WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

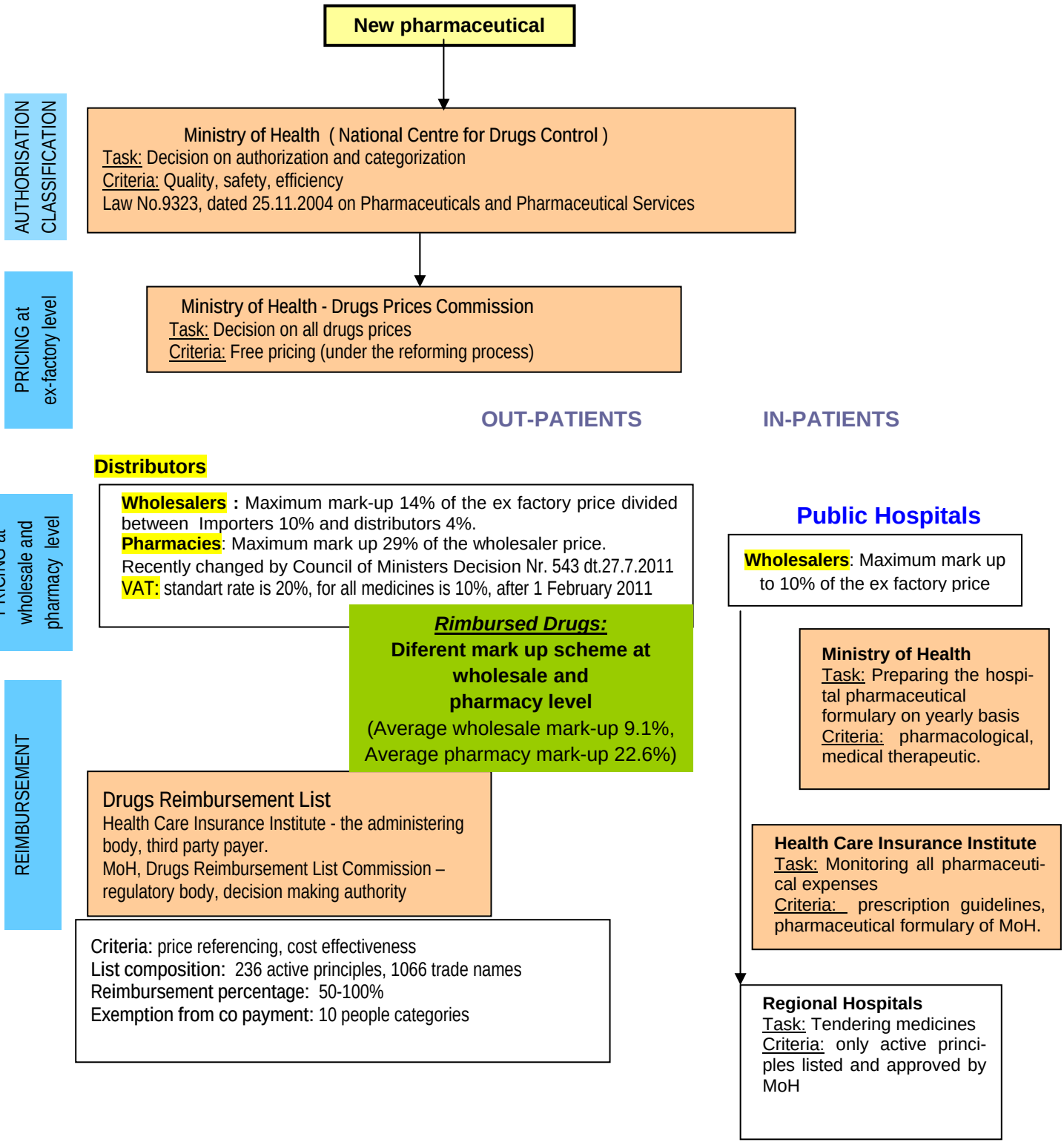
Gesundheit Österreich GmbH

PPRI Conference 2011

Country Poster Book

Albania

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



THE PHARMACEUTICAL SYSTEM IN ARMENIA IN THE IN- AND OUT-PATIENT SECTOR

Margarit Melikyan

DRUG UTILIZATION RESEARCH GROUP
ARMENIA

Total population **3,083,000**
Life expectancy at birth m/f (years) **66/74**
Gross national income per capita (PPP international $) **6,310**
Total expenditure on health per capita (Intl $) **241**
Total pharmaceutical expenditure (TPE) **AMD 23,103 million (US$ 75.5 million)**
Total expenditure on health as % of GDP **4.7**
Total pharmaceutical expenditure per capita **AMD 7,030 (US$ 23**)
Total number of registered drugs **4500**
Number of domestic manufacturers **10**
Number of wholesalers **30**
Number of retailers **1500**

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 and 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.*

PRICING

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.

REIMBURSMENT

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, erythropoietin, micofenolat mofetil and analogs.

REFORMS

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.

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PPRI Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

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 authorization and registration
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) — in consultation with — **Prescription Committee**, **Restriction Committee**

Task: Decision on prescription, dispensing requirements and if a medicine fulfills the criteria of medicines
Criteria: Directive 92/56/EEC, Austrian Medicines Act, Prescription Act, Prescription Ordinance

BASG/AGES PharmMed is also in charge of **pharmacovigilance**

