# The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis

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# The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis

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# Executive summary

- Research on 6 product categories accounting for 21% of the brand retail market for pharmaceuticals in 6 European countries, reveals the following about parallel imports and their impact on the various stakeholders:

- Direct savings accruing to statutory health insurance organisations from the conduct of parallel trade are modest both in absolute and relative terms. These savings (in **€ '000)** are as follows for 2002:

| | Norway | Germany | Sweden | Denmark | UK[1] | Netherlands[1] |
|---|---|---|---|---|---|---|
| € | 563 | 17,730 | 3,770 | 3,002 | 6,887 | 12,762 |
| €[1] | - | - | - | - | 55,887 | 19,119 |
| % Total market | 0.3% | 0.8% | 1.3% | 2.2% | 0.3% | 2.2% |
| % Total market[1] | - | - | - | - | 2.8% | 3.6% |

Note: [1] Includes **estimates** for the clawback.

- Parallel traders are the main beneficiaries of parallel trade; their direct (gross) *maximum* benefits in 2002 (shown below in **€ '000**) exceed considerably those accruing to statutory health insurance. These benefits are invisible.

| | Norway | Germany | Sweden | Denmark | UK | Netherlands |
|---|---|---|---|---|---|---|
| € | 12,757 | 97,965 | 18,453 | 7,371 | 518,013 | 49,667 |
| €[1] | - | - | - | - | 469,013 | 43,199 |
| Mark up | 46% | 53% | 60% | 44% | 54% | 51% |
| Mark-up[1] | - | - | - | - | 49% | 44% |

Note: [1] Includes **estimates** for the clawback.

- No (measurable) direct benefits accrue to patients due to the structure of user charges in the study countries. Consequently, patient access to medicines is unaffected.

- Some measurable direct benefits accrue to pharmacists (see below in **€ '000**) in countries where incentives exist to dispense parallel-imported medicines or where direct discount negotiations between pharmacists and wholesalers are allowed. The extent of such discounts from wholesalers to pharmacists cannot be known with precision, however.

| | Norway | Germany | Sweden | Denmark | UK[1] | Netherlands |
|---|---|---|---|---|---|---|
| € | 563 | 0 | 0 | 0 | positive | 6,382 |
| Mark-up | 2% | 0 | 0 | 0 | positive | 6% |

Note: [1] Excludes revenues for pharmacy from discounts on NHS price; these are product related and positive.

- Hardly any evidence is found on price competition or price convergence between locally sourced and parallel-imported products over the 1997-2002 period in the six study countries. Therefore, the hypothesis that pharmaceutical parallel trade stimulates price competition and drives prices down in destination (importing) countries over the long-term is rejected. There is also very little evidence lending support to the argument that parallel trade stimulates (price) competition among exporting and importing countries. Thus, the arbitrage hypothesis of price equalisation or price approximation is also rejected.

- A country survey has shown that a number of low-price countries (Greece, Spain, France) are introducing measures to account for the extent of parallel exports from their territory. By contrast, traditionally high-price countries seem to have mature policies, which also enable them to benefit somewhat from this activity (especially the UK, the Netherlands, Germany, Sweden and Denmark).

- The lack of sizeable direct benefits to health insurance organisations, the limited price competition in individual markets, the existence of reported product shortages in some member states, and the size of absolute and relative profits accruing to parallel traders, may force policy-makers to re-evaluate the rationale behind parallel trade. This implies taking into account the dynamic impact it may have on patients in some member states and on the research-based pharmaceutical industry in terms of location, manufacturing and research.

# The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis

## 1. Background and objectives

Pharmaceutical parallel imports are defined as the legal importation into a country where a patent has been registered for the same product which is patented and legally marketed in another country without the authorization of the patent holder. Within the European Union, a series of European Court of Justice (ECJ) rulings[i,ii,iii,iv,v,vi,vii,viii] or opinions[ix], underpin the legitimacy of pharmaceutical parallel trade. As a result, it is also encouraged by the governments of several Member States, particularly those where price levels for in-patent pharmaceuticals are at or above the European average (most frequently, the UK, Germany, Sweden, Denmark, the Netherlands, without excluding cases of individual products being traded from traditionally low-price countries).

Over the past few years there is evidence that parallel trade is expanding at least in certain therapy areas or individual products. Based on European jurisprudence, the free movement of goods and the exhaustion of intellectual property rights underpin the establishment of one free common internal market in the EU. The endeavour to assure a single intra-EU market is further reflected in numerous decisions by the ECJ, as outlined above.

The legal treatment of parallel imports varies widely across countries and stems from each jurisdiction's choice of territorial exhaustion of intellectual property rights (IPRs). Under international exhaustion, rights to control distribution expire upon first sale anywhere and parallel imports are permitted. Under national

exhaustion, first sale within a nation exhausts internal distribution rights but IPRs holders may legally exclude parallel imports or exports. Finally, a policy of regional exhaustion permits parallel trade within a group of countries but not from outside the region.

The rationale for PT comes from expected price differences between source and destination countries. These price differences should be higher than any anticipated or un-anticipated costs from performing PT, thereby allowing parallel traders to profit out of this activity. Such costs include, among others, transport and transaction costs - those resulting from obtaining marketing authorization to distribute a product in destination countries - but also hedging against exchange rate differentials. The lower the above costs and the greater the price differentials between source and destination countries, the greater the potential for PT in principle.

Within this context, the objectives of this paper are, first, to map out policies on parallel trade in the EU Member States and Norway, and, secondly, to provide a stakeholder analysis of welfare effects by building on the available theoretical and empirical literature and by testing a number of economic hypotheses. The paper analyses the direct effects from parallel trade on the various stakeholders, namely health insurance organizations, patients, pharmacies, parallel traders and the pharmaceutical industry. The likely competition effects within importing (destination) countries and across exporting and importing member states are also examined.

Section 2 provides a review of the available literature on pharmaceutical parallel trade; section 3, discusses the hypotheses, the data and the methodology employed. Section 4, provides an exposé of national policies on pharmaceutical parallel trade, dividing them into direct and indirect. Section 5, presents the general trends on pharmaceutical parallel trade in six European countries over the 1997-2002

period, focusing on market shares for specific products selected across six product categories. Section 6, discusses the direct effects from the conduct of parallel trade and the impact on all stakeholders, whereas section 7 and section 8 present the intra-country and inter-country effects respectively. Finally, section 9 draws the main conclusions.

## 2. Literature review

### *2.1. Literature search*

We conducted a literature search in an attempt to identify studies, both theoretical and empirical and either peer reviewed or not peer reviewed on parallel trade and pharmaceutical parallel trade. The search strategy entailed three key elements: firstly, the identification of keywords, secondly, the selection of country coverage, and thirdly, the selection of time period. The following keywords were used:

- Parallel trade
- Cross-border trade
- Parallel imports/exports
- Pharmaceutical parallel trade/imports/exports
- Exhaustion of rights and parallel trade
- Regional exhaustion of rights
- Regional exhaustion of rights and free movement of goods
- Drug re-importation
- Drug parallel trade/imports/exports
- Parallel trade and price discrimination
- Perfect arbitrage and pharmaceuticals
- Imperfect arbitrage

The coverage of the research is international, including both developed and developing countries, although, the analysis in subsequent sections covers parallel trade within the European Union (EU). Finally, the period under investigation is 1975 - 2003. The following databases were searched:

- Medline
- PubMed
- BIDS/ISI
- ECONLIT
- EMBASE
- EUROPA
- SOCIOFILE
- Additional (official) literature was obtained from the website of the European Court of Justice
- Further material was obtained through the internet from other official sources (EC, national governments), trade organizations, commercial reports, and other papers or reports published by academic or commercial organizations.

The type of literature that emerged covered the range of possible publications, including:

- Articles in peer reviewed journals (health economics-related and health policy-related, both qualitative and quantitative)
- Working/discussion paper or work in progress
- Official reports and cases published by competent authorities
- Unpublished papers and reports both from government agencies and individual investigators
- Books
- Papers and reports from commercial sources

The literature has subsequently been categorized and appraised in terms of:

- First, the quality and robustness of the evidence (strong, moderate or weak) over time and across countries and
- Second, the relevance to the subject under investigation (high, medium, low)

Finally, common themes have been identified, in accordance with the above two appraisal criteria and gaps have also been identified in the existing evidence-base.

From the above sources, we were able to identify 38 studies (peer reviewed papers, books, working papers, and reports) on the subject of parallel trade/imports; over 66% these were of theoretical/conceptual nature and the remaining 33% had (some) quantitative evidence on parallel trade.

### *2.2. General trends*

A considerable body of peer reviewed theoretical literature has emerged over the past decade on parallel trade discussing welfare implications of parallel imports and the impact on the trademark owner. [x,xi,xii,xiii,xiv,xv] A fair amount of that literature is general in nature and draws upon evidence from intellectual property (IP) - intensive industries. In pharmaceuticals, there is continuous and unabated interest in parallel trade, particularly in Europe, where the principle of regional exhaustion of intellectual property rights holds. Under regional exhaustion, rights end upon original sale within a group of countries, thereby allowing parallel trade among them, but are not exhausted by first sale outside the region.

A number of empirical studies have also emerged over time demonstrating the costs and benefits arising from pharmaceutical parallel trade.[xvi,xvii,xviii,xix] Evidence from market research sources and other published reports[xx,xxi,xxii] suggests that parallel trade is expanding significantly at least in certain therapy areas or individual products. Other evidence provided by advocacy groups[xxiii], suggests that there is a proliferation

of parallel trade with the traditional paradigm of low-priced countries being the exporters and high-priced countries being the importers, being on the wane. Recent evidence[xxiv], also finds that pharmaceutical parallel trade yields significant benefits to statutory health insurance; these benefits increase as parallel trade expands. The corollary thereof is that efficiency in pharmaceutical markets and welfare benefits to society increase; there is also, it is argued, an undisputed welfare benefit to patients through improved access, due to lower overall costs or cost-sharing for an identical medicine[xxv]. Other empirical research concludes that there are moderate benefits to statutory health insurance organizations[xxvi,xxvii] and that rents to parallel-importing firms are considerable compared to the price effect on the market.[xxviii]

Whether empirical or theoretical, the literature we identified seems to be focusing on one or more of the following themes:

- Parallel trade as imperfect arbitrage;
- The rationale for parallel trade;
- The theoretical predictions from the conduct of parallel trade, especially with regards to competition;
- The welfare effects of parallel trade (theoretical as well as empirical predictions);
- Evidence on cross-country price variability;
- Conceptual discussion of policy issues;
- Empirical evidence;

We summarise the evidence according to each of the above themes in the sections that follow.

### *2.3. Parallel trade as imperfect arbitrage*

Purchasing in a lower-priced country and re-selling in a higher-price country is technically termed as "arbitrage" although in the context of trade with manufacturer-authorised distribution it receives the qualification of "parallel trade."[xxix] This form of arbitrage is the result of price differences and the source of such price differences may be due to price discrimination across markets by the original manufacturers or, simply, may result from differences in the way countries regulate their markets. In pharmaceuticals, differences in regulatory practices across countries, especially in the European Union, provide the basis for parallel trade.[xxx,xxxi,xxxii] Arbitrage is meant to eliminate or reduce such price differences across borders.[1]

The most often cited cause of PI is the existence of profitable differences in prices for different products exceeding transport costs. Some studies argue that PT is distinctive from 'pure arbitrage'[xxxiii] because parallel traders assume some risks in their activities. Indeed, PT is a form of "imperfect arbitrage", not necessarily because of the risks involved (since risks apply in any other form of arbitrage), but because of the transaction costs involved and which are different from zero. As several studies have already noticed[xxxiv], (pharmaceutical) PT is an unambiguous form of arbitrage because it refers to movements of identical products across borders and arises due to price differences among markets. However, unlike pure arbitrage, (pharmaceutical) parallel trade arises within markets subjected to heterogeneous regulation and, consequently, it would not necessarily lead to price equalization. Indeed, economic theory would predict that in unregulated markets and in the absence of product differentiation, arbitrage would give rise to (a Bertrand-type) price competition

[1] Price equalization is the result of perfect arbitrage, whereas in the case of imperfect arbitrage, price approximation (not price equalization) is the outcome, due to transaction costs.

leading towards a so-called "race towards the bottom" where price equalization would occur. Let us examine some of the distinctive features that characterize (pharmaceutical) PI as a specific type of arbitrage.

First, the mechanism that leads to price approximation or equalization among internationally traded products, does not immediately apply to pharmaceuticals. Price differences in pharmaceuticals arise from the way countries regulate their pharmaceutical markets and are often determined by negotiations between governments/sickness funds and industry rather than being market based, as is the case for products such as CDs or perfumes, which are frequently parallel traded.

Second, (pharmaceutical) PT results in part from the lack of existing "barriers to arbitrage" such as the *lack of total vertical control in the distribution chain* by the originator right holder. Maintaining vertical restraints, on the other hand, implies considerable transaction and information costs and, thus, weak distribution control leads to some wholesalers in low price countries re-directing part of their stock to parallel traders who export to high price countries. In addition, (strong) vertical control may be judged by competition authorities to be anti-competitive.

Third, although some studies find that PT in general may be beneficial particularly for high-priced countries, in pharmaceuticals there seems to be a conflict between the competing objectives of promoting *dynamic efficiency* (or paying adequately for innovation) and *static (allocative) efficiency* (or meeting the objective of short-term cost-containment goals). Because PT is not necessarily an innovation-driven activity, its development might weaken the strength of originator manufacturers' innovative capacity.

Finally, although pharmaceutical PT evolves with the speed of economic integration in Europe, it is understood that it would probably not exist if the European

Union Member States could move towards a common approach to pharmaceutical pricing/reimbursement.[2] Therefore, it can be argued that PT is the short-term consequence of an unbalanced process towards increasing economic integration rather than purely the result of a single market for pharmaceuticals.

### *2.4. Rationale for parallel trade*

The issue of pharmaceutical parallel imports continues to generate controversy among the various stakeholders. Regulation of PI in pharmaceuticals has become an issue of intense debate in the global trading system. Advocates of strong international patent rights for new medicines support a global policy of banning PI, arguing that if such trade were widely allowed it would reduce profits in the research-intensive pharmaceutical sector and ultimately slow down innovation. Moreover, PI could make it difficult for health authorities in different countries to sustain differential price controls and regulatory regimes. At the other end of the spectrum, public-health authorities maintain that it is important to be able to purchase drugs from the cheapest possible sources, thus favouring an open regime for PI. Whether or not such imports actually take place, the threat that they might do could force manufacturers to lower prices. It is evident that policymakers in developing countries especially would place a higher weight on affordability of medicines than on promoting R&D abroad.[xxxv]

The literature considers two broad reasons[xxxvi] why parallel trade might arise: one is to arbitrage away international price discrimination, the other is to free-ride on investments made by intellectual property right (IPR) holders. In the first of these, a holder of an IPR on a particular good (who is, by definition, a monopolist) would like to set different prices in different markets with different elasticities of demand.

