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**Parallel Trading in Medicines:
Europe's Experience and Its Implications for
Commercial Drug Importation in the United States**

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FOREWORD

While American policymakers debate the cost and safety issues associated with legalizing the importation of prescription drugs, cross-border importation has long been taking place within the European Union (EU). The EU has three decades of experience with *commercial parallel trade* of pharmaceuticals between countries. Under this practice, pharmacies and wholesalers in countries with relatively high drug prices (e.g., Germany or the United Kingdom) are allowed to purchase the identical products from EU member states with lower prices (e.g., Spain or Greece) for resale in their country, even though they may be protected by patents.

In an effort to understand the implications of legalized commercial drug importation for the United States, AARP's Public Policy Institute has investigated the EU's regulatory structure and experience with parallel trade of pharmaceuticals, focusing on the legal provisions that allow parallel trade; the safety of imported drugs; the distribution of cost differences among consumers, health insurers, and distributors; and the impact of parallel trade on pharmaceutical research and development. When considering the EU experience, it is particularly important to recognize the differences in existing drug coverage between many EU countries and the U.S. and how these differences are likely to affect consumer savings. Even though this report does not provide all of the answers that policymakers need in assessing the pros and cons of legalized drug importation in the United States, it is hoped that the information contained herein will contribute to and enhance the policy debate.

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EXECUTIVE SUMMARY

Background

It is illegal for Americans to import prescription drugs either for personal use or for resale (except under very limited circumstances). Although there is broad public support for legalizing drug importation from certain countries, the federal government has not, to date, exercised its authority to allow importation of prescription drugs on the basis that the high costs of ensuring the safety of imported drugs would outweigh the small benefit that consumers would receive from lower prices. Nevertheless, Congress continues to consider legislation that would allow drug importation from Canada and other industrialized countries, and many U.S. states and localities are seeking ways to legally import low-cost versions of branded medicines.

As the drug importation debate proceeds in the United States, a large body of experience in this practice has been established over the last 25 years within the original 15 member states of the European Union (EU) and other Western European countries that allow commercial importation of pharmaceuticals.¹ This practice, formally known as parallel importing (PI), is defined in the EU as the legal importation of specific branded drugs, by licensed distributors, from one country's market into another. Parallel importing is not only legal but is strongly encouraged as national policy in some EU countries, including countries with a strong research-based pharmaceutical industry. In some EU countries with relatively high prescription drug prices, parallel importing was estimated to account for as much as 20 percent of total brand name prescription drug sales in 2002.

Purpose and Methodology

The purpose of this *Issue Paper* is to examine the European experience with parallel trade of pharmaceuticals with respect to the following questions:

1. What legal framework is used in the EU to implement commercial drug importation and to maintain safety?
2. Are there drug safety problems among EU countries that engage in parallel importing of pharmaceuticals?
3. Are there savings from importation in the EU, and to whom do savings accrue?
4. Does parallel importing seem to have an adverse effect on pharmaceutical research and development (R&D) and the future development of innovative new medications?

This analysis is limited to the EU's experience with commercial importation (that is, importation by drug wholesalers that are licensed to engage in parallel trade). Therefore, one cannot use the findings of this research to draw conclusions about the potential impact of

¹ Throughout this paper, discussions about EU countries may also include reference to Norway, Iceland, and/or Liechtenstein, which are not members of the EU but are members of the broader European Economic Area (EEA), which is composed of the EU and these three countries. In general, EU regulations and rulings of the European Court of Justice (ECJ) relating to parallel trade are also applicable to the EEA.

personal importation of pharmaceuticals (including internet purchases from licensed foreign pharmacies) in the United States.

The data and information used in this analysis were acquired through primary and secondary sources. Primary sources included interviews and discussions with European experts on economic, regulatory, and drug safety issues. Secondary sources consisted of reviews of peer reviewed and other published literature on the issue of parallel trade in pharmaceuticals, the authors' review of legal cases, opinions, and rulings from national courts in the EU and the European Court of Justice (ECJ), and unpublished literature on parallel trade.

Principal Findings

Legal and Regulatory Framework Supporting Commercial Parallel Trade in Europe

The practice of parallel trade of pharmaceuticals simply means that a licensed pharmaceutical distributor in any EU member state can, after obtaining proper authorization, import any drug from another member state, so long as the drug that is being imported is identical to the drug that is locally sourced, that is, it contains the same active ingredient and is produced by the same manufacturer. Controversy over parallel trade in the EU primarily has focused on: (1) the principle of free movement of goods between member countries versus the intellectual property rights of patent holders to limit where and how their products are sold and (2) the principle that member states retain the right to govern property ownership (including ownership of intellectual property). The European Court of Justice (ECJ) has consistently ruled that EU member states may not prohibit a product—even a patented product—from being resold in any member state once the product has legitimately been put on the market in one member state.

However, there are certain limitations on parallel trade. For example: (1) the EU treaty does not allow products to be parallel imported from outside of the EU (and the European Economic Area) so long as a marketing authorization holder operates within the EU; (2) drug manufacturers are allowed to block the sale of an imported product if its original packaging has been modified in a way other than what is necessary to permit its sale in the importing country; (3) member states are allowed to prohibit or limit exports to protect human life and public health; (4) manufacturers can manage their inventories of a given product in a member state, so long as they do not explicitly ban exports to other member states.

In addition to EU policies that allow parallel importing of pharmaceuticals, some member states have policies *promoting* the use of parallel imports. These policies, which are in place even in countries that are home to a vibrant research-based pharmaceutical manufacturing sector, may take the form of government-approved incentives for pharmacies and/or health care providers to purchase cheaper branded drugs from EU countries that impose lower medicine prices.

The EU and its member states have strict regulations that are designed to ensure the safety of pharmaceutical parallel imports. Importation is allowed only by licensed distributors. Importers are required to abide by either centralized EU regulations or national regulations that are carried out by regulatory entities analogous to the U.S. Food and Drug Administration (FDA). While differing slightly from one another, these entities establish the

same standards for drug safety, quality, and efficacy. In addition, drug manufacturers have the right to recall any parallel imported product that violates safety standards or threatens the value of their trademarks. As a result, the safety of drugs imported from fellow member states is not perceived as either a significant public policy issue or as a threat to public health.

Evidence on the Effects of Commercial Parallel Trade of Pharmaceuticals on Safety, Access, Costs, and the Pharmaceutical Industry

- **Drug safety.** The European experience provides important insights into issues such as drug safety—specifically that safety problems and issues regarding the supply of PI drugs are few and relatively insignificant. No documented cases of counterfeit drug supply have to date been attributed to parallel trade. While some problems have been reported with the repackaging of, the relabeling, and the placement of consumer inserts in a number of PI pharmaceutical packages, such problems do not seem to raise significant concerns among consumers and health care providers in the EU even though incorrect or inadequate information in consumer inserts could present a serious threat to public health. No information is available on the extent to which identified problems have (or have not) caused health consequences.
- **Impact on drug supply in exporting countries.** While there have been anecdotal reports of drug shortages in exporting countries, there is no widespread evidence of shortages.
- **Distribution of price savings among stakeholders.** While the European experience suggests that a relatively small share of the savings from parallel importing accrue to consumers and health financing systems, this may be due in large part to health insurance systems in EU countries that offer consumers few (if any) incentives to seek lower-priced drugs and in which drug prices are already regulated. The degree to which drug importation provides savings to consumers and to the health care system is heavily influenced by the financial incentives and regulatory structures of the importing country's health care market, as well as by the consistent availability of imported products. In practice, any efficiency savings from lower drug costs are usually plowed back into the system to maintain benefit levels, in effect providing savings to the health care system by limiting the expenditures needed to maintain those benefits.
- **Impact on drug manufacturers.** Any price reductions and/or increased supplier profits that occur as a result of parallel trade of pharmaceuticals in the EU likely come from reduced revenues to pharmaceutical manufacturers. However, it is difficult to determine how lower manufacturer revenues associated with PI affect pharmaceutical R&D spending and even more difficult to predict how any changes in spending might affect the development of innovative drug treatments.

The Relevance of the EU Experience for U.S. Medicine Purchasers and Users

The European experience shows that commercial importation from countries with strong drug regulatory systems can take place without apparent adverse consequences to consumers. However, the EU's experience with incorrect labeling or consumer inserts on some PI drug packages also suggests that close monitoring of the quality of information contained on and in imported drug packages is important.

The evidence from Europe suggests that, for consumers to benefit from parallel distribution five conditions need to be satisfied simultaneously. First, consumers need to have a financial incentive to seek lower cost drugs, either because they pay a substantial share of drug costs or they lack prescription drug coverage. Second, consumers must be aware that the parallel-distributed option may be available and actively seek to have a PI version from their pharmacy. At the same time, pharmacies or third-party payers may need to actively inform consumers that lower-priced PI drugs are an available option. Third, price differences between parallel-distributed and locally sourced drugs have to be meaningful for payers to be able to see in practice that they can benefit financially. Fourth, a sustainable supply of parallel-distributed drugs needs to be in place for consumers to realize financial benefits over the longer term. Fifth, the perception of the parallel-distributed and locally sourced drug must be the same or comparable, i.e., consumers must not perceive a parallel-distributed medicine with scepticism and, as is sometimes the case in Europe, suspicion (in most cases due to different packaging compared with what they are used to, different language on the box, a different color pill, or other similar variables).

Conclusions

Even if all of the legal and policy issues associated with legalizing drug importation were overcome, such an approach, while reducing prescription drug costs for many individuals, would not necessarily by itself make drug costs affordable to American consumers or reduce the burden of rising pharmaceutical costs faced by consumers and their third-party payers. Actions to promote more cost-effective use of pharmaceuticals, such as the United Kingdom's establishment of the National Institute for Health and Clinical Excellence (NICE) to conduct and disseminate research on comparable effectiveness of medical treatments, could well play a greater role than parallel trade in rationalizing pharmaceutical costs over the long term.

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1. INTRODUCTION

Background

Rising prescription drug prices in the United States have led to an increase in demand by American consumers for access to prescription drugs at prices paid in other countries. Consumers of prescription drugs in the United States face two financial burdens that consumers in Europe and Canada do not. First, Americans—particularly those without health insurance—tend to pay the highest prices in the world for many prescription drugs. On average, manufacturer prices for 54 widely used brand-name prescription drugs in countries such as Australia, Canada, France, Germany, Greece, and the United Kingdom ranged from roughly 40 percent to 60 percent of U.S. prices in 2003.² Second, while most Europeans and Canadians have nearly comprehensive coverage for prescription drugs, many Americans pay a substantial share of prescription drugs costs, either because they lack health insurance coverage or because their insurance imposes substantial cost sharing.

Although many Americans have lowered their prescription drug costs by purchasing their drugs from other countries—either in person at foreign pharmacies or through mail-order pharmacies—it is against current U.S. law for anyone other than the manufacturer to import medications into the United States except under very limited circumstances.³ This limitation applies to both importation for personal use (personal importation) and importation for resale (commercial importation). It is also illegal to advertise or otherwise promote imported drugs in the United States. However, the federal government has not strictly enforced its ban on individuals importing prescription drugs for personal use, and the U.S. Department of Health and Human Services (HHS) estimates that Canadian pharmacies alone filled 12 million prescriptions for U.S. residents in 2003, with an equivalent number of prescriptions illegally entering the United States from other countries.⁴

Efforts have been made at both the Federal and state levels to legalize limited importation of prescription drugs into the United States. In 2000, for example, Congress passed legislation that would allow commercial importation—that is, importation by wholesalers and pharmacists—of Food and Drug Administration (FDA)-approved drugs for sale in the United States, as long as the HHS secretary could certify to Congress that implementing the new law would pose no additional risk to public health and safety and would result in a significant reduction in the cost of prescription drugs to American consumers. More recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (known as MMA) directs the HHS secretary to promulgate regulations to allow U.S. pharmacists and wholesalers to import prescription drugs from Canada. This law also requires the secretary to establish safeguards to ensure that drugs imported from Canada are safe and effective, and it establishes standards with which an importer must comply.

Despite these measures, commercial and personal importation of prescription drugs into the United States remains illegal, largely because of safety concerns regarding imported

²Prices are for sales to retail outlets only; HHS Task Force on Drug Importation. *Report on Prescription Drug Importation*. Washington, DC: U.S. Department of Health and Human Services (December 2004).

³The FDA does exercise some discretion in enforcing its policy on drug importation for personal use. For example, the FDA may allow individuals to import up to a three-month supply of drugs for personal use if the intended use is for a serious condition for which an effective treatment may not be available in the United States. See HHS Task Force on Drug Importation, 2004, p. 5.