VIGILANCE

PRICING at ex-factory level

Federal Ministry of Health (BMG) — in consultation with — **Pricing Committee**

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

Price notification for medicines with price changes or outside the Reimbursement Code (EKO) in the out-patient sector
"free pricing"

Pharmaceutical companies

PRICING at wholesale and pharmacy level

Medicines distributed via

Wholesalers: Maximum regressive wholesale mark-up scheme set by the **Federal Ministry of Health (BMG)** (2 different schemes, one for green + yellow box products, one for the remaining)

Pharmacies: Maximum regressive pharmacy mark-up scheme set by the **Federal Ministry of Health (BMG)** (2 different schemes: one for "privileged" (e.g. sickness funds) and one for private customers)

Hospital purchasing body (individual hospital pharmacist or joint purchasing body) — in cons. with — Hospital pharmacy and/or pharmaceutical depot

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

REIMBURSEMENT

Main Association of Austrian Social Insurance Institutions (HVB) — in cons. with — **Pharma-ceutical Evaluation Board**

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

Public hospitals which receive public funds

Federal Ministry of Health (BMG) — in cons. with — Federal Commission of Regional decision makers / payers (BGK); Working group on DRG

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 — in cons. with — Pharmaceutical and Therapeutic Committee in hospital

Task: Decision on use of medicines

Pharmaceutical formulary per hospital (owner)

Reimbursable medicines

National Reimbursement Code

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

Green Box
For prescription of medicines no approval necessary
< EU average price

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

No general reimbursement (only on individual basis)

