Albania

Flowchart of the pharmaceutical system in the in- and out-patient sector, 2011

New pharmaceutical

Ministry of Health (National Centre for Drugs Control)
Task: Decision on authorization and categorization
Criteria: Quality, safety, efficiency
Law No.9323, dated 25.11.2004 on Pharmaceuticals and Pharmaceutical Services

Ministry of Health - Drugs Prices Commission
Task: Decision on all drugs prices
Criteria: Free pricing (under the reforming process)

OUT-PATIENTS

IN-PATIENTS

Distributors

Wholesalers: Maximum mark-up 14% of the ex factory price divided between Importers 10% and distributors 4%.
Pharmacies: Maximum mark up 29% of the wholesaler price.
Recently changed by Council of Ministers Decision Nr. 543 dt.27.7.2011
VAT: standart rate is 20%, for all medicines is 10%, after 1 February 2011

Drugs Reimbursement List
Health Care Insurance Institute - the administering body, third party payer.
MoH, Drugs Reimbursement List Commission – regulatory body, decision making authority

Criteria: price referencing, cost effectiveness
List composition: 236 active principles, 1066 trade names
Reimbursement percentage: 50-100%
Exemption from co payment: 10 people categories

Public Hospitals

Wholesalers: Maximum mark up to 10% of the ex factory price

Ministry of Health
Task: Preparing the hospital pharmaceutical formulary on yearly basis
Criteria: Pharmacological, medical therapeutic.

Health Care Insurance Institute
Task: Monitoring all pharmaceutical expenses
Criteria: prescription guidelines, pharmaceutical formulary of MoH.

Regional Hospitals
Task: Tendering medicines
Criteria: only active principles listed and approved by MoH
THE PHARMACEUTICAL SYSTEM IN ARMENIA
IN THE IN- AND OUT-PATIENT SECTOR

Margarit Melikyan
DRUG UTILIZATION RESEARCH GROUP
ARMENIA

Armenia has adopted the WHO Essential Medicines Policy in 1998 by stipulating in the RA Law on Medicines that "The RA population is guaranteed availability of access to medicines included in the List of Essential Medicines".

In 1999 the Basic Benefits Package was established. Based on a set of criteria, it defines 'vulnerable' and 'special' segments of the population that are eligible to receive medicines.

The Ministry of Health has approved
- List of Essential Medicines,
- Procedure of organization and financing of state-guaranteed free medical assistance and services has been adopted,
- Procedure of dispensing of free or discount medicines,
- Procedure of procurement, receipt, maintenance, recording and dispensing of medicines by health facilities.

Armenia declared its independence in 1991, and then changed its economy system from socialism to capitalism. All the pharmaceutical organizations (producers, wholesalers, pharmacies) were privatized and new legislation and regulation were enforced.

At present prices for all medicines are regulated only by market in Armenia.

There are no legal or regulatory provisions affecting pricing of medicines. The government does not run an active national medicines price monitoring system for retail prices. Regulations exist mandating that retail medicine price information should be publicly accessible.

No fixed wholesale mark-ups: according to expert opinions the average wholesale mark-ups are about 15%.
No fixed pharmacy mark-ups: according to expert opinions the average pharmacy mark-ups are about 20%.
No mark-ups at hospital level.

VAT: According to the legislation of Republic of Armenia the Value Added Tax (20%) has been effected on medicinal products since 2001.

The Positive list is based on National list of Essential medicines (300 medicines).

List of diseases and social groups eligible for free or discount medicines has been approved.

For some of the defined population groups (e.g. people with first and second degree disabilities, children under 7 and etc.) medicines are provided free of charge.

For some of the defined population groups (e.g. people with third degree disabilities, elderly persons and etc.) the government is obligated to provide partial subsidies.

The following medicines are considered to be provided free of charge:
- Antipsychotics, antineoplastic and narcotics, antidiabetics, antiepileptics, anticoagulants after valve prosthetics, colchicines, cyclosporine, erythropoetin, micofenolate, mofetil and analogs.

According to the new Healthcare and Pharmaceutical legislative reforms it is planning to implement medicines price regulation and reimbursement system in Armenia.

- Implement the State Insurance System.
- Develop and adopt a medicines reimbursement procedure, including the restricted provision of only essential and orphan medicines for reimbursement, definition of reference price and co-payment possibility.
- Develop and adopt selection criteria for essential and orphan medicines, as well as procedures for preparation, approval and revision of lists.
- Revise (i) the existing lists of social groups eligible for free and discount medicines and the list of diseases; (ii) names of medicines in lists of goods received through regular tenders, (iii) the medicines dispensing procedure taking into consideration also provision of orphan medicines for uncommon diseases.
AUSTRIA

Flow chart – pharmaceutical system in Austria in the in- and out-patient sector

New medicine

AUTHORISATION/CLASSIFICATION

European Medicines Agency (EMA) or Austrian Federal Office for safety in health care (BASG) / Austrian medicines and Medical Devices Agency (AGES PharmMed)

- Task: Decision on registration and authorization
- Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Austrian Medicines Act

Austrian Federal Office for Safety in Health Care (BASG) / Austrian Medicines and Medical Devices Agency (AGES PharmMed)

- Task: Decision on prescription, dispensing requirements and if a medicine fulfills the criteria of medicines

PREPARATION AT MANUFACTURER LEVEL

Federal Ministry of Health (BMG)

- Task: Calculation of EU average price for medicines applying for inclusion in Reimbursement Code (EKO) in the out-patient sector
- Criteria: External price referencing

PREPARATION AT PHARMACY LEVEL

Pharmacies

- Maximum regressive pharmacy mark-up scheme set by the Federal Ministry of Health (BMG)

Wholesalers

- Maximum regressive wholesale mark-up scheme set by the Federal Ministry of Health (BMG)

Trading companies

- Calculation of EU average price for medicines applying for inclusion in Reimbursement Code (EKO) in the out-patient sector

BASG/AGES PharmMed is also in charge of pharmacovigilance

VIGILANCE

Red Box

- Ex-ante approval of head physician necessary
- Max. EU average price or price indicated by industry, as long as there is no EU average price fixed by the Pricing Committee
- Contains new medicines available in the Austrian market that have applied for inclusion in the national reimbursement code.
- Decision on inclusion in Green or Yellow Boxes within 90 days (if decision includes also the price, period is extended to 180 days); if negative decision: delisting of the product of the Red Box

Light Yellow Box

- Medicines for defined indications
- Ex-post control of prescription behavior
- Max. EU average price

Dark Yellow Box

- Medicines with essential added therapeutic value
- Ex-ante approval of head physician necessary
- Max. EU average price

Non reimbursable medicines and medicines not applied for inclusion in the Reimbursement Code (reimbursement on individual application possible)

Price notification

Reimbursement

Main Association of Austrian Social Insurance Institutions (HVB)

- Task: Decision on the reimbursement status
- Criteria: Eligibility for reimbursement, pharmacological, medical therapeutic, pharmacoeconomic criteria

National Reimbursement Code

- Red Box
- Green Box
- Light Yellow Box
- Dark Yellow Box

Not listed

Pharmaceutical formulary per hospital (owner)

IN-PATIENT

Hospital purchasing body (individual hospital pharmacist or joint purchasing body)

- Task: Price negotiations or tendering of medicines
- Criteria: Depending on the product or on the market situation of the medicine

Federal Ministry of Health (BMG)

- Task: Definition and assessment of DRG groups (LKF) and medical services (MEL) and inclusion of medicines
- Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria

Hospital/ Hospital owner association

- Task: Decision on use of medicines

Federal Commission of Regional decision makers / payers (BGK)

- Working group on DRG

Pharmaceutical companies

- Hospital pharmacy and/or pharmaceutical depot

Public hospitals which receive public funds

Federal Commission of Regional decision makers / payers (BGK)

- Working group on DRG

Pharmaceutical and Therapeutic Committee in hospital

Hospital/ Hospital owner association

- Task: Decision on use of medicines

Pharmaceutical formulary per hospital (owner)
# Belgium National Institute for Health and Disability Insurance (NIHDI)

## Flow Chart Pharmaceutical System (In- & Out-Patient Sector)

### Marketing Authorization (new pharmaceutical)
- **Minister of Public Health or EMA**
  - Task: decision on marketing authorization and registration
  - Criteria: quality-safety-efficacy

- **Advisory board (Federal Agency FAGG):** Registration Committee

### Pricing
- **Ex-salary level**
  - **Minister of Economic Affairs**
    - Task: maximum price setting
    - Criteria: statutory pricing (external and internal price referencing)

- **Advisory boards (Federal Agency for Economic Affairs):**
  - Price Committee for Pharmaceuticals (reimbursable)
  - General Committee for Price Setting (non-reimbursable)

