July 1, 2004

Department of Commerce
ATTN: Kristie Mikus
14th and Constitution Avenue
Room 4039
Washington, DC 20230

RE: Request for Information Pursuant to a Study by Department of Commerce on International Drug Pricing as Required by Section 1123 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

INTRODUCTION

The Generic Pharmaceutical Association (GPhA) appreciates the opportunity to provide input to the U.S. Department of Commerce's International Trade Administration on international drug pricing. GPhA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. More than half of all prescriptions dispensed in the United States last year were filled with generics, yet generic drugs represent less than 8 percent of total pharmaceutical expenditures. No other industry has made, nor continues to make, a greater

contribution to affordable health care in this country than the generic pharmaceutical industry.

GPhA is committed to a balance between innovation and access. To that end, we are committed to innovation in medicines and the preservation of intellectual property protections both in the United States and abroad. With this fragile balance as our main concern, we strongly believe that it is essential that new trade agreements take into consideration existing U.S. measures relating to the accessibility of affordable pharmaceuticals. Accordingly, if trade agreements contain certain provisions that promote innovation, yet are devoid of other essential provisions that foster access to generics (such as the Bolar, generic exclusivity and declaratory judgment provisions), American's access to affordable medicines could be severely harmed as a result of future harmonization measures.

The generic pharmaceutical sector is uniquely impacted by harmonization of agreements on intellectual property protections for pharmaceuticals — particularly insofar as they increase market exclusivity periods or fail to include essential access provisions. New trade agreements could potentially affect American consumers' access to affordable drugs as well as the business interests of the U.S. generic pharmaceutical industry. As evidence to support our concern, we need only look at the fall-out of the harmonization efforts relating to TRIPS. A study conducted by University of Minnesota Professor Stephen Schondelmeyer concluded that the cost of the TRIPS harmonization efforts would "exceed six billion over the next two decades." The study also suggested that "[t]he annual generic savings lost by American consumers due to delayed generic entry [as a result of TRIPS] will range from $200 million in some years to over $500 million in other years."[1] Accordingly, the important role that generic drugs play in providing American consumers with affordable medicines can, and should be expanded into other nations; yet, we also

[1] S. Schondelmeyer, "Economic Impact of GATT Patent Extension on Currently Marketed Drugs," PRIME Institute, University of Minnesota, March 1995.

must be diligent in our efforts to preserve U.S. provisions that ensure access to affordable medicines here at home.

DISCUSSION

As the ITC responds to the Medicare Prescription Drug Improvement and Modernization Act of 2003's mandate to study and report on the drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development (OECD), GPhA urges it to consider the impact of such practices on the balance between innovation and access.

QUESTIONS

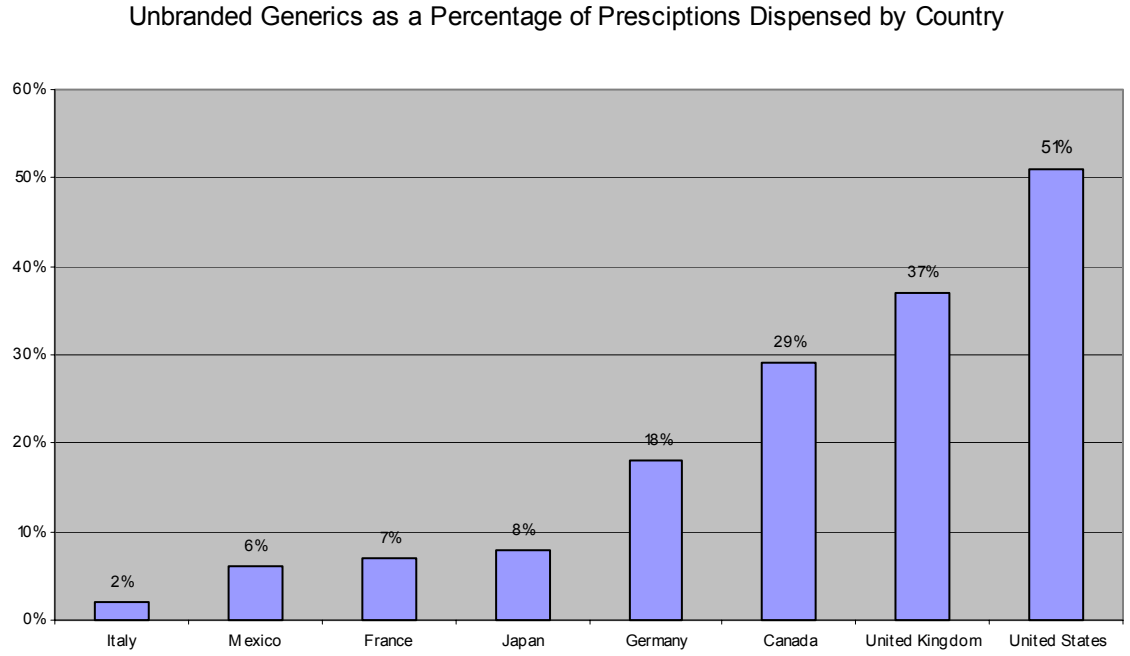
1. How do OECD countries set pharmaceutical prices? Within OECD countries, what mechanisms do governments use to control pharmaceutical expenditures?

The pharmaceutical pricing policies of OECD countries vary significantly and, thus, there is not one global policy that dictates how pharmaceutical prices are set. Countries generally follow into one of two categories: (1) highly regulated countries, such as Japan, Canada, and Italy; and (2) less regulated countries, like the U.K., Germany and the U.S. Consequently, some highly regulated countries use complex and aggressive price control schemes, whereas other countries in this category model their pharmaceuticals prices after neighboring countries. Because of the complexities and variants of pricing schemes of member countries, we have attached a chart outlining the practices of many of the OECD countries.

Of significance is the fact that in countries where prices of pharmaceuticals are heavily regulated, the generic utilization is low.[2] For example, in Italy the unbranded generic

[2] See Foreign countries data based on P.M. Danzon and L.W. Chao, "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries," October, 2003;

utilization rate is 2 percent. Likewise, in France and Japan, the unbranded[3] generic utilization rate is 7 percent and 8 percent, respectively. In contrast, countries with less regulation (Germany, U.K., U.S.), the generic utilization rates are much higher.[4] While Canada is a highly regulated country with price controls, Canada also has other significant governmental policies that encourage generic utilization.[5]



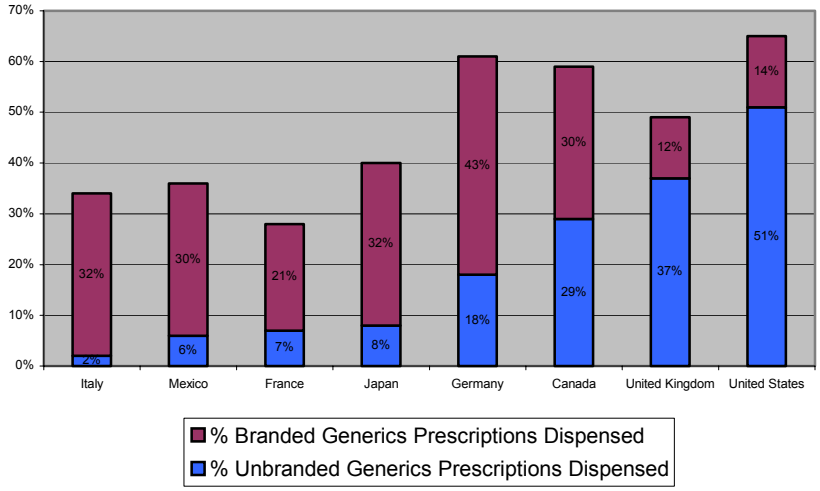
[3] "Unbranded generics" compete on price and, thus, are generally not marketed to physicians. In contrast, "branded" generics are products that compete partly on brand image and are marketed to the health care community.

[4] Id.

[5] In Canada, the generic drug price is about 80% of the brand price. Canada has had policies to encourage compulsory licensing and for pharmacists to dispense generics. Id.

Foreign countries data based on P.M. Danzon and L.W. Chao, "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries," October, 2003; U.S. data from IMS Health, 2003; Reugers News, Generic Drugs Sales Soaring to $80Bln by 2008, citing Graham Lewis of IMS Health discussing international generic growth, which confirmed the 2003 generic utilization rates of France (6%) and Italy (2%).

Branded & Unbranded Generic Drugs as a Percentage of Prescriptions Dispensed



Foreign countries data based on P.M. Danzon and L.W. Chao, "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries," October, 2003; U.S. data from IMS Health, 2003.

Another essential fact is that in the United States, the vast majority of generics are "unbranded" generic products. Thus, in the United States unbranded generics compete on price and not on the "marketing image" of the product. Competing on price within a free market system allows that U.S. to encourage strong generic substitution (51 percent), while also benefiting from a low percentage of total drug costs for these products (generics account for about 8% of the total U.S. pharmaceutical expenditures). In contrast, in

Germany, most of the generic products are "branded generics" (they compete on market image of the product) and the country has a total utilization rate of branded generics and unbranded generics of 61 percent. Yet, Germany's overall cost for these products is much higher, equally 34 percent of total sales.[6]

2. If price controls and other government cost mechanisms were eliminated in OECD countries, how and to what degree would pharmaceutical prices and expenditures change in those countries and in the United States? What effects would these changes have on the sales and profits of pharmaceutical manufacturers?

Although generic drugs account for over half of the prescriptions filled in the United States, the generic utilization rates in most other OECD countries are much lower. For example, in Spain, Japan, France, and Australia, 10% or less of prescriptions are filled with generics.

When prices of brand pharmaceuticals are heavily regulated by foreign governments, and in some cases the price of the generic artificially inflated, there is less incentive for consumers to switch to generics. Lower utilization also decreases the market for generic manufacturers and results in reduced competition. By removing the price regulation from the brand drugs, the need and the market for generics will expand, leading to more manufacturers, greater competition, lower generic drug prices, and ultimately greater overall cost savings than currently realized through price controls.

In the United States, governments, insurers, and individuals still have the ability to pay less for their prescriptions because of the robust generic drug market. In Canada, for instance, some generic drug prices are six to ten times more expensive than the U.S. generic

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[6] Id.

equivalent.[7] If Canadians had access to generic drugs at the price that they are in America, it would save the system $400 million annually.[8] Most other countries could save similar amounts or more by allowing the generic industry to flourish in their countries, by removing price controls, allowing true competition, and providing incentives for consumers to switch to generics when they are available.

Additionally, the generic drug industry in the United States produces cost savings while maintaining the incentive and reward for innovation of new and vital medicines. This balance rewards both the consumer and the manufacturer by encouraging research and development of new products now and providing a pathway for affordability in the future.

3. Could OECD countries reduce costs by increasing the use of generic drugs? What steps would the governments need to take to facilitate the use of generic drugs?