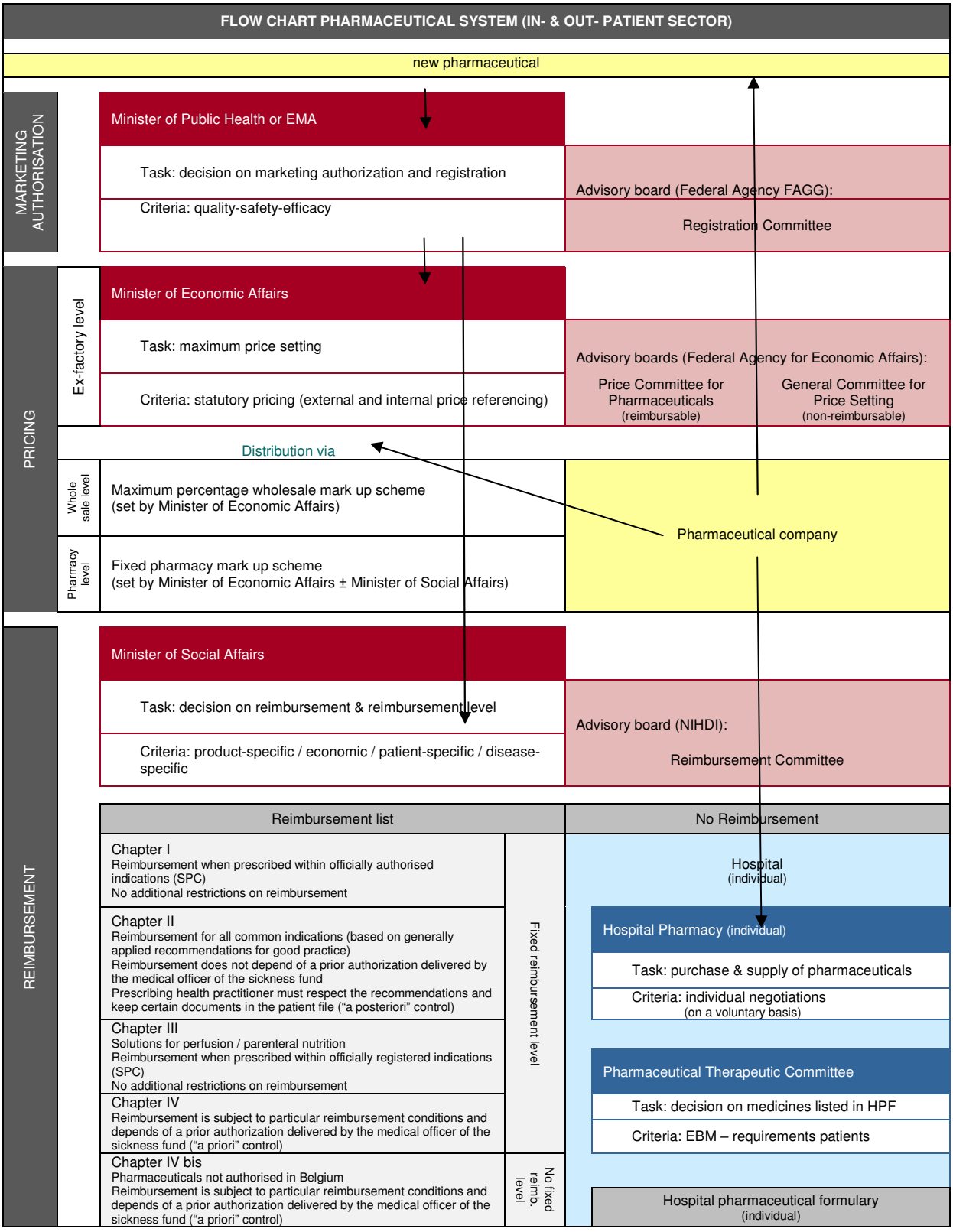
Not listed
Non reimbursable medicines and medicines not applied for inclusion in the Reimbursement Code
(reimbursement on individual application possible)

Price notification

OUT-PATIENT | IN-PATIENT

BELGIUM

National Institute for Health and Disability Insurance (NIHDI)



INTERNATIONAL HEALTHCARE AND HEALTH INSURANCE INSTITUTE

PPRI Pharmaceutical Pricing and Reimbursement Information

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

Marketing Authorisation and Classification –New pharmaceutical

European Medicines Agency/ Bulgarian Drug Agency (BDA)

Task: Decision on marketing authorisation
Criteria: Quality, safety, efficacy, (Bulgarian Law on Pharmaceutical Products or Regulation EC 726/ 2004

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-vigillance

⇩

Pricing and Reimbursement of Medicines for out- and inpatient sectors

- Ø Regulation of prices of the POM in the Positive Drug list (PDL) according the lowest referent member state countries' price;
- Ø Regulation of the prices of generic medicines out of the PDL;
- Ø Registration of maximum retail sale price of POM medicines, out of PDL and OTC medicines

Pricing, based on external price referencing

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

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

Standard VAT – 20% for all medicines

⇔

Transparency Committee under Council of Ministers as appeal structure

Pricing & Reimbursement Committee (PRC) –under Ministry of Health (MoH)

- Ø Approves, changes, exclude the price of the medicines **in the PDL**; Approves, changes, exclude the price of the POM **out of PDL and OTC** medicines; Approves, changes, exclude the price of the **generic POM** out of PDL ; Approves/Registers price of **medicines from Parallel Import**;
- Ø Approves or changes the pharmaco-therapeutic formularies and treatment algorithms;
- Ø Includes, changes or exclude POM in the PDL;
- Ø Maintains and updates the PDL;

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)

AnexN3

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

C R O A T I A

AUTHORISATION

Croatian Agency for Medicinal Products and Medical Devices (ALMP)

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

VIGILANCE

ALMP is also in charge of **pharmacovigilance**

REIMBURSEMENT

Croatian Institute for Health Insurance (HZZO)

HZZO's Management board

decision

Criterion: Budget impact

opinion

Committee for medicines

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.

advice

Professional associations

PRICING

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.