- **Distribution via**
  - **Maximum percentage wholesale mark up scheme** (set by Minister of Economic Affairs)
  - **Fixed pharmacy mark up scheme** (set by Minister of Economic Affairs ± Minister of Social Affairs)

### Reimbursement
- **Minister of Social Affairs**
  - Task: decision on reimbursement & reimbursement level
  - Criteria: product-specific / economic / patient-specific / disease-specific

- **Advisory board (NIHDI):** Reimbursement Committee

### Reimbursement List

<table>
<thead>
<tr>
<th>Chapter I</th>
<th>Reimbursement when prescribed within officially authorised indications (SPC)</th>
<th>No additional restrictions on reimbursement</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Chapter II</th>
<th>Reimbursement for all common indications (based on generally applied recommendations for good practice)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reimbursement does not depend of a prior authorization delivered by the medical officer of the sickness fund</td>
</tr>
<tr>
<td></td>
<td>Prescribing health practitioner must respect the recommendations and keep certain documents in the patient file (&quot;a posteriori&quot; control)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter III</th>
<th>Solutions for perfusion / parenteral nutrition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reimbursement when prescribed within officially registered indications (SPC)</td>
</tr>
<tr>
<td></td>
<td>No additional restrictions on reimbursement</td>
</tr>
</tbody>
</table>

| Chapter IV | Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the medical officer of the sickness fund ("a priori" control) |

<table>
<thead>
<tr>
<th>Chapter IV bis</th>
<th>Pharmaceuticals not authorised in Belgium</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the medical officer of the sickness fund (&quot;a priori&quot; control)</td>
</tr>
</tbody>
</table>

### Hospital Pharmacy (individual)
- Task: purchase & supply of pharmaceuticals
- Criteria: individual negotiations (on a voluntary basis)

### Pharmaceutical Therapeutic Committee
- Task: decision on medicines listed in HPF
- Criteria: EBM – requirements patients

### Hospital Pharmaceutical Formulary (individual)
- No fixed remb. level
BULGARIA
International Healthcare and Health Insurance Institute
Gergana Andre gandre@zdrave.net
Pharmaceutical system in Bulgaria in the in- and out-patient sector – August 2011

<table>
<thead>
<tr>
<th>Marketing Authorisation and Classification – New pharmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>European Medicines Agency/ Bulgarian Drug Agency (BDA)</strong></td>
</tr>
<tr>
<td><strong>Task:</strong> Decision on marketing authorisation</td>
</tr>
<tr>
<td><strong>Criteria:</strong> Quality, safety, efficacy, (Bulgarian Law on Pharmaceutical Products or Regulation EC 726/2004)</td>
</tr>
</tbody>
</table>

| **Task:** Decision on prescription and dispensing requirements |
| **Criteria:** Law on Pharmaceutical Products and Regulation N3 for the criteria for classification of the pharmaceutical products and the documentation for changes in the classification (SG 28/14.03.2008) |

According to the Law on Pharmaceutical Products and Regulation N2/2008 BDA is responsible for the pharmaco-vigilance

<table>
<thead>
<tr>
<th>Pricing and Reimbursement of Medicines for out- and inpatient sectors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ø</strong> Regulation of prices of the POM in the Positive Drug list (PDL) according the lowest referent member state countries’ price;</td>
</tr>
<tr>
<td><strong>Ø</strong> Regulation of the prices of generic medicines out of the PDL;</td>
</tr>
<tr>
<td><strong>Ø</strong> Registration of maximum retail sale price of POM medicines, out of PDL and OTC medicines</td>
</tr>
</tbody>
</table>

Pricing, based on external price referencing

Decision on reimbursement and level of reimbursement, based on pharmacological, medical therapeutic and pharmaco-economical criteria

Price is regulated on ex-factory level with regressive mark-ups for wholesalers and retailers.

Standard VAT – 20% for all medicines

<table>
<thead>
<tr>
<th>Pricing &amp; Reimbursement Committee (PRC) – under Ministry of Health (MoH)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ø</strong> Approves, changes, exclude the price of the medicines in the PDL;</td>
</tr>
<tr>
<td><strong>Ø</strong> Approves, changes, exclude the price of the POM out of PDL and OTC medicines;</td>
</tr>
<tr>
<td><strong>Ø</strong> Approves, changes, exclude the price of the generic POM out of PDL;</td>
</tr>
<tr>
<td><strong>Ø</strong> Approves or changes the pharmaco-therapeutic formularies and treatment algorithms;</td>
</tr>
<tr>
<td><strong>Ø</strong> Includes, changes or exclude POM in the PDL;</td>
</tr>
<tr>
<td><strong>Ø</strong> Maintains and updates the PDL;</td>
</tr>
</tbody>
</table>

Pricing of POM out PDL & OTC – 30 days

Pricing & Reimbursement of medicines in the Positive Drug List – 60 days

Positive Drug List – 3 Annexes;

| Anex N1 |
| Outpatient sector |
| Full or partial reimbursement by National Health Insurance Fund – up to 25%, 50%, 75%, 100% as per its’ annual budget |
| Possibility for additional negotiation of the reimbursed price in the PDL |

| Anex N2 |
| Inpatient sector |
| Subject for possible 100% reimbursement in public/municipal hospitals by hospital budget |
| Open tender under Public Procurement Act (PPA) |

| Anex N3 |
| In and out patient |
| Subject for possible 100% reimbursement by MoH/ state budget for infectious diseases, AIDS, vaccines, force major & others |
| Open tender under PPA |

PDF created with pdfFactory Pro trial version www.pdffactory.com
**Croatian Agency for Medicinal Products and Medical Devices (ALMP)**

- Decision on authorization and registration
- Quality, safety, efficacy - Croatian medicines Act and associated ordinances

**Croatian Institute for Health Insurance (HZZO)**

- HZZO’s Management board
- Committee for medicines
- Provides opinion based on criteria and ranks medicines that would increase expenditure.
- Criterion: Budget Impact
- Professional associations
- Provides opinion based on criteria and ranks medicines that would increase expenditure.
- Criteria: Importance from the public health viewpoint; Therapeutic importance; Relative therapeutic value; Assessment of ethical aspects; Quality and reliability of data and assessments from reference sources.

**HZZO**

- External price referencing and internal price referencing
  - Original breakthrough products: up to 100% of the average price in Italy, France and Slovenia.
  - Original me-too products: up to 90% of the price of equivalent products in Croatia.
  - Generic products: up to 70% of the average price in Italy, France and Slovenia and/or up to 90% of the price of the last bioequivalent generic introduced to the list.

**Pharmacy**

- No mark up for HZZO reimbursed medicines
- Service charge paid for dispensing instead.

**Hospital pharmacy**

- Price negotiations or tendering; HZZO reimburses as listed

**2009/2010 REFORM**

1. Pharmaceutical expenditure on the decline 3rd year in a row
2. 85 innovative products listed from July 2009 to July 2011 (45 in total from 2002 to 2009)
3. Pay back and cross product agreements introduced for innovative medicines
4. ISPOR aligned criteria for Budget Impact Analysis introduced
5. Reimbursement process made public on HZZO’s web site
6. ePrescriptions introduced nationwide by January 2011
7. Ethical promotion agreement introduced with substantial penalties in place
8. Mandatory personalized reporting of all pharma expenditure on publicly employed
The majority of patients with chronic and severe diseases are eligible for free medical treatment by the state. Consequently, the majority of these treatments are provided in the public hospitals. For every registration at a public hospital, a small fee applies (2 euro). Public hospitals are centrally controlled by MOH, while the vast majority of private hospitals belong to doctors-shareholders.

- All public hospitals have pharmacies. The pharmacists deal with supply, dispensing and monitoring of consumption. Medicines are centrally procured by MOH through tendering and are distributed to public pharmacies upon demand. Private hospitals do not have pharmacies. Private hospitals procure their medicines from private pharmacies at the pharmacy wholesale price plus a reduced mark-up pharmacy profit.

- Hospital pharmacies are not involved in decision making, regarding the introduction of a new product to the formulary. However, they control prescriptions and may refuse to dispense a product through the implementation of restrictions and therapeutic protocols defined by the Pharmaceutical Therapeutic Committee (PTC).
### Purchasing of medicines in the hospital sector

- MOH procures centrally medicines through tenders for public hospitals at considerably lower prices (range of 15-80%), due to the fact that the volume requested by MOH, is guaranteed (±30%). Private hospitals obtain their medicines through private pharmacies.

- Private hospitals get their medicines at the Pharmacy Wholesale Price (statutory pricing) plus a 15% mark up pharmacy profit (instead of 37% that would lead to the Pharmacy Retail Price). In case of non-availability, private hospitals may procure the medicines through public pharmacies at the tender price, plus 20% administrative costs. Since January 2011, a 5% VAT was applied on all medicines.