⁴HHS Task Force on Drug Importation, 2004.

drugs. Both the 2000 and 2003 laws required safety certifications by the HHS secretary, and failure to provide these certifications has prevented the laws' importation provisions from being implemented. Most recently, an MMA-mandated HHS task force on drug importation concluded in its December 2004 report that it would be possible to safely import drugs through commercial distributors from Canada, but that doing so would result in little savings and would require substantial costs and legislative action to ensure safety. The report also recommended continuing the ban on personal importation, asserting that it would be extraordinarily difficult and costly for the FDA to ensure the safety and effectiveness of imported drugs. The task force concluded that legalized drug importation would adversely affect research and development for new pharmaceuticals; could raise legal and constitutional challenges to enforcement of intellectual property rights and trade agreements with foreign countries; and would create substantial liability concerns among consumers, manufacturers, distributors, pharmacies, and other entities. It also noted that some imported drugs—particularly generics—are usually more expensive than U.S. generics.

Despite the conclusions of the HHS task force, there is still strong popular support in the United States for allowing importation of prescription drugs—particularly from Canada.⁵ Congress continues to consider legislation that would allow commercial and personal drug importation from Canada and other industrialized countries,⁶ and many U.S. states and localities are seeking ways to import low-cost versions of branded medicines that are sold (and might originally have been made) in America; some have already begun to do so.

As this debate proceeds in the United States, a large body of experience in cross-border trade of prescription drugs has been established over the last 25 years within the original 15 member states of the European Union (EU) and other Western European countries that allow commercial importation of pharmaceuticals. This practice, formally known as parallel importing, is defined in the EU as the legal importation of specific branded drugs from one country's market into another by licensed distributors.⁷ (Personal importing of prescription drugs is not legal within the EU.) Parallel importing is not only legal but is strongly encouraged as national policy in some EU countries, including countries with a vibrant research-based pharmaceutical industry. Such importing takes place within a context of an economic union of countries that has established standardized requirements for free trade of goods as well as country-specific systems for providing universal and comprehensive health insurance coverage and regulating prescription drug prices.

⁵ For example, 79 percent of respondents in a July 2004 AARP poll of Americans aged 50 and over supported legalizing importation of prescription drugs from Canada. *AARP July 2004 Rx Importation Survey: News Release*, July 16, 2004. Retrieved from www.aarp.org/research/health/drugs/a2004-07-16-survey.html.

⁶ See, for example, S.334/H.R.700 *Pharmaceutical Market Access and Drug Safety Act of 2005*; S.184/H.R. 275, *IMPORT Act of 2005*; S.109/H.R. 328, *Pharmaceutical Market Access Act of 2005*, 109th Congress.

⁷ See, for example, Maskus KE (2002). Parallel imports in a model of vertical distribution: theory, evidence and policy. *Pacific Economic Review*, 7:319–334; Knox D, Richardson M (2002). Trade policy and parallel imports. *European Journal of Political Economy*, 19:133–151; Richardson M (2002). An elementary proposition concerning parallel imports. *Journal of International Economics*, 56:233-245; Maskus KE, Chen Y (2003). Vertical price control and parallel imports: Theory and evidence. *Review of International Economics*:12 (4):551-557; Ahmadi R, Yang BR (2000). Parallel imports: challenges from unauthorized distribution channels. *Marketing Science*, 19(3):279–294; Malueg DA, Schwarz M (1994). Parallel imports, demand dispersion and international price discrimination. *Journal of International Economics*, 37:187–196.

Purpose and Methodology

The purpose of this *Issue Paper* is to assess the EU experience with parallel importing of pharmaceuticals and to draw from that experience lessons for the United States. Specifically, it examines the European experience with parallel trade of pharmaceuticals with respect to the following questions:

1. What legal framework is used in the EU to implement drug importation and to maintain safety?
2. Are there drug safety problems among EU countries that engage in parallel importing of pharmaceuticals?
3. Are there savings from importation in the EU, and to whom do savings accrue?
4. Does parallel importing seem to have an adverse effect on pharmaceutical research and development (R&D) and the future development of innovative new medications?

This analysis is limited to the EU's experience with commercial parallel importation (that is, importation by drug wholesalers that are licensed to engage in parallel trade). Therefore, one cannot use the findings of this research to draw conclusions about the potential impact of personal importation of pharmaceuticals (including internet purchases from licensed foreign pharmacies) in the United States.

An additional caveat is that the reference to member states of the EU is limited to the 15 countries that were EU members before the beginning of May 2004 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, the Netherlands, and the United Kingdom).⁸ Ten new European countries (eight from Eastern Europe, plus Cyprus and Malta) joined the EU in May 2004. EU enlargement meant that parallel trade would be allowed from these countries only as long as their intellectual property rights provisions were identical to those prevailing in the EU for the product in question; otherwise, parallel trade from these countries would not be allowed.

The data and information for this study were acquired through primary and secondary sources. Primary sources included interviews and discussions with 12 national experts in 11 European countries on the basis of a mailed questionnaire on economic and regulatory issues (Appendix A); six additional experts provided insights on drug safety issues on the basis of a list of questions sent to them (Appendix B).⁹ The questionnaires were administered in January 2004, and all of the contacted experts completed and returned their surveys. Of the remaining six experts, two discussed the EU legal framework (European Commission), two discussed the treatment of parallel imports by the European Medicines Evaluation Agency (EMA), one commented on safety issues from a member state perspective (Medicines and Healthcare Products Regulatory Agency [MHRA]), and one provided an industry perspective

⁸ Throughout this paper, discussions about EU countries may also include reference to Norway, Iceland, and/or Liechtenstein, which are not members of the EU but are members of the broader European Economic Area (EEA), which is composed of the EU and these three countries. In general, EU regulations and rulings of the European Court of Justice (ECJ) relating to parallel trade are also applicable to the EEA.

⁹ These 11 countries were Denmark, France, Germany, Greece, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom.

of parallel trade regulation in EU member states (Association of the British Pharmaceutical Industry [ABPI]).

Secondary sources consisted of:

- Searches in the peer reviewed literature on the issue of parallel trade in pharmaceuticals (keywords included pharmaceutical parallel trade, drug parallel trade, parallel importation, and drug reimportation).
- Other published literature, including discussion papers and other documents from government bodies, supranational organizations (e.g., European Commission, European Parliament), and international organizations, as well as reports from market researchers.
- The authors' review of legal cases and opinions or rulings from national courts in the EU and from the European Court of Justice (ECJ).
- Unpublished literature, including informal reports and other gray literature.

Monetary values used in this paper were converted from foreign currencies into U.S. dollars using the June 2, 2005 currency exchange rates listed on the website <http://www.x-rates.com>. The currency exchange rates found at this website are gathered from the Federal Reserve Bank of New York, representing the 12 noon buying rates and the International Monetary Fund, according to their availability.

The paper is organized as follows. The next section (2) presents background on the reasons why parallel trade exists in the EU and the scope of such trade. Section 3 presents the legal framework for parallel trade of pharmaceuticals. Section 4 describes the provisions for ensuring the safety of imported drugs in Europe. Section 5 discusses the effects of parallel trade of pharmaceuticals on safety, costs, and the pharmaceutical industry. Section 6 discusses implications of the EU experience for the United States.

2. REASONS FOR AND SCOPE OF COMMERCIAL PARALLEL TRADE OF PHARMACEUTICALS IN EUROPE

A fundamental principle underpinning European health systems is universal, publicly financed or publicly regulated health insurance coverage that includes prescription drugs. Universal prescription drug coverage, coupled with minor copayments, implies that, in many European countries, consumers typically have little or no incentive to resort to parallel importing for personal use. For example, as shown in Table 1, cost sharing per prescription in Germany and the United Kingdom is limited to a maximum of about US\$12, while in the Netherlands there is no cost sharing for prescription drugs priced at or below the reference price of therapeutically similar medications. In fact, parallel trade in Europe is associated exclusively with commercial importation, notably by parallel distributors (PDs), which are wholesalers whose activities are regulated by the country in which they are incorporated. Typically, parallel distributors are subjected to the same regulation by member states as are wholesalers.

Table 1: Cost Sharing for Pharmaceuticals in Selected European Countries, 2004

Country	Type of cost sharing for all prescription pharmaceuticals
Denmark	<ul style="list-style-type: none"> • Deductible: DKK 510 (about US\$85) annually (no deductible for children) • Coinsurance of 15%–50% of drug price (lower coinsurance at higher levels of cost) • Out-of-pocket spending limit for persons with chronic illnesses.
Germany	<ul style="list-style-type: none"> • Coinsurance: 10%, up to a maximum of €10 per prescription (about US\$12)
Netherlands	<ul style="list-style-type: none"> • No cost sharing for drugs at or below the reference price • For nonreference products, consumers must pay the amount by which the product's price exceeds the reference price
Sweden	<ul style="list-style-type: none"> • Annual deductible of SEK 900 (about US\$120) • Declining co-insurance for drugs costing between SEK900 (about US\$120) and SEK4,300 (about US\$575) • Total annual co-payment ceiling (including deductible) per person or per family, is SEK1,800 (about US\$240)
United Kingdom	<ul style="list-style-type: none"> • Copayment UK£6.40 (about US\$12)* • No cost sharing for elderly, children, low-income citizens, and persons with certain chronic conditions
Norway	<ul style="list-style-type: none"> • No coinsurance for children under age 7 • Coinsurance of 12% for children 7–16 years old and elderly (up to about US\$23 per prescription); 30% for all others (up to about US\$50 per prescription)

*The copayment in the UK increased to UK£6.50 as of April 1, 2005.

Source: Authors' analysis of a questionnaire of policies facilitating pharmaceutical parallel trade in selected EU countries, 2004.

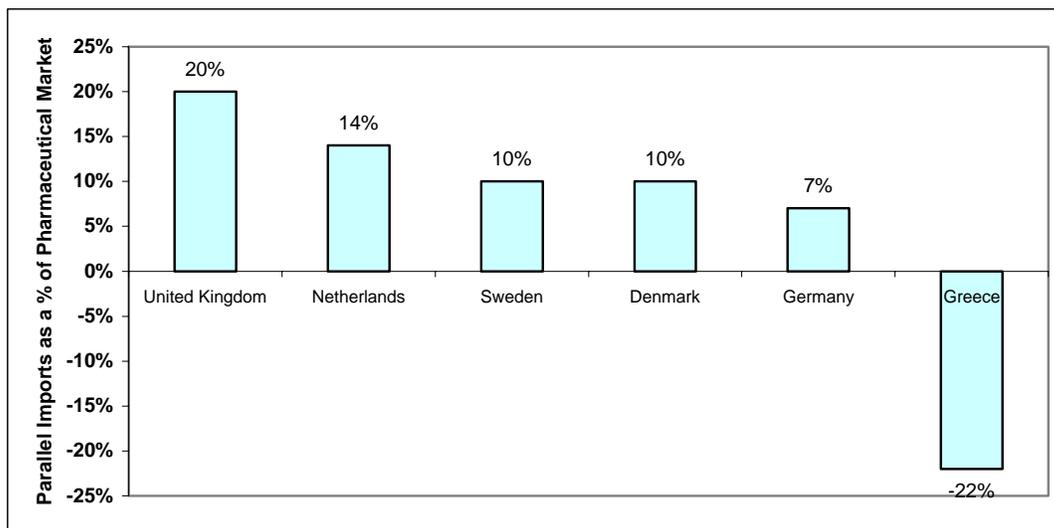
One of the most significant forces driving parallel trade of pharmaceuticals in the EU is the opportunity for PDs to take financial advantage of substantial price differences among European countries for identical medicines by buying drugs in lower-price countries and selling them in higher-price countries. By contrast, in the United States, the demand for imported drugs is driven by consumers who are seeking to reduce their out-of-pocket prescription drug costs. Although each country in the EU imposes some form of regulation to restrain prescription drug costs, the stringency of those regulations varies substantially from country to country. For example, in Denmark—which has historically enjoyed a relatively strong research-based pharmaceutical industry with emphasis on both manufacturing and research and development (R&D)—the regulatory system is designed to keep medicine prices at the average European level. In contrast, Greece—which has a limited indigenous pharmaceutical industry capacity—strives to achieve the lowest EU price.¹⁰ In the United Kingdom (UK)—where successive governments have recognized that the pharmaceutical sector is an important part of the national economy—the Pharmaceutical Price Regulation Scheme (PPRS) permits free pricing of new medicines but controls the ability of manufacturers to increase prices and subjects them to rate of return regulation on their sales to the National Health Service (NHS).

Parallel trade accounts for a substantial share of the pharmaceutical market in many high-priced EU countries as well as in some non-EU countries, such as Norway. In some EU countries with relatively high prescription drug prices, it is estimated that the total value of

¹⁰ Although the Greek High Court ruled against that nation's "lowest European price" system of control in 2001, no substantive change in practice was seen until April 2005, when the new government announced changes in the price-setting mechanism for new pharmaceuticals (the new rule takes into account up to four of the lowest-price countries in the EU).

parallel imports of pharmaceuticals exceeded \$12 billion in 2002;¹¹ *parallel importing* in these countries accounted for as much as 20 percent of total brand name prescription drug sales that year.¹² Among low-price EU members that serve as sources of parallel imports of pharmaceuticals, *parallel exporting* was as high as 22 percent of total brand name pharmaceutical sales (Figure 1).

Figure 1: Official Government Estimates of Parallel Importing/Exporting, as Share of Total Brand Name Pharmaceutical Market in Selected EU Countries, 2002



Note: Negative numbers refer to pharmaceutical parallel exports. While France, Italy, Portugal, and Spain are also net parallel exporters, there are no official data on the level of pharmaceutical parallel trade in these countries.