[2] This does not imply a single pan-European pricing strategy.

Parallel imports remove that ability and may lead to uniform pricing on the monopolist. If the monopolist is able to segment markets on the basis of geographical location, then it will maximise profits by charging a higher price in markets with lower demand elasticity. Permitting PIs then allows entrepreneurs to purchase the product in the high-elasticity low-price market and sell it in the low-elasticity high-price market, which leads to the monopolist charging a uniform price and thus arbitrages away price discrimination.

It has also been argued[xxxvii] that allowing PIs is (weakly) attractive to a country irrespective of its tariff regime and the extent to which it is also setting a tariff or not. However, the attractions of allowing PIs can be overcome by other considerations, notably a sufficient concern for (i) the profits of domestic license holders, or (ii) the political contributions of the global monopolist in the country under consideration.

Uniform pricing, as a result of PT, in an environment originally characterised by 3rd degree price discrimination, might actually reduce aggregate welfare if it leads to fragmented markets being left without adequate supplies. It has been noted[xxxviii] that uniform pricing may be welfare-reducing, from a global perspective, if demand dispersion is high enough. The losers from uniform pricing are, of course, small open economies that may not be supplied.

### *2.5. Theoretical considerations*

The majority of work in the area of PT in general links price discrimination, and the impact of parallel trade through trade policy and the selection of optimal tariffs. There is also some work on competition. Theoretical work on pharmaceuticals is limited.

The territorial basis for the legal protection of Intellectual Property Rights after the TRIPS agreement allows each country to set up its own policy covering PI.[xxxix] However, within the development of trade integration arrangements, the territorial principle may be extended to a regional exhaustion regime under which rights end upon the original sale within the countries involved in a specific trade area. As a result, PT is becoming increasingly common within the EU and potentially also in other large trade areas such as NAFTA. Indeed, the US has recently opened its frontiers to drug re-importation.[3] On the other hand, some advocate a global ban on parallel trade even if it is a non-tariff barrier as a natural extension of IPR owners to vertically control the product chain. Their rationale for this argument lies in their conviction that there are ambiguous long-term benefits from PT. [xl]

As territorial arrangements move from the principle of national, to regional, to international exhaustion, the implications for different stakeholders differ markedly. A policy of national exhaustion amounts to a government-enforced territorial restriction on international distribution. Countries following this regime choose to isolate their markets from "unauthorized" foreign competition in legitimate goods traded under recognized IPR protection. Thus, original manufacturers retain complete authority to distribute goods and services themselves or through dealers, including the right to exclude PI through border controls. In contrast, countries permitting PI are not territorially segmented and do not recognize any right to exclude imports of goods in circulation abroad. Note also that in principle a country could treat parallel imports and parallel exports (PE) separately. New Zealand moved in that direction recently. It is possible that a country might permit PI and ban PE in order to encourage low prices

[3] In addition, it's a common feature to observe a grey market for drugs distributed in Mexico and Canada.

on its market and avoid potential product shortages. It is also possible that a country could ban PI and permit PE in order to sustain export opportunities for its distributors.

The European Union is very active in preventing restrictions on *internal* parallel imports. The first major competition policy enforcement in the EU concerned an attempted dealership territoriality within the EU and theoretical work suggest[xli] that, `generally, policies worldwide firmly support parallel imports' (p. 169). Grey market car sales alone in Germany have been estimated at US$6 billion.[xlii] The size of the grey market in the US as far back as the mid-1980s has been estimated at US$7 billion.[xliii]

Other theoretical work[xliv] also suggests that when all countries simultaneously choose their PI regime, any Nash equilibrium involves the abolition of restrictions on PIs by all countries served by the monopolist. From this perspective, one would anticipate that any high-price country (importing country) in a world without PIs would wish to liberalise its PI regime and might experience a price reduction. On the other hand, low-price (exporting) might experience price increases. [xlv] The overall welfare effect may be ambiguous, and, even, negative.

Formal economic analysis of parallel imports treats them as a channel for overcoming third-degree price discrimination across countries.[xlvi] In a model focusing on price differences at the retail level and ignoring distribution issues and countries differing in demand elasticities for homogeneous goods, then parallel imports may lead to uniform international prices. Again, the impact on global welfare is ambiguous and depends on the balance of consumer surplus created in some areas and eliminated in others. Moreover, some high-elasticity (low-demand) nations might be eliminated as export markets under uniform pricing. Other literature discusses

problems that exist when parallel importers free ride on the marketing and service investments of authorized wholesalers.[xlvii,xlviii]

The countries that would like to permit parallel importing are those that are discriminated against in its absence, namely `high-price' countries that can `undo' price discrimination. While countries facing high demand elasticity might favour discrimination, in this set-up they cannot enforce it globally when high-price countries permit parallel imports.[xlix]

Further work[l] considers a model in which an importing country chooses both its PI regime *and* its trade policy; within that context, it is shown that allowing PIs is always attractive to a country with no trade barriers. It is also shown that if the country is setting a tariff, the optimal tariff is lower in the presence of PIs than in its absence. Nevertheless, the suggestion that high-price countries would in principle wish to actively encourage PIs still holds in the tariff-setting context. Thus, a country facing a higher price, net of its optimal tariff, in a segmented market, can always do better still by permitting PIs and adjusting its optimal tariff appropriately. While facing a high price under price discrimination is a sufficient condition for a country to favour uniform pricing, it is not a necessary one. However, if a country faces a lower price, then its PI regime is irrelevant in determining whether or not the monopolist will segment the two markets, whether or not the country favours uniform pricing.

Price discrimination is not normally held to be anti-competitive once there are justifiable reasons for price differences. It is clear, that, in order to maintain a regime of price discrimination, the possibility of arbitrage must not exist. In the economics literature, it is a well established result that, from a welfare viewpoint, a price discriminating monopolist can welfare-dominate a non-price discriminating monopolist. However, the creation of exclusive territories (which by definition

minimises intra-brand competition) may be used to dampen inter-brand competition.[li] Following two studies,[lii,liii] economies with large markets and inelastic demand, as far as they would face higher prices with price discrimination, would benefit from (pharmaceutical) parallel trade other things being equal. This is independent of these countries' market size and their ability to innovate in the area of pharmaceuticals.

### *2.6. Welfare effects of parallel trade*

The normative implications on welfare of increasing parallel trade are ambiguous as acknowledged by several studies. A number of theoretical studies have been identified in this area. Recent theoretical work[liv] suggests that it is clear that a monopolist, such as the owner of a valuable patent or trademark, will choose to engage in international price discrimination. This study considers whether social welfare might increase if the monopolist were prevented from doing so and if that is the case, then one way to bring this about would be to permit and intensify arbitrage.

Earlier work[lv] suggested that arbitrage would increase welfare since the gain in consumer surplus would exceed the value of lost profits. This analysis has been extended to include not just the price-setting decision of the monopolist but also the initial decision to invest in developing a product of a certain quality. This part is surely critical when discussing the supply of goods protected by patents and trademarks – the very reason for granting such intellectual property rights is to encourage investment in supplying high quality products. It is found that in such cases welfare will fall if arbitrage is permitted. The reason for this is that although arbitrage will help high valuation consumers obtain lower prices, it will also reduce the incentive of the monopolist ex ante to invest in supplying such a high quality product;

this may have an adverse effect on the "high-valuation" customers, and overall consumer surplus may even fall.

One assumption in this analysis worth reflecting on is that consumer surplus is additive – this is one reason why consumer surplus on aggregate can rise under arbitrage. Under an arbitrage regime prices in high valuation countries fall; by contrast, they rise in low valuation countries (consumers in high valuation countries benefit from arbitrage while consumers in low valuation countries lose). The gains for consumers in high valuation countries are greater than the losses for low valuation since the former group values the product more. One may reasonably suppose that high valuation consumers are in the rich developed countries and the low valuation consumers are in poorer countries. If arbitrage gains exist and the low valuation consumers gain from arbitrage then the low valuation consumers may not be net losers. However, if the presence of arbitrage simply means that the owner of the protected good sets a uniform price in all markets then we may be particularly concerned about the loss of welfare to low valuation consumers.

The above study makes clear that the low-income consumers are better off under a regime of international price discrimination as long as they are not the direct beneficiaries of arbitrage. Price discrimination in this case is akin to Ramsey pricing, and the prevention of arbitrage is a mechanism for enforcing this allocation of costs. This notion seems to have been accepted in the recent WTO agreement to permit international trade in generic copies of patented pharmaceutical products such as AIDs treatments (in order to permit some countries to obtain supplies at a lower cost), where high income countries specifically undertook not to take advantage of this opportunity.

Further arguments are provided on the benefits and drawbacks from allowing parallel trade among countries.[lvi] In a model that accounts for the differences between countries in terms of health system (reflected in the level of patient co-payments), and in terms of drug needs (reflected in the patients' valuation for the drug), it is shown that parallel trade leads to price convergence between countries, makes the individuals of the importing country better off, while making the ones of the exporting country worse off and decreases the profit of the monopoly producer. Moreover, it is shown that the public expenses in both the importing and the exporting countries are reduced with parallel trade.

It is also shown that the effect of parallel imports on total welfare is ambiguous. This certainly contradicts numerous statements made over the negative effect of parallel trade on total welfare, associated with lower international price discrimination. These statements ignore the positive effects associated with the increased competition faced by the monopoly producer in the importing country. Nevertheless, there are two cases where the effect on the total welfare of allowing parallel trade can be stated unambiguously. First, parallel trade may *increase* total welfare when it takes place between two countries differing in their *health needs only*. The rationale behind this positive effect relies on the re-allocation of pharmaceutical consumption from individuals with relatively lower drug needs in the exporting country, towards individuals with relatively higher drug needs in the importing country. Second, parallel trade may *decrease* total welfare when it takes place between countries differing in their *health systems only*. In that case, drug consumption is re-allocated from individuals with relatively higher drug needs to individuals with relatively lower drug needs. A direct interpretation of the above arguments would be as follows: parallel trade might increase total welfare when it

takes place between two countries with the same level of income and patient co-payments, and different drug needs (e.g. to account for the higher needs for malaria or AIDS treatment) in some countries than in others. On the other hand, parallel trade between industrialized countries, characterized by similar high income levels and epidemiological conditions, and different drug reimbursement levels, might decrease total welfare.

In the short run, PT may yield benefits to consumers in high price markets but may harm consumers in markets that would have low prices if PT were not permitted; thus, prices across borders would not be uniform.[lvii] Furthermore, price uniformity in the presence of increasing returns to scale can have an adverse effect on all countries (both high-price and low-price).[lviii]

A recent study[lix] takes into account the endogenous effects of PT on the quality of pharmaceuticals. It is argued that product quality will fall because lower investment will be devoted to those products under PT, and therefore global welfare could fall. In addition, even though PT might contribute to the objective of short-term cost-containment, it might sacrifice profits of manufacturers and thus, arguably, funds devoted to innovation. Regarding cost-containment, it should then be quantified whether PT leads to important savings to consumers – either direct or indirect through savings to health insurance. Regarding innovation, it is important to quantify which are the profits of parallel importer companies because they are funds forgone from research-based companies which are then transferred to non-research companies.

At the other end of the spectrum, it has been argued that supporting PT helps reduce the monopoly power of manufacturers' maximising profits through (third degree) price discrimination which takes into account differences in PPP and demand across countries within a single market.[lx] The power of monopolists may be reduced;

nevertheless, the question remains whether that monopoly power can be reduced in a sustainable manner if such an attempt is made in an environment of price discrimination that most frequently arises from different regulatory practices across countries.

Consequently, the welfare effects of PI might be harmful for owners of property rights while providing few benefits to other stakeholders.

### *2.7. Cross-country price variability*

The effect of price discrimination across countries has also been examined in the literature as one of the key areas that may give rise to parallel trade across countries. It has been found that both price discrimination and free-riding seem to be the main drivers of parallel trade[lxi]. Exchange rate movements may also play a very important role in inducing parallel trade[lxii]. Other studies have found that price discrimination is the main driving force behind exclusive territories.[lxiii] Further work has been conducted on the possibility that goods may flow from high- to low-price countries.[lxiv] It is further considered that any barriers to trade are unambiguously bad for small economies that cannot influence world prices[4]. To get an idea of the welfare losses from not having wholly free trade, in a recent article[5] it was stated that the cost of EU protectionist policies amounts to 7% of European GDP. However, these results are derived in models of perfect competition, however, and it has been shown that imperfect competition can give rise to incentives for individual countries to diverge from a policy of free trade. From a competition perspective, the possibility of imports from abroad lessens the power of firms to raise prices in a particular country.

[4] Large countries can manipulate the terms of trade to their advantage and have an optimal tariff greater than zero.
[5] *Vide* 'The Economist', May 22nd 1999

### *2.8. Policy issues*

The discussion so far has taken the behaviour of the monopolist as essentially passive. Yet one might anticipate that the monopolist might wish to take steps to reduce the impact of or eliminate parallel trade, perhaps through closer integration into or control over distribution channels (as has been suggested in the case of Japan where government policies might permit parallel imports de jure while private practices limit them de facto), or through explicit controls on re-exports, or, even to propose a policy combining contract, tort, and antitrust law to regulate parallel imports.[lxv]

There is active debate over the question of whether to establish a global ban on parallel imports or to maintain national policy discretion. Three arguments are made in favour of permitting parallel trade. The first argument is that restrictions on such trade essentially act as non-tariff barriers (NTBs) to goods that have escaped the control of IPRs owners. Because these barriers partition markets, they both violate WTO proscriptions against NTBs and forego consumer gains from market integration. As trade economists might put it, if international price differences exist because of manufacturers' attempts to set market-specific prices, the situation would be no different from price differences coming from other demand or supply characteristics.

A second argument is that parallel imports help prevent abusive price discrimination and collusive behaviour based on private territorial restraints. In this sense, a policy of international exhaustion complements competition policy and limits the scope of IPRs.[lxvi] The claim that buttressing territorial restraints with restrictions against parallel imports could generate collusion is consistent with past evidence from the United States.[lxvii,lxviii] A final argument in favour of PT is that government enforcement of territorial rights invites rent-seeking.

