GESUNDHEIT ÖSTERREICH GMBH
GESCHÄFTSBEREICH ÖBIG

PHARMACEUTICAL SYSTEMS IN THE EUROPEAN UNION 2006

Fact Sheets

Gesundheit Österreich GmbH
Geschäftsbereich ÖBIG

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List of Abbreviations

ABPI	Association of the British Pharmaceutical Industry (United Kingdom)
AEMPS	Agencia Españolade Medicamentos y Productos Sanitarios / Spanish Agency of Pharmaceuticals and Medical Devices (Spain)
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé / French Agency of Security for Medical Products (France)
AGES PharmMed	Österreichische Agentur für Gesundheit und Ernährungssicherheit / Austrian Agency for Health and Foodsafety (Austria)
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency (Italy)
ASVG	Allgemeines Sozialversicherungsgesetz / Austrian Social Health Insurance Law (Austria)
ARSZMP	Agencija Republike Slovenije za zdravila in medicinske pripomočke / Agency of Medicinal Products and Medical Devices of the Republic of Slovenia
Art.	Article
ATC	Anatomic, therapeutic, chemical classification of the WHO
BASG	Bundesamt für Sicherheit im Gesundheitswesen / Austrian Federal Agency for Safety in Health Care (Austria)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte / Federal Institute for Drugs and Medical Devices (Germany)
BGMA	British Generic Manufacturers Association (United Kingdom)
BMG	Bundesministerium für Gesundheit / Ministry of Health (Germany)
BMGF	Bundesministerium für Gesundheit und Frauen / Federal Ministry of Health and Women's Issues (Austria)
BNF	British National Formulary (United Kingdom)
CEPS	Comité Economique des Produits de Santé / Pricing Committee (France)
CIP	Cost, insurance and packaging
CFH	Pharmaceutical Care Committee (Netherlands)
CRM	Commission de Remboursement des Médicaments / Medicines Reimbursement Commission (Belgium)
DGE	Direccao-Geral da Impresa / Directorate-General Enterprise (Portugal)
DH	Department of Health (United Kingdom)
DMA	Lægemiddelstyrelsen / Danish Medicines Agency (Denmark)
DoHC	Department of Health and Children (Ireland)
DP	Drugs Payment (Ireland)
DRG	Diagnosis-Related Groups
DTC	Drugs and Therapeutic Committee (Malta)
EEA	European Economic Area (Ireland)
EEC	European Economic Community
EHIF	Eeesti Haigekassa / Estonian Health Insurance Fund (Estonia)
EKO	Erstattungskodex / Reimbursement Code (Austria)
EOF	National Organisation for Medicines (Greece)

EFP	Especialidades Farmaceuticas Publicitarias / Specific OTC products (Spain)
EU	European Union
EüM	Egészségügyi Minisztérium / Hungarian Ministry of Health (Hungary)
FD	Farmacijos departamentas prie Sveikatos apsaugos ministerijos / Department of Pharmacy under the Ministry of Health (Lithuania)
FPS	Service Public Fédéral / Federal Public Service (Belgium)
G-BA	Gemeinsamer Bundesausschuss / Federal Joint Committee (Germany)
GMS	General Medical Services (Ireland)
GÖG	Gesundheit Österreich GmbH
GSL	General Sales List (United Kingdom)
HILA	Lääkkeiden hintalautakunta / Pharmaceuticals Pricing Board (Finland)
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board (Austria)
HPSS	Health Care Procurement and Supplies Services (Malta)
HTD	High Tech Drugs (Ireland)
HVB	Hauptverband der österreichischen Sozialversicherungsträger / Federation of the Austrian Social Insurance Institutions (Austria)
IMB	Irish Medicines Board
INFARMED	Instituto Nacional da Farmácia e do Medicamento / Medicines Agency (Portugal)
IPHA	Irish Pharmaceutical Health Care Association
IRF	Institut for Rationel Farmakoterapi / Institute for Rational Pharmacotherapy (Denmark)
KELA	Kansaneläkelaitos / The Social Insurance Institution (Finland)
LFN	Läkemedelsförmånsnämnden / Pharmaceuticals Pricing Board (Sweden)
LTI	Long Term Illness (Ireland)
MA	Medicines Authority (Luxembourg)
MF	Ministerstvo finance / Ministry of Finance (Czech Republic)
MHRA	Medicines and Healthcare Products Regulatory Agency (United Kingdom)
MoH	Ministry of Health
MZ	Ministerstvo zdravotnictvi / Ministry of Health (Czech Republic)
MZ SR	Ministerstvo Zdravotnicta / Ministry of Health (Slovakia)
N. a.	Not available
NAM	Lääkelaitos / National Agency for Medicines (Finland)
NCPE	Irish National Centre of Pharmacoeconomics' St. James' Hospital
NHS	National Health Service
NHSBSA	National Health Service Business Service Authority (United Kingdom)
NICE	National Institute of Health and Clinical Excellence (United Kingdom)
No.	Number
NRT	Nicotine Replacement Therapy
OEP	Országos Egészégbiztositasi Pénztár/ National Health Insurance Fund (Hungary)
OGYI	Országos Gyógyszerészeti Intézet / National Institute of Pharmacy (Hungary)

OTC	Over-the-Counter Pharmaceutical
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen
PK	Preiskommission / Pricing Committee (Austria)
POM	Prescription-only medicines
PPI	Pharma Price Information (service on price information offered by GÖG/ÖBIG)
PPRI	Pharmaceutical Pricing and Reimbursement Information (EU Project coordinated by GÖG/ÖBIG)
PPRS	Pharmaceutical Price Regulation Scheme (United Kingdom)
SAM	Lietuvos Respublikos Sveikatos Absaugos Ministerija / Ministry of Health of the Republic of Lithuania (Lithuania); Ravimiamet / State Agency of Medicines (Estonia)
SGB	Sozialgesetzbuch / Social Security Code (German)
SM	Sotsiaalministeerium / Ministry of Social Affairs (Estonia)
SMEs	Self-employed and Energy - Market regulation - Division of prices and competition (Subdivision of Belgian FPS)
SMR	Evaluation of Medical Benefit (France)
SUKL	Státní Ústav pro Kontrolu Léciv / State Institute for Drug Control (Czech Republic / Slovakia)
TÉB	Technológia Értékelő Bizottság / Technology Evaluation Committee (Hungary)
TRF	Tarif Forfaitaire de Responsabilité (France) / Name of Reference Price system
UCM	Union des Caisses de Maladie / Union of Sickness Funds (Luxembourg)
UNCAM	Union des Caisses d'Assurance Maladie / National Union of Health Insurers (France)
URPL	Urzad Rejestracji Produktów Leczniczych, Wyrobów Medycznychi Produktów Biobójczych / Office for Registration of Medicinal Products, Medical Devices and Biocides (Poland)
VAT	Value Added Tax
VLK	Valstybinė ligonių kasa prie Sveikatos apsaugos ministerijos / State Patient Fund under Ministry of Health (Lithuania)
VVKT	Valstybinė vaistų kontrolės tarnyba / State Medicines Control Agency (Lithuania)
VZA	Valsts zalu agentura / State Agency of Medicine (Latvia)
WHO	World Health Organisation
WGP	Wet Geneesmiddelenprijzen / Law on Medicines Prices (Netherlands)
YPAN	Ministry of Development (Greece)
Yrs.	Years
ZCA	Zalu Cenu Valsts Agentura / State Medicines Pricing and Reimbursement Agency (Latvia)
ZZZS	Zavod za zdravstveno Slovenjie / National Health Insurance Fund (Slovenia)

FACT SHEETS

Introduction

The Health Economics team of the Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG (Austrian Health Institute) has a long tradition of surveying and analysing health care and pharmaceutical systems in Europe.

The studies "Pharmaceuticals - Market Control in Nine European countries" (1998), "Pharmaceutical Expenditure - Cost-Containment Strategies in the European Union" (2001) and "Pharmaceutical Systems in the New EU Member States" (2005) are just three examples of reports providing concise information on reimbursement, pricing and distribution of pharmaceuticals in several European countries (see also the list of publications in the Annex to this report).

Additionally, ÖBIG runs the Pharmaceutical Price Information (PPI) service, which offers independent and up-to-date information on the prices of pharmaceuticals at all price levels (ex-factory price, pharmacy purchase price, pharmacy retail price) in the 25 EU Member States (year 2006) plus Norway and Switzerland. More details on our service may be obtained in the Annex to this report.

To keep the PPI service updated, ÖBIG continually keeps track of the developments in the European pharmaceutical systems. As a result of this continuous monitoring, ÖBIG is pleased to present the report called "Pharmaceutical Systems in the European Union 2006".

The report consists of two parts:

- For each EU Member State, the present Part 1 provides in 25 fact sheets concise, country-specific information on market authorisation, pricing, reimbursement and distribution of pharmaceuticals in 2006.
- Part 2 offers a comparative analysis, with key information displayed in tables and figures.

For better understanding, a glossary with relevant terms used in this study is included at the in the Annex to this report. The exchange rate used for all calculations of Non-Euro national currencies into € is the average annual rate 2005 as published by the Austrian National Bank on basis of the European Central Bank.[1]

Further in-depth information on the European pharmaceutical systems will be provided by the PPRI "Pharma Profiles", which are comprehensive country reports on pharmaceutical pricing and reimbursement. The PPRI Pharma Profiles will be published in course of the summer of 2007. The Pharmaceutical Pricing and Reimbursement Information (PPRI) project (http://ppri.oebig.at) is funded by the European Commission, Public Health and Consumer Protection Directorate-General and co-funded by the Austrian Ministry of Health and Women's Issues, and aims to increase transparency in the field of pharmaceuticals.

[1] www.oenb.at/de/stat_melders/datenangebot/zinssaetze/wechselkurse/wechselkurse.jsp

The coordination of the PPRI project is in the hands of the Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG (the main partner) and the Regional Office for Europe of the World Health Organisation, WHO Europe (the associate partner).

A total of 44 national institutions (mainly competent authorities) in the field of pharmaceuticals from all Member States and Albania, Bulgaria, Canada, Norway and Turkey as well as international institutions such as the EMEA and OECD participate in the PPRI network.

Austria, Belgium, Cyprus, Czech Republic
Denmark, Estonia, Finland, France, Germany
Greece, Hungary, Ireland, Italy, Latvia
Lithuania, Luxembourg, Malta, Netherlands
Poland, Portugal, Slovakia, Slovenia
Spain, Sweden, United Kingdom

Pharmaceutical System in Austria

Fact Sheet 2006

Market authorisation

Competent authority	Austrian Federal Agency for Safety in Health Care (BASG) / supported by the Austrian Agency for Health and Foodsafety (AGES PharmMed)
Legal basis	Directive 2004/27/EC and national legislation: Medicines Act 1983 (Arzneimittelgesetz 1983) as amended
No. of pharmaceuticals	12,140 (including homeopathic pharmaceuticals, excluding pharmacy preparations; counted incl. different pharmaceutical forms and dosages, excl. pack sizes), of which 8,188 are prescription-only medicines (POM) (2005)

Pricing

Competent authority	Austrian Ministry of Health and Women's Issues (BMGF) supported by the Pricing Committee (PK)
Legal basis	Price Act 1992, Austrian Social Health Insurance Law (ASVG)
Scope of price control	Statutory pricing for reimbursable pharmaceuticals Free pricing (notification system) for non-reimbursable pharmaceuticals
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	In accordance with the Price Act of 1992 the Federal Austrian Ministry of Health and Women's Issues (BMGF) supported by the Pricing Committee, is entitled and obligated to set a "national price justified in terms of the national economy". In 1999 the procedure changed, and the former statutory pricing for all pharmaceuticals was replaced by a notification system for non-reimbursable pharmaceuticals, meaning that manufacturers have to notify the manufacturer price for new products or price changes to the BMGF. Pharmaceuticals applying for reimbursement fall under the statutory pricing system, where the BMGF advised by the Pricing Committee sets the EU Average Price. Prices for pharmaceuticals included in the Reimbursement Code (EKO, cf. reimbursement) may be further negotiated with the Federation of Austrian Social Health Insurance Institutions (HVB). The Austrian Health Institute (GÖG/ÖBIG) supports the Pricing Committee and is responsible for checking the prices submitted by the manufacturers.

