dimension of the financial effects of different national price levels has two components. The direct effects of price regulation and the indirect effects of parallel trade, which are due to a spill over of the price regulation in one market to other markets. Although theoretically clearly to identify, both components are hard to measure or even to estimate in practice:

a) The **direct financial effect of price controls** in a market is the loss of profit for the ROPE in this market: the difference between the price that the ROPE would charge for its new product and the price that it is actually allowed to charge under the existing price regulation multiplied by the quantity of medicines sold in a market. Even if parallel imports are ignored, price regulation has spill over effects to other markets because the regulation of prices in some countries is explicitly oriented at the prices granted in other countries.

b) Estimations concerning the **dimension magnitude of parallel trade** and its financial impact differ to a large degree and furthermore represent to a certain degree the position of the source towards parallel trade. Exact information does not exist or is not available. Parallel trade existed already in 1990 for six of the seven most sold medicines in Europe (Arnold 2000: 15). The pharmaceutical

[20] Up to 25% of the pharmacy price – the parallel trades offer the imported product only marginally cheaper than the price in the import country – a hint to the low competition among them (see Darbà/Rovira (1998: 134) and Moebius/Becker (1985: 288)).

industry itself delivers other figures, and emphases the fact that even if the overall impact of parallel trade is low, the impact of parallel trade on the basis of individual firms and individual products can be immense and highly damaging to the enterprise by undermining its (financial) ability to conduct further R&D and assert its position in the stiffening international competition. According to the data collected by the European Association of Euro-Pharmaceutical Companies[21], EAEPC, only in seven countries substantial parallel imports exists at all, the overall share of parallel imports in the EU is 1,4%, about 890 Mio. ECU, ranging from a share of 14 % (200 mio. ECU) in the Netherlands to 2% (20 mio. ECU) in Sweden (based on 1997, data from the EAEPC homepage). According to the EAEPC, the impact of parallel trade on the innovative capacity of the European pharmaceutical industry is negligible and does not currently endanger future innovations nor will do so for the foreseeable future. Representatives of the pharmaceutical industry estimate the loss due to parallel and re-imports as to be as high as several hundred million Euros per year (Freisler 1998: 26) and further hold the position, that the prices are not too high in the (northern) HPCs but too low in the (southern) LPCs. The Commission estimates the magnitude of parallel trade to be 370 to 435 mio. ECU, which would be about 2 % of the EU's overall pharmaceutical market (Commission (1992): 1). Estimates in the literature differ largely: Darbà/Rovira (1998: 131) estimate the overall share of parallel imports in the EU to be 3 to 3.5% in 1995 and 1% in 1985, Danzon (1997b): 10) estimates for 1992 a share of 5%. The most recent study by National Economic Research Associates (NERA (National Economic Research Associates) (1997), conducted for the Swiss pharma-association Interpharma, came up with an estimation of a 45 billion ECU, which would be as much as 28% of the overall market with a yearly growth rate of 20%. For Germany, the Handelsblatt[22] reported for 2001 an increase of parallel imports by 50% to 800 Mio. Euro, with a further tendency to increase. However, all these figures do not tell us something about to what degree an individual products and an individual ROPEs are affected.

2.4. Further effects of price regulation and parallel trade

The immediate effects of parallel trade are of financial nature and do only concern the pharmaceutical industry, where they take the form of financial losses, but there are several indirect effects which concern other actors as well:

a) Innovations are critical for the competitiveness and survival of a **pharmaceutical enterprise**. Capability, capacity and the incentive for a ROPE to invest in R&D depend on the environment in which the selling of pharmaceuticals takes place (see Oberender/Rüter (1988: 17) for a list of potential factors influencing the incentive to innovate: see Wille/Mehnert/Rohwedder (1994: 66) and also the encompassing report by Gambardella/Orsenigo/Pammolli (2000), which was the basis for the recent G10 process). If prices are regulated and parallel imports decrease the expected profit for an innovative medicine, both the financial incentive to invest in R&D and the financial capacities for R&D

[21] See the EAEPC's position paper prepared for the third Round Table - obtainable via www.eaepc.org .
[22] „Pharmakonzerne behindern günstige Grau-Importe", Handelsblatt, 23.1.2002

are reduced. In the long run, this diminishes the competitiveness of ROPEs based on price regulated markets in comparison with ROPEs whose home market is unregulated and therefore allows higher profits. If the prices are regulated at the level of production costs, innovation can no longer be financed and the ROPE has to change its field of activity towards the production of generics which were originally developed by other enterprises (see for the argument Scherer (1993: 113) and Danzon (1997a: 46ff)).