At the same time, several arguments are made in favour of prohibiting or regulating the extent of parallel trade. First, price discrimination can raise welfare under certain circumstances.[lxix] Banning parallel trade partitions markets and supports perfect discrimination[lxx]. In contrast, parallel imports push the global economy toward uniform international pricing, subject to transport and marketing costs. Thus, consumers in economies with inelastic demand should face higher prices under price discrimination than under uniform pricing. If such countries are not significant developers of intellectual property, they are made worse off by price discrimination.

Countries with high demand elasticities should face lower prices under price discrimination. In the presence of parallel trade, such countries might not be supplied by foreign IPR owners because local demand might be insufficient under uniform pricing.[lxxi] In this view, international exhaustion could lower the well-being of developing economies through higher prices and lower product availability. Despite this possibility, most developing economies prefer not to restrict parallel trade.[lxxii] This position reflects concerns that banning parallel imports would invite abusive behaviour in their markets on the part of foreign rights holders. Furthermore, many nations see opportunities for being parallel exporters. Indeed, foreign restrictions on parallel imports are seen as backdoor attempts by industrial countries to close markets through implicit NTBs.

A second complaint is that firms engaged in parallel imports free ride on the investment, marketing, and service costs of authorized distributors. These distributors incur costs of building their territorial markets through advertising and post-sale service activities. Thus, they require protection from parallel traders who procure the same goods without incurring similar costs. In this view, restrictions on parallel imports are a natural component of the right of IPRs proprietors to control vertical

markets. Such restrictions may be pro-competitive, both through increasing inter-brand competition and through providing incentives to build markets and provide services.

A related point is that efficient international distribution could require a strong vertical control within an enterprise and that private contracts may be inadequate for this purpose. Exclusive distribution rights make it easier to monitor marketing efforts and enforce product quality. However, it may be difficult in foreign markets to enforce private contractual provisions prohibiting sales outside the authorized distribution chain. In this view, restrictions on parallel trade complement the existence of exclusive territories.

Finally, from a conceptual perspective and in the absence of real data to test this hypothesis, it has been argued that arbitrage may improve societal welfare but only marginally, whereas the majority of such benefits accrue to those who perform arbitrage.[lxxiii,lxxiv,lxxv]

From this discussion it follows that whether regulating parallel imports is beneficial or harmful is an empirical issue and depends on circumstances regarding demand parameters, market structure, and innovation. Thus, it is not surprising that policies differ across countries.

Parallel imports from outside the EU are banned in all IPRs fields but the European Court of Justice (ECJ) has consistently upheld the right to re-sell legitimately procured goods within the area as a necessary safeguard for completing the internal market.

The United States enforces a “first-sale doctrine", by which rights are exhausted when purchased outside the vertical distribution chain. Thus, U.S. firms cannot preclude purchasers from re-selling products anywhere within the United

States. This doctrine is seen as an important policing device for exclusive territories, which are permissible subject to a rule-of-reason inquiry. Regarding parallel imports in trademarked goods, the United States follows a "common-control exception", affirmed by the US Supreme Court. The principle allows trademark owners to block parallel imports except where both the U.S. and foreign trademarks are owned by the same entity or where the U.S. and foreign trademark owners are in a parent-subsidiary relationship.[lxxvi] Further, the ability to block such imports rests on a showing that they are not identical in quality to original products and could cause consumer confusion. Owners of American patents may bar parallel imports under a right of importation. Copyrighted goods may not be parallel imported under terms of the Copyright Act of 1976. Recent attempts by producers of trademarked goods to extend this protection by claiming copyright protection for labels have been denied by the Supreme Court.

Japan permits parallel imports of trademarked and patented goods unless they are contractually barred or their original sale was subject to foreign price regulations. Goods protected by copyright law may be traded, except for motion pictures. Japanese case law has affirmed that Japan is substantially more open to parallel imports than is the United States.[lxxvii] Australia generally allows parallel imports in trademarked goods but patent owners may restrict them. Australia eliminated protection for copyrighted compact disks in 1998, following on its earlier deregulation of book imports. In a similar vein, New Zealand is open to parallel imports of copyrighted goods. As these cases suggest, high-income economies with relatively little stake in developing intellectual property (at least in the past), such as Japan, Australia, and New Zealand, take a liberal view of parallel imports.

India follows a regime of international exhaustion in trademarked and patented goods. Its protection against parallel imports of copyrighted goods is stronger, in

keeping with its traditional protective stance in copyrights. In general, few developing countries restrict parallel imports in any field of protection.

### *2.9. Empirical evidence on the impact of pharmaceutical parallel trade*

Three empirical studies exist examining the impact of pharmaceutical parallel trade within the EU context. The first studied the effects of parallel trade on the pharmaceutical industry. [lxxviii]They developed a model in which an original manufacturer competes in its home market with parallel-importing firms. The two key hypotheses in their theoretical analysis are, first, if the potential for parallel imports is unlimited, the manufacturer chooses deterrence and international prices converge and, second, with endogenously limited arbitrage, the manufacturing firm accommodates and the price in the home market falls as the volume of parallel trade rises. The authors test their hypotheses on data from the Swedish market for 1995–98. Before 1995 Sweden prohibited parallel imports of pharmaceutical products, but entry into the European Union, on January 1, 1995, required Sweden to allow them. Simple empirical tests from Sweden suggest that the prices of drugs subject to competition from parallel imports increased but less than those for other drugs between 1995 and 1998. Roughly three-quarters of this effect can be attributed to the lower prices of parallel imports and one-quarter to lower prices charged by the manufacturing firm. Econometric analysis finds that rents to parallel importers (or resource costs in parallel trade) could be more than the gain to consumers from lower prices.

Similar results were found in another recently published study, where the objective was to measure reductions in pharmaceutical expenditures due to the entry of parallel imported pharmaceuticals in Finland.[lxxix] Realised savings due to parallel importation remain low during 1998-2001, since parallel imports have not intensified

price competition. Potential savings for March 2000 – March 2001 were estimated to vary between €3.4 million and €10.2 million, depending on the assumptions made.

Finally, using proprietary data, a recent empirical study[lxxx] examined five EU countries and concluded that considerable financial benefits accrue to health insurance organisations and patients from the conduct of pharmaceutical parallel trade.

All three studies also conclude that the potential for parallel trade in the European Union (EU) has grown with the accession of low price countries and the harmonisation of registration requirements. The direction of benefits seems to be clear-cut but runs in opposite directions.

### *2.10. Conclusions*

The literature, both theoretical/conceptual and empirical suggests that parallel trade (whether in pharmaceuticals or in other industries) is tantamount to imperfect arbitrage. Where different countries are involved and where the principle of regional exhaustions applies, there are differences between PT in pharmaceuticals and PT in other consumer-related industries, which arise from the peculiarities of the pharmaceutical market and the fact that it is a regulated industry, at least in some constituent parts of the entity where regional exhaustion applies. Therefore, the welfare improving effects associated with the conduct of arbitrage, might not apply in the case of pharmaceuticals because of price regulation; the latter also inhibits price equalisation across borders.

The literature also demonstrates that price discrimination may lead to welfare improvements. If this is the case, theory suggests that promoting parallel trade would remove the incentives for price discrimination, and this, in turn, might lead to welfare reduction. Overall, parallel trade may achieve price reductions and could potentially

reduce the rate of growth of pharmaceutical expenditure in high-price countries whereas it would increase prices in low-price countries. However, taking into account that high-price countries are normally those where pharmaceutical innovation is undertaken, the rationale for those countries to favour the extension of parallel trade might be questioned. To that end, there is a conflict between static (or allocative) and dynamic efficiency within those countries.

In the literature of pharmaceutical parallel trade, there seems to be a tradeoff between arguments in favour of competition and patent protection on the one side and industrial policy on the other. Nevertheless, within the European Union, current jurisprudence on the subject, embraces the free movement of goods and competition arguments, although, various authors have considered the implications of the competition arguments in research-based industries, either from a theoretical or from a conceptual perspective.

The literature also suggests that whether regulating parallel trade in different industries, including pharmaceuticals, is beneficial or harmful to societal welfare is also empirical issue and depends on parameters such as demand and demand-side policies, regulation, market structure, and innovation. Consequently, it is not surprising that policies on PT differ across countries.

## 3. Hypotheses, data, methods and research endpoints

### *3.1. Hypotheses*

On the basis of the above literature a set of hypotheses was developed and these were tested in subsequent analysis. The hypotheses were derived from the economic and policy-related literature, both published and unpublished, theoretical/conceptual and empirical, and were as follows:

**Hypothesis 1 concerns cross-country effects**: From a theoretical standpoint (pharmaceutical) parallel trade results in significant re-distribution from low- to high-price countries in terms of lower prices in the latter.[lxxxi] This is the standard "arbitrage" hypothesis suggesting that "price equalisation" across countries (subject to taking into account the transaction and other costs of arbitrage) is the result of conducting parallel trade, leading to improved (allocative) efficiency in the market place.[lxxxii] Published empirical evidence on pharmaceuticals from Sweden contradicts this hypothesis[lxxxiii] and the objective within the context of this study would be to re-test this hypothesis for the Swedish case as well as five other EU countries.

**Hypothesis 2 concerns destination country effects**: Assuming homogeneous products, standard economic theory postulates that (pharmaceutical) parallel trade results in (strong) price competition in destination countries, which may lead to an overall price reduction in (pharmaceutical) prices, and which, in turn, has measurable and positive impact on payers and consumers. Empirical evidence from Finland contradicts this[lxxxiv] and similar evidence from Sweden suggests that benefits from price competition are product specific and are on many occasions negative.[lxxxv]

**Hypothesis 3 concerns aggregate welfare effects**: If (price) competition is a result of parallel trade, then there should be price convergence leading to overall improvements for payers in terms of lower prices in the short term and enhanced market competition in the medium term. Nevertheless, the theory also suggests that the direction of welfare effects is ambiguous.[6]

**Hypothesis 4 refers to the impact on consumers/patients**: Benefits to patients are significant and patient access to innovative, effective, but expensive medicines is improved. Patients benefit both directly, through reduced co-payments, and indirectly, through the savings passed on to them by health insurance organisations. Thus, lower prices due to parallel trade improve patient access to medicines.[lxxxvi]

**Finally, hypothesis 5 relates to the impact on industry**: (Pharmaceutical) parallel trade does not affect the ability of industry to operate profitably and does not harm its innovative capacity because it affects a small part of the market. Standard microeconomic theory also postulates that the loss to producer surplus forces

[6] The ambiguity of welfare effects outlined in this hypothesis (as well as the nature of competition highlighted in hypothesis 2 previously), implies that there may be far reaching implications for equity and welfare overall. The literature review in the previous section has been revealing in that respect, for two reasons. First, there are usually at least two countries involved in parallel trade, one (or more) exporting, the other importing. Even if we assume that overall welfare levels in importing countries rise due to parallel trade (which in itself may be an optimiastic result according to some published research), we are not aware of the direction of welfare effects in exporting countries. Indeed, the direction of such effects may be negative, hence, the overall welfare balance between exporting and importing countries is ambiguous. There is little empitrical evidence on the welfare effects in exporting countries, and these ought to be considered in some detail. Second, there is a tradeoff between static and dynamic welfare, in other words, how the likely short-term gains from parallel trade in medicines are valued vis-à-vis the likely long-term impact of parallel trade on drug R&D. Although it would in principle be difficult to quantify this tradeoff, the debate around the competitiveness of the European pharmaceutical sector, suggests that there may be a negative impact over the long-term, although not fully attributable to parallel trade.

producers (industry) to become more efficient.[lxxxvii] There are, however, suggestions that this may not apply to research-based industries such as pharmaceuticals.[lxxxviii,lxxxix]

### *3.2. Data sources*

In order to pursue evaluate the costs of and benefits from parallel trade to different stakeholders we developed a methodology that allows their accurate estimation and applied this methodology to Denmark, Germany, the Netherlands, Norway, Sweden and the United Kingdom as our case studies.

We used the Intercontinental Medical Statistics (IMS) database for all study countries. IMS collects and reports market data on sales, prices and market shares, among other things, of all products and product presentations and for a large number of countries. The data collected and reported are based on actual pharmacy sales; IMS acknowledges that the level of precision of its data is 94.9% for the largest world pharmaceutical markets, which include Germany, France, Italy, UK, and Spain and slightly lower (92.6%) for all other world markets it covers[xc]. For instance, reported prices by IMS may differ from those reported by competent authorities in individual countries, but reporting errors are well within acceptable margins. A distinction is made between the retail and the hospital market in each country. For the purposes of our research we focused on the retail markets in all study countries. We requested and obtained data for the period 1992-2002 for six product categories. As prior to 1997 the extent of parallel trade was hardly noticeable, the selected study period was 1997-2002.

### *3.3. Focus of analysis*

The research exercise focused on six product categories, namely

- Proton pump inhibitors (PPI),
- HMG CoA reductase inhibitors (statins),
- ACE I inhibitors,
- ACE II inhibitors,
- Serotonin selective re-uptake inhibitors (SSRIs), and
- Atypical anti-psychotics.

We selected these categories because products within these are used to treat a wide range of disorders, such as peptic or duodenal ulcer, primary and secondary prevention of heart disease, hypertension, angina, depression, and psychoses that have significant impact on patient health (in terms of improved mortality and morbidity) as well as health care budgets. In addition, the above categories include a large number of high-volume products, a significant proportion of which were patent protected during the study period. Our six product categories accounted for 14% - 28% of the total (retail) expenditure on prescription medicines (see **Table 3.1**). For each product and product formulation within these product categories, we obtained quarterly data on market shares, prices, and sales. For a number of countries (notably Denmark, Germany, the Netherlands, Norway, Sweden, and the United Kingdom) and for each product, IMS reports separately prices, sales and market shares from both local sources and parallel imports (PI). We also had access to IMS price and sales data for the same products from Austria, France, Greece, Ireland, Portugal, Italy, and Spain. In total, the obtained dataset included 13 European countries.

Due to their high relative price levels and the possibility to identify whether product sales were locally-sourced or PI, Denmark, Germany, the Netherlands, Norway, Sweden and the United Kingdom were our "destination" countries. The remaining countries were added in order to capture the price spread between each of these and each of the destination countries. Indeed, Austria, France, Greece, Italy, Portugal, and Spain, were predominantly, price regulated markets during the study period[7], hence we expected that their average price level would be lower than that of our destination countries, making them a *potential* source of parallel exports for certain products or product presentations. Nevertheless, this classification did not preclude the source of parallel exports being one or more of the countries that are generally considered to be high price countries (e.g. the UK, the Netherlands, or Sweden) if sufficient price differences exist between these countries for a given product or product presentation.

Indeed, as **table 3.2** shows, prices of the same product (adjusted for DDD and pack size) differ significantly among EU member states. Furthermore, **Table 3.2** also shows that with few exceptions, parallel trade can theoretically take place between any 2 countries, provided that sufficient price differences exist.