Sources: Data were provided by national experts as part of the questionnaire survey on economic and regulatory issues of pharmaceutical parallel trade in their respective countries. Specific data sources are: Sweden: Institute of Health Economics (IHE), 2003; Denmark: Association of the Danish Pharmaceutical Industry (LFN), 2003; Germany: Research Foundation of Social Insurance (AOK), 2003; Greece: Social Insurance Organization/Hellenic Industrial Research Organization (IKA/IOBE), 2003; the Netherlands: Foundation for Pharmaceutical Statistics (SFK), 2003; United Kingdom: Intercontinental Medical Statistics (IMS) estimates, 2003.

Furthermore, the role of parallel trade has increased in recent years (Figure 2), particularly in the United Kingdom, Germany, and Sweden (where parallel trade was not legal prior to 1995). Published research and market sources suggest that parallel trade within Europe was on the rise between 1999 and 2003.¹³ The introduction of the Euro in some EU member states may have contributed to the increase in parallel trade, because this common currency has made potential savings more discernable and has facilitated purchasing and

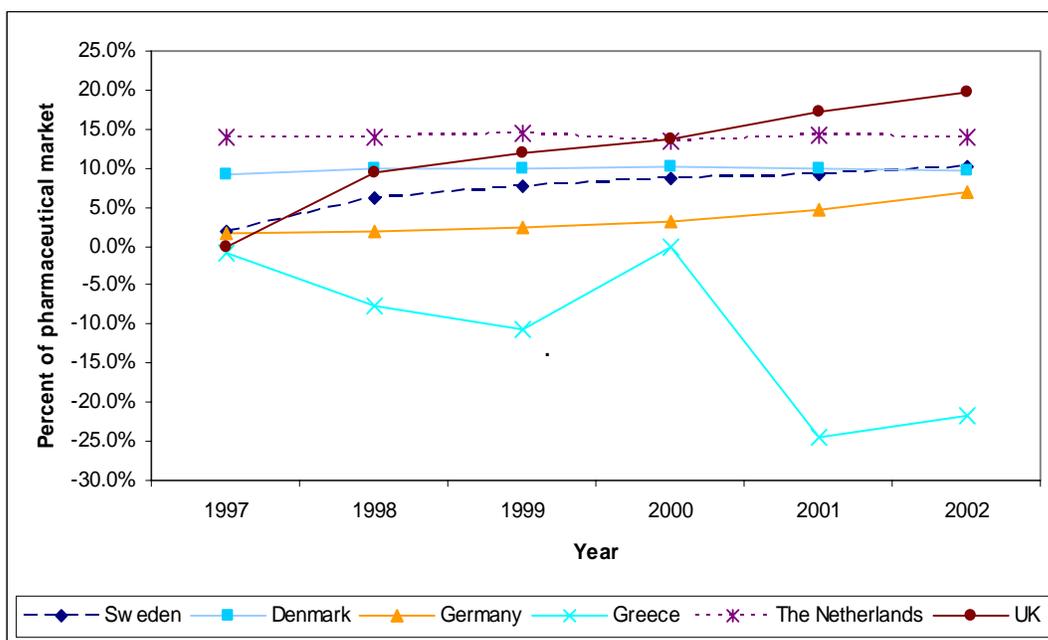
¹¹ Richard C. Morais (April 2004) "Pssst ... Wanna Buy Some Augmentin?; Move over, heroin pushers. Pharmaceutical arbitrage is rapidly emerging as the globe's hottest drug-dealing business", *Forbes*: 112.

¹² West P, Mahon J (May 2003). *Benefits to payers and consumers from parallel trade*. York, UK: York Health Economics Consortium. Retrieved from <http://www.yhec.co.uk>

¹³ See, for example, Danzon P (1998). The economics of parallel trade. *Pharmacoeconomics*, 13:293–304; Linnosmaa I, Karhunen T, Vohlonen I (2003). Parallel importation of pharmaceuticals in Finland: Effects on markets and expenditures. *Pharmaceutical Development and Regulation*, 1:67–74; West and Mahon, May 2003; Arfwedson J (2003). *Parallel trade in pharmaceuticals*, Paris.: NERA, SJ Berwin & Co.; The economic consequences of the choice of regime of exhaustion in the area of trademarks (1999) London: Urch Publishing; *Pharmaceutical parallel trade*. (1999). London: Urch Publishing; Reuters Business Insight (2001). *The global parallel trade outlook 2001–2006: A country-by-country analysis*. London: Author; West and Mahon, May 2003; Ganslandt M, Maskus KE (2004). Parallel imports and the pricing of pharmaceutical products: Evidence from the European Union. *Journal of Health Economics*, 23(5):1035–1057.

reselling processes.¹⁴ However, recent jurisprudence by the European Court of Justice that allows manufacturers to monitor their supply chain may have a negative impact on the dynamics of parallel trade and, according to preliminary indications, may have led to an overall reduction of such trade in 2004.¹⁵

Figure 2: Market Value of Pharmaceutical Parallel Imports/Exports and Their Share as a Percent of the Total Brand Name Pharmaceutical Sales in Selected EU Countries, 1997–2002



Note: Negative numbers refer to pharmaceutical parallel exports. While France, Italy, Portugal, and Spain are also net parallel exporters, there are no official data on the level of pharmaceutical parallel trade in these countries. Sources: Data were provided by national experts as part of the questionnaire survey on economic and regulatory issues of pharmaceutical parallel trade in their respective countries. Specific data sources are: Sweden, Institute of Health Economics (IHE), 2003; Denmark, Association of the Danish Pharmaceutical Industry (LFN), 2003; Germany, Research Foundation of Social Insurance (AOK), 2003; Greece, Social Insurance Organization/Hellenic Industrial Research Organization (IKA/IOBE), 2003; the Netherlands: Foundation for Pharmaceutical Statistics (SFK), 2003; United Kingdom, Intercontinental Medical Statistics (IMS) estimates, 2003.

¹⁴ Kanavos P. (2000). The single market for pharmaceuticals in the European Union in light of European Court of Justice Rulings. *Pharmacoeconomics*, 18(6):523–33; Kanavos P (1998). Single European market and Monetary Union: Macroeconomic implications for pharmaceutical spending. *Pharmacoeconomics*, 13(1 Pt 1):9–20.

¹⁵ The jurisprudence refers to the Bayer-Adalat case. (The full judgment of the Adalat case [January 6, 2004] may be accessed from the European Court of Justice website: <http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&docrequire=alldocs&numaff=C-2%2F01+P&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>). Also, in early 2005, the Advocate General of the European Court of Justice issued an opinion on a pending parallel trade case (the GSK Greek abuse of dominant position case). The rulings in the Bayer-Adalat case and the opinion on the GSK Greek case were in favor of industry positions. However, in June 2005, the Court ruled that it had no jurisdiction over the GSK Greek case and referred the case back to the Greek competition authorities.

3. THE LEGAL FRAMEWORK SUPPORTING COMMERCIAL PARALLEL TRADE IN EUROPE

The practice of parallel trade of pharmaceuticals simply means that a licensed pharmaceutical distributor in any EU member state can, after obtaining proper authorization from European or national drug regulatory authorities, import any drug from another member country, so long as the drug that is being imported is identical to the drug that is locally sourced, that is, they contain the same active ingredient and are produced by the same manufacturer. Just as importation of prescription drugs into the United States has been controversial, so has been the parallel trade of pharmaceuticals in the EU. However, in the EU, the controversies are not linked to concerns about drug safety or to concerns that drug distribution systems are not under the continuous control of the home country's regulatory authority. Rather, concerns have arisen from two potentially conflicting principles in the EU treaties and subsequent legislation: (1) the principle of free movement of goods between member countries versus the intellectual property rights of patent holders and (2) the principle that member states retain the right to govern property ownership (including ownership of intellectual property).

Free Movement of Goods between EU Members

The current dominating rule in the EU governing parallel importing stems from Article 28 of the EU treaty, which prohibits all measures that could restrict the free movement of goods between member countries. This prohibition includes goods protected by intellectual property rights, such as pharmaceuticals. Under Article 28, once a product has been placed on the market in one member state, it cannot be prevented from being resold in any other member state (this is known as the "principle of regional exhaustion of rights").

Conflicting with Article 28, however, are separate provisions in the EU treaty relating to intellectual property that allow manufacturers to limit how their patented products are sold. Specifically, the treaty contains various exceptions to its rules on free trade that justify the protection of industrial and commercial property rights, the exhaustion of rights, and the pursuit of public health. In addition, the treaty stipulates that none of its provisions shall in any way prejudice the rules in member states governing systems of property ownership.

These two conflicts have given rise to several legal cases brought before the European Court of Justice (ECJ), the body charged with, among other things, settling disputes between member countries and European institutions. The ECJ has consistently upheld the view that, once a product has been legitimately put on the market in one member state, it is a breach of Article 28 to prevent the product from being resold in another member state, even if the product is protected by the exclusivity granted by a patent or other intellectual property right in the latter state.

The ECJ has consistently reinforced its opinions on competition and abuse of dominant position (see Table 2). Any agreements preventing, restricting, or distorting competition or affecting trade are prohibited. This includes limiting or controlling markets, imposing export bans,¹⁶ and engaging in differential treatment with trading parties, thereby

¹⁶ Characterized as an agreement between undertakings that prohibits a dominant firm from exporting from one member state to another, thereby affecting free trade.

placing them at a competitive disadvantage. Under the separate Article 82, any abuse by a party in a dominant position within the common market is prohibited. This includes vertically integrated supply chains (e.g., wholesalers owning pharmacies or pharmacy chains) where a manufacturer may abuse its position over a distributor. Examples of this abuse include exploitation of dual pricing¹⁷ and pricing systems that do not allow for a rational profit margin for economic players, thus creating an unfavorable and potentially unviable market.

Table 2: Parallel Trade in the EU—Main Issues and Outcomes at the European Court of Justice

Issues	EU Law and Jurisprudence
<ul style="list-style-type: none"> • Exhaustion of intellectual property rights • Free movement of goods 	<p>Once an original manufacturer puts a product on the market in a member state, it has exhausted its rights, and the rules of free movement apply. The inability to obtain full patent protection does not affect this exhaustion of rights; however, this only applies within the EEA (comprising the EU, plus Iceland, Norway, and Liechtenstein).</p>
<ul style="list-style-type: none"> • Differences in the product • Relaxation of controls • Cooperation of authorities 	<p>Medicines must be therapeutically identical for parallel trade between countries, that is, same active ingredient, same amount, same dosage form, and bioequivalent. A member state is only permitted to require a new market authorization for a pharmaceutical product that is already covered by a market authorization in another EU member state for specific reasons, including (1) the existence of scientific uncertainty about the constituents; (2) different therapeutic effects of the many variants of the same medicine; and (3) the use of different excipients.</p>
<ul style="list-style-type: none"> • Patent protection • Dual pricing • Price regulation 	<p>The patentee has the exclusive right to manufacture and put into circulation industrial or commercial products for the first time and to oppose infringements related to the “specific subject matter” of the patent right. The manufacturer may not engage in dual pricing to prevent exportation. Furthermore, price regulation from the exporting state is prohibited from restricting the free movement of goods.</p>
<ul style="list-style-type: none"> • Banning exports • Limiting supplies to wholesalers 	<p>The patentee can prohibit exports implicitly so long as: (1) there is no agreement between legal entities (enterprises); (2) the ban is unwritten; and (3) there is no systematic monitoring of the final destination of the product.</p>
<ul style="list-style-type: none"> • Repackaging • Modifying package size 	<p>In repackaging, the importer must: (1) not affect the original condition of the product, including the inclusion of instructions and information; (2) state on the packaging that it has been repackaged; (3) not damage the reputation of the trademark through the presentation; (4) give advance notice to the trademark holder—the ECJ suggested 15 working days; (5) only perform “necessary” repackaging, that is, the least intrusive method and not solely for the purpose of gaining commercial advantage; and (6) not modify the package size under the specific market authorization.</p>

Source: Adapted from Merkur SM, Kanavos P (April 2004). *EU parallel trade of pharmaceutical products: What does the law allow?* (mimeo). London: LSE Health and Social Care, London School of Economics.

Restrictions on Commercial Parallel Trade of Pharmaceuticals

One important limit on these provisions is that the regional exhaustion of rights applies only within the European Economic Area. Provisions of the EU treaty do not allow products to be imported from outside the EU or the EEA. In addition, no parallel trade is allowed from any of the eight Eastern European member states to the other members of the

¹⁷ Many economists advocate dual pricing (also known as Ramsey pricing), that is, recovering more of the fixed costs (e.g., R&D) from those more able to pay than from others, provided that the variable costs of every sale are recovered.