- Tenders are published by Pharmaceutical Services and tenders above 133000 euro are made public to TED Europe as well. The official price list of MOH with Pharmacy Wholesale and Retail prices is also published. The inclusion of medicines in the formulary of hospitals is decided by a central national Pharmaceutical and Therapeutic Committee (PTC), following a request from a doctor. In private hospitals, doctors decide for the medicines they will use.

### Financing of medicines in the hospital sector

- Private hospitals payments are completely out-of-pocket by the patient.

- Regarding public hospitals, financing is done through the block funding of MOH. There are different categories of beneficiaries according to income, disease and employment status (i.e. public servants, government officers etc). In total, about 85% of the population is entitled to free medical coverage by public hospitals.

- There is only one hospital formulary in Cyprus in public hospitals, although some specialised medicines are available only in certain hospitals. In Cyprus, negative lists do not exist.

- Vulnerable Groups: All patients with certain diseases are eligible for free medical care concerning the specific disease, irrespectively of the income and their beneficiary status. This applies only in public hospitals.

- MOH has introduced a copayment scheme for public sector beneficiaries. Under this scheme, public sector beneficiaries are referred to private pharmacies and MOH reimburses 30-40% of the value of the product. This applies only in a small number of diseases.

### PRICING

- Cyprus applies External price referencing. In the basket of countries, there is one expensive, 2 medium priced and one country with low prices. A 37% pharmacy mark up is added in order to deliver the Pharmacy Retail Price. These prices are relevant only in the out-patient private sector. All out patient private sector expenses are covered by the patients unless he/she has a personal insurance.

---

1 Tenders Electronic Daily (TED)
Denmark

Flow chart – pharmaceutical system in Denmark in the in- and out-patient sector

European Medicines Agency (EMA) or Danish Medicines Agency (DKMA).
- Task: Decision on authorisation and registration
- Criteria: Quality, safety, efficacy etc. (Directive 2004/27/EC) and Danish medicines Act, No. 1189 of 12 December 2006

Danish Medicines Agency
- Task: Categorises pharmaceuticals into POM, pharmacy-only OTC, OTC for limited free sale and OTC for general free sale.
- Criteria: Safety, suitability for self-medication etc. (Danish Medicines Act, No. 1189 of 12 December 2006 and Executive Order on Prescriptions, No. 165 of 20 February 2007)
- Task: Decides if pharmaceuticals (generics) are substitutable or not substitutable.
- Criteria: Active ingredients (ATC 5-level), bioequivalence, strength, package (Section 81 of the Danish Medicines Act, No. 1189 of 12 December 2006 and Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/401/01))

Pricing scheme: However, the DKMA has to be notified of the pharmacy purchase price (PPP).
- No permanent price control: Prices are set freely.
- Prices are subject to subsequent control by the Danish Competition Council.

DKMA advised by the Reimbursement Committee
- Task: Decides on eligibility for general or conditional reimbursement
- Main criteria: Therapeutic value and cost-effectiveness according to the Danish Health Act, No. 546 of 24 June 2005 and Executive Order, No. 180 of 17 March 2005 on Reimbursement

Distribution

- Hospital purchasing agency (Ampex) owned by the regional health boards
- Hospital pharmacy
- Pharmaceutical companies
- Hospital
- Order
- Buy
- Delivery
- Wholesalers
- Delivery
- Pharmacy
- Delivery
- Hospital pharmacy
- Order
- Pharmacy-shops
- Delivery
- Supermarkets, pharmacies
- Delivery
- Pharmaceutical and therapeutic committees
- Task: Decision on the pharmaceuticals to be supplied in hospital pharmaceutical formulary

Reimbursement types

- General reimbursement: Prescription-only pharmaceuticals eligible for reimbursement automatically
- General conditional reimbursement: Prescription-only pharmaceuticals prescribed for specific diseases
- General conditional reimbursement: OTC pharmaceuticals prescribed for specific diseases or to patients in general
- Individual reimbursement: Application from doctor

The amount of reimbursement is calculated on the basis of the price of the cheapest pharmaceutical with the same active substance (ATC-level 3) (reimbursement group = substitution group).

All hospital treatment in public hospitals, including pharmaceuticals, is provided free of charge to the patient.
The pharmaceutical system in Estonia in the in- and out-patient sector

**New Medicine**

**EMA**
Estonian State Agency of Medicines consulted by Marketing Authorisation Committee
Task: Decision on marketing authorisation

**State Agency of Medicines**
Task: Classification, decision on prescription, dispensing restrictions

**Register of Human Medicines**
**Register of Veterinary Medicines**

**Pricing**

**Ministry of Social Affairs**
External and internal price referencing for reimbursable medicines, set maximum wholesale purchase price

**Out-patient Pharmacy**
Maximum regressive/margin mark-ups set by Government

**In-patient Pharmacy**
Price negotiations by each hospital

VAT 9% (pharmaceuticals and medicinal devices), others goods at pharmacy VAT 20%

**Reimbursement**

**Ministry of Social Affairs consulted by Drug Committee**
Task: Decision on pricing and reimbursement

**Ministry of Social Affairs (MSA)**
Price Agreements, reference prices

Regulation of MSA „List of pharmaceuticals reimbursed by EHIF“

- 50% 3.20 € + 50% of reference price
- 75%/90% Diagnosis-based: 1.28 € + 25%/10% of reference price
- 100% Diagnosis-based: out-of-pocket payment
- 1.28 € + 0% of reference price

Special groups
75% turns to 90% for children ≤ 16y, disabled and retired people. Children ≤ 4 y -100%.

Additional reimbursement: if the patients annual expenses for the pharmaceuticals ≥ € 383,47

National Institute for Health Development
Opioid dependence treatment
Public procurement
State Budget

Estonian Health Insurance Fund (EHIF)
Negotiate treatment scheme price
Contracts with health care providers
Hospital Drug Committee
Formulary (no central regulation)

Regulation of Government „List of the health care services of EHIF“

The prices of pharmaceuticals have binded into the reference price of hospital day or price of health care service and are reimbursed 100% by EHIF

**Non-reimbursed**

For individual reimbursement of unregistered medicines, application is made directly to Health Insurance Fund

**Out-patient**

**In-patient**

Hospital Drug Committee can decide over purchase of non-reimbursable medicines from hospital budget
FINLAND

Pharmaceuticals Pricing Board (Lauri Pelkonen)\textsuperscript{1},
Ministry of Social Affairs and Health (Ulla Närhi)\textsuperscript{2}

Major reforms from 2009 till now
- Generic reference price system (4/2009)
- Pharmaceuticals covered by analogous process patent return substitutable (4/2009)
- New unit was established in the Finnish Medicines Agency to build capacity in HTA expertise (11/2009)
- Electronic prescriptions (5/2010)
- Limited prescribing right for nurses, opticians and self-employed dental hygienists (7/2010)
- Health Care Act (5/2011)

Current and planned measures
- Government’s programme 2011-2015:
  - pharmaceutical cost savings €113 million
  - reform of reimbursement system
  - co-payments and scope of reimbursement system
- Medicines Policy 2020:
  - medicines policy objectives for the coming decade have been created in co-operation with stakeholders

Current pharmaceutical pricing and reimbursement system (as of 9/2011)

Pricing
Outpatient care:
- Statutory pricing for reimbursable pharmaceuticals at wholesale price level; internal and external price referencing for reimbursable pharmaceuticals, health economic evaluation (a new active medicinal substance)
- Reimbursement status and wholesale price granted max. for 5 years (new active substance max. for 3 years)
- No wholesale mark up scheme
- Degressive pharmacy mark up scheme for all pharmaceuticals
- VAT rate of 9% on pharmaceuticals (8% until 30\textsuperscript{th} June 2010)

Inpatient care:
- Price negotiations or tendering of pharmaceuticals

Reimbursement
- Positive list in place
- Reimbursement categories:
  - Basic reimbursement 42%
  - Lower special reimbursement 72%
  - Higher special reimbursement 100%
  - Additional reimbursement after reaching the annual limit to co-payments (€675 per year in 2011)
- Co-payments depending on reimbursement category (58% / 28% / €3 per medicine / €1.50 per medicine)
- Generic substitution and reference price system in place
- Pharmaceutical formulary per hospital
- Medicines administered during inpatient care covered by hospital daily fees

\textsuperscript{1} Pharmaceuticals Pricing Board, Ministry of Social Affairs and Health, 00023 Government, lauri.pelkonen@stm.fi
\textsuperscript{2} Ministry of Social Affairs and Health, 00023 Government, ulla.narhi@stm.fi
The pharmaceutical system in France in the in- and out-patient sector

**New medicine**

**European Medicines Agency (EMA) or French Health Products Safety Agency / Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)**
- **Task:** Decision on authorization and registration
- **Criteria:** Quality, safety, efficacy (Directive 2004/27/EC) and Public Health Code

**French Health Products Safety Agency / Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)**
- **Task:** Decision on prescription, dispensing requirements and if a pharmaceutical fulfills the criteria of pharmaceuticals
- **Criteria:** Directive 92/56/EEC, law on prescription requirement, prescription requirement order etc.