### *3.4. Deciding on the analytical approach*

From a methodological standpoint, the defined daily dose (DDD) adjustment is a robust way to compare prices of drugs in different countries and in a consistent manner. However, in practice, parallel trade of pharmaceuticals does not occur on the basis of comparing DDDs across countries, but on the basis of judging what the most popular packs are in destination countries and what sources can possibly supply these

[7] The type of regulation differs by country and may include command-and-control measures as well as negotiated schemes between government/health insurance organisations and industry.

most popular packs with the greatest possible approximation that would also result in the lowest possible costs associated with parallel importation (e.g. re-packaging). Because there are huge differences in presentations (dosage and pack size) it might be the case that although prices are low in a particular country and for a particular presentation these might not match with the most common presentation in a potential destination country. Consider, for instance, the case of Austria. **Table 3.2** suggests that Austria would be a favourable source of parallel exports for many products on the basis of DDD- and pack size-adjusted prices. However, the most common presentations sold in destination countries, such as Germany, the UK and the Netherlands, never quite matched those available in Austria. This does not necessarily mean that there are no parallel exports from Austria, but there certainly are not for the most common presentations across the 19 products and for the selected destination countries considered in this study. Because of this inconsistency, published empirical research[xci] typically uses quasi-hedonic regression analysis to adjust for the impact of different presentations across countries/markets. For the purposes of our research, we reported the DDD cum pill-adjusted prices in **table 3.2** in order to provide a measure of the price differences across countries but followed the route of comparing pack prices (for locally-sourced and PI products) within destination countries, and matching these with the prices of the same packs in potential export countries. As we were not concerned with the construction of a price index, the best way forward was to compare product presentations like-for-like across countries, having taken as benchmarks the ones in each country.

### *3.5. Data analysis*

As the IMS database provides data in crude format, a number of simple transformations were required in the original dataset in order to bring the data in the desired format. Sales data were available per product presentation (dosage and pack size) at ex-manufacturer prices and were originally expressed in US$. We used the end-March 2003 Dollar-Euro ($/€) exchange rate to convert sales data into Euros (€).

IMS expressed prices at public (retail) level and these were available in Euros for each country. By having access to wholesale and retail margins as well as national VAT rates across all sample countries, we were able to express prices at ex-manufacturer level for each product and product formulation in each country. By dividing (ex-manufacturer) sales with (ex-manufacturer) prices, we were able arrive at total volume (packs) sold per quarter and for each product presentation.

In order to arrive at annual data for volume sold per presentation and for a given year, we aggregated all four quarters for that year. In order to arrive at the average price for each product presentation for a given year, we took the un-weighted price average of the four quarters for that year.

### *3.6. Volumes of locally-sourced and PI products*

We were able to aggregate all product volumes in each of our destination countries and separate them into total volume sold by the originator company ($Q_i^{orig}$) and total volume sold by all parallel importers ($Q_i^{PI}$),where ***i*** denotes product. With regards to the originator company sales and in the case of a licensing agreement, where more than one originator companies were operating, we aggregated their respective sales volumes per product presentation. Where more than one parallel

importing companies were operating, we also aggregated their respective sales volumes per product presentation, in order to arrive at a total volume figure per year for PI and for each product presentation. We excluded all generics from our analysis. We were able to identify sales on a company basis and by presentation and confirmed the identity of each company, i.e. whether they were generic or parallel-importing.

### *3.7. Prices of locally sourced and PI products*

Of the price data available, we took the public (retail) price for each presentation and considered the following prices:

- First, the price of the locally-sourced original product in each of the destination countries, $P_{ij}^{orig}$, ***j*** denoting a destination country; this is the public price used by sickness funds or the health service for reimbursement purposes.
- Second, the parallel import price of the same product presentation in each of the destination countries, $P_{ij}^{PI}$. This is the public price of parallel imported product and is in the majority of cases different (and lower) than the price of locally-sourced original ($P_{ij}^{orig}$). Being faced with several parallel importers per product presentation, we took the average price of all parallel importers for the same presentation in order to arrive at the parallel import price for that presentation in a particular destination country.[8]
- Finally, we considered the three lowest public prices among all 13 countries in our sample countries for exactly the same product and product presentation as in a specific destination country ($P_{it}^{orig*}$), where ***t=1,2,3*** and denotes potential source (exporting) countries. These prices would give us an indication of

[8] In fact, price differences among different parallel importers for the same product and product presentation were, at best, marginal, implying that there is absence of competition among parallel importers.

where parallel importers would be very likely to source from and would also enable us to compare prices in potential exporting countries, with PI prices and locally-sourced product prices in destination countries[9].

As retail margins and VAT rates differ across countries, we also arrived at pharmacy purchase prices (PPP) in potential export countries in order to determine whether these would make any difference to our selection of lowest, second lowest, and third lowest price country, and where this was the case, we adjusted our selection accordingly.

We assume that parallel traders are rational agents seeking to maximise their rents and would therefore want to source from the cheapest source(s) possible, provided that:

(a) These sources are of adequate size to cover demand in the destination country;

(b) Given a favourably low price in potential export countries, product presentations (pack sizes) in the potential source country match (precisely or closely) the most popular pack sizes in destination countries; and

(c) Given a favourably low price in potential export countries, there may be cultural issues and existing business partnerships that influence decisions to source from a particular EU member state.

The selection of the three lowest-priced countries reflects exactly the above issues. These prices are directly observable by parallel traders. **Figure 3.1** shows the relationship between the above set of prices.

When comparing the prices of locally-sourced product presentations with those of PI presentations, we endeavoured to match product presentations (dosage and pack sizes) precisely; this meant, for example, that the 10mg/56 pill pack of locally-

[9] The validity of this assumption was tested with data from the Netherlands, where the source (country) of parallel imports to the Netherlands is known.

sourced olanzapine, was matched with the same strength and pack of PI olanzapine. We re-calculated the PI pack sizes to match those in each destination country for the same dosage and adjusted their prices accordingly only if pack sizes differed. In accordance with our expectations, Portugal, Spain, Greece and Italy were indeed among the lowest, second-lowest or third-lowest price countries in the majority of cases, but on several occasions France, Denmark, Sweden, UK and Belgium featured as well.

### *3.8. Price spread and price variability*

Having selected prices, we were able to construct indices of price variability and price spreads (the latter in €). These were calculated to capture the difference between PI prices and locally-sourced prices within each destination country (intra-price variability) and the difference in prices of original products among each destination country and the lowest, second-lowest and third-lowest potential export countries (inter-price variability).

- The intra-price spread (and intra-price variability) would enable the calculation of absolute (relative) savings to health insurance organisations in destination countries per pack sold and per product presentation. The intra-price spread (γ) was calculated as shown in equation 3.1 below:

$$\gamma = P_{ij}^{orig} - P_{ij}^{PI} \qquad (3.1)$$

- The intra-price variability (Δγ) was calculated as shown in equation 3.2 below:

$$\Delta\gamma = \frac{P_{ij}^{orig} - P_{ij}^{PI}}{P_{ij}^{orig}} \qquad (3.2)$$

- Inter-price spread (and inter-price variability) was computed as the difference between the PI price in a country and the prices of the three lowest potential exporting countries. The inter-price spread (ζ) was calculated as shown in equation 3.3 below:

$$\zeta = P_i^{CBT} - P_{it}^{orig*},\ t=1,2,3 \qquad (3.3)$$

- Similarly, the inter-price variability (Δζ) was calculated as shown in equation 3.4 below:

$$\Delta\zeta = \frac{P_i^{PI} - P_{it}^{orig*}}{P_i^{PI}},\ t=1,2,3 \qquad (3.4)$$

### *3.9. Direct visible savings to health insurance organisations*

We calculated savings accruing to health insurance organisations or health services as the effect of price differences (intra-price spread) between locally sourced and PI products multiplied by the PI volume for a product. Savings accruing from the intra-country price spread refer to the difference between what sickness funds or the health service in each destination country would pay if the market were served with the locally-sourced products and what would pay if the market were served by parallel imports times the quantity of parallel imports sold in a reference year, assuming an

inelastic demand for pharmaceuticals in destination countries.[xcii] That equals the intra-country price spread times the total PI volume as shown in equation 3.5 below:

$$S_{ij} = Q_{ij}^{PI}(P_{ij}^{orig} - P_{ij}^{PI}) \qquad (3.5)$$

Both prices, $P_{ij}^{orig}$ and $P_{ij}^{PI}$ are pharmacy purchase prices (PPP). We also calculated the savings as a percentage of the total product market in a country, as follows:

$$\Delta(\mathrm{S_{ij}}) = \frac{(P_{ij}^{orig} - P_{ij}^{PI})Q_{ij}^{PI}}{(P_{ij}^{orig}Q_{ij}^{orig}) + (P_{ij}^{PI}Q_{ij}^{PI})} \qquad (3.6)$$

Equation 3.6 provides an indication of the amount saved by statutory health insurance organisations or the national health service as a proportion of total pharmaceutical expenditure. In equations 3.5 and 3.6 we assumed similar patterns of demand for locally-sourced and PI medicines and inelastic demand for medicines.

Finally, in addition to the direct price effect, we also examined the extent to which there was a competition effect, in terms of price convergence within each destination country, thereby yielding further savings to the health service or sickness funds. For this purpose, we examined the correlation coefficient (***r***) for each product's locally-sourced and PI prices; we also applied the t-test to test the hypothesis of price versus no-price convergence for the 1997-2002 period on a quarterly basis.

### *3.10. Revenues and gross profits to parallel importers*

Parallel traders, as rational agents, observe prices in different countries and exercise arbitrage between countries by taking advantage of price differences and

trying to minimise their transaction costs. In each of the destination countries in question, the total revenue of parallel traders is equal to the volume sold by them, multiplied by the price they sell at. Discounts may also be given by wholesalers and parallel traders to pharmacists. With the exception of the UK and the Netherlands, all other study countries operate on the basis of fixed wholesale and retail margins, although discretionary discounts may be offered from the former to the latter.

Theoretically, parallel traders have greater leverage to offer higher discounts to pharmacists in destination countries since they obtain their products from cheaper sources within the EU than their official wholesale counterparts in destination countries. However, it is impossible to ascertain the extent of these discounts, therefore, it was not possible to credibly introduce them into the parallel traders' revenue function. It can be argued, however, that the discounts offered by parallel traders to pharmacies in destination countries may cancel out with the discounts that parallel traders obtain from wholesalers in potential export countries.

It can be argued that wholesalers in potential exporting countries may have an incentive to sell to parallel traders for a number of reasons: first, because by selling a large quantity to a single agent (as opposed to distributing smaller quantities to several smaller agents – i.e. community pharmacies), they forego part of their transaction (i.e. distribution) costs; to that end, parallel exporting is an economically efficient operation compared with distribution to community pharmacies. Second, local wholesalers might sell to parallel traders at a lower discount, as compared with selling to pharmacies, and thus, the actual transaction price is nearer to the PPP. This makes the case for parallel exports even more economically convincing for local wholesalers. However, we did not have access to dealings occurring between local

wholesalers and parallel traders, therefore, we based our calculations on the PPP in the parallel exporting country being the actual transaction price.

From the stream of revenues, we were also able to arrive at parallel traders' likely gross profits from their operations. We took prices in the three lowest price EU countries[10] and based our analysis on the assumption that each destination country would be served entirely by these countries. Having considered the three lowest price countries in the EU we were able to calculate the *maximum* gross profits of parallel trade operations (based on the assumption that the lowest price country supplies a particular destination country), and *average* gross profits (based on the assumption that the three lowest countries supply a particular destination country) on a product by product basis and for each country. We are not in a position to calculate gross profits with 100% accuracy, but the range we considered, i.e. maximum gross profits (considering that the lowest priced EU country supplies a particular destination country) and average gross profits (considering that the three lowest priced EU countries supply a destination country) provides a realistic perspective.

The prices we considered in each destination country and the source (exportation) countries were pharmacy purchase prices (PPP), ($P_{ij}^{PI,PPP}$ and $P_{it}^{orig*,PPP}$ respectively) as parallel traders observe these prices, since they purchase primarily from wholesalers in the exporting countries[11], or are wholesalers themselves.

[10] Although our sample of countries excludes Finland, it is not likely that this country would feature within the range of the 3 lowest price countries in the EU and would also have a capacity problem to supply other EU markets at adequate quantities.

[11] It is also understood that a fraction of parallel exports may arise from direct purchases from pharmacists in exporting countries, but this is a costly operation for parallel traders since retail prices have already been marked up by the applicable retail margins in each country and which range from 20-33%. By definition, direct purchases from pharmacies would involve, most frequently, small quantities. We were not able to capture this effect.

Profits were calculated for the set of product presentations that account for at least 60% (and often 80% or 90%) of each product market and then extrapolated for the rest of the product market, whilst always ensuring that the presentation of the parallel imported pack matched precisely the presentation from the export country.

On the basis of the above methodology, profits ($\boldsymbol{\pi}$) were the difference between PI revenues in each of the destination countries and acquisition costs in the potential exporting countries. Two measures of profitability are obtained: first, profit levels (in Euros) and, second, profits as a share of total parallel import sales (mark-ups). Profits ($\pi$) were calculated as shown in equation 3.7 below:

$$\pi = q_i^{PI}(P_{ij}^{PI,PPP} - P_{it}^{orig*,PPP}), \quad t=1,2,3 \qquad (3.7)$$

Mark-ups (MU) have been estimated by dividing profits with revenues as follows:

$$MU = \frac{(P_{ij}^{PI,PPP} - P_{it}^{orig*,PPP})Q_{ij}^{PI}}{P_{ij}^{PI,PPP}Q_{ij}^{PI}}, \quad t=1,2,3 \qquad (3.8)$$

and, therefore, they provide a measure of relative gross profitability.

Of course, it is acknowledged that parallel traders incur certain costs by engaging in parallel trade. Such costs include transportation across borders, storage in destination countries, distribution costs in destination countries, as well as regulatory costs in terms of obtaining marketing authorisation for PI products. Arguably, the average cost per unit declines as volume rises, therefore rational parallel traders have an incentive to maximise operations in destination countries in order to reduce total cost per unit. Although operational costs such as transportation, storage and distribution are difficult to account for, regulatory costs, related to obtaining

marketing authorisation, were available from national regulatory authorities and these are summarised in **table 3.3**. It can be seen that these costs are modest.