EU unless intellectual property rights for any relevant product in the former are identical to those in the latter.¹⁸

The rules governing parallel trade in the EU do allow certain specific protections on the intellectual property of a trademark holder. Specifically, Article 30 of the EU treaty allows a trademark holder to block the sale of an imported product bearing that trademark if its original packaging has been modified in a way other than what was necessary to permit its sale in the importing country (e.g., by altering the trade name, altering the color of the box or packaging, or changing the product inserts [other than translating them]). Article 30 also allows member states to prohibit or limit exports to protect human life and public health.¹⁹

In addition, manufacturers can manage their inventories—that is, they are free to make reasonable estimates of the amount of a given product required in a member state and to supply an appropriate volume to meet that country's demand. (The consequence of such practices might be localized shortages of drugs if PDs divert significant amounts of such a supply to other EU states.) The only restrictions on inventory management is that manufacturers may not explicitly ban exports to other EU member states; monitor the final destination of products; or make written agreements with wholesalers or other direct purchasers to restrict supply.²⁰

The protections of trademark holders also require that, if a parallel distributor repackages a product (i.e., replaces the original blister pack and reboxes the product)²¹, it is obliged to protect the condition of the product. When repackaging, the importer must also insert a new leaflet in the destination country's language (if it is different from the source country's language), the product's container must state that the product has been repackaged, and the trademark holder (i.e., the patent holder) must be informed that repackaging has occurred.

Specific National Policies Affecting Commercial Parallel Trade of Pharmaceuticals

National policies to promote the use of parallel imports may take the form of government-approved incentives for pharmacies and/or health care providers to purchase cheaper branded drugs from EU countries that impose lower medicine prices (brief summaries of countries' policies relating to parallel imported (PI) drugs are provided in Appendix C). While schemes that promote parallel imports may seem to undermine or second guess official national policies that allow higher pharmaceutical pricing as a means of providing an incentive to the pharmaceutical industry to invest in manufacturing and R&D

¹⁸ On May 1, 2004, the EU admitted 10 new member states, eight from Eastern Europe (Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, and Slovenia) plus Cyprus and Malta. With regard to pharmaceuticals and the potential for parallel trade from the newly admitted member states, application of the principle of derogation will guide potential flows from the region. The principle of derogation applies to the eight new Eastern European members, but does not apply to Cyprus and Malta. It essentially means that, where intellectual property rights for individual products are the same in the eight accession countries as they are in the EU-15, then parallel trade within the territory comprising the 10 new member states is allowed. The EU-15 countries have signed a document outlining the new rules and accepting the principle of derogation, but there are few signs concerning the potential for enforcing this.

¹⁹ European Court of Justice (1976). *Case 104/75 Adrian DePeijper, Managing Director of Centrafarm BV [1976] ECR 613*.

²⁰ See Adalat case (January 6, 2004).

²¹ In EU countries, most prescription medications are dispensed in blister packs rather than in bottles.

activities, these policies serve the competing domestic objective of containing the costs associated with their health insurance systems.

Within European Union countries that allow higher-than-average EU prices for pharmaceutical products, there is a variety of schemes and controls that relate to parallel importing. In some countries, pharmacists are required by law to provide parallel imported pharmaceuticals when available. By contrast, other countries use payment incentives to pharmacies to encourage them to dispense parallel imported drugs and impose financial penalties on pharmacies that do not engage in such dispensing (see Table 3).

Table 3: Policies Used to Promote Use of Parallel Imports (PI) in Selected European Countries, 2004

Policy to Promote Use of PI Drugs	Denmark	Germany	Netherlands	Norway	Sweden	United Kingdom
Pharmacy required to inform patient of availability of PI product	X	X			X	
Pharmacy quota on PI dispensing rates		X				
Financial incentives for pharmacy to dispense PI drugs			X	X		X
Financial incentives for dispensing lower-price drugs in general, including PI drugs				X	X	
Lower consumer out-of-pocket contribution for PI drugs than for domestically sourced products (either from price differential or from lower cost sharing for PI drugs)	X		X		X	

Source: Authors' analysis of a questionnaire about policies facilitating pharmaceutical parallel trade in selected European countries, 2004.

4. PROVISIONS FOR ENSURING SAFETY OF IMPORTED DRUGS

In the EU, the safety of drugs imported from fellow member states is not perceived as either a significant public policy issue or as a public health concern. The reason is that all EU countries share the same regulatory procedures for approval of and marketing authorization for prescription medicines and—because importation from outside the EU is disallowed—the source of prescription medicines is identifiable. Commercial importers are required to abide by either centralized EU regulations or national regulations that, while differing slightly from one another, establish the same standards for drug safety, quality, and efficacy; each member country's government and the original manufacturers themselves—who have the right to recall any PI product that violates safety standards or threatens the value of its trademark—provide oversight. This section summarizes these regulations, including rules for obtaining approval for parallel distribution and for modifications a parallel distributor (PD) can or must make to package labeling and other consumer information (and what modifications cannot be made).

General Process for Obtaining Authorization for Parallel Distribution of a Pharmaceutical Product

The institutional framework for approving parallel distribution of a drug is analogous to the process by which a new pharmaceutical product gains marketing approval within the EU. Specifically, marketing approval processes are identical among EU countries, and

medicines can receive marketing approval from either a centralized EU body—the European Medicines Evaluation Agency (EMA)—or national regulatory agencies. Each of these entities is analogous to the U.S. Food and Drug Administration in that they are responsible for certifying drug safety and efficacy in their respective jurisdictions. Typically, drugs do not need to be approved in each country: EMA approval automatically authorizes marketing of a drug in all EU countries (centralized procedure), and all other members mutually grant approval through an equivalent local agency (mutual recognition procedure), allowing for some minor variations in requirements.

For both the centralized and the decentralized procedures, the regulatory authorities apply a legislative framework that has been developed through EU law and ECJ jurisprudence on the subject. The rules applying to *centrally* authorized products are slightly different from the parallel importation of medicines authorized *nationally* because of potential differences between the marketing authorization granted by the member state of origin and the one granted by the member state of destination. Member states are required to have simplified national registration rules for parallel distributors. If the health authorities of the destination country already have relevant information for the original medicine, as submitted by the manufacturer when it applied for marketing authorization, the parallel distributor is under no further obligation to supply such information.

For new products that have been approved centrally through the EMA, parallel distributors have the option of applying for parallel distribution for a particular product through the EMA, in which case their parallel distribution license authorizes them to parallel import into any EU country. The alternative would be for parallel distributors to go through the national procedure, where they would be allowed to parallel import only into the country to which they submit an application. Parallel distributors that target single countries may prefer to do so via national channels. Similarly, as the number of centrally approved products is relatively small (following establishment of the EMA in 1995), frequently, and for older products, the national procedure is the only viable approval mechanism.

To import pharmaceuticals between EU member states, a parallel distributor is normally engaged in activities defined as wholesale distribution and needs to have a wholesale distribution license to receive authorization from either the EMA or a national drug approval agency. The PD must agree to abide by the regulations established by those agencies to assure safety of the imported product and to guarantee the rights of the manufacturer with respect to protecting the value of its trademark. The PD must obtain separate approvals for each presentation of a drug (e.g., strength, dose, form, and package size) as well as for the same presentation that is imported from different countries (i.e., Spain versus Greece).

EMA Regulation of Parallel Distribution

For distribution of a centrally approved product within the EU, parallel distributors' first step is to notify the EU Marketing Authorization Holder (MAH)—that is, the manufacturer that holds the authorization to sell the product in the EU—before applying for approval to distribute the product to another country. The EU MAH details can be found on the outer carton or in the package leaflet of the originator product. The notification must be given to the European headquarters of the company in question, not the national affiliate. Notification is important for two reasons: first, because the MAH has the right to approve any

changes in labeling or in the original packaging, and, second, because such notification allows the manufacturer to notify the PD in case a product recall is necessary.

Once the MAH holder has been notified, the PD then applies for authorization from either the EMEA (for a centrally authorized drug) or from the authority responsible in a specific destination country. Within the European context, as long as a marketing authorization already exists for a particular product (whether from the EMEA or from a national regulatory authority), and the PD is a licensed distributor in its home country, the marketing authorization procedure for parallel distribution is a simple procedure and cannot be turned down; for this purpose, the term “notification” is used. The PD “notifies” the EMEA (or any national regulatory agency) that it is about to begin parallel distribution, in which case the compliance criteria outlined below apply and the relevant fees are paid to the regulator.

The EMEA requires extensive commitments from a parallel distributor and imposes specific standards on procedures to be followed before parallel distribution is allowed. In particular, on receiving and approving an application, the EMEA awards a license to a PD to perform parallel distribution of a particular product sourced in a particular member state. Any time a parallel distributor wishes to begin activities for a new product, or for an already parallel-distributed product from another member state, a new application for a license by the EMEA is required. The EMEA charges a fee of €3,480 (about US\$4,250) per PI authorization application (i.e., per distributor, per drug, and per country of importation). The fee allows parallel distribution for that product and is valid for five years.

Restrictions on parallel distributors. The only changes that PDs are allowed to make to the packaging of a centrally authorized medicine are those strictly necessary for marketing the product in a destination country (such as using a different language for the consumer leaflet and labeling purposes). Changes in package sizes may only be made within the scope of what has been approved in the EU marketing authorization. The EMEA must approve mock-ups of any proposed changes of the product’s package and of new consumer leaflets before a parallel distributor markets a product, and the manufacturer of the product has to be kept informed at all stages and given the opportunity to view and approve such mock-ups.

Furthermore, the EMEA does not accept any proposals from parallel distributors to bundle existing presentations of a centrally authorized product to create a larger package size, even if this package size is covered by the marketing authorization of the medicinal product in question. The reason is that different presentations are subject to separate central marketing authorizations. In this case, the PD will need to repackage the product to produce a larger pack, provided the latter has obtained marketing authorization (MA) within the EU.

Parallel distributors are required to provide EMEA with separate notifications for each presentation of a medicine (i.e., different package sizes and strengths require separate notifications). Where a drug has two or more names, a separate notification is needed for each name.²² Under no circumstances is the PD allowed to alter in any way the trade name under which a product is sold, as this would constitute a trademark violation. Any changes to the packaging beyond those outlined above require the parallel distributor to hold a valid

²² For example, the nonsteroidal anti-inflammatory drug, Voltaren, is sold as Voltaren in Greece and Voltarol in Spain. Because of the differences in name, a PD would need separate authorizations to import from both countries.

manufacturing authorization from either the EMEA or an EU member state (i.e., the parallel distributor would have to be authorized to be a drug manufacturer).

For instance, the ECJ has defined operations such as “removal of blister packs from the original external packaging and their insertion into new external packaging” or “addition to the packaging of new user instructions or information or the fixing of self-stick labels” as repackaging that always requires a valid manufacturing authorization. The parallel distributor can carry out the repackaging activities or outsource it to another company, subject in either case to having a valid manufacturing authorization.²³ If repackaging occurs, EU law requires the parallel distributor to identify the repackager and the MAH manufacturer on the medicinal product in the language of the destination state. In addition, the EMEA recommends the mentioning of the “parallel distributor,” as described below:

- The outer labelling of the package is required to include the following text, in the language of the member state of destination (i.e., a product imported from Greece to the United Kingdom should have the following information in English):

Parallel-distributed and repackaged by...(name and address of PD)

- Or, if the packager and repackager are different entities,

Parallel-distributed by...(name and address of PD) *and repackaged by...*(name and address of repackager)

PDs are allowed to identify more than one repackager in the initial PD notification provided they include two sets of mock-ups, each clearly identifying one of the repackagers. Where the PD has identified more than one repackager in this notification, it should only mention on the outer label the repackager of the batch in question.

If practical, the inner labeling of the package should also include the name of the PD and repackager; however, this inclusion is not compulsory. It is acceptable to mention only the name of the PD. As with the outer label, where the PD has identified more than one repackager in this notification, it should mention on the inner label only the repackager for the batch in question. The particulars must appear in the official language or languages of the member state where the product is placed on the market. This does not prevent these particulars from being included in several languages, provided the particulars appear in all of the languages used.

The EMEA considers adding a PD internal code to packaging material to be good practice and acceptable, provided it is not presented as part of the core text of the labeling and package leaflet. The original batch number must always be retained. This includes mentioning a “repack batch” or the addition of a prefix or suffix to the original batch number to reflect additional packaging activities.

²³ The parallel distributor (who holds a license to market PI product—therefore he or she is the marketing authorization holder) can do one of two things: either repackage the product in his or her own facilities (in which case he or she also needs to have a manufacturing license) or subcontract with a third party who will repackage in his or her own facilities, and, in this case, this party also has a manufacturing license. Regardless of the preferred option, the name and address of the parallel distributor *and* the repackager need to be written on the (new) box of the product that emerges from this process.

Speed of EMEA approval. PDs receive approval to parallel distribute a product relatively quickly once they have provided all necessary information to the EMEA and the MAH holder. On receipt of an initial PD notification, the EMEA checks its validity within five working days and informs the parallel distributor of the start of the regulatory check or requests any missing/incorrect information. The EMEA checks conformity of the proposed labeling and package leaflet within 30 days after validation of the notification and notifies the parallel distributor of any objections/comments. Within its initial notification, the EMEA requests a color copy of the repackaged sales presentation. If such a copy is not acceptable, the EMEA may request an actual specimen. Where there are no objections or when the PD has completely addressed any objections, the EMEA issues a notice that the regulatory check is complete and parallel distribution can begin. This notice is sent to the parallel distributor, the national authority of the member state of destination, and the MAH of the medicinal product.