Criteria	External price referencing (= cross-country referencing / international price comparison), affordability for consumers, national economic situation
Wholesale margins	Statutory regressive maximum mark-up schemes for all pharmaceuticals - two mark-up schemes depending on the reimbursement category
Pharmacy margins	Statutory regressive maximum mark-up schemes for all pharmaceuticals - one for privileged customers (e.g. sickness funds) and one for private customers
VAT	20% on pharmaceuticals (standard VAT rate: 20%)

Reimbursement

Competent authority	Federation of Austrian Social Insurance Institutions (HVB) consulted by the Pharmaceutical Evaluation Board (HEK)
Legal basis	Austrian Social Health Insurance Law 2003 (ASVG), Rules for Procedure for publishing the Code of Reimbursement according to Art. 351 ASVG
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	*Erstattungskodex, EKO*: Positive list of products qualifying for general reimbursement, divided into 3 boxes (red - yellow - green) with different reimbursement conditions *"Not Listed*": Sort of negative list containing product categories excluded from general reimbursement like contraceptives or hospital-only products. Reimbursement possible on individual application by a doctor for a specific patient.
Reimbursement rates	100%
Criteria	Pharmacological, medico-therapeutic and health economic evaluation (e.g. internal price referencing)
Reference price system	No
Prescription fee	€ 4.60 per prescription
Other co-payments	No
Country-specific	For reimbursement eligibility of some pharmaceuticals (e.g. red box or not listed products) individual prior approval of a control doctor of HVB *("Chefarzt")* is needed

Distribution

Manufacturers	24 manufacturing companies, some international companies offices
Wholesalers	35, multi channel system
Pharmacies	1,183 community pharmacies (incl. 18 branch pharmacies and 5 hospital pharmacies for out-patients)
Other retailers	About 1,000 self-dispensing doctors

Pharmaceutical System in Belgium

Fact Sheet 2006

Market authorisation

Competent authority	Federal Public Service (FPS) Health, Food Chain Safety and Environment - Directorate-General Medicines
Legal basis	Directive 2004/27/EC and national legislation: Royal law of 3 July 1969 for the registration of pharmaceuticals (*Arrêté royal du 3 juillet 1969 relatif à l'enregistrement des médicaments*)
No. of pharmaceuticals	N. a.

Pricing

Competent authority	FPS Economy, SMEs, Self-employed and Energy - Market regulation - Division of prices and competition, advised by the Medicines Pricing Commission
Legal basis	Pricing regulations from 22 January 1945 (*Loi sur la réglementation économique et les prix de 22 Janvier 1945*), Ministerial Decree from 29 December 1989 concerning the prices of reimbursable pharmaceuticals (*Arrêté ministériel relatif aux prix des médicaments remboursables du 29 Decembre 1989*), Ministerial Decree from 29 December 1989 concerning the prices of non-reimbursable pharmaceuticals (*Arrêté ministériel relatif aux prix des médicaments non remboursables du 29 Decembre 1989*)
Scope of price control	Statutory pricing for all pharmaceuticals except non-reimbursable pharmaceuticals considered as “new”
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	Manufacturers apply for a price of a pharmaceutical at the FPS Economy, SMEs, Self-employed and Energy, which fixes the maximum manufacturer prices within 90 days in case of POM and within 60 days in case of OTC. If the deadline has expired without a decision, the price proposed by the manufacturer is accepted. For “new” (i.e. either a new active ingredient or therapeutic indication) non-reimbursable pharmaceuticals a price notification system is in place.
Criteria	Pharmaco-economic evaluation, external price referencing, internal price referencing (maximum manufacturer price excluding VAT for large packages of reimbursable pharmaceuticals must be at least 20% lower than the maximum unit price of the smallest reimbursable package)

Wholesale margins	Statutory regressive maximum mark-up scheme, valid for all pharmaceuticals
Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for all pharmaceuticals
VAT	6% on pharmaceuticals (standard VAT rate: 21%)

Reimbursement

Competent authority	FPS Social Security, advised by the Medicines Reimbursement Commission (CRM)
Legal basis	Royal law for health insurance from 21 December 2001 (*Arrêté royal du 21 décembre 2001 fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans le coût d es spécialités pharmaceutiques*)
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list (*Liste des spécialités pharmaceutique rembours-ables*), divided into chapters depending on the indications and the nature of the pharmaceutical
Reimbursement rates	Reimbursement rates of 100%, 75%, 50%, 40%, 20% (depend-ing on the reimbursement category of the pharmaceutical) and reimbursement rates of 85% for invalids (depending on their revenue), orphans, pensioners, widows and widowers as well as their dependants
Criteria	Therapeutic value expressed, the maximum price set by the FPS Economy, SMEs, Self-employed and Energy and the price proposed by the manufacturer, importance of the pharmaceuti-cal, the budgetary implications, cost-benefit ratio
Reference price system	Yes, since June 2001
Prescription fee	No
Other co-payments	Co-payment rates of 80%, 60%, 50%, 25% (and 15% respec-tively for certain population groups) and 0% If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	146
Wholesalers	23, multi channel system
Pharmacies	5,200 community pharmacies
Other retailers	No

Pharmaceutical System in Cyprus

Fact Sheet 2006

Market authorisation

Competent authority	Ministry of Health (MoH)
Legal basis	Directive 2004/27/EC and national legislation
No. of pharmaceuticals	2,209 (including different pharmaceutical forms and dosages) in the private system, 700 active ingredients in the public system (2005)

Pricing

Competent authority	Ministry of Health (MoH)
Legal basis	Law of Medicines of Human Use, Article 91 (2)
Scope of price control	Statutory pricing for all (locally produced and imported) pharmaceuticals in the private system, i.e. selling of pharmaceuticals through pharmacies Public procurement (tendering) for pharmaceuticals in the public system, i.e. dispensing of pharmaceuticals to eligible out-patients in hospital pharmacies
Price level controlled	For imported pharmaceuticals: wholesale price level (pharmacy level through mark-up scheme) For locally produced pharmaceuticals: manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	In the private system the prices are statutorily set by the MoH on the basis of the advice of the Price Committee within the Department of Pharmaceutical Services. Additionally, there is a public system where pharmaceuticals are purchased through tendering operated by the Department of Pharmaceutical Services of the MoH.
Criteria	External price referencing for imported pharmaceuticals, production price plus mark-up for locally produced pharmaceuticals (in the private system) Tender price, therapeutic benefit, safety, quality and efficacy (in the public system)
Wholesale margins	No statutory wholesale mark-up. The wholesale margin for imported pharmaceuticals is freely negotiated between the importer and the wholesaler. Statutory linear maximum mark-up of 20% on locally produced pharmaceuticals. No mark-ups in the public system.

Pharmacy margins	Statutory linear maximum mark-up of 33% for imported and locally produced pharmaceuticals. No mark-ups in the public system.
VAT	No

Reimbursement

Competent authority	MoH, advised by the Drugs Council Department of Pharmaceutical Services
Legal basis	Law No. 70(I)2001
Reimbursement scheme	Population-group-specific reimbursement
Reimbursement list(s)	Positive list
Reimbursement rates	100% or 50% (public system) and 0% (private system)
Criteria	Proof of the cost-effectiveness of the pharmaceutical
Reference price system	No
Prescription fee	No
Other co-payments	In the private system patients have to pay the full price of the pharmaceutical. In the public system eligible patients receive pharmaceuticals free of charge (group A: politicians, retired civil servants and their dependants, students, people that receive social welfare and people with very low income) or are required to pay 50% of the tendered price of the pharmaceutical (group B: people with low income).
Country specific	Pharmaceutical market is split into a parallel private and a public system

Distribution

Manufacturers	55 (5 locally producing manufacturers - exclusively generics) and 50 international pharmaceutical companies offices
Wholesalers	60 importers
Pharmacies	440 community pharmacies (in the private system)
Other retailers	40 hospital pharmacies, acting as community pharmacies for eligible patients under the public system

Pharmaceutical System in Czech Republic

Fact Sheet 2006

Market authorisation

Competent authority	State Institute for Drug Control (SUKL)
Legal basis	Directive 2004/27/EC and national legislation: Medicines Act
No. of pharmaceuticals	14,000 (including different pharmaceutical forms and dosages, but excluding different pack sizes) are registered; 8,000 were POM; only around 2,000 actually available on the market (2003)

Pricing

Competent authority	Ministry of Finance (MF)
Legal basis	Act No. 526/90 Coll.
Scope of price control	Statutory pricing for all pharmaceuticals except non-reimbursable OTC products Free pricing for non-reimbursable OTC products
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	The Ministry of Finance sets the maximum manufacturer price as well as a combined mark-up for wholesalers and pharmacies. There are no price negotiations, the MF accepts the price the pharmaceutical companies have applied for.
Criteria	External price referencing, cost-benefit analysis for imported pharmaceuticals and production costs for locally produced pharmaceuticals
Wholesale margins	Statutory combined linear maximum mark-up for wholesalers and pharmacies, valid for all pharmaceuticals
Pharmacy margins	
VAT	5% on pharmaceuticals (standard VAT rate: 19%)

Reimbursement

Competent authority	Ministry of Health (MZ), advised by Drug Categorisation Committee
Legal basis	Health Insurance Act No. 48/1997 Coll.
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list
Reimbursement rates	Apart from one exception (anti-allergic pharmaceuticals that have a fixed reimbursement price), there are no fixed reimbursement rates for pharmaceuticals or patient groups.
Criteria	Internal price referencing, pharmaco-economic criteria
Reference price system	Yes, since 1995
Prescription fee	No
Other co-payments	Different co-payment rates (no fixed percentage rates) (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	Around 250 companies
Wholesale	160 companies with a wholesale license, 5 dominate the market, multi channel system
Pharmacies	1,850 community pharmacies
Other retailers	Drugstores and other retail outlets (e.g. corner shops, petrol stations, supermarkets) are allowed to sell a limited range of OTC products

Pharmaceutical System in Denmark

Fact Sheet 2006

Market authorisation

Competent authority	*Lægemiddelstyrelsen* (Danish Medicines Agency, DMA)
Legal basis	Directive 2004/27/EC and national legislation: Act No. 1180 as amended by 12 December 2005
No. of pharmaceuticals	7,393 pharmaceuticals (counted by pack sizes); 4,083 were qualified for reimbursement (including 390 OTC) (2004)

Pricing

Competent authority	*Lægemiddelstyrelsen* (Danish Medicines Agency, DMA)
Legal basis	Act No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004 Executive Order BEK No. 237 of 24 March 2006 (Pharmacy margins)
Scope of price control	In general free pricing for all pharmaceuticals, Manufacturers/ Importers have to notify their prices to the DMA (cf. procedure) Public procurement for all pharmaceuticals used in hospitals
Price level controlled	Wholesale price level (pharmacy level through mark-up scheme)
Procedure	Technically, pharmaceutical companies may freely set the price for pharmaceuticals when placing them on the market. They are only obliged to inform the DMA of the wholesale price of the product (price notification). Still, the prices of reimbursable pharmaceuticals (POM and OTC) are indirectly influenced by the reimbursement system (in particular by the reimbursement price).
Criteria	Not applicable, see reimbursement
Wholesale margins	Since 2001 wholesale mark-ups are no longer regulated but are freely negotiated between the manufacturer and the wholesaler.
Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals (mostly OTC) are not regulated.
VAT	25% on pharmaceuticals (standard VAT rate: 25%)