If foreign governments implemented aggressive generic substitution measures, they would likely realize savings that equal or exceed those of gained through price controls.
As previously stated, in the United States, 51% of all prescriptions filled are with generics, but they only account for 8% of the total drug costs. Research has shown that a 1% increase in generic utilization results in an additional 1% savings for consumers.

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[7] Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002
[8] Id.

The United States has adopted many different strategies for increasing substitution for generics by consumers. They include:

1. **Rigorous Federal Generic Abbreviated Approval Program: Yielding Consumer Confidence**
   U.S. law demands that generic pharmaceuticals must be the same as their brand counterparts. FDA assures that the generic product will provide the same medicine and produce the same medical results as that of the brand product. And, thus, FDA ensures that the variability of switching between a brand and U.S. generic product is not different than the variability between prescription refills of the same brand product. The only difference is cost.

2. **State Substitution Laws:**
   Most states have generic substitution laws that encourage the dispensing of generic pharmaceuticals, including mandatory substitution models. Also, some state programs have used more aggressive formulary and co-payments measures to provide an incentive to consumers to use generics.

3. **Economic Dispensing Incentive**
   Pharmacist and other healthcare providers have economic incentives to dispense U.S. generic pharmaceuticals.

4. **Consumer Education**
   Public and private entities provide educational consumers on the value of generic pharmaceuticals.

In the United States, government agencies, private market payers, and other interested groups have sought to educate consumers on generic drugs. Generic drugs are exactly the same as their brand equivalent and required to be approved by the Food and Drug Administration to be interchangeable. Health benefit plans and government programs that cover prescription drug costs for their beneficiaries have used among other things,

formularies, mandatory substitution, tiered co-payments, step therapy programs, and other means to encourage generic use. Driving consumers to generics by formulating preferred options through formularies or creating incentives for consumers through the differential of out-of-pocket costs between brands and generics have both proven successful for controlling costs in America without controlling prices being charged by the manufacturers.

The strength of the U.S. generic industry also been enhanced by several key congressional measures contained within the section 11 of the MMA, which have enabled generic drugs to enter the market more quickly. The provisions address among other things:

(1) Restoring the Value of Generic Exclusivity Reward to challenge questionable brand patents that needlessly block generic competition
(2) Preserving the Roche-Bolar provision that allows generic firms to develop drugs prior to patent expiry so that consumers will have timely access to affordable medicine.
(3) Eliminating multiple thirty month stays that needlessly delayed the introduction of affordable medicines.
(4) Shoring up the ability to bring a Declaratory Judgment action to secure timely resolution of patent disputes.

Yet, more can be done to further enhance the United States' utilization of generic pharmaceuticals and, thereby provide consumers and health care providers with additional cost savings. Actions include, but are not limited to: (1) solidifying a definitive, efficient pathway for affordable biopharmaceuticals; (2) mandating the use of therapeutically equivalent generics in all federal and state programs; (3) removing all needless generic substitution carve outs in federal and state programs; (4) having generic approvals be an Administration priority, with agency consults, legal and scientific issues resolved in a timely fashion, resulting in generic approval times of 180 days or less; (4) conducting scientific research to support the approval of nonsystematic generic medicines; (5)

substantially improve the funding for and staffing of the FDA's office of generic drugs; and (6) educating consumers of the value of generic medicines.

CONCLUSION

As the Commerce Department produces its report on drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development (OECD) and their effects on the United States, GPhA appreciates the opportunity to provide information on how generics can play an important role in providing access and savings. The generic drug industry in the United States has seen substantial growth over the past 20 years thanks to the Hatch-Waxman Act of 1984, which struck the balance between innovation and access. If countries with strict price regulations were to liberalize their regulations and provide incentives to encourage a vibrant and competitive generic drug market, the savings from generic utilization would provide access to quality medicine and also yield significant financial headroom to fund new innovative medicines. Also, a strong generic industry would produce more savings over time than the current pricing systems the foreign countries may have now, as well as spur innovation of new medicines.

Americans have access to both the newest medicines and affordable generic drugs thanks to open competition, protections for intellectual property, strong access provisions and rewards for taking risks. If other countries were to open their markets to true competition and infuse strong generic utilization policies into their health care system, utilization rates for generics should increase and lower overall drug expenditures.

Submitted by:
Generic Pharmaceutical Association

GENERIC PHARMACEUTICAL ASSOCIATION
ATTACHMENT I

EGA Survey 2004 on Pricing & Reimbursement Systems
www.egagenerics.com

The following tables and notes provide a summary of a selection of the information gathered from the survey EGA carried out recently on pricing and reimbursement systems throughout the EU and Greater Europe. The results of this survey represent the situation in the various countries as reported to us in January/February 2004. While every effort has been taken to ensure the accuracy of this presentation, P&R systems are notorious for changing frequently, so be sure to check with the appropriate authorities to verify the current status of any given point.

TABLE I: PRICING SCHEMES FOR GENERICS

Free Pricing?	D, FIN, S , UK , LT MT
Regulated pricing?	
% Below Originator	A(25-30%), B(26%), E(30%), F(30-40%), I(20%), NL(40%), P(35%), CRO(5%), CY(10-20%), EE(30%), HU, LV (20%), RO, SI , TR(20-30%)
Maximum price (index price)	DK, BG, CZ, PL, SK
Negotiable (price/volume)	IRL, PL

Notes:

S: Free, below originator price.

UK: Need to differentiate between hospital market, brand market etc. Changes due later in 2004.

LT: Price is proposed by producer, but if it is more than 5% higher from the average in all European countries where product is registered, it will be
difficult for the the product to receive reimbursement status (indirect price control mechanism).

MT: A call-for-tender system (including price) exists for products financed and distributed by the State.

LV: Price used to be 20% lower because of reimbursement policy (if higher, off reimbursement list); negotiable pricing is to be expected soon.

SI: Price must be 10% below existing products on the market. The maximum price for medicines is 85% of the average wholesale price (so-called comparative price) for the same product (or at least the same active substance and pharmaceutical form) in Italy, France and Germany. The maximum price for generics is 95% of the comparative price or 77.5% of the originator price if generic is not available.

TR: The price of a generic product cannot be more than 80% of the originator for the initial generic product to come to market. This price decreases for subsequent generic products.

TABLE II: GENERIC PRESCRIBING

Question	Yes	NO
Are doctors encouraged to prescribe generics?		A, B, D, GR, NL, BG, CRO, CY, EE, HU, PL, SI , TR
If yes: Is this done through... Budgetary restrictions? Budgetary incentives? Other means?	 I, LV, LT, MT, RO, CZ, SK E , IRL, P , UK DK, F, FIN, S	

Notes:
I: If the doctor prescribes an originator product that costs more than an equivalent generic medicine and if does not want the pharmacist to substitute the prescribed product with a generic, this decision must be explained and justified.
LT: Not very strictly controlled after bad experience. This is politically very sensitive.
MT: Regulated by purchasing/State Formulary mechanism, not individual budget.
CZ: Yes but limited.
E: In Spain several autonomous regions have competencies over pricing & reimbursement issues. In some of these, prescribing is encouraged by budget, in some by incentives, and in others both means are used.
P: The Portuguese government has run a highly successful "pro-generic" information campaign aimed at consumers.
UK: Primary care budgetary targets incentivise the use of generics. Generic prescribing is the norm in hospitals.
DK: Generic substitution.
F: In June 2002 consultation fees were raised to €20 in exchange for increased generic prescribing, but no direct incentives to prescribe generics were established.
FIN: Formally no, but generic substitution was implemented on 1 April 2003. The substitution system encourages doctors as they want to control/know which products patients are actually receiving, and if patients are asking for less expensive products.
S: Generic substitution rules require dispensing the least expensive product at the pharmacy. Budgetary

restrictions exist at local levels, but not for individual doctors.
SI: Only budgetary monitoring and comparison of individual prescription habits between doctors, but without legal restriction.

TABLE 3: GENERIC SUBSTITUTION

Question	YES	NO
Is Generic Substitution Allowed?	D, DK*, E, F*, FIN* , I*, NL, P*, S*, EE*, HU, LV*, LT, MT, PL, RO, SI	A, B, GR, IRL, UK , BG, CRO, CY, CZ , SK, TR

Notes:
***** In many cases doctors can prevent generic substitution by ticking a box or by writing "NS" (No Substitution) on the prescription form.
D: Doctor's decision / Pharmacist's voluntary decision.
E: Doctor's decision. Is allowed in certain situations, such as when a prescription does not respect the reference price or if the pharmaceutical company is not delivering due to stock problems.
FIN: Generic substitution is obligatory, but the patient has the final word. Even when the generic product is refused, the patient will still receive full reimbursement for the more-expensive originator product.
I: Legal obligation.
NL: Doctor's decision.
S: Substitution is compulsory, unless the patient is willing to pay the difference in price.
UK: Not in local pharmacies. Substitution is general practice in hospitals.
CZ: Only in exceptional cases when there is no prescribed product; not very often used.

TABLE 4: INFORMATIONAL CAMPAIGN

Question	YES	NO
Has the govt. undertaken an active information campaign on generics for consumers?	E, F, I, P, SI	A, B, DK, D, GR, FIN, IRL, NL, S, UK, BG, CRO, CY, CZ, SK, TR, EE, HU, LV, LT, MT, PL, RO

Notes:
I: Two years ago in 2002.
SI: It was more an education campaign.

Abbreviations Used

A— Austria	**I — Italy**
B — Belgium	**IRL — Ireland**
BG — Bulgaria	**LV — Latvia**
CRO — Croatia	**LT — Lithuania**
CY — Cyprus	**MT — Malta**
CZ — Czech Repub.	**NL — Netherlands**
DK — Denmark	**PL — Poland**
D — Deutschland	**P — Portugal**
E — Spain	**SK — Slovakia**
EE — Estonia	**SI — Slovenia**
FIN — Finland	**S — Sweden**
F — France	**TR — Turkey**
GR — Greece	**UK—United Kingdom**
HU — Hungary	

Generic Pharmaceutical Association

ATTACHMENT II : GENERAL OVERVIEW OF PUBLIC LITERATURE

COUNTRY	SOURCE	PRICING
Australia	(LSE Health): Stevens, Alan, "Pharmaceutical Pricing and Reimbursement Policies in Australia", 2001.	**Pharmaceutical Benefits Scheme (PBS):** Considerable subsidies are paid for pharmaceuticals covered by the PBS, which means that the price to the consumer is lower than it might otherwise be. Pharmaceuticals listed under the PBS fall into three broad categories: - Unrestricted: these medications have no restrictions on their therapeutic uses; - Restricted Benefit: the listing in the PBS Schedule details the specific therapeutic uses for which these medications can be prescribed; and - Authorized Required Benefit: as with the Restricted Benefit, the Schedule lists the specific uses for which these medications can be prescribed is required to obtain prior approval from the Government's Health Insurance Commission. **Pricing of pharmaceuticals:** Demand for prescription pharmaceuticals is significantly influenced by the operation of the taxpayer-funded PBS. Accordingly, pharmaceutical firms are keen for their products to be listed on the PBS to generate sales. Products will be considered for listing after receiving marketing approval from the Therapeutic Goods Administration (TGA), which considers safety and efficacy issues. Applications for listing on the PBS are considered by the independent Pharmaceutical Benefits Advisory Committee (PBAC) which consists of medical specialists, general practitioners, a pharmacist and a consumer representative. When recommending which drugs and medicinal preparations should be subsidized through the PBS, the Committee