Once approved, all proposed changes to a PI product's packaging or leaflet formats must be resubmitted to the EMEA, which checks the validity of any wholesale, distribution, or manufacturing licenses submitted as part of a PD notification. However, responsibility for any subsequent action rests with the drug regulatory authority (the "competent authority") of the relevant country or countries, and the trademark owner is responsible for checking that repackaging has not damaged its reputation. The EMEA cannot request an inspection of a PD (doing so is the responsibility of the national regulatory body); however, if the manufacturer believes that the manner in which the product is licensed threatens the product's commercial performance for whatever reason, the manufacturer can ask that the PD product be recalled on the basis that continued sales might endanger brand loyalty.

National Drug Approval Agency Regulation of Parallel Distribution

Where a marketing authorization has been issued by a national authority rather than the EMEA, the applicant PD must submit an application (i.e., notification) for parallel distribution to that agency. National agencies have developed requirements to ensure that PI pharmaceuticals meet their safety and quality standards (see Table 4), and all countries that parallel import have such requirements in place. Member states that parallel export only do not necessarily need to have these requirements in place.²⁴ To comply with regulations, PDs have to submit applications and the relevant fees to receive a PI license. The fees regulators charge for PI applications are a fraction of those levied for new medicine applications.

Responsibilities of Parallel Distributors in Case of Product Defect

Throughout the European Union, the parallel distributors of medicines have clear responsibilities in the event of a product defect; the EMEA, and the national regulatory agencies through it, have guidelines regarding these responsibilities. As the holder of a distribution license, PDs are required to have an effective system for receiving complaints and, when necessary, organizing product recalls. In the case of product recall, the PD must inform the appropriate national authority to initiate the rapid alert system, and it must also inform the marketing authorization holder (i.e., the manufacturer). If a recall originates earlier in the supply chain (i.e., in the country from which the product was exported), PDs

²⁴ France was such an example until recently, but it adopted a set of regulations for parallel imports on January 27, 2004. The rationale in the French case for adopting PI regulations was that EU enlargement and accession of a number of countries with lower price levels for pharmaceuticals might enable parallel importation into France.

must be informed by the original manufacturer, who—as a result of the original PD application process—is aware of all legal PDs of the product.

PDs are then required to trace the distribution of the medicine they have supplied, initiate recall procedures, and inform the relevant national authority. Thus a product recall of a parallel imported medicine leads to the recall of the product in all EU destination countries. In theory, this process is exactly the same as the recall process for domestically sourced drugs. In practice, however, recalls for repackaged products (e.g., the contents are put into new blister packs and then into a new box written in the local language and containing a new consumer information leaflet), as opposed to products that have only been reboxed (e.g., the original contents are simply placed in a box written in the local language, with a new consumer information leaflet), are more problematic. When a product is repackaged, different batches of product might be placed in a new box.

Table 4: Direct Costs of Obtaining a Parallel Distribution License and Duration of Marketing Authorization in Selected European Countries, 2004

Country	Cost to obtain a parallel import license and duration of marketing authorization*
Denmark	<ul style="list-style-type: none"> • Annual fee of DKK7,950 (about US\$1,300) plus application fee of DKK15,095 (about US\$2,500) or renewal fee of DKK13,975 (about US\$2,300) • Application good for five years
France	<ul style="list-style-type: none"> • Fees not known • Application good for five years; reapplication must be filed three months before expiration to extend authorization
Germany	<ul style="list-style-type: none"> • €1,380 (about US\$1,700) • Application good for five years; reapplication must be filed three months before expiration to extend authorization
Greece	<ul style="list-style-type: none"> • €80 (about US\$220) • Application good for five years
Italy	<ul style="list-style-type: none"> • €24.20 (about US\$650) per product • Application good for five years
Netherlands	<ul style="list-style-type: none"> • €1,465 (about US\$1,800) per product • €5,672.25 (about US\$7,000) per year for holding a PI license
Portugal	<ul style="list-style-type: none"> • No published data on fees
Spain	<ul style="list-style-type: none"> • No published data on fees • Application good for five years
Sweden	<ul style="list-style-type: none"> • SEK15,000 (about US\$2,000) • Application good for five years
United Kingdom	<ul style="list-style-type: none"> • £1,465 (about US\$2,700) • Application good for five years, but normally continues in force only as long as both UK license and EMEA marketing authorization remain in force
Norway	<ul style="list-style-type: none"> • NOK 70,000–80,000 (about US\$11,000–US\$12,500), plus control fee of 0.7% of sales volume of the MA holder • Application good for five years, given that original product has been marketed in EMEA for six years
EMEA (for centrally approved products)	<ul style="list-style-type: none"> • €3,480 (about US\$4,300) for each Parallel Distribution notification • Application good for five years

*Regulatory authorities do not impose fees for parallel exporting.

Source: Authors' own research from direct contacts with national regulatory authorities and the EMEA, 2004.

Costs to Regulatory Agencies of Assuring Safety of Parallel Imports

Once PI authorization is granted, the nature of the drug regulatory structures described above is such that the EMEA and EU member states incur virtually no costs in assuring safety of parallel imported drugs. Because the system is closed (i.e., drug imports are only allowed from other EU or EEA member states that have identical processes for drug approval and quality control), regulatory agencies do not directly incur any major expense testing the quality of products being imported. In addition, regulatory agencies do not incur costs in monitoring the labeling and packaging of imported products, because such actions are under the purview of the private sector. Drug manufacturers are responsible for checking the labels and package mock-ups that parallel distributors are required to submit to them (and to the regulatory authorities) before the drug can be imported. Manufacturers are also responsible for reporting problems associated with labeling and packaging. The parallel distributor is responsible for the costs of any such problems, including the costs of product recalls, and is at risk for losing its license or being sued by the manufacturer if problems persist.

5. EVIDENCE ON THE EFFECTS OF COMMERCIAL PARALLEL TRADE OF PHARMACEUTICALS ON SAFETY, ACCESS, COSTS, AND THE PHARMACEUTICAL INDUSTRY

Among the controversial issues influencing the drug importation debate in the United States is, first, whether importation would create entry points for counterfeit products or would otherwise endanger the safety of the drug supply; second, whether foreign sources of supply would dry up as manufacturers reduced stocks to exporting countries or those countries raised prices; third, whether the cost reductions associated with importation would result in any savings to consumers or other payers of prescription medications rather than largely being absorbed by distributors (i.e., wholesalers and pharmacies); and fourth, whether importation would adversely affect pharmaceutical R&D and innovation. The European experience provides important insights into issues such as drug safety—specifically that safety problems and issues regarding the supply of PI drugs are few and relatively insignificant.

The European experience offers fewer insights for the U.S. on drug savings, access, and the impact on the pharmaceutical industry. While the evidence suggests that a relatively small share of the financial benefits accrued from parallel importing go to consumers and health care systems, this may be due in large part to health insurance systems in EU countries that offer consumers few (if any) incentives to seek lower-priced drugs and in which drug prices are already regulated. The European experience offers only anecdotal evidence of drug shortages in exporting countries and on whether shortages have led to problems with access to needed medications. Furthermore, European experience provides little insight into dynamic effects of parallel trade on long-term price changes or innovation and development.

Effects of Commercial Parallel Trade on Drug Safety

Despite the substantial volume of parallel imported pharmaceuticals in the EU each year, no documented cases of counterfeit drug supply can to date be attributed to this type of trade. Such a record indicates that the regulatory provisions in place in the EU have been an adequate safeguard against counterfeiting of pharmaceuticals.

By contrast, some incidents involving other regulatory violations relating to repackaging, relabeling, and consumer leaflet content of parallel imports have been reported. It should be noted, however, that the small amount of evidence concerning such events, which is largely anecdotal, comes from drug manufacturers that have incentives to reduce the extent of parallel trade. Identification and reporting of problems rests with the manufacturers, which have legal responsibility for monitoring quality issues having to do with parallel distribution of their products. Direct contacts with four leading pharmaceutical manufacturers, as well as published evidence, have revealed examples of regulatory violations across all destination countries, but, apparently, not of sufficient importance to warrant product recalls.

Specifically, most of the anecdotal reports of problems associated with PI repackaging, relabeling, and consumer inserts have occurred in high-volume destination countries such as the UK, the Netherlands, and Germany. Regarding *consumer inserts of parallel imports*, reported problems have been incorrect or inadequate information relating to the use and storage of medicines; failure to translate inserts into the language of the destination country; failure to update consumer inserts; incorrect expiration dates; wrong information about the number of tablets in the pack; incorrect address of originator company given; and wrong country of origin indicated. Regarding *labels and packaging of parallel imports*, reported problems have focused on misleading information for practitioners about administration of the drug; differences in stated formulation and composition between the source and destination country presentations; failures such as not translating the days of the week on blister packs; labels being affixed to packs in ways that obscure legally required information such as batch numbers and/or original trademarks; incorrect or omitted information regarding the original manufacturer; and package sizes larger than those allowed for by marketing authorizations.

These incidents have led to complaints by products' original manufacturers and, occasionally, to litigation. Problems with labeling, packaging, and/or inserts of parallel imports have led to some product recalls. For instance, in Germany there were 50 recalls for parallel imported products between January 2002 and August 2003 (because some of these recalls may have been on different batches of the same product, the actual number of products affected most probably was less than 50; by way of comparison, there are over 40,000 drug product formulations on the market in Germany). Only one case has been reported of a product recall in one country that failed to trigger a product recall in another destination country.²⁵

Commercial Parallel Trade and Drug Shortages

Increased personal drug importation from Canada to U.S. residents has resulted in many manufacturers decreasing their supply to the Canadian market to levels estimated to cover only Canadian residents' demand.²⁶ While such actions are not widespread in Europe, over the past few years there have been a number of complaints—predominantly by consumers and pharmacists—about product shortages in exporting countries due to parallel

²⁵ European Federation of Pharmaceutical Industries and Associations, quoted in Kanavos, P, and Holmes, P (2005). *Pharmaceutical parallel trade in the UK*, London: Civitas. In this case, a product recall in Belgium for a drug that had been parallel exported to Germany did not generate an equivalent product recall in Germany.

²⁶ See, for example, Strahinich, J “Novartis: We may cut cheap Canadian drugs,” *Boston Herald*, November 18, 2004:46; Bloomberg News. “Merck tightens sales to Canada,” *Boston Globe*, January 20, 2005; Connolly, C “Pfizer cuts supplies to Canadian drugstores,” *Washington Post*, February 19, 2005:A10.

exporting. There is no evidence on the magnitude of reported shortages nor of whether shortages have led to problems with access to needed medications; most of the evidence comes from newspaper articles and concerns expressed by pharmacists' associations, and there have been no systematic studies of drug shortages.

While there is no widespread evidence of drug shortages in exporting countries, there have been anecdotal reports of shortages in France, Italy, Spain, and Greece that have led to problems of access to individual drug products.²⁷ Many EU countries, reacting to concerns about drug shortages, have introduced or amended legislation to account for parallel trading activities on their territory. For example, in 2001, concerns about shortages in Greece led the Greek National Drug Organization (EOF), the national regulatory authority, to issue a circular requiring companies to report, on a confidential basis, the quantities of drugs they are exporting.²⁸ A further circular followed, instructing companies to supply the market with the quantities needed to cover local demand, plus a 25 percent safety margin.²⁹ In 2003, Spain adopted a law requiring wholesalers to reveal the destination of products they bought from the manufacturers. In both countries, however, there is little information on whether drug exporters comply with these requirements.

Indeed, it is possible that the ECJ may construe the right to monitor the final destination of products as being against EU competition law, but the response of EU institutions³⁰ to these measures is unclear. France has reduced the attractiveness of newer products for parallel trade by introducing measures that allow manufacturers to charge higher prices in France for new medicines. The fact that national regulatory authorities have acted (almost unilaterally) to increase their information about and understanding of the problem could be indicative of a more serious problem of perceived or actual drug shortages, in that disproportionate quantities have been exported rather than being distributed nationally.

Product shortages have also been reported in some importing countries, such as Denmark, where pharmacists must normally dispense the cheapest version of any given drug. Shortages of PI medicines arise when their distributors have not adequately foreseen, or have been unable to meet, local demand in destination countries. In some instances, prices of parallel imported products have, as a consequence, temporarily risen above prices of locally sourced products.

Distribution of Price Savings among Stakeholders: Theory

A key question concerning parallel trade of pharmaceuticals has to do with the distribution among stakeholders of the substantial differences in prices between high-price and low-price EU member states. Allocation of financial and nonfinancial benefits of parallel trade to a country's health system and consumers is the subject of debate and research. In theory, parallel trade has the potential to provide the following direct benefits to stakeholders in destination (i.e., importing) countries:

²⁷ Kanavos P, Costa-Font J, Merkur S, Gemmill M (2004). The economic impact of pharmaceutical parallel trade in the European Union member states: A stakeholder analysis. London: London School of Economics.