### *3.11. Direct financial benefits to pharmacists*

As we could not ascertain the extent and magnitude of discounts from parallel traders to pharmacists in destination countries, we based our estimations on the basis of data and margins that we could account for. As Denmark, Germany, Norway or Sweden do not have a clawback system in place, along the lines that exists in the UK or the Netherlands, and Germany operates, since April 2002, a system whereby sickness funds require pharmacists to provide evidence that they supply from PI sources for up to 5.5% of their turnover for 2002 (7% from January 2003)[12], it is fair to assume that any discounts from wholesalers or parallel traders to pharmacists directly benefit the latter and it is unlikely that such discounts are in any form being passed on to the public or sickness funds. As we are not in a position to estimate their effect, we did not consider them in our analysis.

### *3.12. Direct financial benefits to the public/patients*

Any discussion of direct benefits accruing to patients from the conduct of parallel trade, would need to take into account the structure of cost-sharing in the study countries. In systems of universal coverage, patients typically cover a small proportion of drug costs on an out-of-pocket basis. There are also cases, where patients are exempt, either because they suffer from a chronic condition, or because of their age (under 18 or over 65), or because of low income. Consequently, drug co-payments make a small proportion of total health care expenditure. In assessing the

[12] There is a penalty if pharmacies do not demonstrate they have reached their parallel import quota.

direct effect of pharmaceutical PI on patients, we considered the cost-sharing structure in each of the destination countries and provided examples of their impact.

### *3.13. Research endpoints*

The research exercise aimed to provide a stakeholder analysis of the impact of pharmaceutical parallel trade in qualitative as well as quantitative terms by examining the impact of parallel trade on both exporting (source) and importing (destination) countries.

The key research endpoints were threefold:

First, to evaluate the *direct* effects that arise from price differences between locally-sourced and PI pharmaceuticals in destination countries. We used the last year of our dataset (2002) to report on as we expected that the financial impact would be highest then. In doing so, we focused mainly on drug list prices, while at the same time attempted to evaluate the impact of discounts in the UK and the Netherlands, although the evidence we provide on this is tentative, particularly for the UK.

Second, to evaluate the nature and extent of competition effects within destination countries, over the 1997-2002 period. The key endpoint here was to examine whether parallel trade leads to price competition and whether there is evidence that price competition between locally-sourced and PI products and whether, leads to downward price convergence.

Third, to evaluate the nature and extent of likely price competition effects across (importing and exporting) countries and over time that would lead prices to converge, namely whether there is any foundation in the arbitrage hypothesis.

## 4. National policies on pharmaceutical parallel trade

It is not surprising that national governments and European institutions have displayed an increased level of preoccupation with parallel trade of pharmaceuticals over the past few years. This has occurred for a number of reasons. Firstly, there are significant differences in the methods of pricing and reimbursing pharmaceuticals across the European Union member states (see **Table 4.1**), which, in turn, result in significant price differences for the same product and product formulation among the member states, thus enabling parallel trade (arbitrage) across borders. The introduction of the Euro, may have made this a less risky and more transparent venture,[xciii,xciv] although quantitative evidence to substantiate this latter point is not available.

Secondly, parallel trade has reached a significant proportion of total national pharmaceutical expenditure in many countries (see **Table 4.2**). Parallel imports reached nearly 20% of the UK market, 14% of the Dutch market, 10% of the Danish and Swedish markets, and 7% of the German market in 2002, significantly up from the late 1990s. By contrast, parallel exports represented 16.7% and nearly 22% of the Greek market in 2000 and 2002 respectively according to official estimates.[xcv,xcvi]

Thirdly, but very importantly, parallel trade represents an interesting, albeit difficult-to-balance, policy dilemma, touching upon the principles of free trade policy, the determination of health and pharmaceutical policy, and the existence or not of industrial policy in the pharmaceutical sector.[xcvii] Unavoidably, conflicts may arise in a situation where the above policies meet: member states wish to exercise their legal right and autonomy to determine their own pharmaceutical policy; wholesalers or parallel traders perform arbitrage of pharmaceuticals across countries exercising their legal right provided by the principle of the free movement of goods and regional

exhaustion of rights; and some governments have an active industrial policy in place, with the objective of promoting innovative research and development (R&D) in the pharmaceutical sector through minimal interventions on the pricing of medicinal products. At the heart of this policy dilemma, lie the freedom in the movement of goods and the exhaustion of intellectual property rights, the former being a cornerstone of European integration, the latter a corollary thereof and a pre-condition for the existence of parallel trade.

The purpose of this section is to briefly highlight the interests that national stakeholders (in particular, health insurance organisations, patients and pharmacies) have from the conduct of pharmaceutical parallel trade. Its purpose is not to exhaustively outline their positions, strengths or weaknesses, but to inform on the relative balance of power. The sub-sections that follow discuss

(i) Institutional policies directly encouraging the dispensing of parallel-imported pharmaceuticals by pharmacies;

(ii) Financial benefits to institutional players (both health insurance organizations and pharmacies) through parallel distribution;

(iii) Other national policies indirectly influencing PI activities at national level; and

(iv) Cost-sharing policies directly affecting patients' access to medicines and their ability to benefit financially from PI.

This section largely draws upon an independent survey conducted in early to mid-2003 on this subject.[xcviii] The countries included in this survey are Denmark, France, Germany, Greece, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom.

### *4.1. Institutional policies directly encouraging the dispensing of parallel-imported pharmaceuticals*

Institutional policies refer to measures explicitly taken by statutory health insurance organizations to lower the cost of reimbursed pharmaceuticals. Such policies may be specifically targeting PI pharmaceuticals or may be referring to the entire market, including PI. There were no institutional policies in place directly encouraging the dispensing of PI pharmaceuticals in France, Greece, Italy, Portugal, and Spain. However, Denmark, Germany, the Netherlands, Norway, Sweden, and the United Kingdom have set up policies encouraging the dispensing of PI products. These are presented in turn and a summary is shown on column 2 of table 4.3.

#### *4.1.1. Denmark*

Although there has been increased focus on PI and a clear promotion of PI pharmaceuticals, the direct interventions toward PI have been based solely on information. There are no specific economic incentives or regulatory claims directed at PI, but PI drugs have been placed under the umbrella of substitution. Pharmacists have a legal obligation to inform patients of the availability of the cheapest PI drug when savings reach DKK 5 on a prescribed product priced to the pharmacy up to DKK 100, 5% if the price is between DKK 100 - 400, and DKK 20 on products priced over DKK 400. Nevertheless, pharmacists have no direct financial incentives to dispense PI pharmaceuticals and it can be argued that, *ceteris paribus*, the structure of the regressive distribution margins may altogether favour locally sourced original products, than parallel imports.

### *4.1.2. Germany*

In the German case there are no incentives to dispense PI pharmaceuticals, but there are disincentives (penalties) for not dispensing them if they are available. The association of sickness funds and the German association of pharmacists have agreed upon a PI quota. This quota is based on the pharmacies' overall business (turnover) with sickness funds and is not product-related. It describes the share that dispensed, imported pharmaceuticals take of the pharmacy's revenue as a proportion of all non-imported pharmaceuticals. The price advantage of PI pharmaceuticals is set at 10% of the pharmacy sale price. The quota was implemented in April 2002 and was set at 5.5%, but increased to 7% with effect from January 2003.

If the pharmacist does not achieve the quota in a given month, the pharmacy's reimbursement bill is reduced for that month. The reduction is the difference between the agreed and the dispensed imported pharmaceuticals multiplied with 10% from the import quota. If the pharmacist exceeds the quota he receives a credit, which can be used to settle the pharmacist's bill when the import quota is not reached. The credit is transferred to the following year if it has not been used. Overall, there is no cash benefit to pharmacists. If the share of PI pharmaceuticals that a pharmacy can dispense is below the general average, the share of imported pharmaceuticals is reduced by 25, 20, 15, 10 and 5% thereby reducing the import quota for the pharmacy in question.[13]

[13] We have no evidence on how the "quota system" in Germany works in practice and whether there may be hidden benefits for some parties involved. For instance, the "quota" provides an implicit incentive for rent-seeking behaviour by pharmacies. Conceptually, some pharmacies might be inclined to show 'on book' purchases of PIs with relatively high prices, while not necessarily disclosing other PI purchases, which could provide significant savings. Alternatively, it may be the case, that PI purchasing and trading could well impose high transaction costs and draw labour away from activities which from a health care perspective could generate higher marginal returns.

### *4.1.3. The Netherlands*

The Netherlands have incentive structures in place allowing both pharmacies as well as the government to benefit financially from the dispensing of cheaper pharmaceutical products, whether these are parallel imported or not. The Dutch policies can be summarised into (a) direct financial incentives to pharmacies and the government and (b) the clawback, a mechanism whereby sickness funds ensure that the discounts Dutch pharmacists receive from wholesalers are being passed on back to them as savings.

Direct incentives and the reference pricing system introduced in the Netherlands in 1988 aimed at persuading pharmacists to dispense generic (especially unbranded) or parallel imported drugs instead of generally more expensive locally sourced branded drugs. Products were classified in clusters based on their generic name, pharmaceutical form, method of administration and strength. A reference price is determined per cluster each month and is set as being the reimbursement price of the most expensive brand in the cluster with a 'reasonable' turnover (at least 15%). If the pharmacist dispenses a drug with a lower price than the reference price of the group in question, the pharmacist may keep a third of the price difference as an incentive, with the remainder of the price difference accruing to the sickness funds. In the past, incentive-related revenues were considered as extra income for the pharmacies. At the end of 1999, the Ministry of Health and Welfare decided that the incentive-related revenues should be considered regular pharmacy revenues in relation to establishing the fixed fee per prescription. Consequently, with effect from January 1st, 2002 the pharmacy tariff has been cut by €0.14, which should, on average, account

for 33% of the price difference between the reference price and the price of a cheaper pharmaceutical, which may or may not be parallel imported.

The second key element of Dutch dispensing policy is the clawback. As of July 1st, 1998 a clawback has been in operation to compensate sickness funds for purchasing economies that pharmacists make by negotiating discounts with wholesalers or parallel traders. As part of the trade-off between accepting a gradually increasing dispensing fee, pharmacists accepted a clawback of 6.82% with a ceiling of €6.80 per prescription. However, the clawback is the same for locally sourced as well as PI products and, therefore, is not exclusive to parallel imports of pharmaceuticals.

As a result of a flat clawback rate being set at 6.82%, pharmacists do have an extra incentive to procure from PI sources carrying higher discounts. This extra incentive is the result of an average discount of 20% pharmacists can achieve in engaging in their purchasing economies, although this applies across the board to single source drugs, parallel imports and generics. Alternatively, the reimbursement price to pharmacists for single source PI drugs is based on the list price of the cheapest supplier per country the drug (form) is originating from, minus 8% (with a maximum per prescription of €9.00).

#### *4.1.4. Sweden*

Sweden has a substitution policy in place that includes generic and PI products. No explicit institutional policies are in place to specifically encourage the dispensing of PI drugs, although county councils make one-off payments to Apoteket, the Swedish pharmacy network, at year-end to compensate them for their work on generics and PI drugs.

### *4.1.5. United Kingdom*

Along with the Netherlands, pharmacy remuneration in the UK differs from other EU countries, in that it is not subjected to fixed (progressive or regressive) margins, other than a dispensing fee per prescription. This allows UK pharmacies, whether independent or chain, to procure from sources that can provide them with the highest discount off the drug list price. Indeed, the 'clawback' system (discount recovery scale) directly encourages pharmacists to procure more cost-effectively. The DoH takes into consideration the "Discount to Pharmacy" given by the wholesaler or parallel trader to the pharmacist. Chain pharmacies are excluded from the inquiry. The DoH refunds the pharmacist based on the NHS price level minus a "clawback" which currently ranges between 6.51% and 13.2% depending of the number of prescriptions dispensed each month. Most pharmacies are falling into the 10.44% bracket. The exceptions to this case are the "zero discount scheme" products in the drug tariff. This scheme applies to products that have a high cost for wholesalers in terms of storage and distribution. It affects about 500 products including 300 fridge-lines (e.g. vaccines), expensive items such as betaferon and controlled drugs that require extensive record keeping. For these products the wholesalers do not discount the product to the pharmacist and the DoH reimburses the pharmacist at NHS-price level without deducting the clawback.

Every pharmacy in the UK, whether it uses parallel-distributed products or not, is subject to the Department of Health's clawback. Given the flat fee structure of the clawback relative to the number of prescriptions, pharmacies have an indirect incentive to procure more from parallel importers, or, indeed, obtain the so-called price-equalisation deals from official wholesalers, as they can keep a significant proportion of the overall discount given. As the average clawback currently stands at

10.44%, if pharmacies achieve a higher discount on this, then they can keep the difference. Other than discounts given to pharmacies, PI pharmaceuticals do not have an incentive to be priced lower than the list price.

#### *4.1.6. Norway*

The Norwegian government does not expressly promote PI-products in pharmaceutical policy. However, the existing "profit-sharing" system is designed to encourage pharmacies to dispense cheaper medicines, including PI drugs. Since Norway has a system of maximum prices both at the retail and wholesaler levels, a pharmacy would be inclined to sell the most expensive version of a drug in order to maximise its mark-up. The "profit-sharing" scheme allows the pharmacy to retain 50% of the difference between the retail price and the maximum retail price of a given drug.

### *4.2. Financial benefits to institutional players by parallel distribution*

According to the theory of arbitrage, the availability of parallel-distributed products, or even just the likelihood of this, can potentially result in lower prices for domestic equivalents than would otherwise be the case. Essentially, arbitrage results in three effects that may impact on health insurance organisations' ability to benefit financially from its conduct:

- The first is price differences between locally sourced and PI pharmaceuticals. In this case, it is assumed that PI product(s) will be priced lower than the equivalent locally sourced in order to attract market share.

- The second effect is the likelihood of price competition between what appears to be perfect substitutes.[14] In this case, health insurance organisations benefit over the long term from better price deals in both locally-sourced and PI pharmaceuticals. From an economic standpoint, this would also imply a rather competitive PI market structure with parallel traders engaging in competition among themselves and undercutting each other by offering better price deals to pharmacies and, by extension, health insurance. It also assumes that the original manufacturer is engaging in price competition over the medium- to long-term.
- The third effect is the impact of discounts (whether price discounts or volume deals) offered to pharmacists in countries where margins are fixed by law. In these cases discounts may in principle be operating at the margin of legality, but are impossible to account for and, are therefore, invisible. Such discounts can be approximated where relevant information exists, e.g. in the UK and the Netherlands, but even in these cases their precise level (i.e. on a product-by-product basis) is impossible to gauge. Nevertheless, discounts, whether formal or informal, result in directly benefiting pharmacies with no additional benefit to statutory health insurance organisations unless there is a clawback system in place, and no benefits to patients unless the latter contribute all or a significant part of the cost of medicines out-of-pocket.