Reimbursement

Competent authority	DMA together with Reimbursement Committee consulted by IRF (Institute for Rational Pharmacotherapy)
Legal basis	Act No. 180 of 17 March 2006
Reimbursement scheme	Consumption-based reimbursement: Before the patient is eligible for reimbursement s/he has to pay the full cost of her/his reimbursable medication up to a threshold of € 64.40 per a 12 month period. After passing this threshold (which is € 0.- for terminally ill patients and children < 18 yrs.), the reimbursement rate rises gradually.
Reimbursement list(s)	Positive list for general reimbursement (for some products only for specific diseases/indications or patient groups) Individual special reimbursement possible on application by doctor for a given patient
Reimbursement rates	100%, 85%, 75%, 50%, 0%
Criteria	Therapeutic value, cost-effectiveness, internal price referencing, budget impact; most OTC are exempt from reimbursement
Reference price system	Yes, since of 1993 Reimbursement basis is the gross pharmacy retail price of the cheapest available bioequivalent product among those with the same ATC-5 code, the same formulation and a similar pack size
Prescription fee	€ 1.24 (but not relevant as it is included in the Gross Pharmacy Retail Price)
Other co-payments	Co-payment rates of 100%, 50%, 25%, 15% and 0% (for reimbursable pharmaceuticals); 12-month co-payment maximum: € 472.37 If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.
Country specific	The use of the term "reference price" was removed from legislation in 2000 and was replaced with the term "reimbursement price (called “System of obligatory generic substitution”)

Distribution

Manufacturers	189
Wholesalers	3 (Max Jenne, Nomeco and KV Tjellsen), multi channel system
Pharmacies	322 community pharmacies incl. 51 branch pharmacies
Other retailers	140 pharmacy shops, 710 OTC shops (*Apoteksudsalg*) affiliated to a pharmacy and about 1,300 *Godkendte salgssteder* (located at supermarkets, gas stations etc*.)*. *Apoteksudsalg* may sale all OTC products whereas *Godkendte salgssteder* may only sell a limited range of so-called general sale OTC. Several Internet pharmacies (sale of OTC products over the Internet is allowed)

Pharmaceutical System in Estonia

Fact Sheet 2006

Market authorisation

Competent authority	State Agency of Medicines (SAM)
Legal basis	Estonian Medicines Act 1996, latest amendment: 2005
No. of pharmaceuticals	2,925 authorised pharmaceuticals (counted incl. different pharmaceutical forms and strengths, excl. packages) (2005)

Pricing

Competent authority	Ministry of Social Affairs (SM)
Legal basis	Health Insurance Act 2002, Regulation of SM No 121, 3.12.2004 “Procedure for entry into price agreement” (RTL 2004, 153, 2321)
Scope of price control	Statutory pricing (after negotiations) for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	The Ministry of Social Affairs (SM) sets the manufacturer price after negotiations (price-volume agreement) with the pharmaceutical company. The decision on the manufacturer price should be taken after the decision on reimbursement; in reality, the process of pricing is incorporated into the reimbursement procedure.
Criteria	Price-volume agreements between the SM and the pharmaceutical companies, external price referencing (Latvia, Lithuania, Hungary, Portugal, France and country of origin)
Wholesale margins	Statutory regressive maximum mark-up scheme, valid for all pharmaceuticals
Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for all pharmaceuticals
VAT	5% on pharmaceuticals (standard VAT rate: 18%)

Reimbursement

Competent authority	Ministry of Social Affairs (SM), advised by SAM and Estonian Health Insurance Fund (EHIF)
Legal basis	Regulation of SM No.123, 8.12.2004 “Procedure for drawing up and amending the list of medicinal products of the Estonian Health Insurance Fund, the contents of the criteria for establishment of the list of medicinal products, and the persons to assess compliance with criteria” Regulation of Estonian Government No. 308 of 26.09.2002 „List of diseases in the case of which a medicinal product intended for the treatment or alleviation of the disease is, upon the existence of a valid reference price or price agreement, subject to entry in the list of medicinal products with a 100 or 75% discount rate”
Reimbursement scheme	Disease-specific reimbursement: Diseases/indications are defined as reimbursable; pharmaceuticals used for the treatment for these diseases are reimbursed at the fixed reimbursement rates (see below).
Reimbursement list(s)	Positive list
Reimbursement rates	Depending on severity of disease 100%, 75% (and 90% for children < 10 yrs., disabled people and insured people > 63 yrs.) or 50%
Criteria	Medical and therapeutic value and safety of the pharmaceutical, cost-effectiveness, budget impact, lack of alternative therapies, severity of illness, special medical needs
Reference price system	Yes, since January 2003
Prescription fee	€ 1.28 per prescription for pharmaceuticals with 100% and 75% (respectively 90%) reimbursement € 3.20 per prescription in the 50% reimbursement category
Other co-payments	Co-payment rates of 50%, 25% (and 10% respectively for specific population groups) and 0%; always 0% for children < 4 yrs. In 50% reimbursement category patients have to pay the amount above € 12.8 per pack If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	6 local (generic) companies, 19 international pharmaceutical companies offices
Wholesale	32 companies with wholesale licence, multi channel system
Pharmacies	316 community pharmacies
Other retailers	158 dispensaries (pharmacy counters)

Pharmaceutical System in Finland

Fact Sheet 2006

Market authorisation

Competent authority	NAM (National Agency for Medicines)
Legal basis	Directive 2004/27/EC and national legislation: Act 395/1987 and amendments 1046/1993, 416/1995 and 296/2004
No. of pharmaceuticals	6,904 pharmaceuticals (including different pharmaceutical forms and strengths); thereof ~ 93% prescription-only medicines (POM)

Pricing

Competent authority	HILA (Pharmaceuticals Pricing Board) consulted by KELA (The Social Insurance Institution of Finland)
Legal basis	Health Insurance Act 1224/2004 and amendment 885/2005, Government Decree on the mark-up 2002/1087, Government Decree on the Pharmaceuticals Pricing Board 1356/2004 and amendment 1110/2005
Scope of price control	Price negotiations for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals
Price level controlled	Wholesale price level (pharmacy level through mark-up scheme)
Procedure	In general, pharmaceutical companies may freely set the price for pharmaceuticals when placing them on the market. However, pharmaceutical companies applying for inclusion of a product to reimbursement have to seek approval of a so-called "reasonable" wholesale price (maximum pharmacy purchase price) for POM and OTC by HILA. Usually there are several negotiation rounds between HILA and company representatives necessary before the "reasonable" wholesale price is officially approved by HILA. Companies may set the PPP below or equal to the confirmed pharmacy purchase price.
Criteria	Therapeutic value, budget impact, external and internal price referencing; For pharmaceuticals with new active ingredients an economic evaluation is mandatory
Wholesale margins	No statutory wholesale mark-up scheme. The wholesale margin is freely negotiated between the manufacturer and the whole-saler.
Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for all pharmaceuticals (except NRT)
VAT	8% on pharmaceuticals (standard VAT rate: 22%) Additionally a progressive, tax-like pharmacy fee payable to the state, ranging from 0 to 11% (on average: 7%)

Reimbursement

Competent authority	HILA consulted by KELA and expert group
Legal basis	Government Decree 1110/2005 amending the Decree on the Pharmaceuticals Pricing Board 1356/2004
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list Since 1.1.2006 HILA has power to introduce a negative list ("zero" list) which has not yet occurred
Reimbursement rates	100% (upper special refund), 72% (lower special refund), 42% (basic refund)
Criteria	Basic reimbursement: therapeutic value Special reimbursement: necessity and economy of product, nature of disease, therapeutic value, available funds Legal basis: Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6
Reference price system	No
Prescription fee	Flat rate deductible of € 3.- for 100% reimbursed pharmaceuticals resp. € 1.50 after annual ceiling sum (€ 616.72 in 2006)
Other co-payments	Co-payment rates of 58%, 28% and 0% (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	64 pharmaceutical companies
Wholesale	2 wholesalers, single channel system
Pharmacies	799 community pharmacies (incl. 193 branch pharmacies and 2 university pharmacies) (2005)
Other retailers	Medicines chest (under the supervision of a pharmacy) for a limited range of OTC products Tobacco-selling shops for the sale of NRT-products (since 2006)

Pharmaceutical System in France

Fact Sheet 2006

Market authorisation

Competent authority	Medicines Agency (AFSSAPS)
Legal basis	Directive 2004/27/EC, national medicines' legislation
No. of pharmaceuticals	About 15,000 pharmaceuticals (incl. different pharmaceuticals forms, dosages and pack sizes, excl. homeopathic products, 2005)

Pricing

Competent authority	Pricing Committee (CEPS), advised by Transparency Committee
Legal basis	Law No. 2004-810 as of 13 August 2004, Framework Agreement between Pricing Committee and Industry Association for the period 2003-2006 *(Accord cadre entre le Comité économique des produits de santé et les entreprises du médicament pour la période 2003-2006)*
Scope of price control	Price negotiations for reimbursable pharmaceuticals except for innovative pharmaceuticals (price notification)
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	The pricing procedure depends on the reimbursement status of the pharmaceutical. In general, the prices of reimbursable pharmaceuticals are negotiated between the manufacturer and CEPS. The pricing decision is taken after the analysis and evaluation of the medical benefit *(Service Médical Rendu, SMR)*, which is the criterion for the inclusion into reimbursement or not. Within this general pricing scheme, there is a pricing notification system for innovative pharmaceuticals and a pricing declaration for specific hospital pharmaceuticals (outside the DRG system) in place.
Criteria	Evaluation of medical benefit, improvement of medical benefit, expected sales, external price referencing
Wholesale margins	Statutory regressive maximum mark-up scheme, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals are free (not regulated).

Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals are free (not regulated).
VAT	2.1% for reimbursable pharmaceuticals and 5.5% for non-reimbursable pharmaceuticals (standard VAT: 19.6%)

Reimbursement

Competent authority	National Union of Health Insurers (UNCAM)
Legal basis	Decree No. 2004-1398 as of 23 December 2004
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Two positive lists *Liste des médicaments remboursables agrées aux assurés sociaux:* containing pharmaceuticals for the out-patient sector *Liste des médicaments agrées aux collectivités*: containing pharmaceuticals for the hospital sector
Reimbursement rates	100%, 65% and 35%
Criteria	Evaluation of medical benefit (SMR) and improvement of medical benefit
Reference price system	Yes, called *Tarif Forfaitaire de Responsabilité* (TFR), introduced in October 2003
Prescription fee	No
Other co-payments	Co-payment rates of 65%, 35% and 0% (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	About 300 pharmaceutical companies, thereof 12 generic manufacturers
Wholesalers	11, multi channel system
Pharmacies	22,691 community pharmacies Hospital pharmacies are allowed to dispense pharmaceuticals to out-patients
Other retailers	About a dozen self-dispensing doctors

Pharmaceutical System in Germany

Fact Sheet 2006

Market authorisation

Competent authority	Federal Institute for Drugs and Medical devices (BfArM)
Legal basis	Directive 2004/27/EC and national legislation: Medicines Act
No. of pharmaceuticals	8,933 (including homeopathic pharmaceuticals; counted excluding different pack sizes, pharmaceutical forms and dosages)

Pricing

Competent authority	Federal Joint Committee (G-BA)
Legal basis	Drug Price Ordinance (*Arzneimittelpreisverordnung*) Art. 2 (2-5)
Scope of price control	Indirect statutory pricing (via reference price system) for POM under the reference price system and for reimbursable OTC products Free pricing for non-reimbursable OTC products and innovative pharmaceuticals
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	Officially, there is free pricing, even though the authorities influence pharmaceutical prices through the reference price system. Price notification is obligatory.
Criteria	Internal price referencing for pharmaceuticals subject to the reference price system
Wholesale margins	Statutory regressive maximum mark-up schemes: • one for POM • one for reimbursable OTC products. Margins for non-reimbursable OTC products are free (not regulated).
Pharmacy margins	Statutory mark-up schemes: • a flat pharmacy fee and a linear maximum mark-up for POM • a regressive maximum mark-up scheme for reimbursable OTC products. Margins for non-reimbursable OTC products are free (not regulated).
VAT	16% on pharmaceuticals (standard rate: 16%), from 1.1.2007 on the VAT rate will be 19%