DISPENSING

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**

CYPRUS

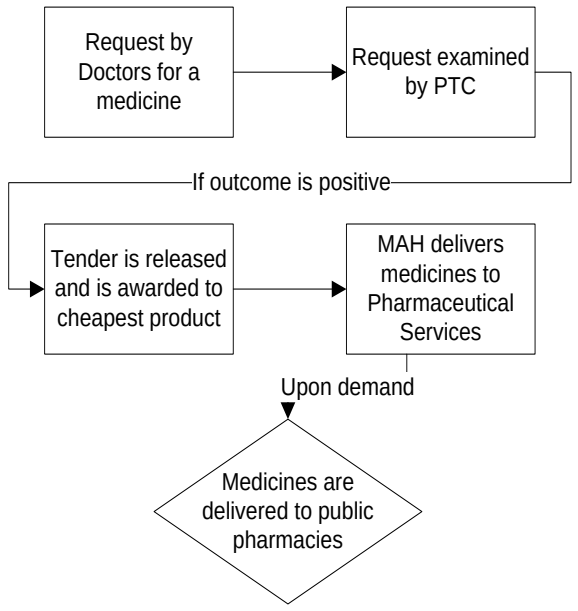
HEALTH INSURANCE ORGANIZATION

PANAGIOTIS PETROU

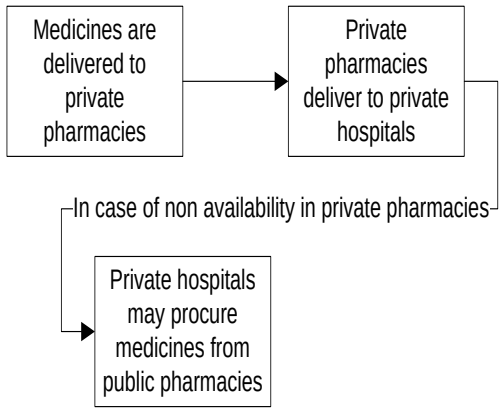
Pharmaceutical provision in hospitals

- 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).

Cyprus – Flowchart of medicines *delivery chain in **public** hospitals*



Cyprus – Flowchart of medicines delivery *chain in **private** hospitals*



Purchasing of medicines in the hospital sector	Financing 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[1] 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.	- 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)

LÆGEMIDDEL STYRELSEN
DANISH MEDICINES AGENCY

Denmark

PHIS Pharmaceutical Health Information System

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

AUTHORISATION/ CLASSIFICATION

European Medicines Agency (EMA) or Danish Medicines Agency (DKMA).

Task: Decision on authorization and registration

Criteria: Quality, safety, efficacy etc. (Directive 2004/27/EC) and Danish medicines Act, No. 1180 of 12 December 2005.

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. 1180 of 12 December 2005 and Executive Order on Prescriptions, No. 155 of 20 February 2007)

Task: Decides if pharmaceuticals (generics) are substitutable or not substitutable

Criteria: Active ingredient (ATC-5 level), bioequivalence, strength, pack size (Section 61 of the Danish Medicines Act, No. 1180 of 12 December 2005 and Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98)

PRICING

Pricing is free. 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 publishes the consumer price and reimbursement price.
The companies can change prices every two weeks