b) The **citizens** profit form lower prices for pharmaceuticals in their role as payers of contributions and taxes but suffer in their role as patients. Lower prices for new medicines lead to lower expenditures but also to a lower level of innovation. Even if only the prices for imported medicines were regulated, so that savings would be realized at the expenses of the foreign producers, the effect would be the same in the long run. The benefit of pharmaceutical innovations, albeit hard to measure in terms of money, is nevertheless existent: gained life years, increased quality of life, restoration of the ability to perform a job and the substitution of other, more expensive forms of medical treatments (see for a general overview Wille/Mehnert/Rohwedder (1994: 44); for an empirical estimation of welfare effects see Lichtenberg (1998, 2000a and 2000b); McGhan (2000), Calfee (2001), Grund (1996); Schweitzer (1997: 148) and Schneider et al. (2000: 30)). In regulating prices, the state is often subject to a certain bias, resulting form the fact that the gains from price regulation are more visible than the losses.

c) While regulating, **the state** has to weight the different objectives: the supply of innovative medicines, a flourishing industry, and a stable level of health expenditure, i.e. social and industrial policy: if he regulates the prices to strictly, he risks the long term survival or the exodus of an *first class economic performer* (Greenwood (1994: 185), see Abel-Smith (1985: 254); Schweitzer (1997: 149); Burstall (1990: 39); Vogel (1997); and Agrawal (1999) for the interaction among states and ROPEs).

3. Stuck in the middle: the impact of the begun but incomplete single market in the EU

As a rational actor, the ROPE will take into account the broader situation and the secondary effects of existing regulations and price differentials when entering into national markets with different price levels. In the following sections, a simple model will show how the partial integration of the European pharmaceutical market impacted on the decision of the ROPE, where and when to introduce a new medicine into a national market. Via this decision, the current regime of a partially integrated market has an impact on all actors, the ROPEs themselves, the patients and the states. The main argument is, that the integration process has left an optimal state without reaching another optimal state, but instead got stuck for political reasons in a situation in which welfare for all parties is diminished.

Background I: constant and inflexible demand for pharmaceuticals

The sale of pharmaceuticals differs from markets for „normal“ products, specifically, there are two kinds of inelasticity to be taken into account. In general, the demand for a product and its reaction to an increase in prices depends on the relevance of the price for the consumption decision and the possible substitutes for the product (see Varian (1991: 105 and 252ff); Elzinga/Mills (1997: 288); as well as Fisher Ellision et al. (1997) and Homann (1999)). For medicines, the demand is exogenous and given in the sense, that it not depends on the conscious decision of consumers: given the demographic situation in a country, on average a certain number of people will be affected by a certain illness and will need a certain medicine – that is the quantity on which a ROPE can base its entry-decision. In the case of in-patent medicines, there are no substitutes – furthermore, in the segment of prescription medicines, the costs are covered completely or to a large part by the health insurance, and are therefore irrelevant for the decision to consume a medicine. The elasticity of demand is therefore very low in the in-patent prescription segment, which is the main focus of this paper, a fact that can be theoretically derived (see for instance Burstall (1990: 3)) and empirically found (for example by De Wolf (1988: 213)). This inelasticity is therefore taken as a fact for the following arguments – as it was taken as a fact in the political discussion[23]. This leads to a second inelasticity: the central question for a ROPE entering a market is, whether the new medicine is reimbursed by the organizations financing the health care system or not, and this decides whether a real profit can be realized with the product. If the product is reimbursed, the quantity that can be sold in the market will be sold – if the product is not reimbursed, it will remain unavailable to the common patient and there will not be a market, apart form some patients who buy it at their own expenses. The state will either “buy” - i.e. reimburse - the product, or there will be no market worth mentioning for the product. That is, if the ROPE enters a national market, a fixed turnover (determined by the given, exogenously determined quantity and the negotiated price level) arises for the ROPE, if the ROPE does not enter, this turnover will be missing.

Background II: entry decisions of ROPEs

In the in-patent sector, the ROPE as the only producer, has - independently of the surrounding regulatory environment - the key decision of each seller, whether to sell or not, which is equivalent to the decision to enter into a market and sell the medicine at the price negotiated with the state. When making the decision the ROPE takes into account what will happen, if the product is available in the market at the given price. The absence or presence of parallel trade significantly affect this decision[24]:

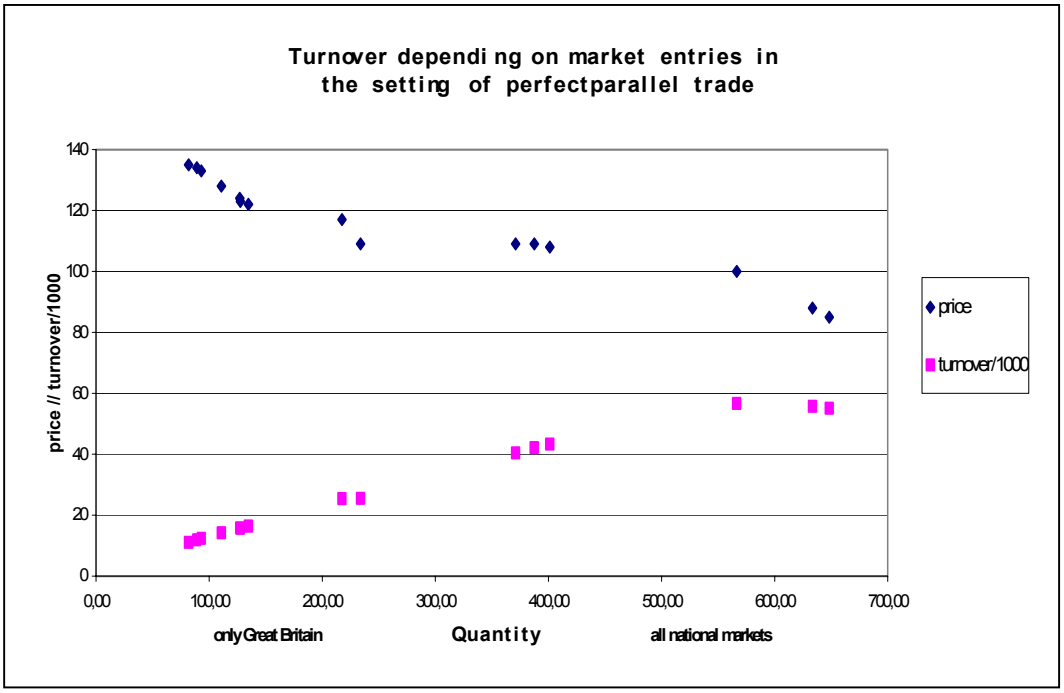
[23] “Where specific products have few or no therapeutic alternatives, they are likely to have considerable market power. This is likely to influence the extent to which liberalization can be achieved without negative impact for patients and health care systems: liberalization can be expected to require much higher levels of price sensitivity on the part of prescribers and careful attention to budgeting.” (Commission 1998: 12).

[24] The decision situation described here is seen as such by the literature (for instance Kanavos (2000), but the central question is not, whether to enter or not, but when to enter: Immediately – risking the start of parallel trade immediately - or after a period of higher profits due to the absence of parallel trade.

a) If there is **no or negligible parallel trade**, the markets are segmented and the ROPE can act like a discriminating monopolist, charging in each country the maximum price the state is ready to accept and extracting the complete willingness-to-pay. Given the above argument on *Ramsey pric*ing, this situation needs not to be seen negative or as an exploitation – each state pays what he is willing to and every state, who is ready to pay at least the cost of production and a contribution to the overall R&D costs, obtains the product immediately.

b) If there is **perfect parallel trade**, the ROPE's new medicine will be bought on the country's market where it is cheapest and sold throughout the EU. For the ROPE, the European market as a whole is one market with a non-continual demand curve: if the ROPE offers the product at a certain price, i.e. enters into a market with a certain price level, all countries which are willing to pay the price will "buy" the new medicine, whereas states who are unwilling to pay the price demanded by the ROPE will not "buy" in this sense. If the ROPE lowers its price, more states will be able to afford the medicine and for each state who "buys" the medicine, a constant amount of turnover arises for the ROPE. The following figure 1 shows in a crude way the argument and the result given data on price levels and market size for the EU member states.

Figure 1: Optimal market entry decision for a ROPE



See the remarks for table 1.

If the ROPE enters only in the market with the highest price level, UK, it can only sell a relatively small quantity of the medicine at the price of 135, leading to a relatively low overall turnover. If the ROPE enters in all markets, it can sell a huge quantity, but only at a price of 85 – in which case all national markets would be supplied by parallel imports from Greece. Since the maximum turnover is reached

when the ROPE charges the price which is acceptable for Germany (where a large quantity compensates for a relatively low price level), Germany will be the limit, and Greece and Spain will not have access to the new medicine[25]. The decision of a ROPE clearly depends on the price and expected quantity for an individual product, but the main idea is nevertheless captured. The difference between a situation, in which parallel trade does not exist, manifests itself in several results: some states are excluded form the access to the new medicine, even if the prices they are willing to pay would cover the costs of production and contribute to the overall costs of R&D. The ROPE realizes a significantly lower profit, because it only obtains the lowest price of all countries in which it entered with the new medicine. The difference between the states willingness-to-pay and the price the ROPE actually obtains is split among the parallel traders, the distribution chain or is realized as savings by the health care system – depending on the competition within the distribution chain. The argument is given in more detail in section 4.2. and illustrated in figure 2.

4. Possible Solutions

4.1. The absence of a pareto-optimal solution

The negotiation situation of the actors involved, e.g. in the Round Tables (see Shechter (1998) and Kotzian (2002)), is characterized by the fact, that each member state can unilaterally realize the price and - given the inelastic demand and the more or less fixed quantity of consumed medicines – the expenditure level for pharmaceuticals, that he prefers. The price level set by the state is instrumental with regard to the expenditure level, represents the calculation of a government interested in reelection, and aggregates the weighted influence of the interest groups involved in health care. Chances for agreement are extremely low in such a setting, since at first sight, no state can do better than he already does. As long as the issue of price levels for innovative medicines is the only issue in a negotiation, every change is a loss to at least some of the states: for instance, if a uniform price regime is established and the common price is set low, states who are willing to support their ROPEs by granting high prices can no longer do so – even if the state or the health insurance keep on paying higher prices, the possibility of imports form markets with lower prices will lead to parallel imports and the price difference is appropriated as profit by the distribution chain and parallel traders. If higher prices where introduced, this would be an immediate expenditure increase for those states who have decided only to grant a low price level. Therefore there is no pareto-superior solution which immediately makes everybody better off and as a consequence, the status quo remains – and has remained in the negotiations, Round Tables and G10, concerning this question.