²⁸ Hellenic Republic, Hellenic National Drug Organisation (October 3, 2001). *Establishment of a database for parallel exports by wholesalers* (circular). Athens.

²⁹ Hellenic Republic, Hellenic National Drug Organisation (November 27, 2001). *Ensuring adequate supply of pharmaceutical products in the Greek market* (circular). Athens.

³⁰ Notably, the European Commission and its various directorates.

Consumers in destination countries theoretically would receive at least some of the benefit from the lower prices of PI drugs if they pay a significant proportion of their medication costs out of pocket. Their pursuit of lower pharmaceutical costs should create competitive pressures for pharmacies to offer lower-price parallel imports. These lower prices should reduce consumers' overall medication costs and improve their access to prescribed medications. In practice, however, European health systems—particularly in the UK, the Netherlands, Germany, Denmark, and Sweden (and, perhaps, although less so, in Norway)—provide comprehensive prescription drug coverage with low to moderate cost sharing requirements. Therefore, even where PI medicines have a price advantage over locally sourced products, consumers are not aware of such price advantages. In addition, some consumers may be reluctant to accept a parallel import.³¹

Theoretically, consumers could also benefit to the extent that parallel imports reduce the costs of providing national health care overall. Specifically, lower drug costs as a result of PI could allow the national health insurance system to maintain or expand benefits and could avoid tax increases needed to finance the system. In practice, any efficiency savings from lower drug costs are usually plowed back into the system to maintain benefit levels, in effect providing savings to the health care system by limiting the expenditures needed to maintain those benefits.

Pharmacies in destination countries can benefit from parallel trade to the extent that they are allowed by their countries' health insurance systems to keep the difference between the ingredient cost and the insurance system's reimbursement rate of the product. In such situations, pharmacists can negotiate discounts with parallel distributors, making it profitable to stock and dispense a parallel-imported medicine that carries the same reimbursement price as a locally sourced product. In the UK, for example, pharmacies are allowed to keep the entire savings from parallel imports (although there are "clawback" mechanisms, described below, for the National Health System to recoup some of those gains).

Statutory health insurance organizations in destination countries may benefit in three ways:

1. *By appropriating part or all of the difference between locally sourced and PI pharmaceuticals at the time of transaction.* For example, in Norway, financial benefits of lower-price PI drugs are split equally between the government and pharmacies, whereas in the Netherlands, until recently, the pharmacist retained one-third of the price difference and surrendered the remainder to the government.
2. *By imposing a "clawback" on aggregate pharmacy sales of pharmaceuticals.* Under a clawback, the national health insurance system assesses a levy on pharmacies, based on a percentage of pharmaceutical sales, to account for an assumed level of savings from parallel trade. In this way, the government shares in PI's financial gains without changing the reimbursement rates for any particular prescription. For example, in the UK, pharmacies are assessed an average clawback of 10.44 percent of sales, regardless of whether they use PI drugs. Clawbacks are designed to capture part of the discounts that pharmacies receive from wholesalers and parallel traders and to provide an incentive to pharmacists to

³¹ Szymanski S (April 2004). Intellectual property rights and parallel trading in pharmaceuticals. London: Imperial College.

procure some volume of their supply from cheaper foreign sources. In addition to the UK, clawbacks are used in the Netherlands.

3. *By inducing price competition that forces down prices of locally sourced products.* Health insurance systems might also benefit if the availability of lower-price PI products creates greater competition that reduces prices of locally sourced products.

The extent to which these differences accrue to stakeholders or parallel distributors depends on how each of these forces affects the marketplace of any particular country. Critics of parallel trade (and of drug importation in the United States) contend that a substantial share of those differences are being absorbed by PDs rather than being passed on to purchasers.³² By contrast, parallel distributors claim governments benefit greatly from the practice.³³

Parallel distributors have the potential to act as profit maximizers, by observing and taking advantage of price differences for the same product between low- and high-price countries (therefore, engaging in *arbitrage*). The practice of arbitrage, coupled with imperfections in the parallel distribution market (e.g., few PDs have stock for a wide range of products; few PDs have continuous supply for a particular product; and only a small number of PDs operate in a particular destination country), suggests that parallel distributors have little economic incentive to offer health insurance organizations in destination countries substantially lower drug prices than for locally sourced products. In this respect, the originator manufacturer is still setting prices in a given product market, and the PDs follow this price setting in what often resembles a duopoly.

Parallel distributors do incur certain direct and indirect costs to import a medicine into a given country, including identifying and maintaining relationships with distributors in the low-price countries, meeting regulatory (safety) requirements (i.e., labeling and packaging), marketing to local pharmacies, and providing discounts to pharmacies in countries where discounts are allowed. According to some sources, such discounts can range between 1.6 percent and 23 percent of list prices.³⁴

As in importing countries, the financial benefit from parallel trade of pharmaceuticals in exporting countries typically accrues to parallel distributors. Anecdotal evidence suggests that wholesalers in exporting countries also may be realizing some benefits by selling large quantities directly to parallel distributors. While this foreign trade provides benefits to national economies, parallel trade of pharmaceuticals may subject residents of exporting countries to some costs, although there is little published evidence of higher costs to date. For example, if a manufacturer reduces its stock within an exporting country to reduce parallel trade, then consumers may face the inconvenience associated with a short-term shortage. An additional cost comes from actions that manufacturers may take to reduce the likelihood of parallel trade on newly launched drugs. A manufacturer may delay launch in a low-price country because of concerns that a high volume will be traded to a higher-price country. Alternatively, a manufacturer may demand—and may be able to get—a higher price

³² For example, the HHS Task Force on Drug Importation estimated that, if commercial drug importation was legalized in the U.S., eighty percent or more of the price differences would accrue to importers. See HHS Task Force on Drug Importation (2004), p. 67.

³³ West and Mahon (2003).

³⁴ West and Mahon (2003).

in the exporting country than it would be willing to accept in the absence of parallel trade, which would raise the costs of pharmaceutical treatments in that country.

Impact of Commercial Parallel Trade on Prices and on Stakeholders: Evidence

Five key studies have examined the effects of parallel trade on the pharmaceutical market in EU countries. Two of these studies examined the impact of parallel trade in pharmaceuticals in (net) parallel importing countries, such as the UK, and also in Germany, Denmark, Sweden, the Netherlands,³⁵ and Norway.³⁶ The remaining three studies were more narrowly focused, analyzing the impact of parallel trade in the UK,³⁷ Sweden,³⁸ and Finland,³⁹ respectively. Only one study (LSE, 2004) examined the impact on (net) parallel exporting countries. These studies' key methodological features, objectives, research endpoints, and key findings are detailed in the following paragraphs. Other than the country focus, key endpoints in the analyses were the impact of parallel trade of pharmaceuticals on prices, consumers, pharmacies, statutory health insurance organizations (through the impact on their drug budgets), parallel distributors, and pharmaceutical manufacturers (see Table 5).

Table 5: Economic Impact of Pharmaceutical Parallel Trade—Topics Covered by Published Studies

Topic	London School of Economics (LSE), 2004	York Health Economics Consortium (YHEC), 2003	Ganslandt and Maskus, 2004	Linnoosmaa et al. , 2003	Economic and Social Research Council (ESRC), 2003
Impact on prices	X	X	X	X	
Savings to consumers	X				
Benefits to pharmacies	X	X			
Savings to statutory health insurers	X	X		X	X
Benefits to parallel distributors	X				X
Impact on pharmaceutical manufacturers	X				X

Source: Based on Kanavos and Holmes, 2005.

Impact on prices. Before examining the evidence on how PI has affected stakeholders in the EU, it is useful to understand how PI has affected prices in imported countries. Many PI drugs have prices that, while lower than those of locally sourced products, are nevertheless higher than they are in the source countries. For each of six higher-price EU countries, Table 6 compares the price of locally sourced products (i.e., those

³⁵West and Mahon (2003).

³⁶Kanavos et al. (2004).

³⁷Szymanski (2004).

³⁸Ganslandt M, Maskus KE (2001). Parallel imports of pharmaceutical products in the European Union. *The Research Institute of Industrial Economics*, Working Paper No. 546.

³⁹Linnoosmaa I, Karhunen T, Vohlonen I (2003). Parallel importation of pharmaceuticals in Finland: Effects on markets and expenditures. *Pharmaceutical Development and Regulation*, 1:67–74.

produced and/or distributed in a particular country by a manufacturer located in that country and using local distribution [wholesale] networks) for three of the most common drug presentations (i.e., name, dose, and package size) to the lowest price in the EU for the comparable product and to the average of the three lowest EU prices. Most of the lowest European prices shown in these examples are 45 percent to 60 percent of the price for comparable locally sourced products; the average price in the three lowest-price countries typically is about 50 percent to 70 percent of the price for locally sourced products. However, in the examples listed below, the PI price in the destination country tends to be much closer to the locally sourced product price—roughly 80 percent to 90 percent of the price.

Table 6: Comparison of Reimbursement Prices for Three Common Drug Products in Six High-Price Countries, 2002: Locally Sourced vs. Low-Price EU Countries vs. Parallel Import

Product name ^a	Package size	Price of locally sourced product (in Euros [€])	Price in lowest-price EU country (in Euros [€])	Average price in 3 lowest-price EU countries (in Euros [€])	Price of PI drug (in Euros [€])
Denmark					
Accupril 10 mg	98	60.68	29.42	40.57	58.68
Zocor 10 mg	98	129.38	61.13	81.76	118.29
Paxil 20 mg	60	100.18	68.16	81.53	87.14
Germany					
Zyprexa 2.5 mg	28	80.90	46.20	50.80	76.70
Risperdal 2 mg	28	110.80	46.70	54.80	99.50
Prozac 20 mg	50	115.70	64.90	57.20	104.10
Netherlands					
Risperdal 2 mg	50	108.60	46.60	56.40	95.80
Zocor 10 mg	30	44.30	18.90	22.80	38.60
Prozac 20 mg	30	24.70	12.30	14.70	20.20
Norway					
Risperdal 1 mg	60	47.66	30.13	32.58	36.21
Clozaril 1 mg	60	63.28	35.49	44.62	60.85
Zocor 10 mg	98	128.48	61.13	81.76	126.98
Sweden					
Risperdal 1 mg	60	311.80	176.00	193.10	272.40
Clozaril 20 mg	30	52.40	30.10	32.70	44.90
Paxil 40 mg	100	181.30	24.70	29.00	154.70
United Kingdom					
Zyprexa 20 mg	100	153.60	88.00	96.90	153.60
Cozaar 50 mg	28	27.10	16.10	17.70	27.10
Zocor 20 mg	28	46.70	17.70	23.20	46.70

Notes: € was equivalent to about US\$1.23 on June 3, 2005. Prices in Denmark, Sweden, and the UK were converted to Euros. Prices are for the most common presentation of the drug in the country. Comparisons with other countries' prices are for the identical presentation (i.e., same manufacturer, strength, dosage form, and package size).

^aThe U.S.-equivalent brand name is used in this table; the European brand name for the same drug may differ (and the drug may have different names in different countries).

Source: Analysis of IMS data (Midas Database), 2002.

The extent to which price differences accrue to stakeholders, and the issue of which parallel distributors get to keep the price difference, depends on how each country's market and regulatory forces (i.e., price regulation schemes) affect the marketplace. For example, in the United States, it is possible that demand for lower-price products—driven by consumers' lack of drug coverage, their co-insurance arrangements, or promotion by third-party payers—

may lead distributors to pass along substantial price savings to consumers. However, the evidence on pricing dynamics in EU is mixed.

Four of the five studies explicitly or implicitly (i.e., through scenario testing) examine the impact of pharmaceutical parallel trade on drug prices in importing countries. Ganslandt and Maskus, using data from Sweden, found that the prices of drugs subject to competition from parallel imports fell relative to other drugs over the 1994–1999 period. Indeed, parallel imports reduced prices by 12 percent to 19 percent. There is evidence that this effect increases with multiple PI entrants. York Health Economics Consortium (YHEC) observed that prices may be affected as a result of parallel trade, but this observation has not been subjected to empirical scrutiny. Linnosmaa et al. found that, if changes in the prices of imported products are due to a competitive effect introduced by parallel importing firms, then this effect yields marginal results. The London School of Economics (LSE) found little evidence of a consistent pattern of price reduction as a result of parallel trade. More recent evidence suggests that, although there is long-term impact on prices, this is attributable to generic penetration rather than parallel trade.⁴⁰ As in the Linnosmaa study, the LSE study concludes that the pricing behavior of pharmaceutical manufacturers may not necessarily change as a result of parallel importing activities.