AFSSAPS is also in charge of pharmacovigilance

**French National Authority for Health / Haute Autorité de Santé (HAS)**
- **Task:** Transparency commission évaluation (CT)
- **Criteria:** Clinical benefit and therapeutic interest (SMR), level of improvement of clinical benefit (ASMR)

---

**EVALUATION**

**OUT-PATIENT**

**PRICING**
- Pricing Committee (CEPS)
  - **Task:** Price negotiations
  - **Criteria:** At ex-factory level, depending on ASMR
- Ministry of Health and Ministry of Finance
  - **Task:** Distribution mark-ups regulation
  - **Criteria:** Wholesalers, pharmacists margins

**REIMBURSEMENT**
- Sickness funds union (UNCAM)
  - **Task:** Reimbursement rate
  - **Criteria:** SMR, reimbursement rates (15%, 35%, 65%)

---

**IN-PATIENT**

**PRICING**
- Pricing Committee (CEPS)
  - **Task:** Reimbursement level for supplementary list and reassigned medicines
  - **Criteria:** At ex-factory level

**REIMBURSEMENT**
- Working group DRGs
  - **Task:** List of medicines included in DRGs with free pricing
  - **Criteria:** Pharmacological, medical therapeutic, pharmacoconomic criteria

**Ministry of Health**
- **Task:** List registration and publication
- 100% reimbursement rate list of medicines on list of authorised medicines in hospitals

---

**DISTRIBUTION**

- Wholesalers
- **Task:** Price negotiations or tendering of medicines
  - **Criteria:** Depending on the product or on the market situation of the medicine

**Pharmaceutical companies**
- Hospital purchasing body or union
  - **Task:** Decision on use of medicines
  - **Criteria:** Depending on the product or on the market situation of the medicine

**Pharmacies**

**Hospitals**

---

**POST AUTHORIZATION**

French Health Products Safety Agency / Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)
- Advertising control and distribution of Rational Drug Use Guidelines Commission
- Pharmacovigilance Commission

---

GREEK MINISTRY OF HEALTH AND SOCIAL SOLIDARITY

The pharmaceutical system in Greece in the in- and out-patient sector

Lena Katsomiti, Pharmacist of National Medicines' Organisation of Greece

Vienna, 29-30/09/2011 for PPRI conference
Iceland

Icelandic Medicine Pricing and Reimbursement Committee.

Flow chart – pharmaceutical system in Iceland in the in- and out-patient sector

New medicine

European Medicines Agency (EMA) or The Icelandic Medicine Agency (IMA)

Task: Decision on marketing authorization and registration
Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Icelandic Act

The Icelandic Medicine Agency (IMA) is an independent regulatory authority that appertains to the Ministry of Health.

Task: Decision on prescription, dispensing requirements and if a pharmaceutical fulfills the criteria of pharmaceuticals
Criteria: Directive 92/56/EC, Icelandic Act, law on prescription requirement, prescription requirement order etc.

The Icelandic Medicine Agency (IMA), is also in charge of pharmacovigilance.

Icelandic Medicine Pricing and Reimbursement Committee (IMPRC)

Task: Calculation of lowest price in the Nordic countries.
Criteria: External price referencing

Price approval for all prescription drugs and hospital drugs. OTC is free price.

University Hospital (LSH)

Task: Assessment and inclusion of new and expensive medicines – S-pharmaceuticals for in and out patients. Paid by NI
Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria

Hospital purchasing body (individual hospital pharmacist or joint purchasing body)

Task: Price negotiations or tendering of medicines
Criteria: Depending on the product or on the market situation of the medicine

State Trading Centre

Hospital pharmacy

Public hospitals which receive public funds

Regional Hospitals

Task: Decision on use of medicines in specific hospitals

Pharmaceutical formulary per hospital

Wholesaler

Free mark up at Wholesale level

Pharmacies

Maximum mark up set by the Icelandic Medicine Pricing and Reimbursement Committee (2 different steps: one for a 9% plus fixed fee and the second step only with fixed fee depending on Wholesale price)

National Reimbursement Code set by the Ministry of Health paid by the National Insurance. Generic substitution, copayment on cheapest drug.

Fully reimbursed – no copayment by patient
ATC: A10, G03HA01, H04A, L, N04A, N05A and S01E

B-code
ATC: A07E, A11CC, C01, C07, C08, C09, D05, D07, H02A, H03B, M01C,

E-code
All other medicines

No reimbursement – fully paid by patient
Drugs that IMPRC does not grant approval antibiotics tablets and syrup, contraceptive tablets, ED products, anti acne and some other product.

Listed pharmaceuticals
Non reimbursable medicines and medicines not applied for inclusion in the Reimbursement Code.

Non listed pharmaceuticals
Medicine that have not applied for reimbursement.

Task: Calculation of Nordic average price
Criteria: External price referencing

Reimbursement approval for all prescription drugs sorted by national code

Pharmaceutical companies

IN - Patient

OUT- Patient
ITALY

AIFA- Italian Medicines Agency

**Task:** decision on authorisation. In Italy marketing authorisation takes place at the same time as the Reimbursement decision.

**Criteria:** quality, safety and efficacy have to be evaluated for a marketing authorisation (Directive 2001/83/EC), Law 219/2006.

**Authorization**

<table>
<thead>
<tr>
<th>Task:</th>
<th>Decision on authorisation. In Italy marketing authorisation takes place at the same time as the Reimbursement decision.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria:</td>
<td>Quality, safety and efficacy have to be evaluated for a marketing authorisation (Directive 2001/83/EC), Law 219/2006.</td>
</tr>
</tbody>
</table>

**AIFA**

**Task:**

Since 2004 a negotiation procedure for all medicines reimbursed by NHS has been introduced (Law 326/2003 art.33). Price negotiations represent the ex factory price to the NHS. The negotiation on price determination and reimbursement decision are managed by the Committee for Pricing and Reimbursement (CPR) and the Technical Scientific Committee (CTC). The current reimbursement medicine classification is: Class A (totally reimbursed by the NHS) and Class C (not reimbursed by the NHS).

**Pricing and Reimbursement at Regional Level**

**OUT-PATIENT**

According to AIFA decision, all medicines listed on the National Pharmaceutical Formulary (NPF) are harmoniously managed by all Regions. The out-patient pharmaceutical pricing is established according to the maximum reference price of NHS purchase through the community pharmacies channel. In order to guarantee a balance in medicine distribution and cost containment, all Regions have adopted the pharmaceutical “Direct Distribution”, which is carried out by two different channels: Distribution of reimbursed medicines to patients by hospitals (e.g. first cycle of therapy at patient’s discharge or specialised out-patient visits) and “Distribuzione per Conto”, which is a distribution of reimbursed medicines to patients through the community pharmacy channel. Those medicines are purchased by the Region and distributed by the pharmacy according to shared stipulations.

**Planning indicators:** (Law n.122/2010) established by AIFA in accordance with Ministry of Health and Ministry of Economics. Tables comparing out patient pharmaceutical consumption and expenditure in each Region for the following therapy classes: A02BC (PPi), C09 (AGENTS ACTING ON THE RENIN-ANGIOTENSIN-SYSTEM), C10AA (HMG CoA reduct. inh.), N06AB (SSRI). The following ratio indicators have been produced:

- A02BC (off patent) / on total A02BC
- C09A / on total C09A + C09C
- C09B / on total C09B + C09D
- C09CA01 (Losartan off patent) / on total C09CA
- C10AA (off patent) / on total C10AA
- N06AB (off patent) / on the total N06AB

**IN-PATIENT**

In-patient pharmaceutical pricing is negotiated by AIFA, but Pharmaceutical Companies must grant rebates to hospitals according to those medicines listed on the Hospital Pharmaceutical Formulary (HPF). Tenders may be provided at Regional level, or may be directly managed by hospitals bargaining their own rebates (Law 264/74, art.9). Some Regions adopt their own Formulary, which may include a limited list of medicines. Some other Regions do not have their own Formulary so they adopt all medicines authorised at National level. The HPF is part of the Regional Hospital Pharmaceutical Formulary (RHFP) and the National Pharmaceutical Formulary (NPFP).