[25] This strategy is exactly the one recommended by the ECJ in the Merck vs. Primecrown judgment. Even if the ROPE wants to avoid public critique that would result from a non-entry due to pure economic reasons, it can always slow down the entry and thereby avoid parallel trade for a certain period.

4.2. Solutions beyond pareto-optimality: negotiation arithmetics, exchange and kaldor-optimality

Even with the situation as described above, two basic options exist, which could have let to a solution of the problem. Both would be based on the compensation of expenditure which would arise to the member states who currently have low price levels if the were accepting higher price levels. In the first solution, this compensation would have taken the "political" form of an issue exchange, in which the LPCs would have been compensated in other issues, in the second solution, the compensation would have been of financial nature, which implemented a kaldor-optimal solution.

Negotiation arithmetic and exchange as basis for potential solutions

The existing differences among the member states concerning the question, what represents an appropriate remuneration for the innovation made by the ROPE, precludes a solution only if this question is treated in isolation. This becomes even clearer if one realistically assumes that the intensity of the interest in the question is correlated with the position: states granting a high price for a new medicine do so in order to recompense the ROPE for its research effort – and would like to see that also all other states pay a price, that is appropriate form the view of the HPC and it can be assumed that they are interested in actively securing that the ROPEs receive an appropriate remuneration in other states as well. If a state doesn't need to care about whether the ROPEs prosper – maybe because he doesn't have any – his interest in the question can assumed to be lower. The classical negotiation analysis (Sebenius' negotiation arithmetic; see Sebenius (1983), but also exchange models like Tullock (1970); Coleman (1990), and Henning (2000)), would recommend an exchange in this situation whereby more issues are treated simultaneously, allowing the actors to make concessions in areas which are of low interest for them in exchange for concessions made by other actors in areas which are in turn of low interest for them. If the HPCs interested in a higher remuneration for new medicines and a strengthening of the European ROPEs could have compensated the southern LPCs for granting higher prices for new medicines by making concessions in other questions (which they already did in several other themes), this would have been of advantage for everybody. Even if the actors are worse off in some questions – like the LPC would have been in the question of pharmaceutical prices – each actor might be better off in the whole. Given this argument, the negotiation setting in which member states, commission and the ROPEs negotiated the question of the impact of national price regulation and parallel trade on the European pharmaceutical industry, e.g. during the Round Tables, was a bad choice because in this mode only one issue – prices as the central theme with distributional impact – was at the table, which precluded an exchange as just described. A better strategy would have been to pursue an inclusion of the question into an IGC, where a compensation on other issues would have been possible - but given the unwillingness of the member states to treat health issues, this clearly was and is not a realistic option.

Kaldor-optimality and the possibility of a single issue solution

However, there is room for a solution even if the price issue is treated in isolation from other issues which could be used to compensate actors worse off under a higher price level. The solution arises

form the fact, that some actors are so much better off under a higher price level that they can compensate actors who are worse off and still be better of than under the current regime of national price differences and parallel trade – the solution developed in the following sections is explicitly based on the compensation and on the concept of Kaldor-optimality (see Kaldor (1939: 550) for the basic idea, Bossert/Stehling (1990: 99/100) for a formal definition and Scharpf (1991) for a very intuitive description).

Basic idea

The basic idea of the proposed regime follows from the fact, that under the current regime of price differentials and parallel trade, the provision of innovative medicines is organized in a way under which different health care systems give "latent" subsidies to other health care systems by unilaterally granting higher prices for new medicines and thereby contribute a higher amount to the costs of the innovation as a collective good, form which every member state benefits independent of its financial contribution. The argument runs as follows. The EU member states can be seen as a club of actors who pool their resources in order to pay another actor, the ROPE, to produce new medicines from which all members of the club benefit. The overall costs of an innovation are independent of the number of club members and are paid from the prices that each club member pays for the medicine – i.e. the price each member state grants. The higher the price, the higher the contribution to the overall costs of innovation. The higher the amount of money all club members pay in total, the higher the innovative activities of the ROPE and the more innovative medicines are returned to the club members. The advantage of this "club" is clearly that the members as a group can, by pooling their resources, afford a level of innovative activity and a supply of new medicines that is higher than each member could if acting alone. The disadvantage of this implicit regime arises form each club members' motivation to minimize his contributions to the common pool while hoping that the other members' contributions will be sufficient to guarantee a sufficient level of innovation. This free rider dilemma does not only exist at the level of the EU member states as a club, but at global level:

> „To the extent that US drug prices exceed those of other countries and the profits thereby generated stimulate additional R&D, a "free rider" problem appears with consumers throughout the world benefiting form R&D that is paid for, in effect, by US patients." (Schweitzer 1997: 150)

A HPC should realize this situation and this already creates a motivation to tackle the theme at the European level. Even if one accepts that states differ with regard to their willingness to contribute to the common pool from which innovations are paid, under the current regime of an imperfect *Ramsey pricing* (price differentials – but no separated markets) the situation is aggravated by the fact that even the states who are willing to pay more cannot guarantee that their contribution gets into the common pool, i.e. the ROPE receives the money, because the state can – for legal reasons – not force the actors in the distribution chain to abstain form buying parallel imported products offered by parallel traders at lower prices.