COUNTRY	SOURCE	PRICING
		must be assured that the drug is effective, safe and cost-effective in comparison with other available treatments. **Price Control Policies:** The majority of prescriptions are written for medications that are subsidized under the PBS. The price of all products listed on the PBS are reviewed annually by the Pharmaceutical Benefits Pricing Authority (PBPA). The price reviewed and agreed to with suppliers is at the price to pharmaceutical level (which includes a 10% wholesaler's margin). In reviewing the price of listed items and in considering the price of items recommended for listing, the Authority takes into account the following factors: 1- PBAC comments on clinical and cost effectiveness aspects of items; 2- The price of alternative brands of a drug; 3- Comparative prices of drugs in the same therapeutic group; 4- Cost information provided by the supplier; 5- Prescription volumes, economies of scale and other factors such as expiry dating, storage requirements, product stability and special manufacturing requirements; 6- The level of activity being undertaken by a company in Australia, including new investment, production, R&D 7- Prices of the drug in reasonably comparable countries; 8- Other relevant factors which the applicant company may with the Authority to consider; and 9- Any directions of the Minister. **Pricing methods used by the PBPA**: 1- Benchmark pricing 2- Cost Plus Method 3- Average Monthly Treatment Cost
	---------- *World Pharmaceutical Markets*, December 18, 2003	

COUNTRY	SOURCE	PRICING
		Prices for New Items: The main mechanism to determine initial prices is the advice of the PBAC which provides advice on clinical effectiveness and cost effectiveness (value of money). In recent years the PBAC has increasingly recommended the use of price/volume arrangements. **Special Cases for Pricing:** Brand premiums: Therapeutic Group Premium Arrangements Special Patient Contribution Arrangements ---------- The Australian market for pharmaceuticals stood at around US$4.9 billion in 2002, equal to US$248 per capita. The per capita figure is relatively low for a developed country due to a number of reasons. Drug prices are relatively low in Australia, compared with many other developed markets, principally due to government price controls. Medicines Australia has estimated that around 87% of drugs are priced below the OECD average. Despite continued pricing and reimbursement pressures, growth in the market stood at around 9.5% (local currency terms) in 2002. This partly reflects the increasing use of the newest, most expensive drugs.
Austria	(LSE Health): Kanavos, Panos, "Austria: Pharmaceutical Pricing and Reimbursement" 2001.	A new pricing and reimbursement system was introduced in October 1998, replacing price controls with a price-contracting scheme involving price/volume agreements and rebates on excess sales. Companies will propose a price to the Krankenkassen, giving all necessary supporting data. The two parties will come to an agreement on price as well as on rebates if agreed sales volumes are exceeded. The product will then be placed on the Social Security Reimbursement list. The paybacks will take the form of either a price cut or a cash rebate depending on the number of packs sold. The previous price law is unaffected, since it provides only that the Minister of Health "may" set maximum prices. For the first time, the agreement provides companies the opportunity to choose between the net price contracts, which have been the norm in

COUNTRY	SOURCE	PRICING
		Austria and price/volume contracts.
Belgium	(LSE Health) Kanavos, Panos & Eggermont, Michael, "Belgium: Pharmaceutical Pricing and Reimbursement", 2001. --- *World Pharmaceutical Markets*, May 19, 2003.	Price setting: A medicine authorized by the Medicines Commission cannot be sold in Belgium until its price has been set by the Ministry of Economic Affairs. The price may be forced downwards later on, if reimbursement status is sought. Pharmaceutical companies submit their price application simultaneously to the Transparency Commission (Ministry of Health) and the Commission des Prix Specialites Pgharmaceutiques (CPSP; Pricing Commission) which advises the Ministry of Economic Affairs. The Pricing Commission is supposed to reach a unanimous decision, but if no consensus is reached all voting members advise the Minister of Economic Affairs independently. The Minister does not need to provide a justification for the price decided upon. As part of the government's efforts to speed up the overall approval, pricing and reimbursement times, the price setting process is parallel to the registration process. No formal system has been yet developed for comparing prices. Members of CPSP believe that setting a fair price is very difficult, largely because of the cost of data (or transfer price) supplied by the applicant are not sufficiently specified or transparent to determine which cost components are included (or double counted) and how much is spent in R&D. Therefore, especially for NCEs, they resort to comparing prices with prices of the same products in other EU member states and with prices of similar products already reimbursed in Belgium. In addition to that particular attention is placed on general and administrative costs, investment in R&D and salary costs. There is no regulation that specifically changes the price of a pharmaceutical product when its patent expires. Generics must be at least 20% cheaper than the branded product to qualify for reimbursement. In March 1994, a law was passed to allow companies to negotiate price-volume contracts for innovative products. **Price revisions:**

COUNTRY	SOURCE	PRICING
		Price revisions (price freezes and cuts) have been very frequent and are partly associated with the country's efforts to meet the Maastricht convergence criteria. --- **Cost Control Policy:** Since 1990, the drug industry has been subject to a tax on pharmaceutical revenues generated by sales of reimbursable drugs. Initially set at 2.5%, the tax has been revised several times and reached 4.5% in 2001. The sales tax represents an annual charge of around 75 million euros to the pharmaceutical industry. In 1996, the Belgian authorities began to implement a number of measures to curtail rising drug expenditure, including a price freeze on all reimbursable pharmaceuticals, a 2% price reduction on all pharmaceutical specialties and a 4% price reduction on drugs registered for more than 15 years. The price reduction for drugs registered for more than 15 years (which was subsequently increased to 8% in 1999 and 12% in 2000) has largely been justified by the fact that Belgian prices for older drugs are above the European average. However, the pharmaceutical industry is concerned that the measure applies not only to old molecules but to all generic forms containing these old molecules, despite the fact that these new preparations have their own R&D costs. In 2000, further price control measures included a 20% reduction in the price of large drug packs, and selective price cuts for drugs in high volume therapeutic classes. In late 1999, the Ministry of Social Affairs asked the CTSP to investigate the possibility of simplifying reimbursement procedures for certain groups of drugs in exchange for significant price cuts from the manufacturers in question. In January 2001, an agreement was reached which saw the price of H2 antagonists cut by one third. In exchange for the

COUNTRY	SOURCE	PRICING
		price cut, prescriptions for H2 antagonists no longer require pre-approval from INAMI. According to the pharmaceutical industry, AGIM, the overall bill to the pharmaceutical industry of the government's price control measures between 1990 and 2002 amounted to 1.4 billion euros, of which 169 million euros in 2000 alone.
Canada	*World Pharmaceutical Markets*, May 26, 2004.	The Patented Medicine Prices Review Board (PMPRB) was created in 1987 to ensure the pricing of patented medicines is not 'excessive'. The PMPRB reviews the prices of all new and existing patented products, whether they are prescription or over-the-counter (OTC) drugs, and has annually published pricing guidelines for manufacturers since 1989. While the PMPRB operates a policy of voluntary compliance, additional powers were given to the board in 1993 under Bill C-91, whereby the Board can reduce excessive prices set by manufacturers, return excess revenues to the federal government, and fine or imprison the violator. Manufacturers are required to report introductory prices within 60 days of the first sale and continue to provide price and sale information for each six month period while the drug remains patented. While there is no requirement for a manufacturer to seek the approval of the PMPRB before implementing a price increase, the PMPRB expects manufacturers to comply with the Guidelines. The PMPRB monitors prices as part of its regulatory mandate, to ensure this is the case. Under the PMPRB Guidelines, price increases are limited to increases in the Consumer Prices Index (CPI). In 2002, the prices of patented medicines declined by an average of 1.2% compared with the previous year. In 2004, the price increases allowed for patented drug products are based on the forecast increase in the CPI of 2.2%. The Guidelines allow a larger increase in some cases, but never more than 3.3%.

COUNTRY	SOURCE	PRICING
	---------- (LSE Health) Corvari, Ron, King, Derek and Sanidas, Micheal, "Canada-Pharmaceutical Pricing and Reimbursement", 2001.	**Policies at the Federal Level: Pricing of Patented Pharmaceuticals:** The Patented Medicines Prices Review Board (PMPRB) is an independent quasi judicial body which protects consumer interests and contributes to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive. The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada for human and veterinary use to ensure that they are not excessive. If, after a public hearing, the Board finds that a price is excessive it may order the patentee to reduce the price and take measures to offset any excessive revenues it may have received. In many cases the price reviewed by the PMPRB is the "factory gate" price at which the manufacturer sells the product to wholesalers, hospitals or pharmacies. The PMPRB's jurisdiction includes patented medicines marketed or distributed under voluntary licenses, has no authority to regulate the prices of non-patented drugs, including generic drugs sold under compulsory licenses and does not have jurisdiction over prices charged by wholesalers or retailers nor even pharmacists' professional fees. The PMPRB regulates the price of each patented drug product, including each strength of each dosage form of a patented medicines. Excessive price guidelines: The Patent Act stipulates those factors that the Board, during the course of a public hearing, must take into consideration when determining whether a medicine is being sold or has been sold at an excessive price. These factors are: - the prices at which the medicine has been sold in the relevant market; - the prices of other medicines in the same therapeutic class; - the prices of the medicines and of the other medicines in other countries;

COUNTRY	SOURCE	PRICING
		- changes in the Consumer Price Index; and - such other factors as may be specified by regulations. If after considering these factors, the Board is unable to determine if a price is excessive, it may consider the costs of making and marketing the medicine as well as well as other factors, which can be specified by regulations or that the Board considers relevant in the circumstances. The PMPRB reviews the average price of each strength of an individual dosage from of each patented medicine. In most cases, the unit is consistent with the assigned Drug Identification Number, or DIN. The Regulations provide for the reporting of the average price per package or the net revenue from each package size of a DIN. Pursuant to the Regulations, the average price or the net revenue should take into account reductions given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts and other such benefits. The Board, in consultation with interested parties, has developed various tests to determine whether the price of a drug product is within the Guidelines. The Reasonable Relationship Test considers the association between the strength and the price of the same medicine in the same or comparable dosage forms. The reasonable relationship test defines a maximum non excessive introductory price for the DIN. The determination will be based on one of three possible tests: Test 1: Same Strength Test Test 2: Unit Price Linear Relationship Test Test 3: Different Strength Test The Therapeutic Class Comparison Test compares the price of the DIN under review with the prices of DINs that are clinically equivalent and are sold in the same markets at prices that the Board considers not to be excessive. The International Price Comparison Test compares the average