All medicines distributed within the in-patient sector, both Class A-(H/OSP) and Class C-(SOP-OTC) are 100% reimbursed by the NHS.
Flow chart – pharmaceutical system in Latvia in the in- and out-patient sector

**AUTHORISATION/CLASSIFICATION**

**European Medicines Agency (EMA) or Latvian State Agency of Medicines (SAM)**

- **Task:** Decisions on market authorisation; classification; vigilance; evaluation of the conformity of pharmaceutical enterprises; ensuring licensing procedures; issuing import, export, transit and distribution licences for pharmaceuticals
- **Criteria:** Quality, safety, efficacy (Directive 2004/27/EC), Pharmaceutical Law, Regulations of Cabinet of Ministers N376

**SAM is also in charge of pharmacovigilance.**

**VIGILANCE**

**The Centre of Health Economics (CHE)**

- **Task:** Decision on the reimbursement and setting a price for reimbursement
- **Criteria:** Cost-effectiveness; Budget impact

**The Centre of Health Economics (CHE)**

- **Task:** Hospital drug list
- **Criteria:** Cost-effectiveness; Budget impact

**PUBLIC HOSPITALS WHICH RECEIVE PUBLIC FUNDS**

**Pharmaceutical companies**

- for peritoneal dialysis,
- vaccines, standard tuberculin and syringes,
- for the treatment of phenylketonuria and other genetically determined diseases.

**Hospital Pharmacy and/or pharmaceutical depot**

**Medical practitioners and professional associations**

**IN PATIENT**

**For Reimbursement products:** Price cannot be higher than the third lowest price in other EU countries and cannot exceed the prices in Estonia and Lithuania

**Medicines are fully reimbursed for in-patient care. Expenses of medicines are included in the health service tariffs**

**FOR INDIVIDUAL PATIENTS**

- **Pharmaceutical formulary**

**HOSPITALS WHICH PROVIDE SPECIFIC TREATMENT**

- for peritoneal dialysis,
- for vaccines, standard tuberculin and syringes,
- for the treatment of phenylketonuria and other genetically determined diseases.

**Additional Hospital drug list – for hospitals which provide specific treatment**

**FOR INDIVIDUAL PATIENTS**

- **Pharmaceutical formulary**

**HOSPITALS WHICH PROVIDE SPECIFIC TREATMENT**

- for peritoneal dialysis,
- for vaccines, standard tuberculin and syringes,
- for the treatment of phenylketonuria and other genetically determined diseases.

**Additional Hospital drug list – for hospitals which provide specific treatment**
The Government regulates the prices of prescription medicines and medicines on the Essential Drug List with Law on Medicinal Products and Medical Devices.

### Wholesale mark-ups
- Regressive scheme wholesales mark-ups 9-15% of medicines cost

### Pharmacy mark-ups
- Regressive scheme mark-ups 15-30% of medicines cost

### VAT
- Standard rate 18%
- Reduced rate for medicines 5%

### Reforms
- Law on Medicinal Products and Medical Devices (2007)
- Transformation of the Bureau of Medicines into Medicines Agency (2010)
- Modifications in the Law on Medicinal Products and Medical Devices – erased articles on fixed mark-ups (2010)
- Modifications in Rules on Determination of of Prices of Medicinal Products according to the modifications of the Medicines Law – in process (2011)

### Positive List of Medicines for in-patients and out-patients (with different codes)
In total 440 INN with more than 765 forms and strengths

#### Reference pricing system since 2007

**Co-payment includes:**
- Regressive scheme according to the medicines reference prices, not more than 20%
- Difference between reimbursed price and fixed price

#### Reforms
- Introduction of Reference pricing system (2007)

### Mechanisms for vulnerable groups
Exempted from participation: special-needs children and particular categories of citizens according to specific government programmes

### Positive List for out-patient sector: 213 INN and more than 375 forms and strengths
- HIF pays the pharmacies the reference price of medicine and the fixed service fee (12-200 MKD) as regressive scheme according to medicines prices

#### Reforms
- Introduction of Reference pricing system (2007)

### Positive List for in-patient sector: 278 INN and more than 390 forms and strengths with specific code for hospital use

#### Pharmacy mark-ups
- Hospitals get budgets from the HIF and use part of it for medicines procurement
- Hospitals make their medicines procurement plan and produce therapeutic formularies
- Hospital pharmacies are part of the hospitals, no service fee is paid to them

#### Reforms
- Reference pricing system (2007)
- Central procurement of hospital medicines by HIF tenders until 2007
- Decentralized hospital procurement in line with the Law for public procurement (2007)
Pharmaceutical Pricing and Reimbursement in Mexico*

National Medicines Regulatory Authority
[Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS]

Public sector
35% volume market share, 20% value market share

Ministry of Health
General Health Council (CSG):
Representatives of all public health care providers

Secondary and tertiary care reimbursement list
Catalogo de medicamentos

Primary care reimbursement list
Cuadro básico

Institutional reimbursement lists
Selected out of both national reimbursement lists, for primary and secondary/tertiary care
(Institutional administrative and purchasing committee or sometimes Pharmaceutical and Therapeutic Committees decides on selection)

Commission for the Negotiation of Medicines Prices (CCNPMIS)
Representatives of all public health care providers

Patented medicines

Institutional procurement agencies
Patented medicines (5.5% volume, 56% value share)
Generic medicines (94.5% volume, 44% value share)

Wholesalers (about 20 in total)

Pharmacies or outlets in public institutions
.. Free of charge
.. Only with institutional Rx
.. Only for medicines included in the reimbursement list
.. No substitution permitted
.. Prescribing by generic name

Retail pharmacies (about 23,500 in total)

Consumers and patients
(by 2010 11% of the population without health insurance)

Physicians working in public sector

Physicians working in public and private sector

Physicians working in private sector

Pharmaceutical companies
(around 90 manufacturers)

Maximum consumer price for patented medicines
(voluntary agreement between pharmaceutical manufacturer and Ministry of Finance)

Patented medicines

Price regulation only applies to patented medicines

About 20% mark-ups

NO VAT on medicines

About 20% mark-ups

**elaborated by Veronika Wirtz, National Institute of Public Health, Mexico; September 2011**


Contact: veronika.wirtz@insp.mx
The pharmaceutical system in Norway in the in- and out-patient sector

New medicine

European Medicines Agency (EMA) or Norwegian Medicines Agency (NoMA)

Authorization / Classification

Task: Decision on authorization and registration

Task: Decision on prescription, dispensing, reimbursement, and if a pharmaceutical fulfills the criteria of pharmaceuticals

NoMA is also in charge of pharmacovigilance

Pricing at ex-factory level is not regulated in Norway

Wholesaler: Not applicable
Pharmacies: Minimum progressive price scheme set by the TPA

Hospital purchasing body: Drug Procurement Cooperation

Task: Tendering of medicines
Criteria: Depending on the product or on the market situation of the medicine

Health Enterprise; hospital

Task: Decision on use of medicines in specific hospitals

National Reimbursement Code

Reimbursable medicines

Green Box: Preapproved prescription
Yellow Box: Preapproved prescription, subject to particular conditions

Reimbursement on an individual basis

Dark Yellow Box: Individual application, approval by HELFO subject to particular conditions

Binding list of preferred products/suppliers
**European Medicines Agency (EMA) or National Medicines Agency (INFARMED)**

**Task:** Decision on market authorisation

**Criteria:** Quality, safety, efficacy (Directive 2004/27/EC)

---

**National Medicines Agency (INFARMED)**

**Task:** Decision on prescription and dispensing conditions

**Criteria:** Decree-Law No. 176/2006, 30th August; Directive n.º 2004/27/CE,

INFARMED is also responsible for pharmacovigilance

---

### PRICING

#### Directorate-General of Economic Activities (DGAE)

**Task:** Retail price of medicines; annual review of prices; exceptional revision of prices and reduction of prices (in exceptional cases)

**Criteria:** Decree-Law n.º 65/2007, 14th March; External Price Referencing (medium prices SP, FR, IT, GR)

---

#### Ministry of Health

**Task:** Reimbursement of medicines; Withdrawal; reassessment; exclusion and sunset clause

**Criteria:** Annex I of Decree-Law n.º 48-A/2010, 13th May

---

### AUTORIZATION/CLASSIFICATION

---

### VIGILANCE

---

### REIMBURSEMENT

---

### DISTRIBUTION

---

### OUT-PATIENT

---

**Pricing**

- **POM (except HOM and restrict POM) + OTC reimbursed**
  - **Directorate-General of Economic Activities (DGAE)**
    - **Task:** Retail price of medicines; annual review of prices; exceptional revision of prices and reduction of prices (in exceptional cases)
    - **Criteria:** Decree-Law n.º 65/2007, 14th March; External Price Referencing (medium prices SP, FR, IT, GR)

- **OTC not reimbursed**
  - **Pharmaceutical companies**
    - **Task:** Establish OTC price
    - **Criteria:** Decree-Law n.º 134/2005, 16th August

- **GENERICs**
  - **Internal Reference Pricing**
  - **c<35% reference medicine price**
  - **if ex-arity price of reference medicine <=10%, the difference applied is 20%**

- **PARALLEL TRADE**
  - **<5% PRP of the 'considered medicines' and essential similar medicines**

- **Public Retail Price (PRP) = ex-arity price + Wholesaler margins (8%) + Pharmacy margins (20%) + Special Tax earmarked for INFARMED + VAT (6%) + PRP = EX-FAC. X1,48**

- **Wholesaler and Pharmacy margins are not regulated VAT (6%)**

---

### Hospital purchasing body (individual hospital or group of hospitals)

- **Task:** Price negotiations
  - **Criteria:** Price must be lower or equal to the one established by Infarmed or SPMs (public procurement).