Reimbursement

Competent authority	Ministry of Health (BMG) and Federal Joint Committee (G-BA)
Legal basis	SGB V Art. 34, 35 and 129
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	There is a negative list, but no positive list. However, POM are, in general, reimbursable (fully or partly reimbursed).
Reimbursement rates	No reimbursement rates; reimbursement at the reference price for pharmaceuticals in the reference price system. Patent-protected innovative pharmaceuticals are fully reimbursed and not part of the reference price system.
Criteria	Internal price referencing
Reference price system	Yes, since 1989
Prescription fee	No
Other co-payments	10% of the gross pharmacy retail price (with a minimum fee of € 5.- and a maximum fee of € 10.- per package) If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	50 research-oriented pharmaceutical companies plus around 350 small and medium-sized companies
Wholesalers	16 full-line wholesalers, multi channel system
Pharmacies	21,392
Other retailers	No

Pharmaceutical System in Greece

Fact Sheet 2006

Market authorisation

Competent authority	National Organisation for Medicines (EOF)
Legal basis	Directive 2004/27/EC and national legislation: Ministerial Decree Y6a/3221
No. of pharmaceuticals	10,521 (incl. different pharmaceutical forms, dosages and pack sizes)

Pricing

Competent authority	Ministry of Development (YPAN) advised by the Pricing Committee
Legal basis	Market Decree 14/89
Scope of price control	Statutory pricing for all pharmaceuticals
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	The Directorate of Prices and Medicinal Products within the YPAN is responsible for determining the manufacturer price of all pharmaceuticals. When deciding on manufacturer prices, the director is advised by the Pricing Committee operating under the General Secretariat of Commerce under the YPAN. Prices are then published in the Price Bulletin by the YPAN with the consent of the MoH.
Criteria	External price referencing for imported pharmaceuticals (referring to the 3 lowest European prices); production cost ("cost-plus") for locally produced pharmaceuticals
Wholesale margins	Statutory linear maximum mark-up of 8.43%, valid for all pharmaceuticals
Pharmacy margins	Statutory linear maximum mark-up of 35%, valid for all pharmaceuticals
VAT	9% on pharmaceuticals (standard VAT rate: 19%)

Reimbursement

Competent authority	Ministry of Health and Social Solidarity advised by EOF
Legal basis	Law 3457/2006
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	The positive list was abolished in December 2005. Now all pharmaceuticals with the exception of OTC and lifestyle products are eligible for reimbursement.
Reimbursement rates	100%, 90% and 75%
Criteria	Therapeutic efficacy and disease/diagnosis
Reference price system	Yes, since May 2006
Prescription fee	No
Other co-payments	Co-payment rates of 25%, 10% and 0% depending on the disease and population group (e.g. income, -pensioners) (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	N. a.
Wholesalers	150 private wholesalers and 30 pharmacy owned co-operatives, multi channel system
Pharmacies	9,500
Other retailers	144 hospital pharmacies and 7 military pharmacies

Pharmaceutical System in Hungary

Fact Sheet 2006

Market authorisation

Competent authority	National Institute of Pharmacy (OGYI)
Legal basis	Directive 2004/27/EC and national legislation: Law 95/2005, Decree 52/2005
No. of pharmaceuticals	5,118 authorised pharmaceuticals (excl. centralised authorised ones) (2005)

Pricing

Competent authority	Ministry of Health (EüM)
Legal basis	Price Act 87/1990
Scope of price control	In general free pricing for all pharmaceuticals Statutory pricing criteria for reimbursable pharmaceuticals (Decree of the EüM 32/2004) Price negotiations for reimbursable pharmaceuticals may take place between manufacturers and Social Health Insurance (OEP)
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	In general, there is a system of free pricing for all pharmaceuticals regardless of their prescription status. Thus pharmaceutical companies are free to set prices of non-reimbursable pharmaceuticals at their will. If a product shall be included in the positive list, the manufacturer has to apply for reimbursement to the OEP stating a proposed manufacturer price. The OEP may accept or reject reimbursement at the proposed price; negotiations between the OEP and the pharmaceutical companies may take place if a pharmaceutical shall be included into reimbursement but the proposed price is deemed to high. Still the OEP does not set prices; rather the pharmaceutical companies may adjust their prices so that the OEP accepts the product for reimbursement.
Criteria	Internal price referencing (therapeutic alternatives at ATC-4 level) and external price referencing (for innovative pharmaceuticals: the lowest price of the reference countries (France, Ireland, Germany, Spain, Portugal, Italy, Greece, Poland, Czech Republic, Slovenia, Slovakia, Belgium and Austria and one additional country is taken), proof of cost-effective price (Decree 32/2004)
Wholesale margins	Statutory regressive maximum mark-up scheme, valid for all pharmaceuticals

Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for all pharmaceuticals
VAT	5% on pharmaceuticals and 15% on para-pharmaceutical products (standard VAT rate: 25%)

Reimbursement

Competent authority	National Health Insurance Fund (OEP), advised by the Technology Evaluation Committee (TÉB)
Legal basis	Law 83/1997 on compulsory health services in the framework of social security, Decree 217/1997 on compulsory health service provision, Decree 1/2003 on the medicinal products co-financed by social insurance and Decree 32/2004 on the inclusion of medicinal products into social insurance coverage
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list
Reimbursement rates	90%, 70% or 50% for pharmaceuticals on the positive list 100% and 90% for expensive pharmaceuticals (indication bound) 100% for pharmaceuticals for eligible (poor) patients
Criteria	Benefit compared to pharmaceuticals on positive list, pharmaco-economic studies (Decree 32/2004)
Reference price system	Yes, since 1997
Prescription fee	No
Other co-payments	Co-payment rates of 50%, 30%, 10% and 0% (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	40 pharmaceutical companies possess a manufacturing licence (products of about 20 local manufacturers available in Hungarian pharmacies)
Wholesale	80 companies holding a wholesale licence, 4 full-line wholesalers and 6-8 smaller wholesalers being active on the Hungarian market, multi channel system
Pharmacies	2,030
Other retailers	155 hospital pharmacies, thereof approx. 65 open to out-patients A few self-dispensing doctors in rural areas

Pharmaceutical System in Ireland

Fact Sheet 2006

Market authorisation

Competent authority	Irish Medicines Board (IMB)
Legal basis	Directive 2004/27/EC and national legislation: The Pharmacy Act 1962, No. 14/1962
No. of pharmaceuticals	7,739 pharmaceuticals (including different pharmaceutical forms, dosages and pack sizes)

Pricing

Competent authority	Department of Health and Children (DoHC) in cooperation with the pharmaceutical industry association (Irish pharmaceutical Health Care Association, IPHA)
Legal basis	Voluntary agreement between the IPHA and the DoHC
Scope of price control	Price agreements for reimbursable pharmaceuticals Price negotiations for reimbursable pharmaceuticals not on the market in the nominated 9 EU Member States for external referencing (see Procedure) Free pricing for non-reimbursable pharmaceuticals
Price level controlled	Manufacturer price (wholesale and pharmacy level through mark-ups and fee-for service)
Procedure	Since 1993 the DoHC has been negotiating an agreement on the methodology how pharmaceutical prices are set with IPHA. A price freeze agreement between IPHA and the DoHC was agreed upon in 1993, renewed in 1997 and extended in 2001 until 2005. In 2006, a further renewal was finalised. In addition, a procedure for price reductions of 20% and 15% respectively of the price for patent expired medicines has been introduced. One of the characteristics of the agreement is that Ireland links the manufacturer price of a new pharmaceutical to the average of the currency-adjusted manufacturer price of 9 defined EU Member States (or those of the defined EU Member States, where the pharmaceutical is available). Prices for new pharmaceuticals not available in these defined EU Member States are negotiated. The manufacturer price for a new pharmaceutical is adapted to the currency-adjusted average manufacturer price in the 9 EU Member States after two and four years.
Criteria	External price referencing: manufacturer price of 9 EU Member States (Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Spain and UK)
Wholesale margins	Different mark-ups for pharmaceuticals depending on the reimbursement status and the Community Drug Scheme

Pharmacy margins	Different mark-ups resp. fixed dispensing fees depending on the reimbursement status and the Community Drug Scheme
VAT	21% on non-oral pharmaceuticals, no VAT on oral pharmaceuticals (standard VAT rate: 21%)
Country specific	3.53% rebate of the manufacturer price for pharmaceuticals dispensed under the GMS Scheme (cf. Reimbursement), excl. patent expired products which are subject to price reductions.

Reimbursement

Competent authority	Product Committee of Department of Health and Children (DoHC), advised by Irish National Centre for Pharmacoeconomics St. James' Hospital (NCPE)
Legal basis	No specific legal basis besides Council Directive 89/105/EEC
Reimbursement scheme	Population-group-specific reimbursement with elements of product-specific and disease-specific reimbursement (so-called Community Drug Schemes): GMS (General Medical Services) Scheme - persons under an income threshold and their dependants, DP (Drugs Payment) Scheme - persons not eligible for GMS, HTD (High Tech Drugs) Scheme - high-cost pharmaceuticals, LTI (Long Term Illness) Scheme - patients with 15 specified illnesses, EEA (European Economic Area) Scheme - residents from one of the other states of the European Economic Area
Reimbursement list(s)	GMS Reimbursement Code and reimbursement list for HTD
Reimbursement rates	100% (in most Community Drug Schemes) and 0% (for patients with expenses below a threshold of € 85.- per month in the DP scheme) respectively
Criteria	Pharmacological, medical-therapeutic and pharmaco-economic criteria
Reference price system	No
Prescription fee	No
Other co-payments	€ 85.- per month maximum for pharmaceuticals in DP scheme

Distribution

Manufacturers	120 pharmaceutical companies
Wholesale	3 full-line wholesalers, multi channel system
Pharmacies	1,333 community pharmacies
Other retailers	Around 140 dispensing doctors. Drugstores and other retail outlets (e.g. corner shops, petrol stations, supermarkets) are allowed to sell a limited range of OTC products

Pharmaceutical System in Italy

Fact Sheet 2006

Market authorisation

Competent authority	Medicines Agency (AIFA)
Legal basis	Directive 2004/27/EC and national legislation: Decree-Law 539/1992, Law 311/2004
No. of pharmaceuticals	8,557 pharmaceuticals on the market (including different pharmaceutical forms, strengths and pack sizes) (2004)

Pricing

Competent authority	Medicines Agency (AIFA)
Legal basis	Law 662/1996, Decree-Law 326/2003, Decree-Law 87/2005
Scope of price control	Price negotiations for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	For reimbursable pharmaceuticals the manufacturer price is determined through negotiations between the pharmaceutical company and the AIFA. For innovative pharmaceuticals a so-called “premium price” is granted.
Criteria	External price referencing - prices in other EU Member States (most important criterion), cost-effectiveness for pharmaceuticals where no effective therapy exists, risk-benefit ratio, therapy costs per day, evaluation of the economic impact on the national health system, estimated market share of the new pharmaceutical
Wholesale margins	Statutory linear maximum mark-up, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals are free (not regulated).
Pharmacy margins	Statutory linear maximum mark-up, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals are, in general, free, however, a regulation provides for a minimum margin.
VAT	10% on pharmaceuticals (standard VAT rate: 20%)

Reimbursement

Competent authority	Medicines Agency (AIFA)
Legal basis	Decree-Law 326/2003, Decree-Law 87/2005
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list (called *Prontuario*)
Reimbursement rates	100% (all pharmaceuticals on the positive list are fully reimbursed; reimbursement rate of 50% was abolished in 2002)
Criteria	Therapeutic benefit following a cost-efficacy evaluation
Reference price system	Yes, since September 2001
Prescription fee	7 out of the 20 Italian regions apply prescription fees (regional fees, the amount is different between the regions)
Other co-payments	If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	330 pharmaceutical companies
Wholesale	300 wholesale outlets (7 full-line wholesalers dominate the market), multi channel system
Pharmacies	17,352 pharmacies (thereof 15,987 private community pharmacies and 1,365 public pharmacies owned by local authorities)
Other retailers	Since July 2006 sale of non-reimbursable OTC products allowed in supermarkets (separate sales area, obligatory presence of a pharmacist)