This section examines the financial benefits accruing to institutional players from parallel importation of pharmaceuticals, particularly those arising from (static) price differences between locally sourced and PI pharmaceuticals. Six countries

[14] Assuming that patients' perception of a locally sourced and a PI pharmaceutical is exactly the same.

reported such benefits, and these are reviewed below (also summarised in column 3 of **table 4.3**).

### *4.2.1. Denmark*

County councils responsible for health and pharmaceutical care delivery may benefit in terms of lower prices of PI pharmaceuticals. Consequently, the entire price difference between locally sourced and PI drugs accrues to them. There are no in-built benefits connected with the dispensing of PI products. As already discussed, the structure of regressive fixed margins for pharmaceuticals in Denmark suggests that it may be more lucrative for a pharmacist to dispense more expensive products. However, pharmacists are by law obliged to inform patients of cheaper available options due to mandatory substitution.

### *4.2.2. Germany*

German pharmacists have both a legal obligation, (Article 129 of the Social Code Book V), to 'issue a more favourably-priced imported medicinal product according to the requirements of the framework agreement' and also a contractual obligation, agreed between the association of sickness funds and the national association of pharmacists, to dispense these if certain conditions on price (generally a minimum of DM 1 or 10% cheaper) are met. Any savings from lower list prices with dispensing under statutory health insurance accrue to the sickness funds. As of April 2002, the contractual obligation for every pharmacy is that it must guarantee each sickness fund that it will dispense PI products to the value of 5.5% of its sickness fund turnover, rising to 7% from January 2003.

Employing reference pricing principles enables the setting of lower reimbursement ceilings for groups of interchangeable products when parallel-traded versions are available. Combining all three types of savings from parallel trade in Germany - direct savings from lower priced parallel trade products, downward pressure on manufacturer prices of other products, and lower reference prices - resulted in total savings of €128 million in 2000. However, the savings from cheaper PI pharmaceuticals have not been possible to disaggregate.

### *4.2.3. The Netherlands*

Dutch sickfunds receive two-thirds of the price difference between the reference price of a cluster and a cheaper parallel-distributed product if the latter is dispensed (the pharmacist retains the balance of the saving). Parallel-traded products are priced a minimum of 3% lower than domestic brands. In addition, prudent purchasing by the profession allows the government to recoup some of the discounts/rebates earned. Estimates suggest that total savings from the clawback source amounted to €68 million in 1999.

Pharmacists are on average granted 2% + 2% by wholesalers for frequent and on-time ordering and paying. Subsequent discounts on generic and parallel imported pharmaceuticals are granted to pharmacists to create a competitive market for manufacturers and wholesalers. The estimated discounts on parallel-imported pharmaceuticals are in the range of 20% and substantially higher than those on locally sourced brands (7%). Of that, the Dutch clawback system forces pharmacists to return 6.82% to the sickness funds, but may keep the difference between what they are obliged to send and what the actual discount rate is.

### *4.2.4. Sweden*

Savings in Sweden accrue primarily from the price difference between locally sourced and PI product. County councils may benefit financially as they are responsible for administering the drug bill and pay for a share of the increase or decrease in the drug bill. The state may benefit from PI as they still pay for the remaining share of the changes in the drug bill year-on-year. On the other hand, the pricing and reimbursement authority (LFN) generally decides the payment to Apoteket for their retail work. If Apoteket is successful in enhancing the generic and PI segments they will receive compensation for their extra costs via an increase in the retail margin. In 2002 Apoteket received a total of SKr50 million (€5.5 million) extra for their additional work with generics and PI. This is a retrospective, one-off bonus payment.

### *4.2.5. United Kingdom*

UK pharmacies have an incentive to search for cheaper alternatives as they are allowed to negotiate discounts with wholesalers. The incentive is provided indirectly through the clawback, which is a flat proportion of their business with the UK NHS, allowing them to search for PI options across the gamut of products they dispense. Evidence from the PSNC suggests that savings from PI would be on average 17.43%, whereas actual discounts of the top 10 products to individual pharmacies range from 1.6% to 24.3% compared with the NHS list price.[xcix] By dispensing more PI drugs they maximise their profits, whilst keeping the returns to the DoH unchanged through the fixed clawback scales. This, of course, may have an upward knock-on effect on future clawback scales, but this would have prospective rather than retrospective action. The DoH estimates for 2001-2002 place savings from this activity at £100

million (€143 million)[c], whereas other estimates elevate the impact of the clawback from parallel imports to the sum of £134 million (€192 million) for 2002.[ci]

#### *4.2.6. Norway*

The National Insurance Administration in Norway retains 50% of the difference between the official maximum pharmacy acquisition price of a reimbursed product on a 'blue prescription' and its actual acquisition price. To encourage cost effective purchasing and to offset losses on the linear mark-up structure, the pharmacist retains the balance of the saving.

### *4.3. Other policies indirectly encouraging (or discouraging) PI activities*

This section discusses the extent to which there are policies in place that would be perceived to be contributing to the use of PI pharmaceuticals. For predominantly parallel-exporting countries, on the other hand, such policies may include regulatory and other measures that may result in limiting parallel exports of pharmaceuticals. Such measures are in addition to policies reviewed in previous sections and are summarised on column 4 of **table 4.3**.

#### *4.3.1. Denmark*

Currently, prices are kept at the average European level. This is the result of an agreement between the government and the pharmaceutical organization (LIF). Understandably, the higher the prices are, the more significant the PT potential and vice versa. The government – industry agreement seems to be somewhat motivated by the fact that EU-pricing would limit this potential. To what extent this has materialized is not known.

### *4.3.2. France*

The recent developments in French pricing and reimbursement represent a watershed in relations between the French MoH and the pharmaceutical industry. The authorities for the first time seem to be explicitly recognising the value of innovation, and, implicitly, show concern over the likely extent of parallel exports from France.

Among the numerous developments in French pharmaceutical policy, the one stirring the most interest is the price notification procedure for major new products, which is the first real attempt to address industry's complaints about the long delays involved in getting centralised products to market in France. The general agreement concluded between the pharmaceutical industry and the French Government (2003-2006) should reduce the time period from the pharmaceutical companies' applications regarding the pricing and reimbursement procedures to the effective commercialisation of innovative medicinal products.

For medicinal products evaluated under the centralised procedure, if a positive opinion is granted by the EMEA Committee of Proprietary Medicinal Products (CPMP) for human use, the applicant will be able to file a pre-instruction dossier with the French "Commission de la Transparence" (Transparency Commission) before the delivery of the European Marketing Authorisation (without prejudice of the final decision of the European Commission). Evaluation of the concerned medicinal product with respect to its registration on the French positive list of reimbursed products can thus start in France before the European Marketing Authorisation is granted.

For medicinal products with a high improvement in medical benefit (a high ASMR – Amélioration du Service Medical Rendu) a price notification procedure will apply. If the ASMR quoted by the "Transparency Commission" stands at level I or II

(i.e. medicinal products allowing an important therapeutic advance, or for which efficacy is importantly improved, or for which adverse reactions are importantly reduced), the pharmaceutical company can propose a convention including a selling price of the concerned medicinal products to the French Economic Committee of Health Products (pricing procedure). If the Economic Committee does not notify its opposition to this proposal in a time period of 15 days, this proposal is then considered as accepted by the Economic Committee, and the final agreement must be signed with the pharmaceutical company without further negotiations. This potentially implies free pricing for highly innovative medicines and, at the same time, reduced potential for parallel exports from France for these products.

### *4.3.3. Greece*

Greece is one of the most aggressive parallel exporting countries within the EU with parallel exports valued at nearly 22% of the retail market (see **Table 4.2**). The Greek pricing system for pharmaceuticals – taking the lowest EU price as the Greek price – keeps prices of prescription medicines low compared with other EU member states and, thus, stimulates parallel exports. Although there are no explicit policies in place attempting to restrict parallel exports, the Greek High Court ruled against the country's system of pricing, requesting that more countries than the lowest-priced country be considered in the determination of the price of a product in the Greek market. This would in principle raise the Greek pricing average, but little has changed since the publication of the ruling itself .

As recently as October 2001, the Greek National Drug Organisation (EOF) issued a circular according to which should report to them the quantities they export on a confidential basis.[cii] Additionally, EOF issued a further circular according to

which companies must supply the market with quantities needed to cover local needs (IMS) plus a 25% safety minimum.[ciii] This follows a further circular, published in 1998 expressing concerns about likely shortages in the domestic market. The driver behind this action was evidence of product shortages in different parts of the country attributed to parallel exporting activity, as argued by the local pharmacists' association (see **Table 4.4**).[15] However, little is known about the enforcement of these circulars, as, indeed, about the way they will be perceived by EU competition authorities.

### *4.3.4. Italy*

In Italy, most of the policies encouraging or discouraging parallel imports concern price regulation. Cross-reference pricing is extensively used. Firstly, most reimbursable products, which were already on the market in 1997 and those that are registered under the national procedure, are subject to the Average European Price (AEP). If prices are set above the AEP, products are automatically delisted. All EU prices (weighted on a consumption basis, excluding Luxembourg and Denmark) and nominal exchange rates are used to calculate the AEP[16]. Replacing the AEP system is under discussion. Since its adoption 1994, this system has been regarded as the most transparent way of regulating prices. Prices below the AEP were allowed to reach AEP at 6 annual steps (currently at step 3, although the timing of these steps has not been kept); step 4 will be applied only if a spending cap on pharmaceuticals is respected, which is currently unlikely. The first step was introduced in 1998, the second step in 1999, and the third step in 2001. The fact that several old products have

[15] Equally, one could also add here that manufacturers might be observing national quotas, which, in turn, makes parallel exportation more visible, at the time when it appears to have reached a significant proportion of the market.

[16] This AEP "version" amended the older method that was based on a simple average of process in the most important EU countries and Purchasing Power Parities, as conversion factors.

not yet reached the average European price, leads to the conclusion that the potential for parallel exports is still significant.

Secondly, pricing of products licensed through the centralised and mutual recognition procedures are negotiated with the central regulatory authority. This negotiation is based (among others) on prices in other European countries (as well as sales forecasts, prices of similar drugs, industrial policy parameters, and economic criteria for major innovations). Parallel exports are not a concern of regulators in Italy and, if a lower than average European price is awarded to a product during these negotiations, then the potential for parallel export remains high.

#### *4.3.6. Portugal*

Portugal's pricing system, of taking the lowest of France, Italy and Spain, often involves negotiations with the authorities, which frequently results in new products achieving the average European price. This indirectly shields the product in question from (extensive) parallel exports.

#### *4.3.6. Spain*

Spain, one of the strongest parallel export countries has recently become uncomfortable with it being considered a major base for parallel exports and has experimented with certain measures in an attempt to introduce transparency over what is distributed in the country and what is exported. In May 2003, the Spanish government proposed a decree allowing dual pricing for products that were parallel-exported, but this was withdrawn a few weeks after its initial introduction. In June 2003, the government introduced a further royal decree requesting that wholesalers register and report the destination of all their products, with emphasis on those which

are parallel-exported.[civ] However, as in the case of Greece that introduced a similar requirement in autumn 2001, little is known about the enforcement of this decree and compliance by wholesalers. Finally, there are also attempts to establish a database allowing access to aggregate data on parallel exports, although it is known when this will become operational and/or accessible.

### *4.3.7. Sweden*

In 2000, the Swedish drug regulatory authority, decreased the fee for parallel import applications and the annual fee for parallel imported products, as an indirect incentive to encourage more parallel import applications. The application fee for PI products currently stands at SKr15,000 (€1,647) compared with SKr200,000-340,000 (€29,960-37,331.5) for a new product. There is free pricing of PI products, if prices are lower than directly imported products.

### *4.3.8. United Kingdom*

In the UK, the latest PPRS Agreement (1999 – 2004) has allowed free price modulation with effect from January 1st, 2001, which has been interpreted by many, including the UK parallel traders association, as a policy that would allow UK-based pharmaceutical companies to fluctuate prices of drugs that are vulnerable to parallel importation in order to restrict their import potential. This presumption/argument has led to a judicial review of the PPRS, which, nevertheless, found in favour of the UK government, in the absence of any robust evidence that free price modulation can be perceived as encouraging pharmaceutical manufacturers to lower prices enough in order to discourage parallel importation.

### *4.3.9. Norway*

Parallel imported products are not specifically targeted in pharmaceutical policy; however, the "profit-sharing" system will encourage pharmacies to dispense cheaper medicines. With respect to discouraging policies it could be argued that Norway's current pricing policy, leading to a national price lower than the European average, limits the extent to which parallel importation is profitable. The maximum wholesaler price of a pharmaceutical product is set on to equal the average of the three lowest package prices found in a group of nine European countries (Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium and Ireland). Thus, the PIs have to resort to countries where the price may be lower, and cases where the Krone is strong in terms of the Euro.

### *4.4. Impact on patient access to medicines*

Theoretically, patients may benefit from pharmaceutical parallel trade through two channels, the one being direct, the other indirect. The direct channel relates to the reduced cost of medicines and the impact this may be having on patient out-of-pocket expenditure. The argument is that to the extent that patients pay a proportion of or all the cost of their medicines out-of-pocket, then parallel trade, through lower prices, can reduce this cost to the patient and enhance patient access to needed medicines. Nevertheless, benefits from this channel remain theoretical since the price difference between locally-sourced and PI products either accrues to health insurance organisations or is split between the latter and pharmacists.

The second channel is indirect and relates to savings that health insurance organisations make through parallel imports. In this case, patients may benefit from the re-allocation of such benefits to purchase better care for patients.

In order to consider the potential impact of the direct channel as described above, one would need to examine the structure of cost-sharing in each of the countries in question. As insurance rights are universal among the countries examined and, therefore, there are no uninsured who pay entirely out-of-pocket for the cost of their medicines, the only welfare improvement for insured patients would arise from the different co-payments (in absolute terms) they would have to pay in order to benefit financially from parallel trade.[17] The co-payment structure in the six countries under investigation is briefly outlined below. **Table 4.5** summarises the cost-sharing policies in each of the study countries.