Given this inefficient regime, one can ask, whether there are better ways to organize the provision of the collective good pharmaceutical innovation. To be acceptable for the actors involved, especially the states with the competence to bring about changes, but also the ROPEs and the Commission, an alternative regime must fulfill the following (normative) criteria:

1. It must be cost neutral, no state should pay more than he is willing to. If losses arise, they must be compensated by gains realized by other states.

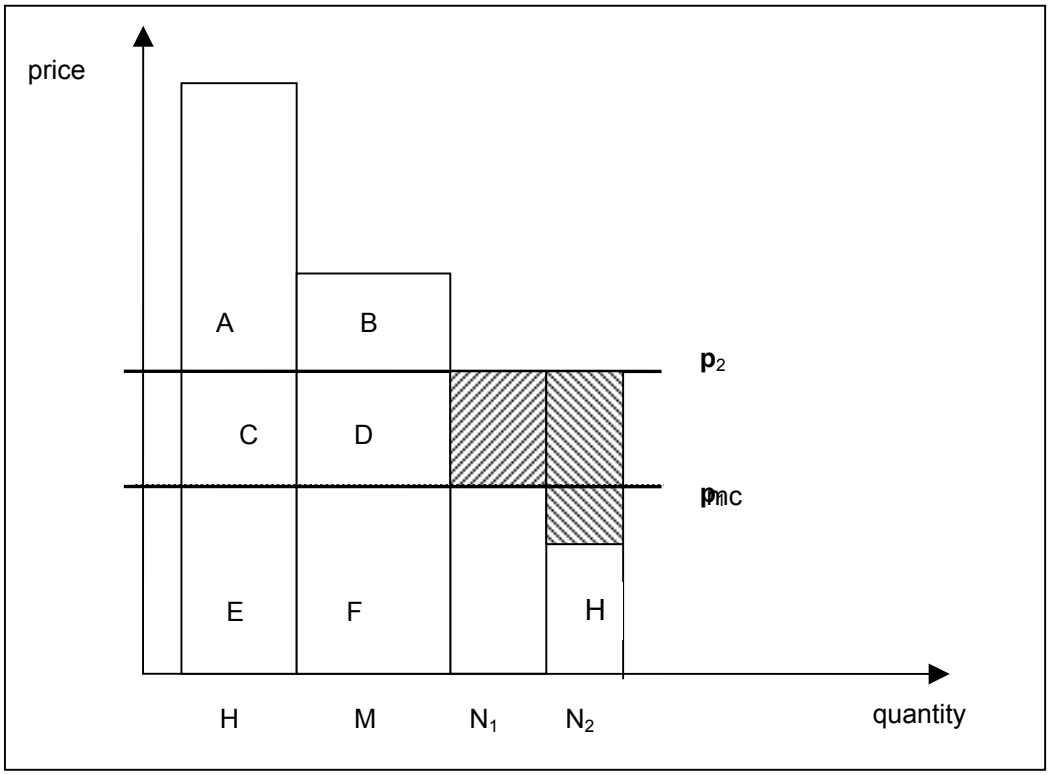
2. A new medicine should be available to all citizens of Europe as soon as possible, no national market should be excluded form access due purely financial reasons.

3. The innovative capability of the European ROPEs should be at least as high as under the current regime.

4. The European Single Market as an institutional aim per se should be realized.

The solution proposed in this section bases on the idea to simulate a Ramsey pricing regime in a situation in which trade is possible – to allow each state to pay what he thinks is appropriate but still avoid price differentials. Central institutional feature is a central price setting procedure or an agency, which sets a single price for the European single market and transfers the savings realized under this price by HPCs to LPCs so that the latter can afford the price. The basic idea is illustrated in the following figure 2.