Pharmaceutical System in Latvia

Fact Sheet 2006

Market authorisation

Competent authority	State Agency of Medicine (VZA)
Legal basis	Directive 2004/27/EC and national legislation: Regulation No. 381/2000, updated in 2004
No. of pharmaceuticals	4,500 pharmaceuticals authorised; 3,195 POM; 1,305 OTC; 750 reimbursable pharmaceuticals (2005)

Pricing

Competent authority	State Medicines Pricing and Reimbursement Agency (ZCA)
Legal basis	Regulation of Cabinet of Ministers of the Republic of Latvia No. 1007 of 7 December 2004
Scope of price control	Statutory pricing (after negotiations) for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals
Price level controlled	Wholesale price level (manufacturer and pharmacy level through mark-up schemes)
Procedure	Pharmaceutical companies apply at the same time for reimbursement and for the approval of the wholesale price at ZCA. The application is reviewed by the Medicines Pricing and Reimbursement Agency ZCA and the Agency of Medicine VZA. After negotiation with the manufacturer the VZA decides on a justified wholesale price.
Criteria	External and internal price referencing, budget impact analysis, pharmaco-economic evaluation
Wholesale margins	Statutory regressive maximum mark-up scheme, valid for reimbursable pharmaceuticals, and a statutory linear maximum mark-up of 15% for non-reimbursable pharmaceuticals
Pharmacy margins	Statutory regressive maximum mark-up schemes • one for reimbursable pharmaceuticals • one for non-reimbursable pharmaceuticals
VAT	5% on pharmaceuticals (standard VAT rate: 18%)

Reimbursement

Competent authority	State Medicines Pricing and Reimbursement Agency (ZCA)
Legal basis	Regulation No. 428 (E0437)
Reimbursement scheme	Disease-specific reimbursement: Diseases/indications are defined as reimbursable; pharmaceuticals used for the treatment for these diseases are reimbursed at fixed reimbursement rates (see below).
Reimbursement list(s)	Positive list
Reimbursement rates	100%, 90%, 75%, 50%
Criteria	Burden of the disease, therapeutic value of the pharmaceutical, cost-effectiveness data, impact on the health care budget
Reference price system	Yes, since July 2005
Prescription fee	No
Other co-payments	Co-payment rates of 50%, 25%, 10% and 0% (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	12 active pharmaceutical manufacturers
Wholesalers	40 wholesalers registered (5 wholesaler dominate the market), multi channel system
Pharmacies	882 community pharmacies
Other retailers	No (sale of selected OTC products is allowed outside pharmacies, in practice not used)

Pharmaceutical System in Lithuania

Fact Sheet 2006

Market authorisation

Competent authority	State Medicines Control Agency (VVKT)
Legal basis	Directive 2004/27/EC and national legislation: Law on Medicines No. I-1633, Executive Order No. 669/2001
No. of pharmaceuticals	4,072 authorised pharmaceuticals (3,054 POM and 1,018 OTC)

Pricing

Competent authority	Ministry of Health (SAM), Department of Pharmacy (FD)
Legal basis	Decree No. 459 of the Ministry of Health of the Republic of Lithuania, as of 12 August 2000
Scope of price control	Price negotiations between the Pharmaceutical Department of the Ministry of Health (SAM) and manufacturers for reimbursable pharmaceuticals; prices are then officially set by SAM. Free pricing for non-reimbursable pharmaceuticals and pharmaceuticals used in hospitals.
Price level controlled	Manufacturer / CIP (cost, insurance and packaging) price level (wholesale and pharmacy level through mark-up schemes)
Procedure	Pharmaceutical companies applying for inclusion of a product to reimbursement have to submit an application to the SAM. Amongst others, the requested manufacturer price (or for imported pharmaceuticals the CIP price = manufacturer price plus import costs) needs to be included in the application. Thus, for reimbursable pharmaceuticals manufacturer / CIP prices are negotiated between the Ministry of Health and the pharmaceutical companies on a yearly basis.
Criteria	For reimbursable pharmaceuticals: internal price referencing (for innovative pharmaceuticals and generics), external price referencing (for setting the reimbursement price; reference countries: Czech Republic, Estonia, Latvia, Poland, Slovakia and Hungary), pharmaco-economic evaluation
Wholesale margins	Statutory regressive maximum mark-up scheme, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals are free (not regulated).
Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals are free (not regulated).
VAT	5% on pharmaceuticals (standard VAT rate: 18%)

Reimbursement

Competent authority	Ministry of Health (SAM), advised by Reimbursement Committee and Council of State Sickness Fund (VLK)
Legal basis	Law on Health Insurance No. I-1343, 21 May 1996
Reimbursement scheme	Disease-specific reimbursement: Diseases/indications are defined as reimbursable; pharmaceuticals used for the treatment for these diseases are reimbursed at the fixed reimbursement rates.
Reimbursement list(s)	Positive list with two categories (List A and List B). • List A covers pharmaceuticals, which are reimbursed with regard to the severity of the disease • List B covers all pharmaceuticals, which are reimbursed because of social reasons (e.g. for children).
Reimbursement rates	100%, 90%, 80%, 50% (List A) 100%, 50% (List B)
Criteria	Impact on the VLK budget, therapeutic advantages of the product over alternative therapies in terms of effectiveness and side effects, product's place in therapy (first, second or third line product in treatment algorithm) and the severity of the disease
Reference price system	Yes, since 2003
Prescription fee	No
Other co-payments	Co-payment rates of 50%, 20%, 10% and 0% (for reimbursable pharmaceuticals). If applicable, the difference between the base price for reimbursement or the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	13 local pharmaceutical manufacturers (2005)
Wholesale	72 wholesale licenses registered (2005), multi channel system
Pharmacies	1,520 community pharmacies (thereof 515 registered community pharmacies with 944 subsidiaries partly organised in chains and 61 hospital pharmacies also serving out-patients, 2005)
Other retailers	No (A few health care centres in rural areas may dispense pharmaceuticals.)

Pharmaceutical System in Luxembourg

Fact Sheet 2006

Market authorisation

Competent authority	Ministry of Health (*Ministère de la Santé*) advised by the Department for Pharmacy and Pharmaceuticals within the Health-Directorate (*Division de la Pharmacie et des Médicaments, Direction de la Santé*)
Legal basis	Directive 2004/27/EC and national legislation
No. of pharmaceuticals	N. a.

Pricing

Competent authority	Ministry of Economy and Foreign Trade (*Ministère de l'Economie*) advised by Competition Direction (*Direction de la concurrence*)
Legal basis	Decree of the Grand Duke of 29 July 2004 on the prices of pharmaceuticals (*Règlement grand-ducal du 29 juillet 2004 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués)*
Scope of price control	Statutory pricing for all pharmaceuticals
Price level controlled	Pharmacy retail price level (manufacturer and wholesale level through mark-up schemes)
Procedure	Market authorisation holders have to submit a price application to the Competition Direction in the Ministry of Economy and Foreign Trade which determines the price at retail level.
Criteria	External price referencing: price of the pharmaceuticals in the country of origin or provenance
Wholesale margins	Different statutory linear and regressive maximum mark-ups/mark-up schemes for all pharmaceuticals, depending on the country of origin or provenance
Pharmacy margins	Different statutory linear and regressive maximum mark-ups/mark-up schemes for all pharmaceuticals, depending on the country of origin or provenance
VAT	3% on pharmaceuticals (standard VAT rate: 15%)

Reimbursement

Competent authority	Union of Sickness Funds (UCM)
Legal basis	Decree of the Grand Duke of 12 December 2002 (*Règlement grand-ducal du 12 décembre 2002*)
Reimbursement scheme	Product specific reimbursement
Reimbursement list(s)	Positive list
Reimbursement rates	100%, 80%, 40%
Criteria	Cost-effectiveness, patients' needs
Reference price system	No
Prescription fee	No
Other co-payments	Co-payment rates of 60%, 20% and 0% (for reimbursable pharmaceuticals)

Distribution

Manufacturers	No pharmaceutical manufacturers
Wholesale	4 wholesalers, multi channel system
Pharmacies	87 community pharmacies
Other retailers	No unless 7 hospital pharmacies

Pharmaceutical System in Malta

Fact Sheet 2006

Market authorisation

Competent authority	Medicines Authority (MA)
Legal basis	Directive 2004/27/EC and national legislation: Medicines Act 2004
No. of pharmaceuticals	2,300 pharmaceuticals (counting different pharmaceutical forms, excl. different dosages and pack sizes) in the private system; 3,200 active ingredients in the public system

Pricing

Competent authority	Ministry of Health (MoH), Health Care Procurement and Supplies Services (HPSS)
Legal basis	Medicines Act 2003
Scope of price control	Free pricing for all pharmaceuticals in the private system, i.e. selling of pharmaceuticals through pharmacies Public procurement (tendering) for pharmaceuticals in the public system, i.e. dispensing of pharmaceuticals to eligible patients in National Health Service (NHS) dispensaries
Price level controlled	Free pricing at manufacturer / CIP (cost, insurance and packaging) price level; however, wholesale and pharmacy level through mark-up schemes
Procedure	In the public system, the HPSS purchases - via a tendering process - pharmaceuticals to be included in the National Formulary (cf. reimbursement). Each contract agreed through the tendering process is valid for a period of 3 years. Contracts can also be awarded for a one-year period in specific circumstances, such as when a very high price is granted. There is free pricing in the private system.
Criteria	Trade price of the tender (public system)
Wholesale margins	Statutory linear maximum mark-up of 15% for all pharmaceuticals in private system. No mark-ups in the public system.
Pharmacy margins	Statutory linear maximum mark-up of 20% for all pharmaceuticals in private system. No mark-ups in the public system.
VAT	0% (VAT of 5% on pharmaceuticals planned from 2010 on)

Reimbursement

Competent authority	MoH, advised by the Drugs and Therapeutics Committee (DTC)
Legal basis	Medicines Act 2003
Reimbursement scheme	Population-group-specific reimbursement: Specific population groups (income threshold, certain diseases/indications or handicaps, certain professions) have access to reimbursable pharmaceuticals (= public system). In the private system there is no reimbursement.
Reimbursement list(s)	National Formulary (Essential Drugs List) - in the public system
Reimbursement rates	There are no reimbursement categories. Patients are either eligible for pharmaceuticals with 100% reimbursement (= public system) or must pay the full cost of their pharmaceuticals out-of-pocket (= private system).
Criteria	Efficacy, safety, registration in EU, cost-benefit, comparison of the pharmaceuticals with alternative treatments on the list, protocol for the use of the pharmaceutical (public system)
Reference price system	No
Prescription fee	No
Other co-payments	In the private system patients have to pay the full price of the pharmaceutical.
Country specific	Pharmaceutical market is split into a parallel private and a public system

Distribution

Manufacturers	1 locally producing pharmaceutical company
Wholesalers	90 (importers)
Pharmacies	210 private pharmacies (private system)
Other retailers	52 NHS dispensaries for eligible patients (public system)

Pharmaceutical System in Netherlands

Fact Sheet 2006

Market authorisation

Competent authority	Medicines Evaluation Board (CBG)
Legal basis	Directive 2004/27/EC and national legislation: Pharmaceutical Supply Act of 28 July 1958 (*Wet op de geneesmiddelen-voorziening*), Decree on registration of pharmaceuticals of 8 September 1977 (*Besluit registratie geneesmiddelen*)
No. of pharmaceuticals	11,440 POM (including different pharmaceutical forms), of which 9,960 were available on the market (2005)