- **No legal framework regarding pricing**
  - In general: Hospital price = ex-arity price + VAT (6%) (Margins are not relevant, unless products are bought from wholesaler or community pharmacy)

---

### Ministry of Health through ACSS and Regional Health Administrations

**Task:** Financing hospital level of activity, including use of medicines, through Diagnosis-related Groups (DRG). The financing of medicines does not depend on the inclusion in a national or Hospital Based formulary.

---

**Applications**

<table>
<thead>
<tr>
<th>Application</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic Committee</td>
<td>Decision on use of medicines in the hospital</td>
</tr>
</tbody>
</table>

**Criteria:** Order n.º 1083/2004

**Pharmaceutical formulary (Addendum) per hospital**
The Pharmaceutical System in Romania in the In- and Out-patient Sectors

Pricing:

Wholesale and Retail Price

| Wholesale mark-ups | 9% VAT for all medicines (POM & OTC) |

<table>
<thead>
<tr>
<th>Ex-factory Price</th>
<th>Wholesale mark-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 50</td>
<td>14%</td>
</tr>
<tr>
<td>50-100</td>
<td>12%</td>
</tr>
<tr>
<td>100-300</td>
<td>10%</td>
</tr>
<tr>
<td>Over 300</td>
<td>8%</td>
</tr>
</tbody>
</table>

Reimbursement:

- **Sublist A**: 90% reimbursement from the level of the cheapest product in the group (ATC level 3-4). Includes essential medicines, typically generics.
  - The grouping is done into clusters of ATC level 3-4. For each cluster, a reference reimbursement price is established at the level of first quartile of all prices per DDD of medicines within the cluster.

- **Sublist B**: 93% reimbursement from the level of the cheapest product in the group (ATC level 3-4). Typically includes original medicines.
  - The grouping is done into clusters of ATC level 3-4. For each cluster, a reference reimbursement price is established at the level of first quartile of all prices per DDD of medicines within the cluster, for "assimilable pharmaceutical forms" (i.e., all immediate release oral forms are assimilable).

- **Sublist C**: 100% reimbursement list includes several sections which are managed differently.
  - **Section C1**: Medicines used in situations where an INN reimbursed in at least three EU countries for at least a year and fulfilling at least one of the following criteria:
    - 1a) New INN, clinically superior to current standard therapy.
    - 1b) New INN, at least as effective as current standard therapy, if price is lower than the price of current standard therapy.
  - **Section C2**: Medicines reimbursed under National Health Programs delivered through hospitals, including DRG, urgent malignancies, TB, multiple sclerosis, diabetes, renal diseases, osteoporosis, hepatitis B/C, transplantation.
    - No longer zero copayment!
    - Since September 2011, a new scheme is in place, which will cover 100% of the price of medicines, unless there are generics (in which case, only the local/ generic generic is reimbursed 100%).
  - **Section C3**: Medicines reimbursed for special groups of persons (children, pregnant women, and young mothers) for care for specified diseases (mainly severe and chronic): hepatitis B/C, transplantation.

List of reimbursed medicines

The list is INN based – inclusion decisions affect all the brands within one INN for the corresponding indication/ATC Code. Only includes POMs with some exceptions for special categories of patients. There are three sublists:

1. **Sublist A**: 90% reimbursement from the level of the cheapest product in the group (ATC level 3-4).
2. **Sublist B**: 93% reimbursement from the level of the cheapest product in the group (ATC level 3-4).
3. **Sublist C**: 100% reimbursement list includes several sections which are managed differently.

1. **Section C1**: Medicines used in situations where an INN reimbursed in at least three EU countries for at least a year and fulfilling at least one of the following criteria:
   - 1a) New INN, clinically superior to current standard therapy.
   - 1b) New INN, at least as effective as current standard therapy, if price is lower than the price of current standard therapy.

2. **Section C2**: Medicines reimbursed under National Health Programs delivered through hospitals, including DRG, urgent malignancies, TB, multiple sclerosis, diabetes, renal diseases, osteoporosis, hepatitis B/C, transplantation.
   - No longer zero copayment!
   - Since September 2011, a new scheme is in place, which will cover 100% of the price of medicines, unless there are generics (in which case, only the local/generic generic is reimbursed 100%).

3. **Section C3**: Medicines reimbursed for special groups of persons (children, pregnant women, and young mothers) for care for specified diseases (mainly severe and chronic): hepatitis B/C, transplantation.
Slovakia – Flowchart of the pharmaceutical system, 2010

**European Medicines Agency (EMA) or State Institute for Drug Control**

**Task:** Decision on authorization and registration  
**Criteria:** Quality, safety, efficacy (Directive 2004/27/EC) and Slovak medicines Act

**Task:** Decision on prescription, dispensing requirements and if a pharmaceutical fulfills the criteria of pharmaceuticals  
**Criteria:** Directive 92/56/EEC, ASlovak Medicines Act, law on prescription requirement, etc.

**Ministry of Health (MoH)**

**Task:** Calculation of EU average price for medicines applying for inclusion in Reimbursement list in the outpatient sector  
**Criteria:** External price referencing

**Ministry of Finance**

**Medicines distributed via**

**Wholesaler**  
Maximum regressive whole sale mark up scheme set by the Ministry of Health (2 different schemes: fixed mark up for hospitals and regressive for outpatient customers)

**Pharmacies**  
Maximum regressive pharmacy mark up scheme set by the Ministry of Health (mark up regulation only for retail pharmacies)

**Hospital purchasing body (individual hospital pharmacist or joint purchasing body)**

**Task:** Price negotiations or tendering of medicines  
**Criteria:** Depending on the product or on the market situation of the medicine

**Evaluation of costs and treatment per case incl. pharmaceuticals**

**Ministry of Health and sick funds**

**Task:** Definition and assessment of cost for bed-days per treatment and medical services inclusion of medicines  
**Criteria:** Pharmacological, medical therapeutic, pharmacoeconomic criteria

**Hospital / Hospital owner association**

**Task:** Decision on use of medicines in specific hospitals

**Public hospitals which receive public funds**  
**Based on**

**Evaluation of costs and treatment per case incl. pharmaceuticals**

**Pharmaceutical companies**  
**Pharmaceutical and Therapeutic Committee per hospital (owner)**

**New medicine**

**VIGILANCE**

**SIDC and IforPH (vaccines) is also in charge of pharmacovigilance.**

**AUTHORISATION / CLASSIFICATION**

**PRICING**

**Pricing at ex-factory level**

**Pricing at wholesale and pharmacy level**

**REIMBURSEMENT**

**List of Reimbursable pharmaceuticals**

**Internal reference pricing ATC 5 level, differentiated by pharmaceutical form, possibly also strength and package.**

**Prescription limitation and indication limitation in the case of reimbursement is for limited cases of licensed diagnosis.**

**5 000 pharmaceuticals in positive list,**

**No general reimbursement body (individual basis)**

**European Medicines Agency (EMA) or State Institute for Drug Control**

**Decision on authorization and registration**  
**Quality, safety, efficacy (Directive 2004/27/EC) and Slovak medicines Act**

**Decision on prescription, dispensing requirements and if a pharmaceutical fulfills the criteria of pharmaceuticals**  
**Directive 92/56/EEC, ASlovak Medicines Act, law on prescription requirement, etc.**
**PHARMACEUTICAL SYSTEM**

**PRICING IN THE OUT-PATIENT SECTOR IN SLOVENIA**

| Legal basis: | • Medicinal Products Act  
|             | • Rules on price setting for medicinal products for human use |
|             | • Agency for Medicinal Products and Medical Devices |
| Responsible institution: | • Agency for Medicinal Products and Medical Devices |
| Prices are set for: | • Prescription medicinal products, financed or intending for financing from public funds  
|             | • Harmonization of prices twice yearly  
|             | • Number of prices set for out-patient sector: 2,600  
|             | • Total number of prices set: 3,700 |
| International price comparison | • Reference countries: Austria, France, Germany  
|             | • Ex-factory prices are used for calculations |