Figure 2: Basic idea of a kaldor-optimal solution



Assume, there are four states: a HPC H, in which the state is willing to pay a high price for a new medicine, a medium price country, M, where the state is willing to pay a medium price and two LPCs, N_1 and N_2, in which the states are willing to pay or can only afford to pay a quite respectively very low price for the new medicine. The prices are assumed to be set by the state and parallel trade is possible. In this situation, the ROPE, when deciding to enter the markets, will take into account what will happen when he enters each market. As said above, the ROPE will choose the markets in order to maximize his turnover – in the given example, it is assumed that it will enter into all markets apart from N_2, because if it did so, the other three markets would be supplied by parallel imports originating form N_2 and it would only realize the price N_2 is willing to pay. The price level at which the quantity sold in the three markets H, M, and N_1 is sold, is p_1, which is the price N_1 is willing to pay and it shall be assumed that the overall turnover at this price level for three markets is higher than the overall turnover for four markets at the price allowed by N_2. Both H and M would prefer that the ROPE receives the prices they are willing to pay (and are possibly effectively paying), but since they cannot forbid parallel trade, the differences between the willingness-to-pay in the markets H and M and the price level resulting of N_1, the sections A, B and C go to the distribution chain and the parallel importers. The ROPE only realizes a turnover which is measured by the sections E, F and G. The part of section H, which represents the difference between the marginal production costs (the mc line) and the price N_2 is willing to pay (if existent) is lost to all actors involved and represents a net welfare loss.

If all countries would agree to pay the price p_2, with the countries H and M compensating the countries N_1 and N_2 out of the difference between their willingness-to-pay and the price p_2, everybody would be

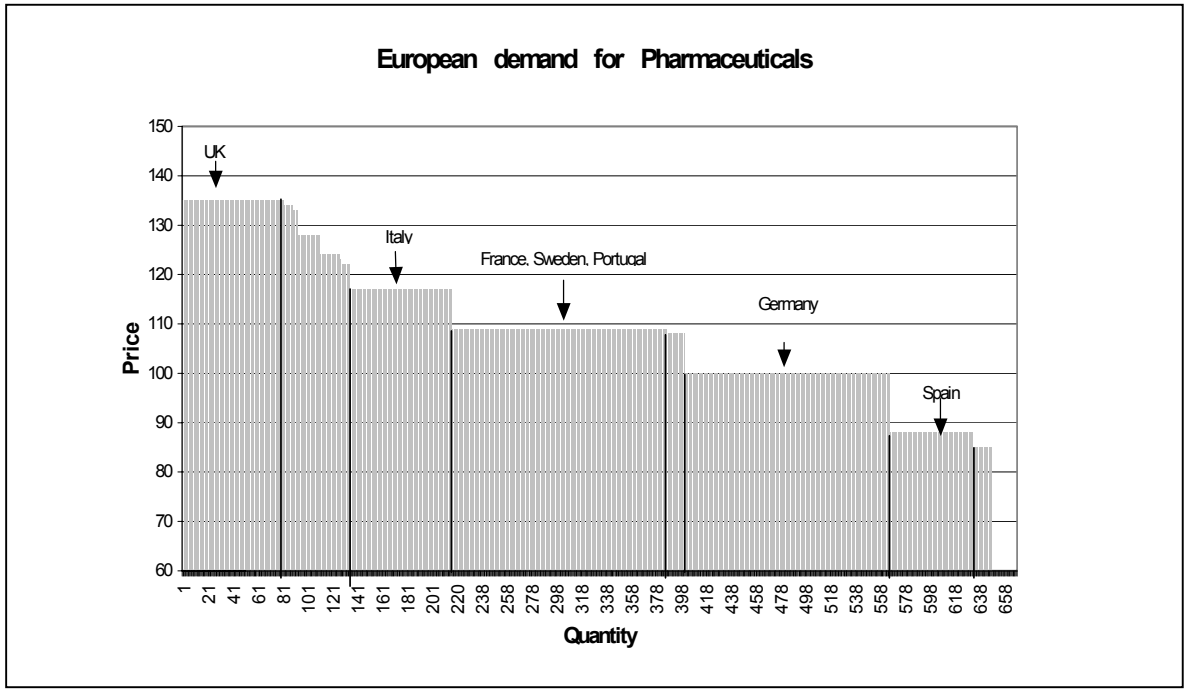
better off: H and M would pay no more than they are willing to, but can assure that the money goes to the ROPE. The countries N_1 and N_2 would also not pay more than they are willing to, but N_2 would have the advantage that it has access to the new medicine. The ROPE would realize higher turnover, since there is an additional, if small contribution form N_2. Even though parallel trade is not outlawed, it is no longer profitable for economic reasons.

In practice, this solution would have to be realized by a central price setting procedure (conducted for instance by an agency – independent or under the control of the member states) in each state is asked to announce his willingness-to-pay and the agency sets a price, which, given the market sizes of the member states, guarantees that the savings realized by HPCs are sufficient to compensate the LPCs. In doing so, the agency can set the price in a way in which all member states still realize some savings or in a way in which everybody pays his maximum willingness-to-pay.

Applicability to the current situation in the EU

The next question is, whether this solution is applicable given the price levels and the market sizes of the EU member states. Given the data in table 1, figure 3 below represents a version of figure 2 adapted to the situation in the EU.

Figure 3: Potential for savings and demand for compensations among the EU member states



Remark: cumulated demand based on data on national pharmaceutical consumption in Table 1

Each column represents the turnover (market size) defined by the price a state is willing to pay (vertical axis) and the quantity which can be sold (horizontal axis). Even at first glance it can be seen

that a price somewhere between the prices granted in Germany and France would be a possible overall price level, allowing for enough savings to compensate the other states. However, the price level can be calculated exactly as is shown in the following. In doing so, I choose a solution under which the complete willingness-to-pay of the states is extracted and the innovative capacity is maximized, which means that a price level is set, under which the savings of the HPCs are completely used to compensate the LPCs.