Such conflicting or mixed results are attributable to (1) differences in data sources, (2) differences in the market covered by the data sources (e.g., whether data sources capture the entire market or a subsection thereof), and (3) differences in research endpoints (e.g., whether the analysis focuses on impact on certain stakeholders and not others). The Economic and Social Research Council (ESRC) study used aggregate data on drug expenditures to arrive at general conclusions about the potential impact of parallel trade on the UK economy. The LSE and YHEC studies both used the proprietary Intercontinental Medical Statistics (IMS) pharmaceutical sales database to calculate the impact of parallel trade on stakeholders. The LSE study took a sample of the pharmaceutical market in all EU countries, comprising six product categories (25 percent of the pharmaceutical market in the countries under investigation) and calculated the impact of parallel trade in six key importing countries (UK, Germany, the Netherlands, Sweden, Denmark, and Norway). Unlike the YHEC study, the LSE study also considered impacts on health insurance, consumers, pharmacies, the pharmaceutical industry, and parallel distributors. The YHEC study, by contrast, focuses on the entire pharmaceutical market in five key importing countries (UK, Germany, the Netherlands, Denmark, and Sweden) and estimates the impact of parallel trade on health insurance, consumers, and pharmacy, using national government statistics, IMS data, and data obtained from parallel distributors.

Impact on consumers. Only one of the five studies (LSE) explicitly examines the direct impact of pharmaceutical parallel trade on consumer access to medicines. The study finds that the impact on consumers is either nonexistent or negligible and depends on the cost sharing system in place, which typically requires relatively small patient contributions compared to that required of most US consumers. If cost sharing is of the flat rate type (whether flat rate per prescription or per pack), then the impact of parallel trade on consumers is zero because they are unaware of price differences. Of the six study countries, the LSE finds that cost sharing systems in the UK, the Netherlands, and Germany do not allow consumers to observe price differences between parallel imported and locally sourced drugs.

⁴⁰ Kanavos P and Costa-Font J (April 2005). *Pharmaceutical parallel trade in Europe: Impact on stakeholders and competition effects*. Paper prepared for the Panel Meeting of Economic Policy, Luxembourg. Accessed from <http://www.cepr.org/meets/wkcn/9/967/papers/Kanavos-Font.pdf>.

When, on the other hand, consumers pay a coinsurance (i.e., a percentage of the drug's cost), the financial benefits are proportional to the price differences between parallel-distributed and locally sourced drugs. (This effect is mitigated if there is a cap on out-of-pocket spending, particularly if the cap is low.) The LSE study finds that Scandinavian systems, operating on the basis of a deductible plus coinsurance up to a predetermined limit (beyond which health insurance reimburses 100 percent of the cost of prescription drugs), might offer marginal benefits to consumers who have chronic conditions. The presence of caps on cost sharing, however, eliminates the practical significance of these gains for chronically ill consumers. YHEC, on the other hand, offers an aggregate (macroeconomic) assessment of cost sharing but also find this to be nonexistent or very small (the latter in Scandinavian countries).

Impact on pharmacies. Both the LSE and YHEC studies that examined the impact of parallel distribution on pharmacies found that in Germany, Sweden, and Denmark, there were no direct and tangible financial benefits for pharmacists. For the Netherlands, the two studies found that pharmacists may gain because of the clawback and other financial incentives provided directly by the government. In the UK, the two studies agreed that retail pharmacies are likely to benefit substantially from parallel trade, but disagreed on the magnitude of the benefit: the YHEC study estimated discounts received from pharmacists to wholesalers, acknowledging that this is a nebulous area, whereas the LSE study accepted that discounts are confidential and, therefore, impossible to gauge with approximation let alone precision. The LSE study also found that pharmacists in Norway benefit by sharing the price difference between parallel-distributed and locally sourced drugs with the government.

Impact on statutory health insurance organizations. Four of the five studies provided a benchmark assessment of savings to health insurance from parallel trade. Despite the differences among studies in terms of the coverage of the market, the methodologies pursued, and the type of analytical tools used, all studies found that, as a proportion of the pharmaceutical market, savings to health insurance organizations are not likely to exceed 2.5 percent and in most cases are less than 1 percent. In practice, any efficiency savings from lower drug costs are usually plowed back into the system to maintain benefit levels, in effect providing savings to the health care system by limiting the expenditures needed to maintain those benefits.

Impact on wholesalers/parallel distributors. Both the LSE and ESRC studies provided benchmark analyses of the likely benefits of parallel trade to parallel distributors. The LSE study examined the impact of parallel distribution on parallel distributors by benchmarking export prices (from exporting countries) with prices of parallel-distributed medicines in importing countries. The LSE study found that parallel distributors are the key beneficiaries from this trade, as they realize the majority of benefits from engaging in arbitrage. In terms of the allocation of benefits from parallel trade, the LSE study found that, of the total impact of parallel trade across six key importing countries, 85.6 percent of the price difference between the importing and exporting market accrues to parallel distributors. This percentage is lower in some countries (e.g., Sweden, Norway, UK) and higher in others (Denmark, the Netherlands, Germany). The ESRC study used a simple macroeconomic analysis for the UK only to arrive at a similar conclusion as the LSE study, namely that parallel distributors realize the majority of pecuniary benefits from parallel trade (about 66 percent of the total pecuniary benefits).

Impact on pharmaceutical manufacturers. Two studies explicitly examined the direct impact of pharmaceutical parallel trade on pharmaceutical manufacturers from a social welfare perspective. The ESRC study examined the impact of pharmaceutical parallel trade on the UK industry and found lower revenues to pharmaceutical manufacturers of approximately €1.1 billion (about US\$1.3 billion) in a given year; this amounts to nearly 9 percent of the UK market for prescription medicines and is allocated as revenue to parallel distributors (€720 million, or about US\$880 million) and as NHS savings (€360 million, or about US\$440 million). The LSE study quantified the impact of parallel trade on drug manufacturer revenues to be approximately €755 million (about US\$925 million) across six countries, for a combined total of 25 percent of the sales for prescription medicines in these countries. As a proportion of the total brand name prescription drug market, this amounts to just under 9 percent and is allocated to parallel distributors, savings to health insurance, and additional revenues to pharmacies.

None of the identified studies assessed the dynamic impact of parallel trade on industry, in terms of quantifying any long-term changes in prices of drugs subjected to parallel trade.

Drug Manufacturers' Reactions to Commercial Parallel Trade

Any price reductions that occur as a result of parallel trade of pharmaceuticals in the EU are likely to come from the reduced revenue to pharmaceutical manufacturers, since these manufacturers would otherwise have sales at the higher prices. (This assumes that lower prices associated with PI have little or no effect on overall use, since residents of EU countries have substantial drug coverage.) One published study—sponsored by a pharmaceutical manufacturer—estimated that parallel importing in 2002 reduced pharmaceutical manufacturers' revenues by €700 million (about US\$860 million), or roughly 8 percent of the market value for the six product categories examined in the six countries included.⁴¹ By contrast, the effect of lower-price imported drugs in the United States on drug manufacturer revenues may be more ambiguous; while manufacturers would receive less revenue per prescription, use might also increase among consumers who otherwise would not fill the prescription because they lack drug coverage or have high cost sharing.

Pharmaceutical manufacturers argue that parallel trade undermines their profitability and, consequently, harms investment in R&D and the potential for discovering new drug treatments, and makes the EU increasingly unattractive for conducting business (thereby causing job loss, cutbacks, and industry relocation over the long term). At the same time, the European countries most affected by parallel importation also have relatively strong research-based pharmaceutical sectors (particularly the UK, Germany, Sweden, and Denmark and, to a lesser extent, the Netherlands). However, it is difficult to determine how lower manufacturer revenues associated with PI affect pharmaceutical R&D spending and even more difficult to predict how any changes in spending affect the development of innovative treatments. High-price countries such as the UK, Germany, Denmark, and Sweden continue to maintain policies supporting pharmaceutical R&D; while directly or indirectly encouraging the use of PI medicines through demand-side measures, their policies pertaining to price setting or reimbursement for innovative products remain relatively liberal (i.e., they allow higher prices for new drugs).

⁴¹ Kanavos et al. (2004).

One response to increased parallel trade of pharmaceuticals is that manufacturers are increasingly unwilling to launch new products in conventionally perceived low-price countries unless a minimum price is achieved in reimbursement negotiations. Moreover, recent jurisprudence by the ECJ essentially allows drug companies to carefully exercise control over their supplies without explicitly restricting PI flows.⁴² To that end, the legal framework allows industry to allocate quotas for each country and, in the future, fewer quantities of product may be available for parallel exporting. Taken together, these effects imply that manufacturers are increasingly responding to the threat of parallel trade.

6. THE RELEVANCE OF EU EXPERIENCE FOR U.S. MEDICINE PURCHASERS AND USERS

The European experience with commercial importation of pharmaceutical products offers a wealth of insights for U.S. policymakers currently engaged in debate on whether or not to allow drug importation into the United States from Canada, the European Union, or other countries. These insights, which are specific to commercial drug importation relate to (a) policing and enforcement of regulations about parallel importation; (b) impact on intellectual property and trademark rights; (c) legal issues; (d) economic implications for different stakeholders, particularly consumers; (e) meeting safety concerns; and (f) the likely impact of parallel trade on pharmaceutical R&D. (The analysis offers no insights on the potential impact of personal importation of prescription drugs, since this practice is not allowed in the EU.) However, the differences between Europe and the United States, particularly in prescription drug insurance coverage and cost sharing policies, imply that any conclusions drawn for the United States entail an element of speculation.

Potential Legal Framework for Commercial Importation

The legal framework for allowing commercial importation in the EU is based on the principle of free trade across national borders that is found in the EU treaty and that is further defined by EU legislation and judgments by the European Court of Justice. The European setting allows regional exhaustion of intellectual property rights, which means that patented pharmaceutical products (as well as other patented products) can move freely only within the EU. Importation from countries outside the EU is illegal if a marketing authorization holder operates within the EU.

Allowing drug importation into the U.S requires decisions about what exhaustion of rights regime it will have. Such decisions typically have been spelled out in legislation that is designed to legalize importation. For example, the Pharmaceutical Market Access and Drug Safety Act of 2005 (commonly known as the Dorgan-Snowe bill) would define exhaustion of rights by allowing commercial drug importation only from Australia, Canada, the EU (excluding those countries that have joined the EU since 2004), Japan, New Zealand, and Switzerland. It would also authorize the HHS secretary to expand this definition by allowing importation from other countries that meet certain specified drug approval standards.⁴³

⁴² European Court of Justice, Bayer-Adalat case (January 6, 2004).

⁴³ S.334, 109th Congress (2005).

Ensuring Safety of Commercial Imported Drugs

The European example suggests that commercial importation of prescription drugs between countries with similar regulatory standards for drug approval and distribution does not necessarily expose the population as a whole to greatly increased hazards. In contrast to concerns raised by critics of drug importation, there have been no cases in the EU of counterfeiting of drugs that have been attributable to drug importation. While there have been problems that have emerged associated with packaging, labeling, product inserts and potential violation of trademark rules, there is no evidence as to whether these problems have had an adverse impact on health care. Nor is there any evidence that these problems have raised substantial concerns among consumers, health care providers, or government officials.

Within the U.S., perhaps the most important issue to resolve concerns how to guarantee that imported products are of the same high standard as products that are specifically produced for the U.S. market. Such issues are not beyond the scope of legislation. For example, safety provisions could include requirements that importers and exporters be registered with the federal government and that the government have the right to inspect facilities and places of business, verify chains of custody of the products, and determine compliance with regulations. To reduce the incidence of packaging and labeling violations of imported drugs in the United States, it may be important that FDA be given the responsibility of identifying such violations, rather than placing the burden on drug manufacturers (as is done in the EU). FDA would also need significant additional resources to provide such oversight and enforcement of such responsibilities.

Potential Impact of Commercial Drug Importation on Savings

The degree to which drug importation provides savings to consumers and to the health care system is heavily influenced by the financial incentives and regulatory structures of the importing country's health care market (and assuming that a sufficient stock of imported drugs are available). In EU countries, where consumer cost sharing tends to be low, savings from PI drugs to consumers and the health insurance systems also tend to be low. Annual savings from use of parallel imported medicines in countries such as Germany, Denmark, the Netherlands, Sweden, and the UK are estimated to range from 1 percent to 2.9 percent of total drug expenditures.

The literature on the economics of parallel trade in the EU, while limited, nevertheless concludes that most of these savings accrue to distributors and other intermediate actors. Those health care systems that are able to achieve some of the savings have explicit systems in place, such as a clawback on pharmacy payments, to capture some of the financial gain from lower-priced drug imports. However, there are few incentives for consumers in EU countries—many of whom have comprehensive coverage for prescription drugs—to seek lower-priced parallel imports, and some statutory health insurance systems do not have the mechanisms in place to capture price savings.

Because U.S. consumers pay much more out-of-pocket for prescription drugs than do their counterparts in EU member states, savings from drug importation in this country would probably be quite different from that experienced in the EU. In the U.S., many consumers

will have an incentive to seek the lower prices that could be associated with using imported medications. Some of these consumers have no drug coverage, while others may be paying a substantial percentage of their drug cost and have gaps in coverage under which they incur all of the cost of their medications.

In addition, third-party payers could design coverage or reimbursement systems to capture some of the savings of imported medications. Under a scenario where commercial importation was legal in the U.S., third-party payers might require clawback payments from network pharmacies (similar to those prevailing in the UK and the Netherlands), or might demand higher discounts from wholesalers to reflect wholesaler acquisition of imported medications. They might also promote consumer choice of imported medicines or penalize consumers for not choosing an imported medication, just as they penalize consumers for not choosing a generic substitute when available.