[17] Of course, there are cases of rationed care or cases where patients' drug of choice is different to the one available and reimbursed by health insurance. In this case, patients contribute entirely out-of-pocket and, assuming there is a PI drug, there are direct financial benefits to them. However, universal coverage implies that patients are automatically insured for the cost of their medicines, particularly for acute, life-threatening and chronic conditions, subject to paying the statutory user charges where and when these apply. There are also cases of patients being insured privately, in which case,

### *4.4.1. Denmark*

In Denmark, the reimbursement system and, consequently, the policy on co-payments, is based on individual need, and the rates for reimbursable pharmaceuticals depend on a given patient's prior consumption of pharmaceuticals within an individual reimbursement period (usually 1 year). All reimbursable pharmaceuticals have an equal status from the point of view of reimbursement. In Denmark, as part of reimbursement reform, and the new rules that apply for reimbursement, co-payment and reimbursement rules for all patients have been updated. For adults, over the age of 18 years, the following regulations apply:

- The basic co-payment (in the form of a deductible) has been set at DKr 510 (€68.5). There is no reimbursement to patients if their annual pharmaceutical expenditure is up to DKr 510;
- Reimbursement is available at a rate of 50% for that part of the reimbursement price above DKr 510 but under DKr 1,230 (€165.2);
- Reimbursement is at 75% for that part of expenditure over DKr 1,230 but under DKr 2,875 (€386.2); and
- Reimbursement is at 85% for any amount exceeding DKr 2,875.
- There is a threshold of DKr 3,600 (€483.6), after which products treating chronic illnesses are reimbursed at 100%.
- With regards to children under 18 years of age, there exists a similar scale to that above, excluding the initial co-payment of DKr 510. However, under-18s are liable to a 50% co-payment for drug expenditures up to DKr 510.

Thus, co-payments in the context of the Danish health care system can be significant, however, their impact is marginal among patients with chronic needs.

### *4.4.2. Germany*

In Germany, the policy on co-payments is a fixed fee per pack and the larger the pack the smaller, proportionately, the fee payable. Patients, especially those with chronic conditions, typically prefer larger packs as the out-of-pocket cost to them is proportionately lower. Again, this does not allow patients to have an idea of the actual cost of drugs they consume; neither does it allow them to benefit financially from potentially available and lower priced PI versions.

### *4.4.3. The Netherlands*

As of September 2003, the Dutch policy on patient co-payments was very simple. No co-payments were in place, other than those in connection with the reference pricing system operating in the Netherlands, whereby patients pay out-of-pocket the difference between the reference price (pharmaceutical reimbursement system - GVS) and the purchasing price for the pharmacy of their drug of choice. Overall, patients pay on average 3.4% of total pharmaceutical expenditure (via community pharmacies) out-of-pocket.[cv,cvi] According to the Dutch Foundation on Pharmaceutical Data (SFK), this figure comprises a total of €18 million on actual co-payments from the price difference within the statutory reimbursement system (GVS), and €100 million on drugs that are not within the reference price system and are subject to full payment by patients (for instance expenditure on selected life-style drugs was: Viagra: €8 million; Orlistat: €4 million; Zyban: €4 million). Should only

the €18 million within GVS is taken into account, then patients bear 0.5% of the total cost of medicines in the Dutch market.[18]

### *4.4.5. Sweden*

In Sweden, according to the recent reimbursement reform, the system of co-payments has changed from a mix of deductibles and percentage co-insurance, to a deductible and a fixed fee per item up to a limit *per annum*. It is stipulated that those patients with the greatest need for pharmaceuticals, ie patients with chronic illness, must have access to drugs even if the cost of some new drugs exceeds SKr 100,000 (€10,980) for some patients. The patient co-payments are as follows:

- The accumulated total co-payment in a 12-month period (deductible) would remain unchanged at SKr 1,800 (€197.6). However, the cost of prescriptions for children under 18 within a family – which may be added together – would be reduced to SKr 900 (€98.8);
- The abolition of the reimbursement scale whereby reimbursement is granted at 50%, 75% or 90%, depending on accumulated total spend, until a patient reaches the SKr 1,800 threshold. Patients would not receive any reimbursement until the SKr 1,800 limit has been reached;
- The introduction of a SKr 40 (€4.4) co-payment per item for all prescriptions once an accumulated total spend of SKr 1,800 has been attained. Any additional medicine is currently distributed free of charge. This additional co-payment would be capped at SKr 1,000 (€109.8) (25 items) per annum.

Payment by instalment is currently permitted for poorer patients. The Swedish reimbursement system protects individuals who need large amounts of medicines

[18] The Dutch market stood at €3.42 billion in 2002.

from incurring large costs. Healthy individuals with a temporary need for treatment are to pay a larger proportion of their prescription costs than individuals with chronic diseases who need to use medicines continuously. For this reason, medicines come under purchase cost maximisation provided the RFV has set a selling price for the product. The term 'purchase cost maximisation' refers to a reduction of the purchase cost. The cost reduction is based on the total cost of reimbursable products purchased by the beneficiary in the course of a year, ie within a period of 12 months following the first purchase. The amount reimbursed is as follows:

A nationwide database, used by all pharmacies, ensures that a patient is correctly subsidised each time they have a prescription for a reimbursable product dispensed. The database keeps information on the amount that the patient has paid within twelve months from the initial purchase of a reimbursed drug.

Although the annual deductible is set at SKr 1,800, patient spending can exceed SKr 1,800 if the patient is prescribed a product that is within the reference pricing system and has a price above the reference price. In such situations the patient has to pay the difference between these two prices every time the drug is dispensed. No patient group is exempt from this co-payment. The only exemption from co-payment is for insulin which is fully reimbursed.

The idea of linking the subsidy to the price of the drug is to make both the prescribing doctor and the patient act in a more cost-efficient way. This can be achieved, eg by getting them to choose a cheaper drug or smaller packs.

#### *4.4.5. United Kingdom*

In the UK, over 80% of all prescriptions are co-payment free, as significant exemptions (age-/disease-specific) apply. For the rest, patients pay a fixed fee per

prescription (£6.20 [€8.9] from April 1st 2002, and £6.30 [€9.01] from April 1st, 2003), which does not allow patients to realise any direct benefits or to know the actual cost of drugs consumed. For patients with significant prescription needs, who are not exempt from the prescription charges, there are 4- and 12-month pre-paid certificates available at £32.90 (€47.1) and £90.40 (€129.3) respectively, thus also minimising the direct out-of-pocket cost of medicines to the patient.

### *4.4.6. Norway*

In Norway, reimbursement is restricted to therapies for long-term conditions, those for which more than 3 months' medication is needed. Hence, patients have to pay in full for most acute conditions and prophylaxis. For medicines accepted onto the reimbursement list, patient co-payments are, 0%, 12% or 30%, depending on the patient's age. Reimbursed medication for children under the age of 7 years free; for older children up to 16 years, and for adults over the age of 67 years, the co-payment is 12% with a maximum of NKr 150 (€17.5) per item on the prescription. For all other patients, contribution is 30% up to NKr 330 (€38.6) per item. A prescription cannot be for more than 3 months' supply of a medicine. Patients' liability for reimbursed prescription drugs and medical fees is limited to NKr 1,320 (€154.4) per person per year. In total, patient co-payments account for about one-third of total expenditure on pharmaceuticals.

### *4.5. Discussion and concluding remarks*

The material presented in this section has shown that all countries (even those considered to be parallel exporters) are introducing or amending legislation to account for parallel trading activities on their territory. IN particular, countries with lower than average price levels, notably Spain, France and Greece, seem to be concerned with the extent of parallel exports from their territory and also seem to be taking (or to have taken) action to account for these. In France, the pricing measures that have been introduced are strictly implicit and in accordance with European law. Spain has recently introduced a royal decree requiring wholesalers to disclose the destination of the products they acquire from manufacturers. Spain has also debated (but did not pass) an amendment in the medicines law allowing 'dual pricing' to pharmaceutical companies. France, in turn has introduced a price notification procedure for major new products, allowing, in principle, flexible pricing for innovative products. In Greece, there exist concerns about the extent of parallel trade and the product shortages that have been noticed and which have been linked with its conduct.

By contrast, traditionally high-price countries seem to have mature policies in place enabling their health insurance systems to benefit somewhat from parallel importation of pharmaceuticals. This is the case particularly in the UK, but also, in the Netherlands, Germany, and, to a lesser extent, Norway. Denmark and Sweden seem to be relying more on an information and substitution strategy rather than active promotion of PIs through financial incentives.

The stakeholders involved in PI distribution are statutory health insurance organisations, pharmacists, patients, parallel traders and pharmaceutical manufacturers. With the exception of parallel traders operating across borders, all other stakeholders are affected at national level.

The discussion in the previous sections highlighted that statutory health insurance organisations in source countries realise no benefits, whereas their counterpart organisations in destination countries may benefit in three ways: first, in the case of price differentials in the list prices of locally-sourced and PI pharmaceuticals the price difference accrues partly or in its entirety to them. In Sweden and Denmark, the entire price difference, where it exists, accrues to the health service and any savings are equal to this price difference times the volume of parallel imported product(s). In the Netherlands and Norway, the government involves pharmacists as direct agents to maximise its financial benefits, by surrendering part of these to pharmacists. In Norway, any likely financial benefits are equally split between the government and pharmacists, whereas in the Netherlands, the pharmacist, until recently, retained one third of the price difference, surrendering the remainder to the government.

The second source of potential revenue to health insurance organisations is the "clawback", which, according to the evidence presented, may arise either because of invisible discounts from wholesalers and parallel traders to pharmacists (UK, the Netherlands), or as a source of compulsion to pharmacists, operating in an environment of fixed wholesale and retail margins, to be able and procure from cheaper sources (Germany). Either way, health insurance organisations want to ensure that part of the benefits accruing to pharmacists by means of higher discounts, accrue to them in the form of lower reimbursement rates to the latter. Whereas discounts from wholesalers/parallel importers to pharmacists, where allowed, are not known with precision, both the UK and the Netherlands, that explicitly allow such discounts as the main source of income for pharmacists in the absence of fixed margins, rely on surveys to establish their approximate extent.

The third way through which health insurance might benefit is price competition, leading to (downward) price convergence in destination countries, although one cannot ascertain the extent to which this is possible.

Pharmacists can also be clear beneficiaries, first, in countries where pharmacy margins are not determined by regulation (e.g. the UK and the Netherlands) or, second, in countries where a financial incentive is provided to them to dispense a parallel-imported medicine (the Netherlands, Norway). In the former, benefits arise from individual negotiation, whereby pharmacists can negotiate discounts with parallel importers (as they do with all other wholesalers), thereby making it profitable to stock and dispense a parallel-imported medicine that carries the same or similar reimbursement price as a locally sourced one. These discounts are invisible and their extent can only be approximated via pharmacy surveys. In the latter case, there is an explicit government policy for pharmacists to keep a proportion of the price difference between the parallel-imported and locally sourced product (1/3 in the Netherlands and 50% in Norway). In these cases, health insurance organisations also benefit financially by retaining part of the price difference.

The benefits to patients in destination countries **theoretically** accrue from the lower prices of PI drugs and on the understanding that patients pay a significant proportion of their medication out-of-pocket; in theory this would reduce their overall medication costs and improve access to essential medicines. In practice, however, European health systems, particularly in the UK, the Netherlands, Germany, Denmark and Sweden (and, perhaps, less so in Norway), provide comprehensive cover with low cost-sharing requirements. In the UK and Germany, patients are not in a position of knowing or guessing the prices of medicines consumed, since they pay a flat fee per prescription (UK) or per pack (Germany). In the Netherlands, patients only pay the

difference between reference drugs and their drug of choice, should the latter be higher. In Denmark and Sweden, the structure of co-payments is slightly different, allowing for a combination of a deductible and a co-insurance up to a limit beyond which all patients are exempt, whereas in Norway a percentage co-payment applies, up to a limit per item. However, any potential direct financial benefits are of theoretical nature only, since any price difference between locally-sourced and PI products either accrues entirely to health insurance organisations (Denmark, Sweden), or is split equally between pharmacists and the health service (Norway). Consequently, it does not directly transpire that pharmaceutical parallel trade enhances patient access to medicines nor that parallel trade reduces prices to the consumers. By contrast, parallel trade may affect access to medicines in parallel exporting countries, as was shown in the case of Greece, where shortages were reported by the National Pharmacists' Association for several products.

At the other end of the spectrum, parallel importers act as profit maximisers, by observing and taking advantage of price differences for the same product between low- and high-price countries. These price differentials are not immediately observable by health insurance organisations. As a result, and given the regulatory structure in high-price countries, parallel importers have no incentive in principle to be altruistic and offer health insurance organisations in destination countries significantly lower prices for the same product than that of the locally-sourced equivalent. In this respect, a given product market in a parallel importing country, often resembles a duopoly. Understandably, parallel traders incur certain costs to import a medicine into a certain country and these are both indirect and direct. The indirect costs relate to search in low price countries, whereas the direct are associated with meeting the regulatory (safety) requirements. In this respect, there is an often

significant element of time and a modest financial element relating to application processing. Another direct cost is the discount they provide to pharmacists where this is allowed. According to some sources this can range between 1.6 and 23%, off the list price.

Finally, pharmaceutical manufacturers are incurring profit losses equivalent to the amount of the parallel import volume into the importing country times the price difference between exporting and importing country. This represents a loss to producer surplus, which is distributed to the above stakeholders.

By using the methodology developed in section 3, the following sections examine the impact of pharmaceutical parallel trade on the various stakeholders. In doing so, section 5 discusses some general trends on parallel trade, whereas section 6 evaluates the direct financial effect for 2002; sections 7 and 8 discuss the intra-country competition and the cross-country convergence effect for the 1997-2002 period respectively.

## 5. Aggregate trends on parallel trade over the 1997-2002 period

Whereas parallel imports (PI) commanded modest market shares in 1997, these increased considerably after 2000. This is a pattern that holds across products that were under patent protection throughout the study period, although patent expiry seems to have a negative effect on the intensity of parallel trade (see *table 5.1*). The effect of patent expiry on parallel trade can be seen on ACE I inhibitors and SSRIs, where PI market shares drop quite significantly from 2000 onwards, as patents on individual ACE inhibitors or SSRIs expire. This is an aggregate observation, nevertheless, it seems to lend support to the hypothesis that patent-protected products are most severely affected by the extent of parallel trade.

Overall, the share of parallel imports in individual product markets increases over time, from about 12% for the 6 product classes in 1997, to just under 20% in 2002; (see *figure 5.1*). Variations can be seen within countries, with Germany experiencing significant increases post-2000, from about 3% of the pharmacy market, to 10% by the end of 2002 (see *figure 5.2*). In the UK, the relevant market share is over 35% in 2002 increasing from 15% in 1997 (see *figure 5.3*), whereas in the Netherlands an overall decline is observed over the study period and for the six product categories from an average of 21.7% in 1997 to 14% in 2002 (see *figure 5.4*).