Pricing

Competent authority	Ministry of Health, Welfare and Sport (VWS), advised by the Pharmaceutical Care Committee (CFH)
Legal basis	Law on Medicines Prices of 25 January 1996 (*Wet Geneesmid-delenprijzen, WGP*)
Scope of price control	Statutory pricing for prescription-only medicines (POM) Free pricing for OTC products
Price level controlled	Wholesale price level (pharmacy level through mark-ups)
Procedure	The Ministry of Health, Welfare and Sport fixes the maximum wholesale price of all POM, after reception of the application from the manufacturer. The WGP procedure is also used to set the prices of generics and parallel imported pharmaceuticals. Free pricing is allowed for OTC products. Prices of OTC products at pharmacy retail level are thus officially free, but in practice OTC products are always sold at the prices mentioned in the price list (“taxe”).
Criteria	External price referencing, pharmaco-economic evaluation
Wholesale margins	No statutory wholesale mark-up. The wholesale margin is freely negotiated between the manufacturer and the wholesaler.
Pharmacy margins	List price and fixed pharmacy fee for POM. Margins for OTC products are officially free (not regulated), but usually depending on the list price.
VAT	6% on pharmaceuticals (standard VAT rate: 19%)

Reimbursement

Competent authority	Ministry of Health, Welfare and Sport (VWS)
Legal basis	Health Insurance Act of 16 June 2005 (*Zorgverzekeringswet*), Decree on Health Insurance of 28 June 2005 (*Besluit zorgverzekering*), Regulation on Health Insurance of 1 September 2005 (*Regeling zorgverzekering*)
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list divided into 3 categories (Annex 1A; Annex 1B; Annex 2), Annex 2 products are only reimbursed under specific circumstances (e.g. prescription by specialist)
Reimbursement rates	100%
Criteria	Since 2005 pharmaco-economic evaluation plays the most important role for reimbursement eligibility. To be included in Annex 1A: therapeutic equivalence (same indications, same route of administration and used by patients in same age category) to one or more already listed pharmaceuticals. To be included in Annex 1B: therapeutic efficacy, cost-effectiveness, side-effects, experience with the pharmaceutical, applicability of the pharmaceutical, ease of use for the patient.
Reference price system	Yes, since 1991
Prescription fee	No
Other co-payments	Only for pharmaceuticals listed in Annex 1A: If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	63 research-oriented manufacturers
Wholesalers	N. a.; multi channel system
Pharmacies	2,322 POM dispensaries, of which 1,732 pharmacies (2005)
Other retailers	3,961 drugstores or drugstore departments within supermarkets; 760 OTC outlets and 4 internet pharmacies

Pharmaceutical System in Poland

Fact Sheet 2006

Market authorisation

Competent authority	Ministry of Health on recommendation of the National Office for Registration of Medicinal Products, Medical Devices and Biocides (URPL)
Legal basis	Directive 2004/27/EC and national legislation: Act of 6 September 2001 on pharmaceuticals
No. of pharmaceuticals	8,089 pharmaceuticals authorised (incl. different pharmaceuticals forms, dosages and pack sizes); 5,905 POM and hospital-only pharmaceuticals; 2,750 reimbursable pharmaceuticals (2005)

Pricing

Competent authority	Ministry of Health, advised by Drug Committee (in consultation with Ministry of Finance)
Legal basis	Act of 5 July 2001 on prices
Scope of price control	Statutory pricing (after negotiations) for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals
Price level controlled	Wholesale and pharmacy retail price level (manufacturer level indirectly regulated through wholesale mark-up)
Procedure	The reimbursement system and the pricing procedure are very much linked: in the course of the application for reimbursement, pharmaceutical companies have to submit an application for price determination. This application has to include the proposed price including its justification, an international price comparison, the price of the pharmaceuticals of the same indication group in Poland, production costs and estimated volume of sales. The advisory Drug Committee provides an assessment of the application with regard to the pricing and reimbursement decision. The Ministry of Health in consultation with the Ministry of Finance finally takes the decision on the maximum wholesale and retail prices.
Criteria	External and internal price referencing, impact on treatment costs, volume of sales, production costs, efficacy, impact on public health
Wholesale margins	Statutory linear maximum mark-up, valid for reimbursable pharmaceuticals. Margins for non-reimbursable pharmaceuticals are free (not regulated).

Pharmacy margins	Statutory regressive maximum mark-up scheme, valid for reimbursable pharmaceuticals Margins for non-reimbursable pharmaceuticals are free (not regulated).
VAT	7% on pharmaceuticals (standard VAT rate: 22%)

Reimbursement

Competent authority	Ministry of Health, advised by Drug Committee
Legal basis	Act of 27 August 2004 on health care services financed from public means, Art. 34-39, 43-46
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	3 lists: Basic List, Supplementary List and Special Reimbursement List for pharmaceuticals for severe or chronic diseases
Reimbursement rates	Reimbursement rates of 100% (Basic List, Special Reimbursement List), 70% and 50% (Supplementary List, Special Reimbursement List)
Criteria	External and internal price referencing, impact on treatment costs, volume of sales, production costs, efficacy, impact on public health
Reference price system	Yes
Prescription fee	€ 0.80 for pharmaceutical specialities and € 1.24 for magistral preparations - in the Basic List, (in general) no prescription fees for pharmaceuticals in the two other reimbursement lists
Other co-payments	Co-payment rates of 50% and 30% (for reimbursable pharmaceuticals in the Supplementary List and some pharmaceuticals in the Special Reimbursement List) and 0% (for reimbursable pharmaceuticals in the Basic List and for some pharmaceuticals in the Special Reimbursement List). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	~ 300 (2005)
Wholesalers	663 wholesalers registered (2005), multi channel system
Pharmacies	~ 11,000 community pharmacies (2005)
Other retailers	Pharmacy stations and drug stores for the sale of certain OTC products

Pharmaceutical System in Portugal

Fact Sheet 2006

Market authorisation

Competent authority	Medicines Agency (INFARMED)
Legal basis	Directive 2004/27/EC and national legislation: Decree-Law No. 72/91
No. of pharmaceuticals	N. a.

Pricing

Competent authority	Directorate-General Enterprise (DGE)
Legal basis	Enactment No. 29/1990 of 13 January, Decree-Law No. 134/2005, Enactment No. 618-A/2005 of 27 July, Framework Agreement between Ministry of Health and pharmaceutical industry for 2006 to 2009 (*Protocolo entro o Ministério da Saúde e a Indústria Farmacêutic (2006-2009)*
Scope of price control	Statutory pricing for prescription-only medicines (POM) Free pricing for OTC products
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	The maximum manufacturer price for POM is statutorily fixed by the Directorate-General Enterprise based on an international price comparison (cf. below)
Criteria	External price referencing (reference countries: Spain, France, Italy and, since the latest Framework Agreement signed in February 2006 also Greece) Methodology based on latest Framework Agreement: Calculation of the average of manufacturer prices of identical or similar pharmaceutical specialities containing the same active ingredient, found in the reference countries instead of the lowest price as done before.
Wholesale margins	Statutory linear maximum mark-up, valid for POM. Margins for OTC products are free (not regulated).
Pharmacy margins	Statutory linear maximum mark-up, valid for POM. Margins for OTC products are free (not regulated).
VAT	5% on pharmaceuticals (standard VAT rate: 21%)
Country specific	INFARMED tax (sales tax) of 0.4%

Reimbursement

Competent authority	Medicines Agency (INFARMED)
Legal basis	Decree-Law No. 118/1992 of 25 June, Decree-Law No. 129/2005 of 11 August
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list
Reimbursement rates	Reimbursement rates of 95%, 70%, 40%, 20%
Criteria	Efficacy, safety, economic advantage, therapeutic benefit and advantage and price
Reference price system	Yes, since 2003
Prescription fee	No
Other co-payments	Co-payment rates of 80%, 60%, 30% and 5% (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	130
Wholesalers	300 are registered, only 130 are active, multi channel system
Pharmacies	2,750 community pharmacies
Other retailers	300 *Postos* (outlets run by pharmacies, mainly located in rural areas), 126 sales outlets for selected OTC products

Pharmaceutical System in Slovakia

Fact Sheet 2006

Market authorisation

Competent authority	State Institute for Drug Control (SUKL)
Legal basis	Directive 2004/27/EC and national legislation: Act No. 140/1998 on Medicinal Products and Medical Devices
No. of pharmaceuticals	14,340 (incl. different pharmaceutical forms, pack sizes and dosages) (2005)

Pricing

Competent authority	Ministry of Health (MZ SR) advised by Categorisation Committee
Legal basis	Act of Scope No. 759/2004
Scope of price control	Statutory pricing for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals (mostly OTC products)
Price level controlled	Pharmacy retail price level (manufacturer and wholesale level indirectly regulated through mark-up schemes)
Procedure	Manufacturers have to submit an application for a maximum pharmacy retail price to the MZ SR. These price proposals are then published on the website of MZ SR. After two weeks, the pharmaceutical companies again submit a price proposal, which can be the same as the first one or below. Due to strategic thinking pharmaceutical companies very often lower their second price proposal. No further adjustments are allowed after the second round. The Categorisation Committee then sets the maximum retail prices according to the “agreed” prices. In case that the price of a pharmaceutical is deemed too high, the Categorisation Committee decides either not to reimburse the pharmaceutical or only partially. After setting of the maximum pharmacy retail price, the manufacturer may apply for reimbursement.
Criteria	External price referencing for imported pharmaceuticals, production costs (“cost plus”) for locally produced pharmaceuticals
Wholesale margins	Statutory maximum mark-ups for all pharmaceuticals, different mark-ups depending on kind of pharmaceutical
Pharmacy margins	Statutory maximum mark-ups for all pharmaceuticals, different mark-ups depending on kind of pharmaceutical
VAT	19% on pharmaceuticals (standard VAT rate: 19%)

Reimbursement

Competent authority	Ministry of Health, advised by the Categorisation Committee
Legal basis	Act of Scope No. 759/2004
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list
Reimbursement rates	3 categories: • Full reimbursement (including vital pharmaceuticals) • Partial reimbursement (including some generics or other equivalent original products) • No reimbursement There are no fixed reimbursement rates.
Criteria	Therapeutic benefit, internal price comparison and production cost of the pharmaceutical
Reference price system	Yes, since 1995
Prescription fee	€ 0.48 per prescription
Other co-payments	Different co-payment rates (no fixed percentage rates) for reimbursable pharmaceuticals. If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	90 (around 40 - 50 research-based pharmaceutical companies and around 40 locally producing pharmaceutical companies)
Wholesalers	36, of which 11 dominate the market
Pharmacies	1,164
Other retailers	88 state-owned hospital pharmacies

Pharmaceutical System in Slovenia

Fact Sheet 2006

Market authorisation

Competent authority	Agency of Medicinal Products and Medical Devices (ARSZMP)
Legal basis	Directive 2004/27/EC and national legislation: Official Gazette of the Republic of Slovenia, No. 78-3708/2003
No. of pharmaceuticals	3,000 pharmaceuticals (excluding different dosages and pack sizes and excluding centrally authorised pharmaceuticals, 2005)

Pricing

Competent authority	Agency of Medicinal Products and Medical Devices (ARSZMP)
Legal basis	Medicinal Products and Medical Devices Act
Scope of price control	Statutory pricing for all pharmaceuticals except non-reimbursable OTC products Free pricing for non-reimbursable OTC products Price negotiations on the reimbursement price for reimbursable pharmaceuticals between the National Health Insurance Fund (ZZZS) and pharmaceutical companies
Price level controlled	Wholesale price level (pharmacy level regulated in the form of a fee-for-service remuneration)
Procedure	The ARSZMP determines the price at wholesale level on the basis of international price comparisons (Italy, France and Germany). The wholesale price of a pharmaceutical may in general not exceed 85% of the average price determined by the price comparison. For imported products an extra 0.5% is added. For generics the price may not exceed 96% of the average wholesale price in three reference countries.
Criteria	External price referencing
Wholesale margins	No statutory wholesale mark-up. The wholesale margin is freely negotiated between the manufacturer and the wholesaler.
Pharmacy margins	Fee-for-service remuneration, valid for all pharmaceuticals
VAT	8.5% on pharmaceuticals (standard VAT rate: 20%)