COUNTRY	SOURCE	PRICING
		transaction price of the DIN under review with the publicly available ex-factory prices of the same medicine sold in countries listed in the Regulations (Germany, France, Italy, Sweden, Switzerland, The United Kingdom and the United States)
Czech Republic	*World Pharmaceutical Markets*, August 19, 2003.	Czech drug reimbursement levels are tightly controlled by the government, and are considered to be among the lowest in Europe. The relevant legislation is No. 509/2002, which replaced the older drug decree 57/1997. The basic format of the price/reimbursement system remains the same, however. Prices for all pharmaceuticals are controlled through the reference pricing system which only allows for the defined daily dose of the cheapest drug within a therapeutic category to be reimbursed. More expensive drugs are prescribed subject to patient co-payment.
Denmark	*World Pharmaceutical Markets,* June 16, 2003	The pricing of all goods in Denmark is monitored by the Competition Council, which has the authority to intervene against unreasonable prices. Prices are assessed on the basis of necessary production and marketing costs. Since 1983, however, special consideration has been given to intensive research and development based industries, such as the pharmaceutical industry. The Council has not, since the 1983 Act was passed, had cause to intervene against prices of medicinal products set by manufacturers and importers. Following the introduction of price freezing in January 1994, free pricing for prescription pharmaceuticals ceased in Denmark. In March 1995, the Ministry of Health entered into an agreement with the pharmaceutical industry, whereby importers and manufacturers reduced the prices of prescription drugs covered by the reimbursement scheme by five per cent. Non-reimbursable prescription drugs and OTCs were subject to a two per cent price reduction. This agreement was in force until 1st April 1997, by which time no new agreement had been reached with the industry on further price reductions. As a result, Act number 224 was passed, introducing a temporary price freeze for medicinal

COUNTRY	SOURCE	PRICING
		products. Under the Act, companies were restricted to the pharmacy purchase prices in force as of 24th March 1997. For new products, first marketed after 1st April 1997, the price could not exceed the initial notified price before 1st March 1998, although exceptions were allowed in special circumstances under the authority of the Danish Medicines Agency. The two-year pricing agreement between the Danish Pharmaceutical Manufacturers' Association (Lif) and the Ministry of Health ended in March 2000, allowing companies to fix their own prices. The agreement, introduced in February 1998, allowed limited growth in health insurance reimbursement spending of 0.8% in 1998 and 3% in 1999. In addition, the prices of reimbursable products could not increase before 1st March 2000, and OTCs were restricted to a 5% increase over the same period. In December 2000, another price freeze was introduced. The freeze covered reimbursable pharmaceutical products and has caused some controversy due to different price ceilings placed on products sold only in Denmark and those also sold in other European countries. Prices for products in the first category were fixed as at 17th November 2000. Prices for products sold outside Denmark were calculated by taking the average price in other European countries as at 17th November. If the average was less than the Danish price, then the average price applied. This price freeze lasted until 25th June 2001, when a new scheme was introduced, whereby prices cannot exceed the average price for the same medicine sold elsewhere in northern Europe. The countries selected for comparison include 11 EU member states along with Iceland, Liechtenstein and Norway, but exclude Greece, Luxembourg, Portugal or Spain. Since October 1991, wholesalers' profits have been determined by competition and are fixed as a result of individual negotiations between wholesalers and manufacturers or importers. Pharmacy

COUNTRY	SOURCE	PRICING
		gross profits are usually fixed in accordance with agreements between the Ministry of Health and the Association of Danish Pharmacy Proprietors. As a result of the agreement between Lif and the Ministry of Health, the pharmacies' gross profit for 1998 was set at DKr 1,876 billion. As with other commodities in Denmark, medicinal products are subject to VAT, currently at 25% of consumer prices. Transparency Lists Subsequent to the introduction of the reference price system in 1993, the Ministry of Health publishes quarterly reference price lists, which also contain price comparisons for the medicinal products covered by the scheme. The National Board of Health informs pharmacists fortnightly of the prices of all available medicinal products on the market for comparison purposes. General practitioners may also subscribe to this information. Generic substitution Since 1991, a generic substitution scheme, the 'G' scheme, has been in operation in Denmark. Under the original scheme, doctors were able to choose to write a generic prescription, leaving the choice of drug to the pharmacist. Since 19th May 1997, however, a 'G' has been printed on all prescriptions and the scheme has effectively operated in reverse. In effect, when a pharmacist receives a 'G' prescription, the cheapest generic product should be dispensed, unless the doctor specifically marks the prescription to the contrary. Substitution is mandatory in the following circumstances: * For medicinal products priced at less than DKr 100, the pharmacist must substitute the medication for the cheapest product, if this is at least DKr 5 below the price of the product prescribed by the doctor; * For medicinal products priced at DKr 100 and upwards, the pharmacist must substitute when a product is available at five per cent or DKr 20 below the price of the prescribed product.

COUNTRY	SOURCE	PRICING
		Patients must be informed of generic substitution, however, and have the right to refuse. In addition, pharmacists are obliged to inform patients of price differences between original products and parallel imported products, following the same guidelines as for generic products. In June 1997, a notice was published by the Board of Medicines instructing doctors how to declare non-substitution preferences on the prescription form. The instructions allow doctors to request no substitution, no generic substitution, or no substitution with a parallel import with a different name from the Danish original. The notice states that if the doctor does not state that a specific product must be dispensed, and if a parallel import with the same name is available, then the pharmacist may dispense either the original or the parallel import under the previous guidelines.
France	*World Pharmaceutical Markets,* November 18, 2003.	The prices of reimbursable drugs are regulated by the government, whereas all other drug prices, i.e. non-reimbursable drugs, and drugs sold to hospitals, are freely set by manufacturers. Since 1994, the price of reimbursable drugs has been set on the basis of negotiations between the company concerned and an interministerial drugs pricing committee initially known as CEM (Comite Economique du Medicament) and then as CEPS (Comite Economique des Produits de Sante) within the context of a series of industry framework agreements which were signed in January 1994, July 1999 and June 2003. In recent years, the pricing system has placed increasing emphasis on the real therapeutic value of products and the work of CEPS has been strengthened through the establishment of a group of experts in the pharmaceutical economics field to assist the pricing committee in its assessment of product value and the criteria for proving clinical improvements over existing products has been strengthened. The pricing process for new products incorporates a number of phases, involving CEPS and the Transparency Commission, which is charged with assessing the medical value of products. Once an

COUNTRY	SOURCE	PRICING
		application has been received, the Transparency Commission assesses the product and gives it a value rating known as the ASMR (amelioration du service medical rendu). This decision is then communicated to the pricing committee which enters into negotiations with the company. Price setting is based on the product's ASMR rating, prices of comparable medicines and projected consumption levels. Pricing decisions are then published in the Official Journal. A total of 1,162 drug pricing applications were received by CEPS in 2002, a fall of 35% over the 1,785 applications made in 2001. Generics accounted for around 36% of applications (31% in 2001). During 2002, CEPS dealt with 1,688 applications from 142 companies, up 12% on 2001. The increase in activity enabled the backlog of applications, which had been rising steadily in recent years, to be cut from 1,319 at the end of 2001 to 793, of which 384 concerned first-time registrations. In recent years, the CEPS has been trying to speed up its decision-making time in line with EU time limits. In 1996, only 17% of products were dealt with in 180 days or less, and the majority of these were generics. By 1999, drug pricing decisions were taking an average of 196 days, close to the EU target, with generics averaging 166 days and products approved through the European centralized procedures taking an average of 231 days. However, the average time taken to reach a pricing decision rose again in 2001 and 2002 to 202 days and 243 days respectively. This was despite the fact that the government had pledged to further reduce the length of the pricing process by speeding up communication between the Transparency Commission and the CEPS, and by reducing delays (currently around two months) in officially publishing pricing decisions. In 2002, first-time registrations were processed in an average of 216 days up from 186 days in 2001 and 177 days in 2000, when 68% of applications were dealt with in less than six months. Applications for generics were processed faster at an average of 135 days for all generic applications and 99 days for first-time registrations. The longest time lapse was recorded for line

COUNTRY	SOURCE	PRICING
		extensions, which took an average of 337 days. According to CEPS, one of the reasons the average time to reach a pricing decision was so much higher in 2002 was its success in cutting the backlog of applications last year, meaning that the committee's workload included a greater proportion of longstanding applications than in previous years. The contract pricing agreement between CEPS and the pharmaceutical industry includes a clause designed to speed up pricing decisions on products approved through the European centralized system. This allows companies to submit pricing applications to the CEPS, following a favorable decision by the Committee for Proprietary Medicinal Products (CPMP), but before an official authorization has been published. Following the signing of a second industry framework agreement in July 1999, all companies with sales over 15 million euros were required to sign a contract with the pricing committee before the end of 1999 or be subject to a payback mechanism if annual drug spending targets are exceeded. Price contracts, valid for a maximum of four years, set agreed prices for all of a company's reimbursable products, and also cover other factors such as annual growth targets, and levels of promotional spending. The pricing system also incorporates a new rebate system, whereby individual companies are required to pay back a certain percentage if their sales levels exceed the agreed annual growth targets. This is in addition to an industry-wide rebate system, which the government can impose if sales growth in certain therapeutic classes is deemed excessive in comparison to the overall annual growth rates for pharmaceutical expenditure. The pricing committee also launched an initiative to eliminate wide variations in prices within therapeutic categories, particularly for those products that have been on the market for many years. This process, which involved drawing up average daily treatment costs for commonly used products, has resulted in a series of imposed

COUNTRY	SOURCE	PRICING
	---------- "Why Foreign Drugs are Cheaper", *The National Journal*, April 17, 2004	price cuts in recent years. The five product categories initially targeted were vein tonics, vasodilators, calcium supplements, magnesium supplements and mucolytics. The pricing review is separate to a review of all reimbursed products launched in mid-1999 by the Transparency Commission to assess at what level products should be reimbursed, if at all (see reimbursement below for further details). In addition to price cuts resulting from the Transparency Commission's review, CEPS also implemented a series of price cuts in 2001 targeting mainly well established high volume products, which were registering high growth rates. A total of 103 products in 253 presentations were affected by this procedure, comprising mainly statins and sartan cardiovasculars, PPIs, antibiotics, antidepressants, H1 antihistamines, growth hormones, triptans and setrons. Price reductions ranged from 1% to 15%, the majority being 4%-5%. CEPS assesses the overall saving at 202 million euros, based on sales volumes in 2000. Whereas the price cuts due to insufficient medical benefit have tended to affect mainly French firms, many multinationals, including GSK, Novartis Pharma, MSD-Chibret, Roche and Lilly, were affected by this measure and in some cases relatively new products had their prices reduced. A third framework agreement was signed between the government and the pharmaceutical industry in June 2003. The agreement, which runs until 2006, maintains the system of rebates incorporated into the previous framework agreement, but introduces a new pricing system for innovative medicines, which should enable companies to benefit from higher prices for these products. Under the new system, manufacturers of new products given a medical value rating of I or II can request a price (valid for five years) broadly in line with price levels of other major European markets (Germany, Italy, Spain, UK), provided the company agrees to recompense the social security system in the event of its initial sales forecasts being exceeded. Products given a rating of III may also