Impact of Commercial Parallel Trade on Pharmaceutical R&D

In the EU, any savings from importation come at the expense of innovative pharmaceutical companies because they lose some amount of revenues in the higher-priced countries. However, there are no studies that show how lower manufacturer revenues from PI affects pharmaceutical R&D and new drug development, either in the countries with PI or in the EU overall. Specifically, it is not known whether PI leads to lower R&D spending by manufacturers, nor whether changes in pharmaceutical R&D affect the development of innovative drug treatments versus development of product extensions of existing products. In addition, some EU countries that engage in PI—notably the UK and Sweden—are home to some of the world’s most successful pharmaceutical manufacturers.

There are a number of possible scenarios for how legalized commercial drug importation could affect the pharmaceutical marketplace in the United States. For example, it is possible that allowing imported drugs could—at least in theory—*increase* drug manufacturers revenues, since some of the consumers who would be buying imported medications may currently not be buying the medicine at all. Another scenario is that U.S. drug importation would not lead to consistently lower prices. Under this scenario, rather than lowering list prices to the retail class of trade, U.S.-based manufacturers that feel threatened by importation may give higher discounts to their preferred customers in order to maintain their market share. The likelihood of this particular scenario is highly dependent on the pressure that imported medicines will exert on the U.S. domestic market. Pressure means large available volumes of medicines to be imported. As manufacturers are in a position to follow their global stock by monitoring consumption patterns in most markets, it is questionable whether sufficient (spare) quantities will be available in Europe or Canada to be imported into the U.S. It may also be the case that the spare quantities will not be available at a price to beat the discount already given to health insurers in the U.S. If this occurs, then drug importation probably would not have a lasting effect on prices.

7. CONCLUSION: IS COMMERCIAL DRUG IMPORTATION A SOLUTION FOR AMERICAN CONSUMERS?

The European example suggests that commercial importation of prescription drugs between countries with similar regulatory standards for drug approval and distribution does not necessarily expose the population as a whole to greatly increased hazards. The evidence from Europe suggests that, for consumers to benefit from parallel distribution, five conditions

need to be satisfied simultaneously. First, consumers need to have a financial incentive to seek lower cost drugs, either because they pay a substantial share of drug costs or they lack prescription drug coverage. Second, consumers must be aware that the parallel-distributed option may be available and actively seek to have a PD version from their pharmacy. At the same time, pharmacies or third-party payers may need to actively inform consumers that this is an available option; the incentive for pharmacies to do this usually is financial. Third, price differences between parallel-distributed and locally sourced drugs have to be meaningful for payers to be able to see in practice that they can benefit financially. The European experience suggests that any savings realized on prescription medications are marginal, chiefly because the majority of such benefits stay within the distribution system, whether this involves wholesalers, parallel distributors or pharmacists. This situation may be quite different in the United States, where some consumers pay all of their prescription drug costs, and many others pay for a substantial share of their drug costs. Fourth, a sustainable supply of parallel-distributed drugs needs to be in place for consumers to realize any financial benefits over the longer term. The European experience shows that PDs are not always able to maintain such a sustainable supply. Fifth, the perception of the parallel-distributed and locally sourced drug must be the same or comparable, i.e., consumers must not perceive a parallel-distributed medicine with scepticism and, as is sometimes the case in Europe, with suspicion (in most cases due to different packaging compared with what they are used to, different language on the box, different color pill, or other similar variables).

But even if all of the legal and policy issues associated with legalizing drug importation were overcome, such an approach, while reducing prescription drug costs for some individuals, would not necessarily by itself make drug costs affordable to American consumers or reduce the burden of rising pharmaceutical costs faced by consumers and their third-party payers. Even in EU countries with high importation, penetration of imported goods is about 20 percent of the market for brand name drugs. Furthermore, even with price regulations, pharmaceutical spending—both in high- and low-priced countries—continues to grow as a result of higher use per person and a change in mix from less-costly to more-costly products. Many EU member states have adopted measures to promote more cost-effective use of pharmaceuticals; key among these is the United Kingdom’s National Institute for Health and Clinical Excellence (NICE), which conducts and disseminates research on comparable effectiveness of medical treatments in order to promote the most cost-effective use of prescription drugs and other health technologies. Such actions may, in the long run, play a greater role than parallel trade in rationalizing pharmaceutical costs.

APPENDIX A: QUESTIONNAIRE ON PHARMACEUTICAL PARALLEL TRADE

1. What are the regulatory and legal requirements for the sale of parallel imported pharmaceuticals in your country?

- focus on the regulatory requirements [if any] for
 1. testing,
 2. authorization/approval,
 3. re-packaging,
 4. re-labelling, inserts/leaflets
- whether the brand name of the original product is allowed to be altered;
- how long is the authorization for a parallel imported medicine valid for;
- what is the cost/fee of a parallel import application

2. Do the government or the Sickness Funds encourage the dispensing of parallel-imported pharmaceuticals? If so, how?

- focus on any [financial or other] incentives provided by the government/sickness funds to pharmacists to dispense parallel-imported drugs, e.g. a higher margin or a higher dispensing fee;

3. Do the government or the Sickness Funds benefit financially from the dispensing of parallel-imported pharmaceuticals? (e.g. through a clawback system). If so, how does such a system work?

4. Are there other policies in place that could be perceived as encouraging or discouraging parallel imports of pharmaceuticals? (e.g. [explicit] movement towards the European Average Price in price-regulated countries; or [free] price modulation). If so, how do they work?

5. Could you provide a brief description of how the wholesale and retail market works in your country, focusing on

- margins for wholesalers for different types of products (in-patent, generics);
- margins for pharmacists for different types of products (in-patent, generics) and whether margins apply per product or per prescription
- fixed dispensing fees or other payments/allowances to pharmacists from health insurance organizations
- any official or unofficial discounts provided by the former to the latter

6. Any data on the extent of parallel imports in your country since 1994?

APPENDIX B: REGULATORY ISSUES RELEVANT TO THE PARALLEL IMPORTATION OF PHARMACEUTICAL PRODUCTS IN THE EUROPEAN UNION

1. What are the regulatory procedures regarding the approval of parallel imported medicines and how do these compare with locally sourced products?
2. What type of drugs get imported, and what are their likely sources (i.e. country)?
3. Given that their drug regulatory agencies do not have oversight over foreign supplies, how do countries address issues of
 - a. Safety
 - b. Inadequate labelling
 - c. Counterfeiting
4. To what extent have countries, as a result of drugs received through parallel importation, had
 - a. Counterfeits
 - b. Expired drugs
 - c. Labelling problems
 - d. Unsafe handling
5. What technology exists to minimise the effect of counterfeit and/or expired drugs, labelling problems or unsafe handling?
6. Do manufacturers reduce shipments to lower-priced countries in order to reduce parallel importing?
7. Is there a problem with unapproved drugs crossing the EU border?
8. Is there a problem with internet drugs or drugs that seem to be coming through an EC country but that are actually coming from somewhere else (e.g. India, Thailand)?

APPENDIX C: POLICIES AMONG SELECTED EUROPEAN COUNTRIES MANDATING DISPENSING OF PARALLEL IMPORTS, 2004⁴⁴

Denmark. In Denmark, pharmacists have a legal obligation to inform consumers of the availability of a PI drug, as long as the saving is greater than a threshold amount. Since Denmark requires variable cost sharing on prescription drugs (deductible plus coinsurance up to a limit, see Table 1 in text) consumers have, in principle, an incentive to accept less costly PI drugs if they are available and offered to them. Pharmacists have no direct financial incentives to dispense PI pharmaceuticals, and it can be argued that, all other things being equal, the pharmacy reimbursement structure may favor locally sourced original products over parallel imports (because the pharmacist margin is a percentage of the price, and a cheaper medicine will result in lower revenue to the pharmacy). However, pharmacists have a legal obligation to inform consumers of the availability of a cheaper PI drug when savings reach DKK 5 on a prescribed product priced to the pharmacy up to DKK 100 (about US\$16.50), 5% if the price is DKK 100–DKK 400 (about US\$16.50–US\$65), and DKK 20 (about US\$3.20) on products priced over DKK 400 (about US\$65). Consequently, savings from dispensing parallel-imported products accrue to the consumer and the national health system, not to the pharmacist.

Germany. Pharmacists in Germany have a legal and contractual obligation to the sickness funds (i.e., health insurers) to offer PI drugs when available. The national association of sickness funds and the German pharmacists' association have agreed to a system under which each pharmacy has a quota for dispensing parallel imports based on pharmacies' overall business with sickness funds. If a pharmacist/pharmacy does not achieve the parallel import savings target set for it in a given month, its reimbursement is reduced. If it exceeds its quota, then the pharmacist/pharmacy receives a credit that can be applied during periods when the import quota is not reached. Pharmacies may be able to renegotiate and reduce the quota limit on the basis of their dispensing patterns.

The Netherlands. The Netherlands has incentive structures in place allowing both pharmacies and the government to benefit financially from dispensing cheaper pharmaceutical products, whether these are parallel imported or not. The Dutch policies can be summarized as: (1) direct financial incentives to pharmacies and health insurance, and (2) the *clawback*, a mechanism whereby sickness funds ensure that the discounts Dutch pharmacists receive from wholesalers are being returned to the sickness funds as savings. In implementing this system, prescription products are 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 at the reimbursement price of the most expensive brand in the cluster that has at least a 15% market share. If the pharmacist dispenses a drug with a lower price than the reference price of the group in question, the pharmacist may keep one-third of the price difference as an incentive, with the remainder of the price difference accruing to the sickness funds. Lower prices may be due to a lower-price generic or a lower-price parallel-imported medicine. 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 incentive-related revenues should be considered regular pharmacy revenues in relation to establishing the fixed fee per prescription. Consequently, since January 1, 2002, the pharmacy tariff has been cut by €0.14 (about US\$0.17), which

⁴⁴ Source: Authors' analysis of a questionnaire survey of policies facilitating pharmaceutical parallel trade in selected EU countries, 2004.

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. A clawback has been in operation since 1998 to compensate sickness funds for purchasing economies that pharmacists make by negotiating discounts with wholesalers or parallel traders. In return for accepting a gradually increasing dispensing fee, pharmacists accepted a clawback of 8% since September 2003 (the clawback had previously been 6.82%) with a ceiling of € (about US\$11) per prescription. However, the clawback is the same for locally sourced and PI products and, therefore, is not exclusive to parallel imports of pharmaceuticals. As a result of a flat clawback rate, 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 by engaging in their purchasing economies, although this applies across the board to single-source drugs, parallel imports, and generics. As an alternative to the above method of setting pharmacy reimbursement, the reimbursement price to pharmacists for single-source PI drugs is based on the list price of the cheapest supplier per country from which the drug (form) originates, minus the 8% clawback, with a maximum per prescription of € (about US\$11).

Sweden. Sweden has no explicit policies to encourage dispensing PI drugs. However, the county councils responsible for (drug) reimbursement make an annual *ex post* payment to Apoteket (the unified Swedish pharmacy network) to compensate it for purchasing and using both parallel-imported, sourced-branded drugs and generic medicines. In 2000, Sweden lowered the fees for PI applications to promote their increased use. Other than the general annual *ex post* payment from government to Apoteket to use PI drugs and generics, there are no explicit financial incentives to Apoteket to dispense PI drugs; by contrast, Apoteket are legally bound to dispense a PI if one is available.

The United Kingdom. As in the Netherlands, low consumer cost sharing means that consumers have little reason to explicitly request PI products, since they do not benefit directly from such products being dispensed. However, also as in the Netherlands, pharmacists face both an incentive to dispense PI drugs and an indirect disincentive for not doing so. Because pharmacists receive the same reimbursement from the NHS regardless of the source of the drug, they face an incentive to dispense a lower-price PI product because they can keep the difference between the PI price and what they would pay to a domestic distributor. However, as in the Netherlands, the NHS assumes a certain level of parallel importing and imposes a clawback (10.4%, on average, in 2002) on pharmacist sales. In this way, the NHS promotes PI and shares in the financial gains from its use.⁴⁵

At the other end of the spectrum, the UK's PPRS, the entity that negotiates prices with manufacturers, has allowed "free price modulation" since the beginning of 1999. An interesting feature of price modulation is that, in principle, it allows companies to lower the prices of medicines that may be vulnerable to parallel import-driven competition, while making compensatory adjustments elsewhere in their product range. However, a judicial review of the PPRS found no robust evidence that the policy, in fact, encouraged manufacturers to lower UK prices selectively to discourage parallel trade.

⁴⁵ The clawback scheme in the United Kingdom does not apply to pharmaceuticals that have a high cost in terms of storage and distribution, such as vaccines requiring refrigeration, other unusually expensive items, or controlled drugs that need special record keeping.

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 at both the retail and wholesaler levels, a pharmacy would be inclined to sell the most expensive version of a drug to maximize its markup. 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.