Reimbursement

Competent authority	Drug Committee at the National Health Insurance Fund (ZZZS)
Legal basis	Official Gazette of the Republic of Slovenia, No. 78-3708/2003 page 11647
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	Positive list and so-called intermediate list
Reimbursement rates	100%, 75% or 25%
Criteria	Indication, efficacy, pharmaceuticals for certain social groups
Reference price system	Yes, since November 2003
Prescription fee	No
Other co-payments	Co-payment rates of 75%, 25% and 0% for certain social groups and diseases/indications (for reimbursable pharmaceuticals). If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	51
Wholesalers	11, multi channel system
Pharmacies	271 community pharmacies
Other retailers	80 common and specialised stores with a restricted range of pharmaceuticals

Pharmaceutical System in Spain

Fact Sheet 2006

Market authorisation

Competent authority	Spanish Medicines Agency (AEMPS)
Legal basis	Directive 2004/27/EC and national legislation: Royal Decree 767/1993
No. of pharmaceuticals	11,783 authorised pharmaceuticals (including different pharmaceutical forms, dosages, and pack sizes), of which 10,074 are POM and 1,127 are *Especialidades Farmaceuticas Publicitarias* (EFP), a specific type of OTC pharmaceuticals

Pricing

Competent authority	Interministerial Commission on Pharmaceutical Prices under the Ministry of Health
Legal basis	Law 66/1997, Law on Medicines and Medical Devices (*Ley de garantítas y uso racional de los medicamentos y productos sanitarios*) 2006
Scope of price control	Statutory pricing for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals and for pharmaceuticals destined for parallel export
Price level controlled	Manufacturer price level (wholesale and pharmacy level through mark-up schemes)
Procedure	The pricing decision for reimbursable pharmaceuticals is taken by the Interministerial Commission on Pharmaceutical Prices. Manufacturers receive a preliminary resolution regarding the Interministerial Commission's proposed price. Manufacturers can appeal in case of disagreement, but they can also choose to launch the product without reimbursement eligibility. The Ministry of Health may set a time period for which the price acceptable for reimbursement is valid, and prices may be revised due to technical, budgetary or health-related issues. Non-reimbursable prescription-only pharmaceuticals are freely priced, but final prices still need to be approved, though it is simply an administrative procedure (price notification).
Criteria	Therapeutic value of the pharmaceutical, sales forecast, external and internal price referencing
Wholesale margins	Statutory regressive maximum mark-up scheme, for all pharmaceuticals
Pharmacy margins	Statutory regressive maximum mark-up scheme, for all pharmaceuticals
VAT	4% on pharmaceuticals (standard VAT rate: 16%)

Reimbursement

Competent authority	Directorate General of Pharmacy and Health Products (*Direccion General de Farmacia e Productos Sanitarios*) of the Ministry of Health
Legal basis	Real Decreto 83/1993, Law on Medicines and Medical Devices (*Ley de garantítas y uso racional de los medicamentos y productos sanitarios*) 2006
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	2 negative lists identifying pharmaceuticals not eligible for reimbursement
Reimbursement rates	100%, 90%, 60%
Criteria	Nature of the illness, grade of innovation, therapeutic value of the pharmaceutical, efficacy, price
Reference price system	Yes, since December 2000
Prescription fee	No
Other co-payments	Co-payment rates of 40%, 10% (up to a maximum limit of € 2.64 for pharmaceuticals for chronic diseases) and 0% (for reimbursable pharmaceuticals) If applicable, the difference between the reference price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	250 pharmaceutical companies
Wholesale	100 wholesalers, multi channel system
Pharmacies	20,461 community pharmacies
Other retailers	No

Pharmaceutical System in Sweden

Fact Sheet 2006

Market authorisation

Competent authority	NAM (*Läkemedelsverket*)
Legal basis	Directive 2004/27/EC and national legislation: Swedish Medicinal Products Act (*Läkemedelslagen)* 1992: 859 as amended by Medicines Enactment (*Läkemedelsförordning*) 2006: 272
No. of pharmaceuticals	About 8,050 authorised pharmaceuticals (including different pharmaceutical forms but excluding different pack sizes and dosages, 2005)

Pricing

Competent authority	LFN (Pharmaceuticals Pricing Board)
Legal basis	Act on Pharmaceutical Benefits etc. *"Lag om läkemedelsförmåner m.m."* (2002:160) from 1 October 2002, esp. Art. 15 LFN Enactment on Pharmacy Mark-ups from 1 November 2005
Scope of price control	Statutory pricing for reimbursable pharmaceuticals Free pricing for non-reimbursable pharmaceuticals (like many OTC)
Price level controlled	Wholesale price level (pharmacy level through statutory mark-up schemes)
Procedure	Manufacturers respectively importers may freely set the price for pharmaceuticals when placing them on the market. However, pharmaceutical companies seeking for reimbursement need LFN to approve a so-called "reasonable" wholesale price for their product. Off-patent pharmaceuticals, generics and parallel imports may be priced freely by pharmaceutical companies as long as the price remains below the most expensive pharmaceutical in their group of substitution (maximum reimbursement price).
Criteria	Medical value of the pharmaceutical, human value principle, needs/solidarity principle, cost-effectiveness principle; internal price referencing for off-patent products and parallel imports
Wholesale margins	No statutory wholesale mark-up. The wholesale margin is freely negotiated between the manufacturer and the wholesaler.
Pharmacy margins	Statutory regressive maximum mark-up schemes for all pharmaceuticals: • One for POM • One for OTC products
VAT	No VAT on POM, 25% on OTC (standard VAT rate: 25%)

Reimbursement

Competent authority	LFN (Pharmaceuticals Pricing Board)
Legal basis	Act (2002:160) and Ordinance (2002:687) on Pharmaceutical Benefits, etc.; LFN Regulation (LFNFS 2003:1) on Applications to and Decisions by the Pharmaceutical Benefits Board Pursuant to the Act (2002:160) on Pharmaceutical Benefits, etc. and LFN Regulation (LFNFS 2003:2) on Non-prescription Drugs.
Reimbursement scheme	Consumption-based reimbursement: Before the patient is eligible for reimbursement he or she has to pay the full cost of his/her reimbursable medication up to a threshold of about € 97.0 per 12 month period. After passing this threshold, the reimbursement rate rises gradually. When a patient has paid up to a ceiling of ~ € 194.- for prescribed drugs, a free pass is issued which exempts him/her from further co-payments over a 12-month period.
Reimbursement list(s)	Positive list called Pharmaceuticals Benefits Scheme Some pharmaceuticals (e.g. naturopathic drugs, drugs for anti-dotal smoking treatment) are excluded from reimbursement
Reimbursement rates	The reimbursement rate depends on the consumption of each patient and not on the product. These rates range from 0% (for patients with expenses below a threshold of € 97.0) to 100% (for patients having a so-called "free card", i.e. those who have reached their 12-month co-payment ceiling of € 93.91).
Criteria	Principle of human value, principle of need and solidarity, principle of cost-effectiveness, principle of marginal benefit
Reference price system	No (abolished, it was in place from 1993 to 2002), replaced by a system of obligatory generic substitution
Prescription fee	No
Other co-payments	Co-payment rate of 100% under threshold of € 97.-, then 50% of the costs between € 97.- and € 183.15 25% of the costs between € 183.16 and € 355.50 10% of the costs between € 355.6 and € 463.25 0% of the costs above € 423.26 If applicable, the difference between the max. reimbursement price and the pharmacy retail price has to be paid by the patient.

Distribution

Manufacturers	70 manufacturers and several parallel traders
Wholesale	2 wholesalers, single channel system
Pharmacies	844 community pharmacies (2005)
Other retailers	29 pharmacy shops selling OTC and health products. 77 hospital pharmacies 850 medicines chests for a selected range of OTC products
Country specific	All Swedish pharmacies, pharmacy shops etc. are fully owned by the state and are organised as a monopoly pharmacy chain called the National Corporation of Pharmacies (a*poteket).*

Pharmaceutical System in the United Kingdom

Fact Sheet 2006

Market authorisation

Competent authority	Medicines and Healthcare Products Regulatory Agency (MHRA)
Legal basis	Medicines Act 1968, national legislation based on Directive 2004/27/EC
No. of pharmaceuticals	14,000 to 15,000 (2005)

Pricing

Competent authority	For (branded) on-patent pharmaceuticals: Department of Health (DH) and The Association of British Pharmaceutical Industry (ABPI) agree on PPRS For generics of category A: National Health Service Business Service Authority (NHSBSA) For generics of category M (W): DH and the British Generic Manufacturers Association (BGMA)
Legal basis	The Pharmaceutical Price Regulation Scheme (PPRS) backed up by the Health Act, sections 33, 35 and 36 Scheme M based on a voluntary agreement backed up by the Health Act Section 34-38
Scope of price control	Indirect price control through the PPRS for reimbursable branded POM and OTC products included in the NHS, based on a framework agreement between the DH and the ABPI for the framework backed up by law. Free pricing for non-reimbursable OTC products, hospital-only pharmaceuticals and generics.
Price level controlled	NHS price level, corresponding to the wholesale price level (pharmacy level regulated in the form of a fixed fee-for-service)
Procedure	In general there is free pricing in the UK. However, the prices of pharmaceuticals reimbursable by NHS are subject to the Pharmaceutical Price Regulation Scheme (PPRS), which is an indirect price control agreement. Under this voluntary system, which is negotiated periodically between the Department of Health (DH and the Industry Association ABPI, a profit framework is fixed for each individual manufacturer. Within this framework manufacturers/suppliers are free to set their prices. Most generics do not fall under the PPRS system. In general, also the prices of generics may be freely set by the manufacturers, but to qualify for reimbursement their price has to be either negotiated between the DH and the British Generic Manufacturers Association (BGMA) or to be calculated by the NHS Business Service Authority.
Criteria	Expected profit, capital investments, R & D expenditure and marketing / promotion expenses

Wholesale margins	The wholesale margins for branded pharmaceuticals are determined within the scope of the PPRS and may be at a maximum of 12.5% of the NHS price (price reimbursed by the NHS). Margins for generics are free (not regulated).
Pharmacy margins	For NHS pharmaceuticals pharmacists get a fixed fee per dispensed pack plus the net ingredient cost of the pharmaceutical at the NHS price Margins for non-reimbursable pharmaceuticals (not included in the NHS) are free (not regulated).
VAT	No VAT on NHS prescriptions, 17.5% on OTC pharmaceuticals, non-reimbursed and private prescriptions (standard VAT rate: 17.5%)
Country specific	Claw-back system, allowing the NHS to re-coup a part of the profits generated by pharmacists
Reimbursement	
Competent authority	DH, consulted by the National Institute of Health and Clinical Excellence (NICE)
Legal basis	Medicines Act 1968
Reimbursement scheme	Product-specific reimbursement
Reimbursement list(s)	British National Formulary (BNF) acts a kind of positive list containing all reimbursable brands 2 negative lists (grey and black list)
Reimbursement rates	100%
Criteria	Prescription status, pharmaco-economic evaluation, efficacy
Reference price system	No
Prescription fee	€ 9.70 per prescription. Alternatively patients may purchase either a four monthly prescription prepayment certificate for € 48.8 or an annual prescription prepayment certificate for € 134.25 to cover all prescription fees for that period. Approximately half of the UK population is exempt from the prescription fee, like persons under 16 and over 60 years, students, pregnant women, mothers, low income groups and patients suffering from a chronic illness.
Other co-payments	No
Distribution	
Manufacturers	82 manufacturers represented in the Association of the British Pharmaceutical Industry, up to 15 parallel importers
Wholesale	12 full-line wholesalers, multi channel system
Pharmacies	12,200 community pharmacies
Other retailers	Self-dispensing doctors Pharmacy stores and supermarkets for the sale of OTC products on General Sales List (GSL)