COUNTRY	SOURCE	PRICING
		benefit from this system provided their sales levels are not expected to exceed 40 million euros by the third year of marketing. According to the pharmaceutical industry association LEEM, around 15 new drugs will be eligible each year. The agreement also promises to cut the time it takes for important new drugs to come to market. A target of no more than 180 days has been set for drugs approved under the centralized European procedure and for drugs with a value rating of III or IV. Innovative products processed under the price proposal procedure will benefit from even shorter times; 70 to 80 days according to LEEM, which is hoping that actual approval times for other drugs with a medical benefit of IV or higher will average 120-130 days. Pharmacy margins are agreed with the government. LEEM calculates that in 2002 pharmacists received an average of 25.2% of the retail price of a reimbursable drug, while manufacturers received 66% of the total price and 3.3% went to wholesalers. The remaining 5.5% went to the government in the form of value added tax (2.1%), and other charges (taxes on advertising, levies on direct sales etc). In September 1999, a new pharmaceutical distribution margin system came into effect. Designed in part to encourage generic substitution by pharmacists, the new system replaced the former six-tier mark-up with a two-tier mark-up of 26.1% on products costing up to 23 euros (ex-factory prices) and 10% on those costing more than 23 euros, in addition to a dispensing fee of 0.5 euros per pack. An additional payment of 0.3 euros is made for some 40 special products including HIV/AIDS medications, preparations used in the treatment of drug/alcohol addiction, and stupefacients. At the same time, generics were allocated a special mark-up, equivalent to the margin applicable to the originator product within each generic group. Whilst pharmacists have benefited from a more favorable system of margins, wholesalers, who were recently criticized in a report by the French Court of Accounts for making excessive profits, stand to lose out, partly through lower wholesale margins, and partly because pharmaceutical manufacturers are now

COUNTRY	SOURCE	PRICING
		able to offer discounts of up to 10.74% on the wholesale price of generics, compared to 2.5% on reimbursable drugs. Figures from LEEM reveal that while the cost of living more than doubled between 1980 and 2000, the retail price of pharmaceutical products increased by only 34% over the same period. According to SNIP, pharmaceutical prices in France, though still not comparable to those in free-pricing countries such as the UK and Germany, are beginning to differ from those in other countries applying a controlled price policy (e.g. Italy and Spain). Overall, French prices are close to the European average, but they remain more than 20% lower than prices in the UK and Germany, although they are 30% higher than prices in Spain. ---------- *How Drug Prices Are Determined:* France, which has a national health care system, caps the total amount it will pay for drugs annually nationwide. At the beginning of each year, drugmakers enter into price and volume agreements with the government. Once a drugmaker sells to the limit, the firm must pay the government a rebate for any additional sales. *Pharmaceutical Industry Complaint:* U.S. drug companies say the volume caps often work against drugs that sell well. They say they cannot in good conscience stop supplying drugs partway through the year and that companies are penalized for any drugs they furnish after reaching their volume limit. *Current Status:* The French government is crafting regulations to get newer, innovative drugs into the market faster. In the meantime, while drug companies are waiting for approval to sell a new drug, they can enter the market and set their own price for six months.
Germany	*World Pharmaceutical*	The 12th Amendment to Medicines Law & Health Reform 2004 came into force 1st January 2004 as part of the GKV modernization

COUNTRY	SOURCE	PRICING
	Markets Pharmaceuticals, May 26, 2004	legislation and the overall reform project called 'Agenda 2010'. The law superseded and built up on the 11th Amendment and continued to focus on cost containment. Following points form the cornerstone of this amendment: - Increased compulsory rebate: manufacturers, which under the 11th Amendment had to grant a 6% rebate, from 2004 have to grant a 16% rebate. At the same time rebates previously given by wholesalers have been reduced roughly by half. Pharmacies will now receive a fixed amount (8.10 euros) per issued prescription in addition to a 3% sales margin. From the selling price pharmacies will then have to grant a 2% rebate to the statutory sickness funds. - Extension of the GKV reference price mechanism to patented prescription drugs: patent protected drugs are to be become subject of the GKV reference price mechanism as soon as three preparations of a substance class are on the market. This new move is largely a response to a declining effectiveness of the GKV pricing mechanism because patent protected drugs brought onto the market after 1996 were exempt from the mechanism, thus leading to a shrinking segment which is actually subject to GKV reference pricing (from 59.9% in 1997, to 50.0% in 2000 to 36.8% in 2002). With the new regulation, only products with a clear therapeutic improvement would be exempt from what is effectively a pricing system for patent protected drugs (though manufactures can set prices higher than GKV guidelines, with the patient however having to pay the difference). Under initial plans the extension and new regulation was to come into force October 1st 2004, although the decision has been delayed several times and, based on latest information, a decision is not expected before 15th June. The principal bone of contention relates to interpretation when a drug has an actual therapeutic improvement. - Bonus system for doctors prescribing generic and cheaper versions. - Extension of 'aut-idem' regulation: on top of pharmacies having to dispense a cheap equal (aut-idem) preparation to the patient

COUNTRY	SOURCE	PRICING
	---------- "Why Foreign Drugs are Cheaper", *The National Journal*, April 17, 2004	unless a doctor specifies a certain drug, it is now compulsory for pharmacies to dispense a cheaper drug even when a already cheap drug was prescribed by the doctor. Industry had argued for an extension of fixed price brackets instead of having compulsory drug substitution alongside these fixed prices. - Restriction of re-imbursement of OTC medicines: as of 1st January 2004 many non-prescription drugs will no longer be reimbursed by the GKV. Exceptions are made for drugs that are taken in relation to severe illnesses. - Restriction of certain prescription drugs: certain drugs will no longer be reimbursed if the insured has reached the age of 18.Also restricted are medications which are primarily aimed at improving the quality of live rather than cure a condition. -'un-economical'drugs or ones with unproven, clear scientific benefit and classified as such back in 1990 are no longer reimbursed. - Mail order of medicines, including prescription drugs, has been allowed since 1st January 2004. - Patient co-payments: patients will have to pay a 10% co-payment per prescription, which is a minimum of 5 euros and a maximum of 10 euros. This will effectively make cheaper drugs more expensive, while expensive ones become relatively cheaper. Co-payment expenditure is limited to a maximum of 2% of gross annual income, for chronic illnesses the limit is 1%. People qualifying for an exemption or limitation include: • children and adolescents aged below 18 years • pregnant women if drugs are needed due to pregnancy • patients who were exempted by status (welfare recipients, unemployment aid recipients, students, etc.) • insurants with a low monthly income (single persons earning less than 952 euros, persons with one child) • If income below 1,309 euros; for each additional relative in the household the limit is raised by 238 euros • chronic sick persons from further co-payments if they spent more

COUNTRY	SOURCE	PRICING
		than 1% of their income for treatment of the same disease • generally all insurants above a limit of 2% of their income --- *How Drug Prices Are Determined:* Germany, which buys more drugs than any other country in Europe, engages in reference pricing. *Pharmaceutical Industry Complaint:* U.S. drugmakers oppose reference pricing because they say it sets prices too low for innovative drugs. *Current Status:* Germany excluded innovative drugs from reference pricing in 1996, but it will reinstitute the practice next year because of budget pressures. Until then, drugmakers must pay the government a 16 percent rebate on all sales of innovative drugs.
Greece	*World Pharmaceutical Markets*, August 19, 2003	Pharmaceutical pricing in Greece continues to be an area of much contention. Government legislation on pricing, introduced in 1997, basing prices for pharmaceutical products on the lowest price of the product in the EU, remains a source of considerable debate. The legislation cut wholesalers' profit margins from 5.8% to 5.0%, and pharmacists' profit margins to 21%. The maximum price for generics was reduced from 86% to 80% of the original drug's price. In November 2000, the EU referred Greece to the European Court of Justice over its pricing system, claiming it violated the treaty on the free movement of goods. The EU has also claimed that pricing and reimbursement processes fail to comply with measures set out in the EU price transparency directive, criticizing in particular the mechanics of its reimbursement system. In November 2001 the Council of State issued their decision, to abolish the regulation providing that the prices of medicinal products were approved under the condition that they did not exceed the lowest price that they have in the other European

COUNTRY	SOURCE	PRICING
		countries. According to Greek legislation after the abolishment of the regulation in question the determination of the prices of medicinal products must be based on the former method applied (average of three lowest prices in Europe). Although the court decision was served, the Ministry of Development proceeded to issue a pricing bulletin based on the previous rules, contrary to the EU judgment. Subsequently, the SFEE deposited two applications to the Council of State for the annulment and suspension of the above price bulletin. The Minister asked for a dialogue with the industry in order to find a compromise solution on the issue of pricing of medical products. This issue is unlikely to be resolved in the near future. The pharmaceutical industry association, the SFEE, has also voiced its concern over the consequences of the country's pricing system, most notably with regard to the possibility of drug shortages. The SFEE claims that the low drug prices in Greece will lead to drug shortages, as wholesalers are bulk buying pharmaceuticals solely to parallel export them to high-priced markets, such as the UK and Germany. Multinational companies have declared their readiness to downsize or even close manufacturing operations in the face of the low prices, with many already refusing to fulfill exceptionally large orders. The government, however, has refused to implement universal price increases, only suggesting that companies apply for individual price rises.
Ireland	*World Pharmaceutical Markets,* November 18, 2003	Under an agreement between the Department of Health and Children and the Irish Pharmaceutical Healthcare Association (IPHA), drug prices in Ireland are currently subject to a price freeze which has been in effect since 1st August 1997 and extended to 31st July 2001. Since this date, either party may give 12 months notice of renegotiations. The agreement covers all reimbursable prescription medicines under the three Community Drug Schemes (outlined below) and all medicines supplied to hospitals and health boards. Under the

COUNTRY	SOURCE	PRICING
		agreement, the price of any new pharmaceutical products introduced to Ireland after 1st August 1997 should not exceed the lesser of the currency adjusted UK wholesale price and the average wholesale price in five reference countries (Denmark, France, Germany, Netherlands and the UK). The DoH may also request cost-benefit studies for new chemical entities. Prices of existing products can be reviewed if the cumulative average increase or decrease of the wholesale pharmaceutical price indices is more than 10% in the aforementioned countries.
Italy	*World Pharmaceutical Markets,* February 24, 2004	In 1994, the Italian government introduced a controversial new pricing system under which pharmaceutical prices are calculated using a 'European average price', as a reference price for drugs on the Italian market. The legislation ruled that all drugs priced above the reference price had to be reduced immediately to that level, while those products with lower prices could raise their prices over a five year period, at the rate of one increment per year. In 1995, across the board price cuts of between 2.5% and 5% were imposed on the industry. Companies with less than 10% growth in turnover between 1993-94 were compelled to make a 2.5% price cut, while those with growth exceeding 10% suffered a price cut of 5%. In 1996, the 'same price for same drugs principle' was introduced, reducing the prices of reimbursed drugs to that of the cheapest product in each therapeutic group, leaving companies with the choice of reducing their prices or having their products de-listed. The system was heavily criticized by the pharmaceutical industry, which claimed it had led to prices in Italy being up to 30% lower than the EU average. The main problems stemmed from the criteria used to calculate the 'European average price', since it was based on prices in only four of the 15 EU countries (France, Spain, Germany and the UK), it included generic drugs in pricing comparisons, and used purchasing power parity (PPP) as a currency conversion mechanism. In many cases, particularly with regard to innovative products, it was not profitable for manufacturers to market their