During the course of the study period, pharmaceutical policy remained unchanged in both Germany and the UK, with pricing freedom for new products and reference pricing for off-patent products in the former and the Pharmaceutical Price Regulation System (PPRS) in the latter.[19]

[19] Without, of course, excluding individual policy measures introduced within the context of national regulatory schemes, such as the price cuts or price freezes, target volumes for pharmaceuticals in individual practices or regional legally set spending caps in Germany over the study period; and the overall price cut (4.5%) associated with a price freeze for about just over a year for branded medicines

However, pharmaceutical policy changed quite significantly in the Netherlands over the study period. Until 1994, there had been no control on the setting of launch prices or restrictions on price changes in the Netherlands. Furthermore, no government had ever imposed price cuts or price freezes. In 1994, a price cut was negotiated, and in 1996 a price freeze was agreed. Both these measures applied to medicines already on the market and new medicines could be priced freely. The big change occurred in June 1996, when a new Drug Prices Act came into effect. The Act forbade companies from offering for sale, selling or supplying any medicine to pharmacists and dispensing doctors at a purchase price (ex-wholesale price), higher than the average of the average real pharmacy purchase prices of "comparable"[20] products in Belgium, France, Germany and the UK. The introduction of an average European pricing system in the Netherlands had an immediate effect of reducing prices of new medicines by an overall 20%,[cvii] and was coupled with the introduction of cost-effectiveness guidelines from summer 2000 onwards for products requesting a price premium.[cviii] These measures, particularly the introduction of the AEP in 1997 may have had an adverse impact on the extent of PI into the Netherlands.

Few PI drugs commanded significant market shares in the six study countries in 2002, but there are important differences across countries and among products (**Tables 5.1 and 5.2**). This is partly dependent on the opportunities for parallel trade, the price differentials between exporting and importing countries and the market size of destination countries. Certain products e.g., Losartan and Simvastatin in the UK, Olanzapine and Risperidone in Germany, command more than 60% of the total product market. Parallel imported Atorvastatin represents 54% of the product market

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within the context of the PPRS in the UK. This measure in the UK was estimated to yield a saving of £200 million per annum at current levels of spending.

[20] Comparability was defined as products having (a) the same active ingredient, (b) the same unit strength, and (c) comparable pharmaceutical form.

in the UK. For most other parallel imported products market shares range between 0 - 20% of the actual product retail market.

# 6. Direct financial effects from parallel trade

## 6.1. Denmark

### *6.1.1. General trends*

The total sales of the 19 products selected, were €138.7 million at PPP level, or just under 17% of the Danish brand prescription medicines market (see **Table 6.1**). Statins feature prominently, and account for 29% of total sales in the sample, of which simvastatin makes 16% of the entire sample. PPIs and SSRIs also have strong market shares (25% each as individual product classes), with omeprazole, simvastatin, citalopram, atorvastatin and sertraline featuring strongly (17%, 16%, 11%, 9% and 9% of total sample sales, respectively). With the exception of simvastatin, quinapril and paroxetine that have PI penetration (market shares) greater than 30% (56%, 39%, and 43%, respectively), and fluoxetine, ramipril, citalopram, sertraline and risperidone with market shares between 17-25%, in all other products, PI market shares range from 0-13% (**Table 6.1**, column 4). The weighted average market share of PI for all 19 products was 28.1% of the branded retail market. In 2002, and for 11 out of 19 products examined, the average price spread between locally-sourced and PI product in the Danish market was 6.6% or lower. Price spreads are higher than 6.6% for fluoxetine (14%), sertraline (19%), ramipril (22.6%), atorvastatin and paroxetine (26%), captopril and enalapril (30%), and risperidone (38%). The weighted average price spread between locally-sourced and PI product, like for like, was 8.4% in 2002 (**Table 6.1**, column 5).

### *6.1.2. Benefits to the Danish health care system*

In Denmark, the only source of direct financial benefits to the health care system is due to the price difference between the locally-sourced and PI product. From equation (3.5) we were able to calculate the direct savings to the health system and from equation (3.6) we were able to denominate these as a proportion of the total sales for the 19 products in our sample in 2002. Savings were calculated for all product presentations for each of the products involved. On the basis of IMS data, the total savings to health insurance from the 19 products examined amounted to just over €3 million, expressed at PPP level in 2002. Two products (simvastatin and sertraline) account for over three quarters (76.2%) of all reported savings to the health care system, (see **Table 6.1**). Four products (atorvastatin, citalopram, paroxetine, and ramipril) yield savings between €100,000 and €210,000 each. No parallel imports were recorded for losartan, valsartan, olanzapine, lapsoprazole, or pantoprazole in 2002. Consequently, financial benefits to sickness funds are concentrated in a handful of products, whereas for the remainder, direct financial benefits are very small. As a proportion of total product sales, direct financial benefits to sickness funds, ranged between 0.1% - 1.7%, the only outliers being paroxetine (4.3%), simvastatin (5%) and sertraline (9.2%). Total savings for all 19 products, as a proportion of total branded sales at PPP level stood at 2.2%. We were able to calculate savings on a product-by-product and presentation-by-presentation basis. Whereas several product presentations are available for a given product, it is usually the most popular presentation or the two most popular presentations that yield the highest (proportionately) savings to health insurance. In **Table 6.2**, and for the product with the highest market penetration in the Danish market (simvastatin), we confirm that the vast majority of savings to health

insurance (86%) accrue from just two presentations (10mg, 98 pack; and 20mg 98 pack). The most popular presentation yields 55.7% of the total product savings.

### *6.1.3. Benefits to patients*

There are no direct financial benefits accruing to patients from the conduct of parallel trade in Denmark. Price differences between locally-sourced and PI products accrue in their entirety to the Danish health care system.

### *6.1.4. Benefits to pharmacists*

In Denmark, pharmacists do not necessarily benefit directly from parallel trade because of the fixed margins they operate with. There are no explicit or implicit financial incentives for them to dispense a PI medicine, although the Danish substitution law requires that pharmacies inform patients of the availability of the cheapest PI source when savings reach a certain level on a prescribed product (see section 4.1.1).

### *6.1.5. Benefits to parallel importers*

Based on equation 3.7 we were able to derive parallel importers' maximum gross financial benefits. We applied the principle of the lowest priced country as the sole source of PI for a particular product presentation as well as the principle of the three lowest priced EU countries for the same purpose. We find that by applying either principle, gross financial benefits accruing to parallel importers are a multiple of benefits accruing to the health care system, and ranged between €6 million and

€7.4 million in 2002 for the same products and at PPP prices[21]. This, expressed as a proportion of total sales for the 19 products we examined, ranged between 4.3% and 5.3%. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter comes from the lowest PPP price in the EU. Gross profits from simvastatin, and citalopram, two products generating significant savings in Denmark and had large market shares in 2002, account for over three quarters of all gross profits (**Table 6.1**). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found that the average mark up in Denmark was 38% in 2002 for the 19 products we examined, ranging from 9% (for sertraline) to 60% (for clozapine) (**Table 6.18**).

### *6.1.6. Impact on industry*

The direct impact on industry in Denmark is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and Denmark for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to sickness funds plus the gross profits to parallel importers. For the 19 products included in this study, the total loss of profitability to industry ranges from €9,029.3 million to €10,373.2 million.

[21] We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figures for Denmark are €1,071 (annual fee) and €2,033.4 (application fee) to obtain marketing authorization for 5 years.

### *6.1.7. Overall conclusions*

Prices of PI medicines are on average 8.4% lower than those of locally sourced equivalents and penetration rates of PI medicines vary significantly. The extent of parallel trade has increased over time and in 2002 accounted for 28.1% of the brand retail market. Few products yield significant savings to health insurance and, by implication, significant profits to parallel importers. Within the context of the Danish health care system and its cost-sharing structure, patients can benefit modestly if their condition is acute and requires extensive treatment with medications. Pharmacists have neither incentives nor disincentives to dispense PI drugs but are obliged to do so by the Danish substitution laws, if a PI drug is available. Pharmaceutical parallel trade does have a modest direct financial impact on the total cost of medicines reimbursed by the health care system to the order of 2.2%. The majority of pecuniary benefits accrue to parallel importers, and less so to the health service by a ratio of 2.01:1 – 2.46:1. Industry incurs a loss in market share in Denmark and a significant loss in profits, which are re-distributed to health insurance and parallel importers.

## 6.2. Germany

### *6.2.1. General trends*

The total sales of the 19 products selected, were €2.21 billion at PPP level, or just under 13% of the German brand prescription medicines market (see **Table 6.3**). Statins feature prominently, and account for 35% of total sales in the sample. Enalapril, ramipril, omeprazole, and pantoprazole also feature strongly (7%, 5%, 16% and 9% of total sample sales, respectively). With the exception of olanzapine, risperidone, lansoprazole and fluoxetine that have PI penetration (market shares) greater than 35% (62%, 62%, 39% and 37%, respectively), and citalopram and paroxetine with market shares between 28-30%, in all other products, PI market shares range from 1-11% (**Table 6.3**, column 4). The weighted average market share of PI for all 19 products was 13.5% of the branded retail market. For 11 out of 19 products examined in 2002, the average price spread between locally-sourced and PI product in the German market was 10% or lower. Price spreads are higher than 10% for lansoprazole (11%), pantoprazole (11%), fluoxetine (21%), paroxetine (15%), and enalapril (13%). For 3 products (atorvastatin, losartan, and clozapine), there were no PI in 2002. The weighted average price spread between locally-sourced and PI products, like for like, was 6.7% in 2002 (**Table 6.3**, column 5). Products with small PI market shares offer higher discounts on average compared with those with large market shares, although this principle does not always hold.

### *6.2.2. Benefits to health insurance*

From equation (3.5) we were able to calculate the direct savings to sickness funds and from equation (3.6) we were able to denominate these as a proportion of the total sales

for the 19 products in our sample in 2002. Savings were calculated for all product presentations for each of the products involved. On the basis of IMS data, the total savings to health insurance from the 19 products examined amounted to just over €17.7 million, expressed at PPP level in 2002. Two products (olanzapine and risperidone) account for over half (54%) of all reported savings to the sickness funds, whereas further 4 products (simvastatin, lansoprazole, pantoprazole, and paroxetine) yield benefits to sickness funds exceeding €1 million each (see **Table 6.3**). Six products (pravastatin, captopril, enalapril, quinapril, ramipril and omeprazole) yield savings below €100,000 each. No parallel imports were recorded for atorvastatin and clozapine in 2002. Consequently, financial benefits to sickness funds are concentrated in a handful of products, whereas for the remainder, direct financial benefits are very small. As a proportion of total product sales, direct financial benefits to sickness funds, ranged between 0.004% - 3.5%, the only outliers being risperidone (6.5%) and lansoprazole (6.2%). Total savings for all 19 products, as a proportion of total branded sales at PPP level stood at 0.8%.

We were able to calculate savings on a product-by-product and presentation-by-presentation basis. Whereas several product presentations are available for a given product, it is usually the most popular presentations that yield the highest (proportionately) savings to health insurance. In **Table 6.4**, and for the product with the highest market penetration in the German market (risperidone), we confirm that the majority of savings to health insurance (60%) accrue from just four (out of the 23 available) product presentations. The most popular presentation yields 26.2% of the total product savings.

### *6.2.3. Benefits to patients*

The products we have considered in this exercise are prescription only medicines and, as such, are subject to modest co-payments by patients, which are related to the product's pack size. Any additional co-payments relate to the difference between the reference price and the drug of choice.

Within the context of the current exercise, patients cannot draw any benefit from parallel trade in Germany, since the cost-sharing structure is a fixed fee related to pack size, alongside a reference pricing system mostly in patent-expired medicines, which has practically no implications for the cost of PI medicines to patients. Furthermore, any price difference between locally-sourced and PI products accrues to sickness funds. We can therefore attribute the benefits to patients to be zero. This does not lend any support to the argument that lower prices from parallel trade also benefit patients via improved access to medicines. This argument might only have validity in the case where patients receive their medications on the basis of private prescriptions and, consequently, have to bear the entire cost out-of-pocket. In this case, any price difference between the locally-sourced and the equivalent PI product would accrue to the patient rather than the insurance company, so long as the latter did not have a prescription drug benefit in place similar to that provided by statutory health insurance.

### *6.2.4. Benefits to pharmacists*

Pharmacists do not benefit directly from parallel trade as they had to observe their PI quota in 2002 as well as operate in a fixed margins environment. The latter, in principle, does not allow (significant) discounts from wholesalers, although, as discussed previously, in practice discounts are routinely offered; however, their extent

is unknown or can be traced with difficulty and may be product specific. Consequently, direct and visible financial benefits to pharmacists are zero, whereas there may be positive but invisible financial benefits to them.

### *6.2.5. Benefits to parallel importers*

Based on equation 3.7 we were able to derive parallel importers' maximum gross financial benefits. We applied the principle of the lowest priced country as the sole source of PI for a particular product formulation as well as the principle of the three lowest priced EU countries for the same purpose. We find that by applying either principle, gross financial benefits accruing to parallel importers are a multiple of sickness fund financial benefits, and ranged between €80.3 million and €98 million in 2002 for the same products and at PPP prices[22]. Expressed as a proportion of total sales for the 19 products we examined, these benefits ranged between 3.6% and 4.4%. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter from the lowest PPP price in the EU. Gross profits from olanzapine and risperidone, the two most heavily PI products in the German market, account for just under two thirds of all gross profits (**Table 6.3**). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found that the average mark up in Germany was 53% in 2002 for the 19 products we examined, ranging from 23% (for pravastatin) to 92% (for captopril) (**Table 6.18**).

[22] We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figure for Germany is €1,380 to obtain marketing authorization for 5 years.

### *6.2.6. Impact on industry*

The direct impact on industry in Germany is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and Germany for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to sickness funds plus the gross profits to parallel importers. For the 19 products included in this study, the total loss of profitability to industry ranges from €98 million to €115.7 million.

### *6.2.7. Overall conclusions*

The spread between prices of locally-sourced versus PI medicines is on average 6.7% and penetration rates of PI medicines vary significantly. The extent of parallel trade has increased over time and in 2002 accounted for 13.5% of the brand retail market. Few products yield significant savings to health insurance and, equally, few products yield significant profits to parallel importers. Patients cannot benefit directly in a market where the majority of products are reimbursed by health insurance; however, they could benefit financially (by the price difference between locally sourced and PI product) if they obtain a prescription for a product that is not reimbursed by health insurance. Pharmacists faced a 5.5% PI quota in 2002 (and an even higher one in 2003) and can incur penalties if they do not dispense a PI drug if the latter is available. Pharmaceutical parallel trade does have a modest direct financial impact on the total cost of medicines reimbursed by sickness funds to the order of 0.8%. The majority of pecuniary benefits accrue to parallel importers, and less so to sickness

funds by a ratio of 4.53:1 to 5.53:1. Industry incurs a loss in market share in Germany and a significant loss in profits, which are re-distributed to health insurance and, mostly, to parallel importers.