**PRICE SETTING - comparison**

- **originator vs originator**
  - PRICE = lowest price * 100%
- **generic vs generic**
  - PRICE = average price* 78%
  - from 2012 % will lower to 74%

Reforms – planned:

- Lowering of % used for price setting  
- Change of calculations for off-patient medicines

**Setting of higher prices**

- • For medicines with high therapeutic value, to prevent withdrawal  
- • Decision of Pricing Committee - measures!  
- • Number of higher prices set for out-patient sector: 110  
- • Total number of higher prices set: 135

**Price structure:**

- • PRICE= ex-factory + wholesale margin + pharmacy margin + VAT  
  - Wholesale margin: % of ex-factory price, 6 classes 10% - 2%, max = 30 €  
  - Pharmacy margin: fixed amount, negotiated with Health Insurance, min = 1,40 €/prescription  
  - VAT: 8.5%, applies to wholesale price and pharmacy margin

**Price negotiations:**

- • Negotiations with Health Insurance Institute  
- • Number of negotiated prices: 1,200

**REFERENCE PRICE SYSTEM**

| Legal basis: | • Medicinal Products Act  
|             | • Rules on requirements and procedure for establishing the mutual interchangeability of medicinal products  
|             | • Rules on classification of medicinal products for human use on the lists |
| Responsible institutions: | • Agency for Medicinal Products and Medical Devices  
|             | • Health Insurance Institute |

**List of highest recognised values:**

- • Includes only interchangeable medicines classified on positive or intermediate list  
- • The value of the cheapest medicine within the group is reimbursed  
- • Substitution in the pharmacy - the cheapest medicine is dispensed or co-payment by the patient  
- • Number of medicines on the list: 800
Pricing policies for medicines
The National Drug Policy, Medicines and Related Substances Act, Pharmacy Act, Health Act, and Pricing Regulations contains regulatory measures which control the sale of medicines in South Africa.

Pharmacists and qualified dispensing practitioners like dispensing doctors can dispense any medicine that is sold in South Africa. Pharmacist’s assistants, under the supervision of a pharmacist are allowed to dispense over the counter medicines. Nurses at clinics, usually in rural areas are allowed to dispense up to schedule 4, after getting permission from the South African Pharmacy Council and the Nursing Council.

The Single Exit Price (SEP) is the selling price for every medicine registered for sale in the private sector out patient. The SEP is the price that leaves the manufacturer site until it reaches the pharmacy or dispensing doctor facility. The only addition to the SEP is the dispensing fee which is included by the pharmacists or dispensing doctor at retail level at the point of dispensing.

Previous SEP Adjustments

<table>
<thead>
<tr>
<th>Year</th>
<th>Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004-2007</td>
<td>5.21%</td>
</tr>
<tr>
<td>2008</td>
<td>6.5%</td>
</tr>
<tr>
<td>2009</td>
<td>13.2%</td>
</tr>
<tr>
<td>2010</td>
<td>7.4%</td>
</tr>
<tr>
<td>2011</td>
<td>0%</td>
</tr>
</tbody>
</table>

The dispensing fee is a maximum and can be discounted by the dispenser. The Single Exit price (SEP) however is not supposed to change at any stage throughout the supply chain other than where the manufacturer makes an application with the Department of Health to decrease their SEP either permanently or temporarily. The changed SEP should be available at the same price to all wholesalers. No rebates, discounts or incentive schemes are allowed in South Africa. SEP reviews are determined and announced by the Minister of Health annually.

Wholesale mark-ups/Logistics fees
Manufacturers and logistics service providers also referred to as wholesalers and distributors negotiate for the logistics fee. A contract should be in place for such agreements. A manufacturer may use as many logistics service providers as they wish which means different logistics service providers may be paid different fees by the same manufacture depending on the outcome of the negotiation and level of service. The logistics fee is expressed as a percentage of the ex manufacturer price.

Pharmacy mark-ups/Dispensing
The current Dispensing fee is arranged in a 4 tiered structure. The dispensing fee paid by the consumer is dependent on the price of the medicine i.e. the SEP (See table below). The pharmacy mark up or dispensing fee is the only mark up to the price that leaves the manufacturer site, regardless of which wholesaler transported the medicine(s) to the pharmacy or any retailer.

<table>
<thead>
<tr>
<th>Dispensing Fee Tiers</th>
<th>SEP Range in rands</th>
<th>Dispensing Fee formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>R 0 &lt; R75.00</td>
<td>46% of SEP + R6.00</td>
</tr>
<tr>
<td>Tier 2</td>
<td>R75.00 &lt; R200.00</td>
<td>33% of SEP + R15.75</td>
</tr>
<tr>
<td>Tier 3</td>
<td>R200.00 &lt; R700.00</td>
<td>15% of SEP + R51.00</td>
</tr>
<tr>
<td>Tier 4</td>
<td>R700.00</td>
<td>5% of SEP + R121.00</td>
</tr>
</tbody>
</table>
In South Africa, Vat is 14% for all commodities including medicines. Tax incentives given to the pharmaceutical industry are within the domain of the Department of Trade and Industry. These arrangements are not part of the Department of Health’s mandate and therefore not covered in the Department of Health legislation. Department of Health policies are mainly supportive and protective of the consumer.

Reforms

Guidelines on Pharmacoeconomic Assessment of highly priced medicines especially new entities was published for comment in 2011. The Pharmacoeconomic Guidelines are in the final stages of reassessment by the Department of Health, following comments from the pharmaceutical industry. South Africa has chosen Spain, New Zealand, Australia, South Africa and Canada as benchmark countries.

Reimbursement in the out-patient sector

List of available EDL items


Tender price system

Over 10,000 items

Price used

Reference price system

3000 SEP items, are listed for the private sector market

Public

Price system

Reference

Price system

IBM in the pipeline and RPS not in place

Database of Medicine Prices in South Africa (www.mpr.gov.za-private-sector)

Co-payment

Copayments are charged to the patient that chooses a medicine that is priced higher than that which is on the PMB list of medicines for the medical scheme. The medical aid option to which the patient belongs also determines the extent of the copayment.

Mechanisms for vulnerable groups

Children younger than 5 years, pregnant mothers, psychiatric patients and the elderly receive free care in public sector facilities in South Africa.

Pharmacoeconomics

Guidelines on Pharmacoeconomic Assessment of highly priced medicines especially new entities was published for comment in 2011. The Pharmacoeconomic Guidelines are in the final stages of reassessment by the Department of Health, following comments from the pharmaceutical industry. South Africa has chosen Spain, New Zealand, Australia, South Africa and Canada as benchmark countries.
South Korea

SeongOk Kim (pipikso@yahoo.co.kr)

The pharmaceutical system in South Korea in the in- and out-patient sector

Korea Food and Drug Administration (KFDA)
- Task: Decision on authorization
- Criteria: Safety, efficacy (Pharmacy act. no. 31)

Central Pharmacy Review Committee
- Task: Recommendation on classification of Rx / non-Rx / OTC
- Criteria: Safety (Pharmacy act. no.18)

Health Insurance Review and Assessment Service (HIRA)
- Task: Decision on registration in positive list
- Criteria: clinical effectiveness, cost-effectiveness
- Sub-committee for pharmacoeconomics
  (* National Health Insurance Act)

National Health Insurance Corporation (NHIC)
- Task: Price negotiation original medicine with pharmaceutical company
- Criteria: clinical effectiveness, cost-effectiveness, budget impact, internal-/external price comparison, etc.
  (* National Health Insurance Act, Guide on price negotiation)

Pharmaceutical Benefit Review Committee / Ministry of Health and Welfare (MOHW)
- Task: The committee adjust and set listed price for essential drugs if price negotiation fails. The minister notify the listed price.