COUNTRY	SOURCE	PRICING
		products in Italy since prices had fallen so low that imported products could only be sold at a loss. The system was, in effect, preventing manufacturers from trading in Italy, and therefore probably in contravention with Article 30 of the Treaty of Rome by restricting the free circulation of goods. The European Commission believed this may be the case, and sent Italy a letter of 'formal notice' citing possible infringement of EU law in 1996. Italy's Council for State followed up the EU action and ordered the Comitato Interministeriale per la Programmazione Economica (CIPE - Interministerial Economic Planning Committee) to change its pricing method. The revised pricing system was eventually finalized in 1998, providing for the use of up to 12 EU countries for pricing comparisons. Products must be marketed in at least four countries, however, two of which must have direct pricing controls. The new system also uses actual exchange rates rather than PPPs. An additional complication is the calculation of 'average weighted sales'. The sales and consumption of specific presentations in various markets is calculated to give a 'unit cost' which is taken into consideration when deciding the Italian price. The new system was effective from 1st July 1998. As a result, price increases were announced for 2,415 reimbursed products in six annual stages, while 333 products were subjected to immediate price cuts. The European Commission was still not satisfied, however, since generics remained in the price comparisons and the new system did not compensate companies for the low prices in force under the previous system. Further changes were initiated through the 1999 finance bill. Under the bill, products which were initially allocated non-reimbursement status and have since been admitted to the reimbursement list, and products which received market authorization through the national system, are subject to automatic price cuts of 15%. Subsequently,

COUNTRY	SOURCE	PRICING
		the prices of the affected products will be increased to the 'average European price' level in six annual stages. Following complaints that the 'average European price' mechanism made it unprofitable for some companies to import and sell their products in Italy, a situation which was deemed to be a violation of the European Union free movement of goods, the CIPE introduced a further change to the pricing procedure. Companies with reason to believe prices for their products have been set too low under this procedure should supply documentation detailing the costs incurred in marketing the products in Italy, along with the price set using the average European price system. The documentation will be examined by a special committee, which will begin a price negotiation with the company within 45 days. A final decision will be made within the succeeding 45 days. The prices of innovative products approved through the EU centralized and mutual recognition procedures are negotiated between manufacturers and the government under a CIPE regulation, using pharmacoeconomic criteria. A variety of factors are considered in the calculation of a product price, for example, cost-benefit ratio, marketing costs, size of the market, the price elsewhere in Europe, domestic sales forecasts, and estimated patient numbers. A product's innovative quality and therapeutic value is taken into account, as is patient outcome and savings to the SSN, for example, through reduction in hospital stay and reduced use of healthcare services. Prices agreed through negotiations are liable to review every two years, and adjusted if sales exceed forecasts. The negotiation procedure should be completed within 60 days of receipt of a company's application. The CIPE regulation does not, however, detail the pharmacoeconomic methodology to be used or the studies companies should submit to the government. For this reason, the

COUNTRY	SOURCE	PRICING
		Italian Group for Pharmacoeconomic Studies (GISF) drafted some basic guidelines in 1999. Class C drugs, which include OTC products, are not subject to government price controls**.** During 1998, a 'code of conduct' was agreed between the industry association, Farmindustria, the OTC association, Assosalute, and the Ministry of Health, following criticism from consumer groups about price increases. Under the code, companies agreed to increase prices only once per year and by a limited amount. Despite the industry's good intentions, however, the antitrust authority (AGCM) investigated the code and concluded that it eliminated competition in a significant proportion of the market and had to be discontinued.
Japan	*World Pharmaceutical Markets,* April 22, 2004	The prices of reimbursable drugs are set by the Ministry of Health, Labour & Welfare, through the Chuikyo (Central Social Insurance Medical Council). Japan's pricing system is complex and often less than transparent; it has long been the subject of international criticism, from PhRMA and others, for failing to adequately reflect the value of innovative patented drugs. Since 1992, the Chuikyo has accepted economic data from manufacturers in support of a preferred price. An appeals system was created in October 2000. In 1999, there were 11,288 drugs listed on the National Health Insurance drug price list. The number of listed drugs has tended to fall in recent years, from over 16,000 in the mid 1980s. More than 2,000 drugs were removed from the list in 1995/96. The future shape of the system is the subject of much debate; a government-proposed reference pricing system was due to be implemented in April 2000, but has now been indefinitely postponed. Drug pricing procedures were, however, altered for 2001, in a move designed to improve transparency within the pricing system. Drug prices are now sent by the MLHW to be considered by the Drug Pricing Organisation (DPO), a body composed of academics and medical experts. The DPO will review

COUNTRY	SOURCE	PRICING
		data submitted by the manufacturer, and the MLHW, and will then send a price recommendation to the Chuikyo. Once a price has been approved by the Chuikyo, the drug should then be listed within 90 days. Drugs put on the price list must be marketed within three months. The DPO is expected to meet at least four times a year. Yakkasa In Japan, there is a difference between the price at which a drug is sold by wholesalers and its official reimbursement price, which is always higher. In effect a discount offered by wholesalers, this price difference is known as 'Yakkasa'. It has long been an important source of income for hospitals and dispensing doctors, who are naturally not keen to see the current situation ended. The level of discount allowed is known as the R Zone (Reasonable Zone). This has been reduced in steps since 1992, from 15% to 2-5% in 1998. The Japanese government has indicated that it will abolish the R Zone, and Yakkasa with it, although wholesalers and some local manufacturers certainly remain opposed to this. Price reductions Drug price reductions take place in April, usually every other year, but sometimes annually. In April 1997, pharmaceutical reimbursement prices were reduced by an average of 4.4%. Some categories were more severely affected, however. Synthetic antibacterial products suffered the biggest cuts, with an average cut of 7.1%. Fujisawa's immunosuppressant, Prograf (tactrolimus) was subject to a special price cut of 33%, under a rule which permits the government to re-price pharmaceuticals where their daily cost is at least 40% more than that of similar products. A further series of wide-ranging price cuts were introduced in April 1998. The prices of nearly 1,600 prescription drugs were reduced by an average of nearly 10%. In April 2000, a maximum 2% R Zone was introduced. The effect of this is to bring reimbursed drug prices down to the average market price, i.e. discounting margins

COUNTRY	SOURCE	PRICING
		will disappear. The effect of the reform is expected to lead to an average fall of 7% in the price of reimbursed drugs. The price reduction for domestic manufacturers works out slightly lower than the average, at 6%. There are around 14,000 reimbursable drugs in Japan; of these, 8,935 had their prices cut, while only 61 drugs received price rises. In April 2002, price cuts amounted to an average reduction of 6.3%, resulting in a [yen]400 billion (US$3.1 billion) loss in revenue to the domestic pharmaceutical industry. Drugs with expired patents faced cuts for the first time, of around 10%, where in the past government had not lowered reimbursement prices The actual figure by prefecture varies from between 13% to around 70%, and out of 47 prefectures, nine have a ratio of less than 30%. Although official figures have yet to be released, industry experts estimate that the government drug price cut due to occur in April 2004 will be somewhere between 5-7%. In the Japanese healthcare budget for 2002, there was an anticipated [yen]280 billion reduction. The reformation of the health insurance system was expected to account for [yen]100 billion with the remaining [yen]180 billion saving through changes to drug pricing and medical fees reimbursement, Prices of both drugs and medical materials cut by 1.4%, with reimbursements for technical fees slashed by 1.3%, a total reduction of 2.7%. Of these revisions, the four most significant changes expected are: • reduced reimbursement prices for original brand products already on the NHI Drug Price List; • special application of the recalculation rule for drugs with modified directions for use or dosage; • promotion of the use of generic drugs; • expanded application of the special healthcare expenditure.
Mexico	*World Pharmaceutical Markets,* April 11, 2003	The pharmaceutical industry is one of the few still subject to government price control. In 1996, however, the Mexican Ministry of Trade and Industry granted the pharmaceutical industry greater flexibility in the drug pricing system, allowing companies to increase prices when they choose, instead of at three monthly

COUNTRY	SOURCE	PRICING
		intervals, as was the case previously. In addition, companies are able to forecast the factors on which increases are based, such as inflation and exchange rate, rather than waiting for them to be published. Under current regulations, maximum drug prices are set in consultation with the Secretaria de Salud (Health Secretariat), the Secretaria de Comercio y Fomento Industrial (Secretariat of Trade and Industrial Development) and the Secretaria de Hacienda y Credito Publico (Ministry of Finance).Prescribed medications are free of charge to public sector patients.
The Netherlands	*World Pharmaceutical Markets,* October 14, 2003	Recent efforts by the Dutch government have focused on encouraging market forces and competition on prices to keep costs low. Pharmaceutical care policy has focused on changing the roles and responsibilities of players involved in the supply of medicines and promoting cost effective prescribing by doctors. In January 1996, against strong opposition from the pharmaceutical industry association, Nefarma, the new Medicines Price Control Act (Wet Geneesmeddelen Prijzen - WGP) was passed, effectively reducing prescription drug prices by around 20% to bring them into line with average prices in Belgium, France, Germany and the UK. Following the adoption of the new law by the Dutch Upper House, Health Minister Els Borst announced statutory maximum prices, initially for around 3,000 medicines. The maximum price is that which can be charged by suppliers to dispensing chemists. Administrative fines of around 45,000 euros are in operation for medicines supplied at prices higher than the specified maximum. Despite industry concerns and alternative proposals, the cabinet decided to implement the WGP with effect from 1st June 1996. All reimbursable drugs became subject to fixed maximum price controls, with the exception of reimbursable over-the-counter (OTC) drugs which were exempted during the first year of the law's implementation. This measure was taken to provide the OTC market with the opportunity to demonstrate that sufficient competition existed within it to justify its exclusion from price regulation. In mid 1998, the government affirmed that free pricing

COUNTRY	SOURCE	PRICING
		for most OTCs would remain. In 1997, the industry association, Nefarma, and the Dutch OPG group, began separate legal proceedings against the 1996 price law. Nefarma took the matter to court over a discrepancy between domestic and external providers and a lack of transparency. By the end of 1997, Nefarma claimed that prices under the new law had declined by an average of 21%. At the end of May 1998, the Council of State finally ruled that the Health Ministry had been incorrectly calculating maximum prices for pharmaceuticals for almost two years. Rather than using the average prices of drugs in the reference countries, the lowest prices had been used unlawfully. The Council of State also indicated that the pricing law may be in breach of the EU directive on transparency because it does not require the Minister of Health to respond to a request for a price increase within 90 days. In addition, by setting the maximum prices for reimbursement so low, imported products could not be sold at a reasonable profit in the Netherlands and, consequently, Article 30 of the EU treaty with respect to free movement of goods may have been breached. Parallel importing into the Netherlands has declined and recorded a negative growth of 2.7% in 2002. Also, despite having rectified the incorrect calculation of maximum prices for pharmaceuticals, prices in the Netherlands remain relatively low and are still subject to fixed maximum price controls.
New Zealand	*World Pharmaceutical Markets,* September 18, 2004	Pharmaceutical pricing in New Zealand is determined by the Pharmaceutical Management Agency (Pharmac), which is owned by the Health Funding Authority. Pharmac's role is to manage the Pharmaceutical Schedule on behalf of the Minister of Health. Pharmac operates a reference pricing system, whereby medicines are reimbursed at the level of the lowest priced product in a particular therapeutic sub-group. It is the responsibility of Pharmac to determine the therapeutic sub-group of a product.