Under the current regime, the expenditure for pharmaceuticals, C_i, in a country i are determined by the given and fixed quantity, M_i, and the price level, P_i, set by the state:

$$C_i = P_i * M_i$$

In the setting of a single European price, P_e , with compensations, the costs are as determined the same way, but in addition there is a positive or negative compensation, K_i, which depends on the difference between the European price and the price a state is willing to pay, multiplied by the quantity of the medicine consumed in this market. If the European price is higher than the price the state would set unilaterally, the state would receive a compensation large enough to cover the additional costs. In order to guarantee that the regime is accepted, it must be cost neutral, i.e. the pharmaceutical expenditure under the new regime must not be higher than before:

$$C_i = P_e * M_i + K_i \qquad \text{with} \quad K_i = (P_e - P_i) * M_i \quad \text{resp.} \quad (P_e - P_i) * M_i - K_i = 0$$

The overall turnover of a ROPE, T, which is the financial basis for the innovative activities is the European price multiplied by the quantity sold throughout Europe. The ROPE's innovative activity, IL, is assumed to be related to the turnover via the following relationship:

$$T = P_e * \sum_{i=1}^{I} M_i \qquad IL = I(T) = \sqrt{FI * T}$$

Hereby the coefficient FI represents the share of the turnover going into R&D – currently about 18.6 % (according to Levy (1999): 175). The functional form of a square root is chosen to capture the diminishing returns of investments in innovative output. The resulting measure, IL, is just a crude indicator to compare the levels of innovative activity under different regimes. The overall welfare consists of the immeasurable gains form innovations and the measurable costs and can not be computed. Given theses conditions, a program was written, which searches for a price level, which fulfills the criteria listed above. Further, the program can be used to compare the welfare implications of a situation with and without parallel trade.

Price level and compensations

The price level under which the savings for the HPCs would exactly suffice to compensate the additional expenditure of the LPCs is 109.7. The turnover of the ROPI would be the same under this

regime as it would be if the markets were still completely separated (*Ramsey pricing*). The compensations are listed in the following table.

Table 1: Prices, quantities and compensations under a uniform European price regime

Country	Market size	Price	Quantity	Price level = 109,7	Country	Compensation
GB	11061	135	81,93	Payers	GB	-2069.12
FIN	959	134	7,16		FIN	-173.66
IRL	523	133	3,93		IRL	-91.39
BEL	2274	128	17,77		BEL	-324.38
NL	2025	124	16,33		NL	-232.78
LUX	66	123	0,54		LUX	-7.16
DEN	872	122	7,15		DEN	-87.62
ITA	9662	117	82,58		ITA	-599.09
POR	1794	109	16,46	Receivers	POR	12.27
FRA	14950	109	137,16		FRA	102.22
SWE	1795	109	16,47		SWE	12.27
AUS	1481	108	13,71		AUS	23.93
D	16528	100	165,28		D	1610.70
SPA	5891	88	66,94		SPA	1455.63
GRE	1271	85	14,95		GRE	369.94
						Sum ~: 0

Remarks: **Market size** at the level of producer prices, in Mio. ECU; (EFPIA 2000), for Luxemburg own calculations based on Ärzte Zeitung (1998: 65). **Producer price level** form Schneider et al. (1999: 57), for Sweden data imputated with AMELIA. **Quantity** is the market size divided by the price level

Welfare implications of the actual and the proposed regime in comparison

If perfect parallel trade exists, the ROPE does not enter into the two markets with the lowest price level (Spain and Greece, see figure 3) and all other markets are supplied by parallel imports from the German market. The potential turnover for parallel trade, measured in an indicator, is 7344 (computed by calculating the “real world” equivalents to the sections in figure 3: willingness-to-pay minus lowest level of producer price multiplied by the quantity, summed up over all states to which the medicine is exported to). The turnover of the ROPE is 9302 (calculated equivalently) leading to an innovation level of 41,6. The introduction of the new regime would lead to a price level of 109,7 resulting in a turnover for the ROPE of 71152 and an innovation level of 115, which is the same as it would be under a return to the status quo ante of separated national markets). The point is, that there is a substantial net welfare loss: the turnover – on which the innovative activity is based – under the new regime or the

status quo ante is not just the sum of the turnover of the parallel traders and the ROPEs under the current regime, but substantially higher. Indeed, it would even make the ROPEs better off, if they would pay the parallel traders for ceasing their activity. This welfare loss accrues independently of what happens to the turnover of the parallel traders – it does not make a difference, whether the turnover is realized by the states or health insurances as a saving or whether it is profit for parallel traders or other actors in the distribution chain. The reason for this lies in the fact, that under the new regime/status quo ante regime, even LPCs contributed to the turnover and therefore to innovative activities of the ROPE – but can not do so under the current regime, because the ROPEs, being afraid of the consequences, will not enter into their market.