Pharmacovigilance
- Post-marketing Surveillance (PMS)
  - Reporting system for drug adverse effect
  - Review on new medicine
  - Drug reassessment

Review of listed medicines
- new criteria of pharmacoeconomics is introduced since Dec. 2006.
  * To date, HIRA has completed 3 out of 48 therapeutic groups in the reimbursement system (treatment of migraine, lipid lowering agents, treatment for hypertension)
  * 14,599 products on positive list (as of Jan. 1. 2009)

Pricing of generic medicines
- 1st – 5th generic : 68% of original medicine
- from 6th generic : 90% of lowest generics

The price of original medicines fall by 20% after entry of 1st generic
  * From Jan 2012, the pricing will be changed:
    - Original : fall by 30%
    - Generic : 59.5% of original medicine at first entry, 53.55% of original medicine 1 year after

Hospitals may have their own formularies which include medicines reimbursed or not reimbursed by the National Health Insurance (NHI) scheme
  * Hospital’s P&T Committee Hospitals over 300-beds have to proceed bid process to procure medicines from wholesaler or manufacturer by law
  * From October 2010, large sized hospitals (usually teaching hospital) could get more margin under M-ATP

Co-payment for adult (6-64 year old) under National Health Insurance (NHI)Scheme (covers 97% of total population)
- Inpatient : 20% of cost (dispensing fee + drug cost)
- Outpatient : 30% of cost (dispensing fee + drug cost)

(Drugs with ceiling of co-payment are reimbursed at 90% of cost)

No regulation for wholesalers’ margin or mark-up
Zero margin (until Sep. 2010) for pharmacies, clinics, hospitals – Reimbursement by actual transaction price, but since October 2010 M-ATP (Market based Actual Transaction Price) allows margin as an income of pharmacies, clinics, hospitals

* Margin is gap between purchasing price and listed price to trigger price competition

Hospitals over 300-beds have to proceed bid process to procure medicines from wholesaler or manufacturer by law

* From October 2010, large sized hospitals (usually teaching hospital) could get more margin under M-ATP

Safety mechanisms for vulnerable person or catastrophic cost under NHI Scheme
- Age: Elderly (65 and over): 1,200won if the cost less than 10,000won, else 30% of cost, Children (under 6): 70% of adult’s cost
- Disease: Cancer 6% (Jan. 2010), Rare disease 10% (Jul. 2009)
- Ceiling of Co-payment : patients exempt if the amount of co-payment reaches over 2. 3. or 4 million won per annum, according to contribution level (respectively low 50 percentile, medium 30 percentile, high 20 percentile)
The pharmaceutical system in SPAIN in the in- and out-patient sector

**European Medicines Agency (EMA) or Spanish Medicines and Medical Devices Agency (AEMPS: autonomous body dependent of the Ministry of Health and Social Policy**

- **Task:** decision on authorisation and registration

**Spanish Medicines and Medical Devices Agency**

- **Task:** Decision on prescription, dispensing requirements and if a pharmaceutical fulfills the Criteria of pharmaceuticals
- **Criteria:** Directive 92/56/EEC, Spanish Medicines Act, Spanish Royal Decrees 1344/2007 and 1345/2007 and Ministerial Orders that state the prescription and dispensing requirements

**MINISTRY OF HEALTH, SOCIAL POLICY and EQUALITY: Directorate-General for Pharmacy and Healthcare Products**

- **Financing Procedure** (Act 29/2006)
  - **Task:** to decide if it is or not reimbursable into the National Health System and fixing price
  - **Criteria:** external price referencing, internal similars price referencing, therapeutic usefulness, budget impact, reference pricing

**Pharmaceutical cost-containment policies and Reforms in 2010/2011:** cuts for generics; dispensing limits; discount of 7.5% for medicines on patent; mandatory INN prescription and dispensing lowest priced medicine as of August 2011

**Pharmacotherapeutic Committee**

- **Task:** to decide on the inclusion of medicines in the formulary
- **Criteria:** selection based on evidence based medicine and pharmacoeconomic criteria. PTC assess every new drug prior to include it in the HPF

**Hospital Pharmacy**

- **Task:** to purchase the medicines for the hospital. Price negotiations, discounts, procurement
- **Criteria:** depending on the product or on the market situation of the medicine

**Pharmaceutical Information System**

- **Medicines Database coordinated with AEMPS**
- **Consumption Database**
- **Inclusion in the National Reimbursement List (Nomenclator Electronic Database)**

**Market Access**

- **Manufacturers**
- **Wholesalers:** maximum regressive margin regulated for all medicines and set by the Ministry of Health
- **Pharmacies:** maximum regressive margin regulated for all medicines and set by the Ministry of Health

**Public hospitals which receive public funds**

**Pharmacotherapeutic Committee**

- **Task:** to decide on the inclusion of medicines in the formulary
- **Criteria:** based on evidence based medicine and pharmacoeconomic criteria. PTC assess every new drug prior to include it in the HPF

**Regional Committees**

- **Area Committees for the rational use in Primary Care**
- **Area Committees for the rational use in Special.
  - Formularies, Guidelines, prescription targets**

**Attempt to achieve coordination**
The pharmaceutical system in Turkey in the in- and out-patient sector

**New Medicine**

**MoH General Directorate of Pharmaceuticals and Pharmacies (GDPP)**

**Task:** Decision on market authorization  
**Criteria:** Proof of efficacy, safety, improvement on current therapies, appropriate technical and pharmaceutical specifications

**MoH GDPP Department of Pricing**

**Task:** Determination of ex-factory price for all pharmaceuticals  
**Criteria:** External reference pricing (Cheapest of France, Greece, Italy, Portugal, Spain)

**Wholesaler**  
Regressive mark-ups

**Pharmacy**  
Regressive mark-ups + 8%VAT

**Hospital Purchasing Committee**

**Manufacturer**

**Social Security Institution Reimbursement Commission**

**Task:** Decision on inclusion/exclusion of products in/from positive list, determination of pharmaceutical equivalent groups, setting reimbursement rules, determining the reimbursement price discount rates and rules for internal reference pricing  
**Criteria:** Severity of disease, pharmacoeconomic evidence, budget impact, ethical considerations, value of the product

**Advises**

**PPRI**

Pharmaceutical Pricing and Reimbursement Information

---

Prof. Dr. Mehtap Tatar  
Hacettepe University Faculty of Economics and Administrative Sciences  
Department of Healthcare Management (mtatar@hacettepe.edu.tr)
United Kingdom

The pharmaceutical system in the UK in the in- and out-patient sector

New medicine

**MARKETING AUTHORISATION**

European Medicines Agency (EMA) or Medicines and Healthcare products Regulatory Agency (MHRA)

Task: Decision on marketing authorisation.


MHRA also responsible for classification of medicines; post-marketing surveillance; ensuring compliance with statutory obligations e.g. advertising and distribution; and pharmacovigilance.

**VIGILANCE**

Department of Health

– Medicines Pharmacy and Industry Group

Task: Set National Health Service (NHS) list price/reimbursement price (out-patient and in-patient sectors).

Criteria: The Pharmaceutical Price Regulation Scheme (PPRS) controls the prices of branded prescription medicines supplied to the NHS by regulating profits. Hospitals may be able to purchase medicines under contract at a discount to the NHS list price. The NHS list price includes a margin for distribution. The Drug Tariff sets the reimbursement prices for generic medicines. No VAT except on OTC medicines.

No separate reimbursement mechanism and most medicines are automatically (100%) reimbursed on the NHS (see below).

Consultation on a new value-based pricing system for branded medicines to be implemented on expiry of PPRS at the end of 2013.

**PRICING AND REIMBURSEMENT**

**OUT-PATIENT**

Department of Health – Medicines Pharmacy and Industry Group

All medicines that can be prescribed on the NHS are fully reimbursed except a small number on a negative list and those on a restricted list that may only be prescribed for certain patients and in certain circumstances.

Hospital Pharmaceutical and Therapeutic Committees

Task: Draw up a formulary of medicines that can be prescribed in the hospital although normally arrangements for exceptions.

Hospital pharmacy purchasing groups and Department of Health Commercial Medicines Unit (CMU)

In England, hospitals purchase most medicines centrally through hospital pharmacy purchasing groups via CMU framework contracts or locally through individual NHS trusts or hospitals.

**IN-PATIENT**

**DISTRIBUTION**

Pharmaceutical companies

Task: Supply medicines via wholesalers or direct to pharmacies and hospitals.

Community pharmacies

Pharmacy mark up not regulated – negotiated with wholesalers.

Patients

In England, fixed co-payment (prescription charge) for each item supplied (£7.40) (also season ticket). But exemptions (90% free).

NHS Prescription Services

Task: Reimburse pharmacies for dispensing NHS prescriptions.

Wholesalers

Wholesale margin not regulated – negotiated with pharmaceutical companies.

NHS Hospitals

Patients

No payment for NHS medicines.

**GUIDANCE**

National Institute for Health and Clinical Excellence (NICE)

Task: Provides the NHS (in England and Wales) with evidence-based recommendations on the clinical and cost effectiveness of most new drugs through its technology appraisal guidance.

Criteria: Technology appraisal guidance is based on a review of clinical and economic evidence. Clinical evidence measures how well the medicine or treatment works - the health benefits. The economic evidence shows how well the medicine or treatment works in relation to how much it costs the NHS and whether it represents value for money.