COUNTRY	SOURCE	PRICING
		In recent years, Pharmac has addressed the task of cost-containment with some relish, refusing to list some new treatments, reducing subsidies and de-listing products, often to the fury of the pharmaceutical industry. For example, prior to June 2000, Pharmac repeatedly refused to provide subsidies for beta-interferon drugs, used by multiple sclerosis patients, citing the drug's high cost. Subsidies for the drug were first refused in 1996, and again in 1999, following a Pharmac review. Pharmac was then directed by the Minister of Health to fund beta-interferon. As a result, a specialist group, the MS Treatments Assessment Committee, was established to implement the funding process. As of June 2000, two beta-interferon products have been funded by Pharmac: Biogen's Avonex and Schering AG's Betaferon. Funding for beta-interferon is, however, only available to patients meeting certain criteria, for which there is a current limit of 180. The patient limit was reached in December 2000, and patients now applying for funding will have to wait until a place becomes available, or funding by Pharmac increases above the 180-patient limit. In 2000, Pharmac also cut subsidy levels for antidepressants by around 60%, a move that played a substantial part in Lundbeck's decision to close its New Zealand operations in 2000. Other drugs have also had their subsidies cut in the last few years, including ACE inhibitors, cholesterol-lowering drugs and calcium channel blockers. Pharmac has issued several drug tenders since its establishment in 1993. Under the tendering process, one brand of drug in a class is given 'preferred supplier' status, for the period of the tender, which is usually between one and three years. Other drugs in the same class are still listed in the schedule and may be prescribed, but the preferred drug must be substituted, unless specifically indicated otherwise by the prescriber. While preferred drugs are always fully reimbursed, non-preferred drugs are not, and may attract no subsidy

COUNTRY	SOURCE	PRICING
		at all. Pharmac claims to have achieved savings of NZ$60 million annually since the introduction of tenders. The tendering process is not restricted to branded drugs and Pharmac accepts tenders for 'sole suppliers' of generic medicines. It was envisaged that there would be a far greater number of generic tenders, but this has never occurred due to opposition. As of January 2001, the sole supply brand for 250mg and 500mg amoxicillin capsules has been Ospamox, and Rubifen is the sole supply brand for methylphenidate. In a number of cases, Pharmac has made agreements with pharmaceutical companies, whereby price cuts are a precondition of entry on to the schedule, or where the company agrees to cut prices elsewhere in order to obtain a given reimbursement price on a new product. In February 2002, the health minister announced the establishment of a national pharmaceutical purchasing strategy with the intention of streamlining the cost of hospital drugs throughout New Zealand. Under this initiative, Pharmac will be granted full authority to purchase pharmaceuticals for each District Health Board, as opposed to the previous process where the DHB's bought drugs directly from manufacturers. This move has been met with scepticism by many DHB's, concerned that Pharmacs relentless efforts regarding cost containment will have a negative effect on local healthcare provision.
Poland	*World Pharmaceutical Markets,* July 14, 2003	Drug pricing: Although the Ministry of Health had proposed to abolish price controls for all reimbursed pharmaceuticals from 1st January 1998, the prices of some products remain under state control amid fears of a soaring drugs bill. The prices of all domestically produced prescription drugs, which represent approximately 70% of the total output of Polish pharmaceutical factories, remain regulated by the Ministry of Finance. Prices are set on the basis of input costs plus a

COUNTRY	SOURCE	PRICING
		20% mark-up. In July 1997, the Ministry of Finance increased the prices of domestic pharmaceuticals by an average of 12%, in line with inflation. In December 2001 Poland's pharmaceutical pricing law was last updated. In the same year the Ministry of Finance raised prices of domestically refunded drugs by 19%, well above the inflation rate. Prices for imported medicines subject to reimbursement are negotiated by the manufacturer with pharmaceutical authorities. The retail and distributor margins are set by the Ministry of Finance. The wholesale margin on drugs, currently 9.91%, is calculated as a percentage of the official wholesale price. Prices and margins for medicines fully paid for by the end-user (imported and locally produced) are not controlled. Pharmaceutical pricing The current difference between setting prices for domestically produced drugs and foreign imports is likely to be against EU regulations. At present, foreign companies are able to negotiate a drug's price for the reimbursement list with the Ministry of Health and Social Welfare, while the Ministry of Finance sets rigid official prices for Polish drugs. Other drugs, i.e. not reimbursed, have market prices. This diversified pricing system will have to be changed in line with EU regulations and a new pharmaceutical law is currently being debated in parliament. It is estimated that the abolition of official prices will lead to a 10-20% price increase and a greater differentiation of the market. Polish health reforms have been towards a decentralized health system, similar to that in the UK, where GPs are the first point of contact for most patients, thereby acting as 'gatekeepers' to secondary care. Some specialists can be approached directly,

COUNTRY	SOURCE	PRICING
		including gynecologists, oncologists, dermatologists, psychiatrists and dentists, but most services require a referral. Prior to the reforms, people could enter the health service at any appropriate point. The progress of reform, however, has been far from smooth. Public dissatisfaction with the speed of reform and the new structure of the sector has been growing. Reform has been handicapped by financial difficulties, largely stemming from a collapse in the collecting of funds through the health insurance system. Added to this has been increasing criticism of the declining standard of healthcare facilities and outmoded equipment. A program of modernization and the installation of new medical equipment, however, has been promised by the government; 297 hospitals are set to be modernized, with 175 set to receive new medical equipment. Four hospitals are planned for closure. A large cut in the health sector workforce has also been forecast, with an estimated 24,000 - 30,000 staff to be laid off. The extent to which these plans have been, or will be implemented, however, remains to be seen.
Portugal	*World Pharmaceutical Markets,* May 19, 2003	Pharmaceutical product pricing is administered jointly by the Ministries of Finance, Health, and Trade. All prices are recorded and reviewed annually by the pharmacy and medicine regulatory body, Infarmed, the Department of Competition and Prices (DCP) and the Pharmacists and Pharmacy Bar. Prices are negotiated between the pharmaceutical industry and the Ministry of Trade, using a comparison system with other southern European countries. Prices are subject to Infarmed approval. In September 2000, new price controls were introduced for non-prescription medicines through Decree 713/2000. The following information must be supplied to the Direccao-General do Comercio e da Concorrencia (Directorate General for Trade and Competition - DGCC):

COUNTRY	SOURCE	PRICING
		* The retail price applicable of the date of the decree or, for Venda Livre (free sale) products, the ex-factory price; * The first price change since the Decree became effective; * Subsequent price changes and justification for these changes; * Any other information requested by the DGCC. If the DGCC considers prices and/or price increases to be unacceptable, it reserves the right to intervene and may set new prices. These new prices will be subject to the approval of the Sectretary of State for Trade and Services and will take effect eight days after notification. Maximum mark-ups were also set in the same decree, at 8% for wholesalers and 20% for pharmacies. These are calculated on the retail price less VAT. The retail price must appear on the outer packaging of the product.
South Korea	*World Pharmaceutical Markets,* August 19, 2004	There are two systems of pricing for pharmaceuticals in Korea, the Standard Retail Price and the Medical Insurance Price. The Korean pricing system is far from transparent and has come under severe criticism from the international industry. As a result, several reforms are currently under discussion. Products are currently classified as OTC or prescription only. A major pricing review was carried out in early 1998. Of the 26,000 pharmaceutical licensed products in Korea, 15,499 were classified as OTC drugs, and 10,698 were classified as prescription only. If anything, there was a slight switch away from OTC products; while 324 prescription drugs were reclassified as OTC, more than double that number of OTC drugs were placed on the prescription only list. Standard Retail Price (SRP)The SRP system is used for drugs not reimbursed under the medical insurance scheme. It was introduced in 1984, to stabilize prices, minimize consumer price discrepancies and guarantee availability of pharmaceuticals. The system is managed not by the government, but by the Korean Pharmaceutical Manufacturers Association (KPMA), the Korean Pharmaceutical

COUNTRY	SOURCE	PRICING
		Traders Association (KPTA) and the Korean Pharmacists Association (KPA). In order to obtain an approved SRP, the drug's supplier must submit its preferred price for the drug, to either the KPMA or KPTA, who will then decide if this price is reasonable, based on criteria such as investment costs, selling expenses and the presence on the market of similar products. The product may not be sold until an agreement with the KPMA/KPTA has been reached. Prices for imported products tend to end up far higher than those for locally produced ones. The SRP for domestic products, usually set by the KPMA, is around 80% of the ex-factory price. For imports, usually set by the KPTA, the SRP is often more than double the import price. Unsurprisingly, it is generally felt that the SRP is due for extensive reform, if not outright abolition, since its principal effects are as an obstacle to free trade and as a way of keeping prices higher than they might otherwise be. Alternatives to the SRP system are currently under discussion. Medical Insurance PriceThe MIP system is used in hospitals, clinics and pharmacies designated as medical insurance facilities by the National Federation of Medical Insurance. The MIP system is managed by the Insurance Management Division, of the Pension & Health Bureau, itself a part of the MHW. In order to obtain an MIP, the supplier of the drug must submit its proposed price to the KPMA, as for the SRP system. The KPMA will recommend a price, based on this data, to the MHW. The ministry then decides on the reimbursement price, after taking into account the likely effects on the insurance budget. In late 1997, it was announced that reviews of reimbursement

COUNTRY	SOURCE	PRICING
		prices would take place monthly and not at six month intervals. This is in response to the rapid depreciation of the won and the country's straitened economic situation. In early 1998, around one fifth of reimbursable drugs had their prices raised, in some cases by over 50%, in order to counter rising production costs due to the rising price of raw materials.
Spain	**"*New Spanish government "will cut health bill to EU levels, views more power for regions",* Pharma Marketletter, *May 14, 2004r*** ---------- **"*Spain- New reference prices will lower the price of over 2,000 drugs",* Espicom Business Intelligence, *October 31, 2003***	Spain's drugs bill rose 60% during 1995-2003 and continued growing last year despite the previous government's introduction of an austere reference pricing system based on the three cheapest drugs in each therapeutic category. The PSOE said in its electoral program that it will introduce a new system, based on pharmaceutical active principles. In late-2003, the PSOE also said it would curb drug spending by introducing visas for the use of expensive medicines, establish a system of personalized drug doses and create a program to foster rational drug use. Overall, it said, the scheme would cut the drugs bill 40% and save the state 3 billion euros ($ 3.58 billion) a year. Farmaindustria had called these proposals "erroneous and unrealistic," claiming that the best way to cut drug spending is by reducing reference prices, encouraging generics, rationalizing drug use and improving health service efficiency. ---------- On October 25th. 2003 the Spanish government published its new Order of Reference Prices in the Boletin Oficial del Estado 25th. According to the Health Minister, Ana Pastor, the new Order will lower the prices of 2,070 drugs, with a market value of just over 1.6 billion euros. These drugs comprise 62 active ingredients in 82 categories, affecting around 20% of all drugs available under the national health system (SNS). Some drug prices will be cut by up to 80%. It is hoped that these cuts will allow the government to continue to finance the newest, more expensive, drugs coming onto the market.