ANNEX

Glossary

Anatomic Therapeutic Chemical Code (ATC)	=	In this classification system pharmaceuticals are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.
Community Drug Scheme	=	Different payment arrangements for services/pharmaceuticals provided in the community and financed by the Primary Care Reimbursement Service (PCRS) in Ireland
Co-payment	=	Out-of-pocket payments of patients for pharmaceuticals within the reimbursement system. They appear in different forms: Fixed co-payments: a fixed amount (like for example a prescription fee) to be paid for a service, a pharmaceutical or a medical device. Percentage co-payment: a certain fixed proportion of the cost of a service or pharmaceutical, with the social health insurance/national health service paying the remaining proportion. Deductible: a fixed amount which must be paid for a service or of total cost incurred over a defined period by a covered person beforehand a social health insurance/national health service, then all or a percentage of the rest of the cost is covered. In case of a reference price system: any difference between the reference price and the pharmacy retail price, which has to be paid by the patient.
External Price Referencing / Cross Country Referencing	=	The practice of comparing pharmaceutical prices across countries. There are various methods applied and different country baskets relevant.
Full liner		Wholesaler offering the full range of pharmaceuticals available in a given market/country. There are no full liners in single channel distribution systems.
Free Pricing	=	Pricing system, where pharmaceutical prices may be freely set by the manufacturer / importer.
Generic	=	Bioequivalent of a branded original pharmaceutical, whose patent on the active ingredient has expired (also called off-patent or multi-source pharmaceutical). By law, a generic product must contain an identical amount of the same active ingredient(s) as the branded product. There are branded generics and unbranded generics on the market. Branded generics also have a specific trade name, whereas unbranded generics use the international non-proprietary name and the manufacturer's name.
Internal Price Referencing	=	A method to compare prices of pharmaceuticals in a country with the price of identical pharmaceuticals (ATC-5 level) or similar pharmaceuticals (ATC-4 level) or even with therapeutically equivalent treatment (not necessarily a pharmaceutical) in a country. Often performed in the course of a reference price system.
Manufacturer Price	=	The manufacturer’s posted price, in some countries also referred to as list price or price to wholesalers. This price does not include any discounts or other incentives offered by manufacturers.
Mark-up	=	Wholesale mark-up: Gross profit of wholesalers, expressed as a percentage of the manufacturer/ex-factory price. Pharmacy mark-up: The gross profit of pharmacies expressed as a percentage of the wholesale/pharmacy purchase price.
Margin	=	Wholesale margin: Gross profit of wholesalers, expressed as a percentage of the wholesale/pharmacy purchase price. Pharmacy margin: Gross profit of pharmacies, expressed as a percentage of the pharmacy retail price.

Market Authorisation	=	A licence issued by a medicines agency approving a pharmaceutical for market use based on a determination by authorities that the pharmaceutical meets the requirements of quality, safety and efficacy for human use in therapeutic treatment. There are the following application procedures possible in the EU: “centralised procedure”, “mutual recognition procedure” (MRP)/“decentralised procedure” and “national procedure”. For homeopathic pharmaceuticals and medical devices no authorisation but a registration procedure is necessary.
Multi channel system		In a multi channel distribution system pharmaceutical companies distribute their products via several wholesalers to pharmacies. Wholesalers do not have exclusive distribution rights on specific products.
Negative List	=	List of pharmaceuticals which cannot be prescribed at the expense of the social health insurance / national health service.
Original Product	=	The first version of a pharmaceutical, developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product in the European Union for 15 years. An original product has a unique trade name for marketing purposes, its so-called brand name.
Over-the-Counter (OTC)		Pharmaceuticals which may be dispensed without a doctor's prescription being submitted and which are in some countries available via self-service in pharmacies a/o other retail outlets (e.g. drug stores). Selected OTC may be reimbursed for certain indications in some countries.
Pharmaceutical	=	Any active ingredient or combination product presented for treating or preventing disease in human beings as animals. Any active ingredient or combination product which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human being or in animals is likewise considered a pharmaceutical.
Pharmaco-economic Evaluation	=	The comparative analysis of alternative courses of action in terms of both their costs and consequences.
Pharmacy Retail Price (gross)	=	The price charged by pharmacists to the general public. It includes any pharmacy mark-ups or dispensing fees and VAT.
Prescription-only-Medicines (POM)		Pharmaceuticals that may be dispensed only on a doctor's prescription.
Positive List	=	List of pharmaceuticals that may be prescribed more or less without further conditions at the expense of a health insurance/national health service.
Price Negotiation	=	A form of pricing procedure, where pharmaceutical prices are negotiated.
Pricing	=	The act of setting a price for a pharmaceutical.
Reference Price System	=	The health insurance/national health service determines a maximum price (= Reference Price) to be reimbursed for certain pharmaceuticals. On buying a pharmaceutical for which a fixed price (~ the so-called reimbursement price) has been determined, the insured person must pay the difference between the fixed price and the actual pharmacy retail price of the pharmaceutical in question, in addition to any fixed co-payment or percentage co-payment rates. Usually the reference price is the same for all pharmaceuticals at a given ATC-4 level (similar pharmaceuticals) and/or ATC-5 level (identical pharmaceuticals) group.
Reimbursable Pharmaceuticals	=	Pharmaceuticals whose costs are, at least partially, covered by the social health insurance / national health service
Reimbursement	=	Reimbursement is the percentage of costs (for a service or a pharmaceutical) which the social health insurance/national health service pays. So 100% reimbursement means that the social health insurance/national health service accept 100% of the costs for a pharmaceutical or service.

Reimbursement Categories	=	Pharmaceuticals eligible for reimbursement are often grouped according to selected characteristics, e.g. route of administration (oral, etc.), main indication (oncology, paediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different reimbursement rates are determined for different reimbursement categories.
Single channel system		In a single channel system pharmaceutical wholesalers have exclusive distribution contracts with individual pharmaceutical companies/importers. Consequently, every wholesaler - being partly assorted - is only able to offer a part range of the pharmaceuticals on the market to pharmacies
Statutory Pricing	=	Pricing system, where pharmaceutical prices are set on a regulatory basis (e.g. law, enactment, decree).
Therapeutic Benefit	=	Synonym to therapeutic value. The effect conveyed on a patient following administration of a pharmaceutical which either restores, corrects or modifies a physiological function(s) for that patient.
Value Added Tax (VAT)	=	A sales tax levied on the sale of goods and services (compulsory for EU Member States). The VAT rate of pharmaceuticals in the EU is often lower than the standard VAT rate of 15%.
Wholesale Price	=	The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up.

Further definitions can be found in the PPRI glossary, see http://ppri.oebig.at

Pharmaceutical Pricing and Reimbursement Information

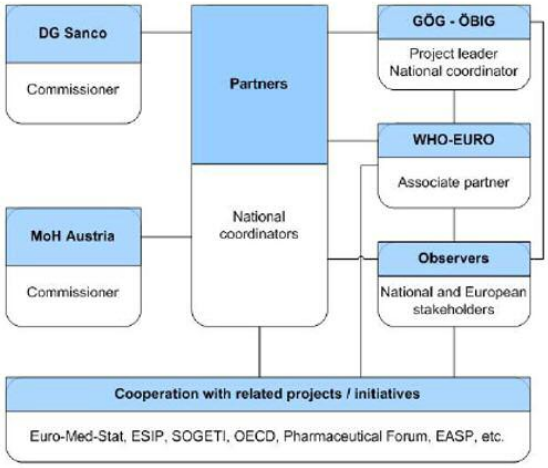
PPRI project

The pricing and reimbursement of pharmaceuticals is a national issue. Consequently there are 25 pharmaceutical pricing and reimbursement systems in the enlarged European Union which often differ greatly. Therefore, the objective of the PPRI project is to develop a network of authorities and institutions in order to improve information and knowledge about the pharmaceutical systems in the enlarged Europe, by providing comprehensive country reports on the Member States and a comparative analysis.

Project organisation

The PPRI project is commissioned and funded by the European Commission, Health and Consumer Protection Directorate-General and co-funded by the Federal Ministry for Health and Women's Issues, Austria. The project team consists of the main partner (GÖG-ÖBIG / Austrian Health Institute), an associate partner (WHO Regional Office for Europe) and a network of 20 partners and more than 20 observers from a large range of EU Member States and other countries such as Bulgaria, Norway and Canada.

The PPRI project is designed to run from April 2005 to summer 2007. The results will be disseminated during a conference in Vienna in summer 2007.



Project description

The PPRI project is subdivided into 6 work packages, which are linked to the specific objectives of the study.

Specific objective of the PPRI project:	Work package(s):	Deliverables of the PPRI project:
Strenghtening the networking of institutions in the field of pharmaceuticals in Member States	WP 1 'Coordination'	Good communication and cooperation within the project, for delivering a project of high quality on time
	WP 2 'Dissemination'	A website (http://ppri.oebig.at) and a conference at the end of the project (Summer 2007, Vienna)
Assessing the information needs concerning pharmaceutical pricing and reimbursement	WP 3 'Assessment'	A questionnaire to be used in the interviews, with a list of key information and data to be collected
Collection, reporting and analysis of information on pricing and reimbursement in Members States	WP 4 'Survey'	Pharma Profiles (=country reports on the pharmaceutical pricing and reimbursement systems) of the EU Member States
Deleveloping indicators for comparative analysis	WP 5 'Development of comparable indicators'	A list of indicators for analysing pricing and reimbursement in a comparative way
Benchmarking pharmaceutical pricing and reimbursement in the enlarged Europe	WP 6 'Comparative analysis'	Benchmarking of pricing and reimbursement in the Member States in a draft report
Dissemination of project results	WP 2 'Dissemination'	International publications and organisation of the summer 2007 conference

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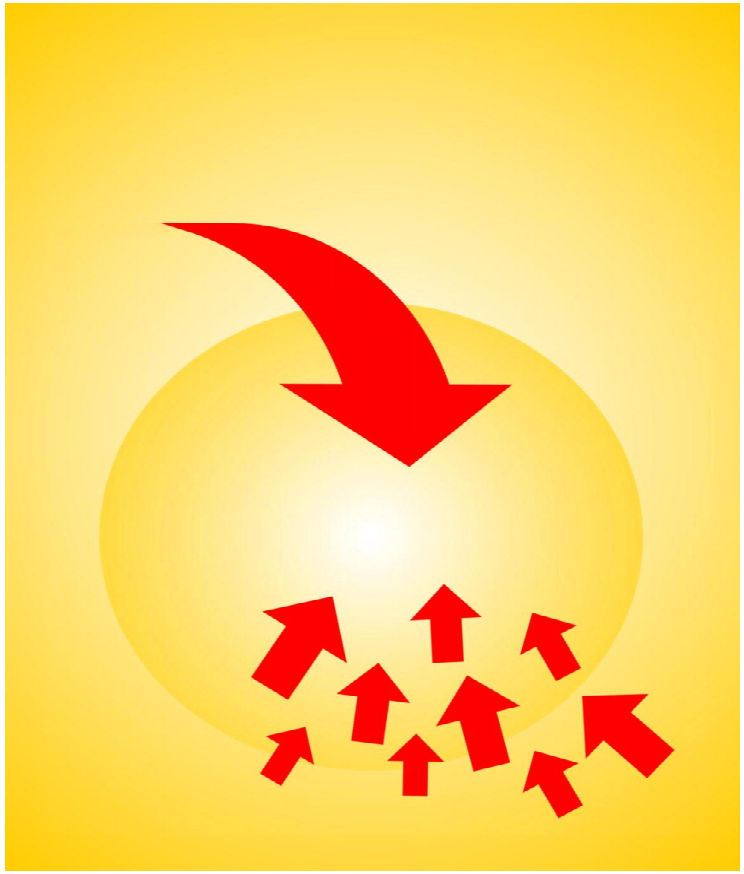

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