Advantages of the centralized price setting regime

Parallel trade exists, and dependent on its degree, the welfare implications described above arise. The proposed regime of a central price setting in combination with compensations would mitigate the welfare losses and fulfils all of the four restrictions and conditions listed above: no state is paying more than his willingness-to-pay and no state pays more than he currently does, all societies have access to new medicines immediately after the (central) authorization – there are no market entry delays which have their reason in the strategic calculations of the ROPE, which wants to avoid losses due to parallel trade as long as possible and therefore keeps out of low price markets for quite a long time. The innovative capacity of the European pharmaceutical industry is higher than currently and also higher compared to a situation in which the profits now realized by parallel traders were transferred to the ROPEs. All member states and patients would profit form the greater innovative capacity leading to more innovative products. And the common market for pharmaceuticals as an institutional goal would be realized.

Why was the solution not seen or implemented?

Even so the kaldor-solution proposed here would be a technically better compromise given the manifold and contradictory aims (savings, access to new medicines, strengthening of the pharmaceutical industry etc.) held by the actors, it was neither proposed in any of the discussions. The question is, why this was the case? Four reasons show, that there are potential problems and risks associated with this solution that need to be tackled and solved before the solution could be implemented:

a) The proposed solution is an improvement given that the current situation is characterized by high levels of parallel trade. If the ROPEs can – by means only known to them, but nevertheless effectively – avoid parallel trade, the solution will not represent a great advantage for them, because the situation is already near to the situation of a *Ramsey pricing*. However, the long lasting and expensive activities of the ROPEs would not make sense if the current setting would be already acceptable for them, especially since the producers of new innovative products would profit the most.

b) Even more serious is the fact, that the solution would introduce an open, clearly visible, financial compensation among the member states. The member states governments are under an enormous

pressure to reduce the expenditure for health care, the distributional conflicts among the actors involved in the provision of health (services, goods etc.) are extreme. No government can politically afford to introduce a system in which funds are transferred from the national health budget to other countries – the compensations under the current regime are in a way invisible, and therefore not subject to public critique. In this situation, the argument to increase the overall welfare by explicitly giving away money form a sector in which it is badly needed in the form of an official subsidy won't be accepted in the political discourse.

c) The compensations are based on the willingness-to-pay of the member states, which can be estimated form the current price levels and the pharmaceutical expenditure. Currently, the true willingness-to-pay is revealed, because there are no further financial effects – the state neither gains nor loses form showing his true willingness-to-pay. But once the payment or reception of compensations depend on the announced willingness-to-pay, there are incentives to misrepresent it in order to achieve reduced payments or higher compensations. No state can prove that what he announces is his true willingness-to-pay – what is missing, is the possibility of a *credible commitment* in which each state can make a credible statement about what he is willing to pay for an innovation.

d) The solution is further burdened with a twofold hold up problem which arises from the problem of how to control the price regime in the long run, once it is installed and operating:

- If a central price setting agency is created, there are no guarantees for the ROPEs that the agency will in the long run set a price level in which the financial benefits in sum at least remain as they are now – the agency can easily set a price level which is lower, making the ROPEs worse off. This could happen, if interest groups and LPCs have much say in the decision making process of the agency, or the budget situation worsens in many member states. The states cannot commit themselves to abstain form setting a lower price, once this setting is established.

- The same problem holds form the view point of the states – once they submit to the decision of an agency, there is no guarantee that it is not "captured" by the industry (in cooperation with the DG Enterprise, which is famous for its pro-industry position) and would consistently set high prices for all new medicines, even circumventing the constraint that the overall willingness-to-pay of all club members must be sufficient to pay for compensations.

The delegation of a price setting competence to an independent agency is therefore unattractive for both the states and the ROPEs, because of the high degree of uncertainty with regard to the resulting prices granted for new medicines.

5. Conclusion

The dilemma of a begun but incomplete integration of the European pharmaceutical market by introducing free trade in pharmaceuticals while retaining national price regulations led to a decrease of the competitiveness and the innovative capability of the European pharmaceutical industry. The rational calculations of the ROPEs when entering into national markets under the condition of parallel trade leads to an overall loss in welfare. The point I tried to make in this paper is that the political development has left an optimal setting, without reaching another optimal setting, but instead got stuck in a sub optimal and inefficient situation with losses for everybody and a net reduction of overall welfare. Although there is a way out, any change is obstructed by at least one of the parties involved in the discussion: the states blocked a movement towards a more integrated market for pharmaceuticals with a centralized price setting, for political reasons and because of the uncertainty associated with a solution introducing a centralized price setting. The ROPEs share the aversion against a centralized solution and feared negative consequences, i.e. substantially lower prices, because of the overall political climate in the member states which is dominated by the motivation to cut and contain the pharmaceutical expenditure. Last, the one-way character of the integration process, embodied in the Commission and the *aquis communautaire* ideology, blocked the way back to national separated markets.

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