COUNTRY	SOURCE	PRICING
	---------- ***Pastor Warns Pharmaceutical Companies that Prices Must Come Down", Global Newswire, October 28, 2003***	Reference prices will be determined by looking at the DDD price for three companies' product in each of the 82 categories. All 82 contain at least one generic. Where a prescribed drug is priced above the reference price, it must be substituted for a lower-priced version, provided that an equivalent drug exists. Drugs with a manufacturer price below two euros are not included in the new pricing scheme. The was widely criticized by consumer groups, the political opposition and local generic manufacturers. The AESEG, which represents Spanish generic manufacturers, has stated that the scheme will damage the generic sector, by lowering prices by 25-30% and placing 30% of generic manufacturers in financial difficulty. This could result in 1,000 jobs being cut and a reduction of investment in innovation. ---------- Ana Pastor, the Spanish health minister, warned that those pharmaceutical groups whose products were overpriced would have to change their strategy once the new reference price system is in place in the Spanish health service. She said that the same drug can vary in price by as much as 80 per cent among different pharmaceutical groups. The health minister said that the companies that will be most affected by the changes will be those that deal in drugs that have been on the market for more than ten years and whose investment has already been recovered.
Sweden	**World Pharmaceutical Markets,** ***December 18, 2003***	The principal pricing authority in Sweden is the National Social Insurance Board (RFV), under the supervision of the Ministry of Health and Social Affairs. The body responsible for fixing medicine reimbursement prices is the Division of Drug Affairs, a unit within the RFV. The basis of medicine pricing is the 1996 Ordinance on Limitation of the Costs of Medicinal Products. A decision is reached on a pricing level after discussions between the RFV and the manufacturer, which take place after the manufacturer has submitted an application. Prior to the RFV

COUNTRY	SOURCE	PRICING
		deciding an appropriate price, the county councils are given the opportunity to express their opinion on the case. The processing period for pricing matters is on average between six and eight weeks. In deciding on a price level, the RFV takes into consideration the economic and clinical value of the product, the impact on the reimbursement bill, the price in the country of origin, and the price and cost of related products. The manufacturer is obliged to provide information relating to the product's price in foreign markets, in particular from Austria, Belgium, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Switzerland, the UK and the USA. Applications for price increases on product lines already marketed are considered only once per annum. Companies are permitted to decrease and increase their prices freely under the allocated price ceiling. Price increases for a product in its first two years after manufacture are rarely permitted. The Division of Drug Affairs authorises over 3,000 prices per annum, with three quarters of applications relating to price changes and around seven per cent concerning new products. In December 1999, the Swedish government passed the ordinance SFS 1999: 1373 regarding a new schedule for state fees for controlling medicinal products. A summary of the new fees can be found in the Marketing Authorisation Fees and Registration Fees sections. The move followed pressure from the Medical Products Agency (MPA), the pharmaceutical regulatory authority, to increase the fees. Reference Pricing System The reference pricing system in Sweden includes around 70 multi-source preparations. The fixed reimbursement price in a group is

COUNTRY	SOURCE	PRICING
		based on the cheapest generic plus 10%. The co-payment fee is based on the reference price, which is revised on a quarterly basis. Only around 10% of market volume is affected, and there are no plans to enlarge the scheme. Price Structure There are three pricing categories in Sweden; the pharmacy selling price (AUP), the pharmacy purchasing price (AIP), and the wholesalers purchasing price (DIP). Pharmacies add 19.6% to their purchasing price, which gives them a margin of 16.4%. Wholesalers add 3.3% to the manufacturers price, which gives them a margin of 3.2%. This accounts for 2.7% of the pharmacy selling price. The price at which manufacturers sell to wholesalers accounts for 80.9% of the pharmacy selling price.
United Kingdom	*World Pharmaceutical Markets,* July 14, 2003	Since 1957, pharmaceutical prices have been controlled indirectly in the UK by the Department of Health, under the Pharmaceutical Price Regulation Scheme (PPRS). The scheme, which has undergone a number of major changes since its inception, regulates the overall profitability of pharmaceutical companies from their sales to the NHS. The PPRS is the product of an agreement between the government and the pharmaceutical industry and provides a framework for negotiation. All branded prescription products are covered by the scheme, whether or not they are under a current patent. Pure generics have been excluded since 1986. Reimbursement of these pharmaceuticals is based on the price levels set competitively in the market. Despite speculation that the voluntary scheme would be replaced by legally binding contracts under the 1999 Health Act, negotiations between the Association of the British Pharmaceutical Industry (ABPI) and the government resulted in a new version of the PPRS. The current agreement runs from October 1999 until October 2004. The government also has 'reserve powers' under the Health Act,

COUNTRY	SOURCE	PRICING
		allowing the Health Secretary to take action against companies that fail to comply with the scheme. Under the new PPRS, branded prescription medicines were subject to a 4.5% price reduction and applications for subsequent price increases must be referred to the Department of Health. All companies are now required to submit detailed financial returns, although those with turnover of less than [GBP]25 million may only need to do so when applying for a price increase. Larger companies need to submit reports annually. Because the scheme is related to profit control, rather than the prices of individual products, prices for new products entering the market do not have to be agreed with the PPRS Branch in order for the product to be reimbursed, and may be set at the discretion of the manufacturer. The company will, however, need to take into account the anticipated effect of the product on its overall profit target. The profit target set under the new PPRS is 21% and profit levels are expected to fall within a 'margin of tolerance'. This has been widened under the new agreement, to between 50% and 140% of the target. If a company's profits are more than 40% above the target they are considered to be excessive and the company will be expected to either reduce its prices or repay the excess to the government. If, however, a company's profits are less than 50% of the target, it can seek a price increase to take it up to 80% of the target.
	---------- [LSE Health], Kullman, David, "United Kingdom-Pharmaceutical Pricing and	There are also additional allowances which recognize R&D. When assessing profit, the basic R&D allowance of 20% can increase to 23%, depending on the number of inpatient active substances with an NHS turnover of [GBP]500,000 or more (up to a maximum of 12).

COUNTRY	SOURCE	PRICING
	Reimbursement Policies", 2001	Generic drug pricing The PPRS does not apply to generic drugs. Instead, their prices are set according to the Drug Tariff. Under this, products fall into one of five categories. Most generics fall into category A, where the price is determined by a weighted average of list prices of three manufacturers and two wholesalers. The pricing system for generics has been under government review since the price rises which occurred as a result of shortages of some products in 1999. A series of transitional price ceilings for specified drugs was established in 2000. This arrangement was extended in 2002, and will remain in place pending agreement on a permanent system of generic pricing. ---------- The National Health Service (NHS) is financed mainly through central government general taxation together with an element of national insurance (NI) contributions: Pricing of Pharmaceuticals: - **Pricing method (s) for ethical pharmaceuticals** The prices of branded prescription medicines supplied to the NHS by the pharmaceutical industry are indirectly controlled through the Pharmaceutical Price Regulation Scheme (PPRS). It is an agreement negotiated between the UK government and the pharmaceutical industry represented by the Association of the British Pharmaceutical Industry (ABPI). This scheme, administered by the Department of Health, controls the profits that

COUNTRY	SOURCE	PRICING
		pharmaceutical companies are allowed to make through their trade with the NHS, whilst recognizing that the industry needs to earn enough money to enable it to develop and market new and improved medicines. The PPRS applies to all licensed, branded medicines sold to the NHS. It does not cover generic medicines nor over the counter (OTC) medicines sold to the general public. On market entry, companies have freedom of pricing for new products, defined as those introduced following a major application for a marketing authorization from the appropriate licensing authority i.e. a new active substance, within the constraint of their profit target under the PPRS. A company continues to have freedom of pricing for line extensions (e.g. new presentations and formulations) for such new products for a period of five years from the grant of the original marketing authorization. Products not subject to a major application for a marketing authorization require the Department of Health's agreement to the price before launch and are subject to negotiation with the individual company. The Department takes into account the company's profitability under the PPRS, the prices of other presentations of medicines and forecast sales. - **Pricing methods for generic products:** The "Maximum Price Scheme" was introduced in August 2000. This scheme prohibits the sale of certain unbranded generic medicines to community pharmacies and dispensing doctors at more than the maximum price. It applies to anyone who sells the generics concerned in these circumstances. It applies to companies whether or not they are members of the voluntary PPRS . ***At the end of 2003 the Department of Health published its proposals for a new system of reimbursing the cost and supply of generic medicines for the NHS following widespread consultation with the industry. This would replace the maximum price scheme introduced in 2000***

COUNTRY	SOURCE	PRICING
		following concerns over costs and availability of generic medicines. Once agreed, the scheme would start in April 2004. Key points include the proposal that prices at which pharmacy contractors are reimbursed would be linked to prices charged by manufacturers and that information from manufacturers would be used to calculate the volume weighted average price. ***The DoH is also proposing that there should be incentives for pharmacies to benefit from procurement decisions where these also benefit the NHS, and if there are a limited number of manufacturers of a generic medicine or the supply is concentrated, manufacturers would be required to seek the Department's agreement to any price increase. Manufacturers and wholesalers would be required to submit quarterly information for generic medicines on their income revenues, cost of purchases and volumes of transactions, although how this would be policed is as yet unknown.*** ***In addition, manufacturers could decide the prices of new generic products at their own discretion following the granting of a marketing authorization, provided the drug tariff was less than the equivalent branded medicine. However, at the same time, the DoH is considering provisions that would prevent companies exploiting this freedom, although these criteria too have not yet been clarified.*** ***The NHS spends over pounds 1 billion each year on generic medicines in primary care. Seventy six per cent of prescriptions were written generically in 2002, with over 53 per cent of scripts dispensed generically the same year. If there were no generics the medicines bill would increase to pounds 11.1bn, so generics provide a pounds 4.6bn saving.***

COUNTRY	SOURCE	PRICING
		Every 1 per cent increase in generics dispensed saves the NHS pounds 39.2 million.