OUTPATIENT SECTOR

INPATIENT SECTOR

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

Reimbursement types

Reimbursable medicines

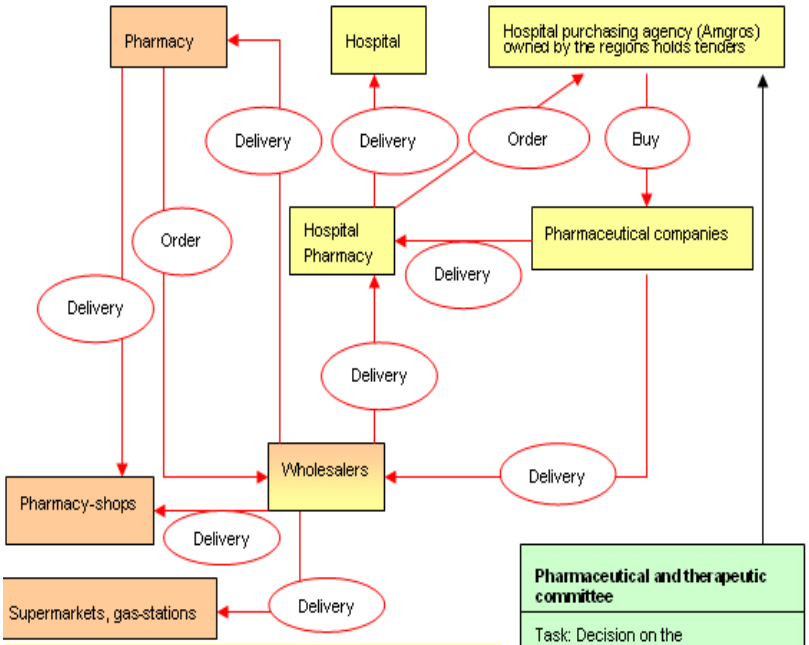
- General reimbursement. Prescription-only pharmaceuticals eligible for reimbursement automatically
- General conditional reimbursement. Prescription-only pharmaceuticals prescribed for specific diseases
- General conditional reimbursement OTC pharmaceuticals prescribed for specific diseases or to pensioners in general

Non reimbursable medicines

- Individual reimbursement on applikation 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 5) (reimbursement group = substitution group).

Distribution



All hospital treatment in public hospitals, including pharmaceuticals, is provided free of charge to the patient.

Pharmaceutical and therapeutic committee

Task: Decision on the pharmaceutical to be applied in hospital pharmaceutical formulary

ESTONIA

Ministry of Social Affairs
Olga Palkmets, Agnes Männik, Dagmar Rüütel
agnes.mannik@sm.ee; tel +372 626 9141

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

Authorisation&Classification

New Medicine

EMA
Estonian State Agency of Medicines consulted by Marketing Authorisation Commitee
Task: Decision on marketing authorisation
Criteria: Quality, safety, efficacy, Directive 2004/83/EEC

State Agency of Medicines
Task: Classification, decision on prescription, dispensing restrictions
Criteria: Directive 2004/83/EEC and Estonian Medicines Act 2002

Register of Human Medicines

Register of Veterinary Medicines

Statistics
State Agency of Medicines
(marketing authorisations`, pharmacy and wholesale licences data; pharmaceuticals advertising, drug utilisation data)

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%

Statistics
State Agency of Medicines
(wholesale and retail sale data, pharmacy statistics)

Reimbursement

Out-patient

In-patient

Ministry of Social Affairs consulted by Drug Committee

Task: Decision on pricing and reimbursement
Criteria: Directive 89/105/EEC and Estonian Health Insurance Act 2005 overall need for reimbursement, availability of alternative pharmaceuticals and treatment options, (comparative) efficacy, safety and cost-effectiveness, budget impact

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%
Diagnose-based: 1,28 € + 25%/10% of reference price

100%
Diagnose-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

Ministry of Social Affairs
<u>TBC, ARV medicines and vaccines (free to patients)</u>
Public procurement
Central warehouse
Treatment centers

<u>Infertility treatment</u>

<u>Security reserve</u>

All are covered from State Budget

National Institute for Health Development
<u>Opioid dependence treatment</u>
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

Statistics
Health Insurance Fund (reimbursement and prescription statistics)

Non-reimbursed

Out-patient

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

In-patient

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

PHARMACEUTICALS PRICING BOARD Finland

PPRI Pharmaceutical Pricing and Reimbursement Information

MINISTRY OF SOCIAL AFFAIRS AND HEALTH Finland

FINLAND

Pharmaceuticals Pricing Board (Lauri Pelkonen)[1],
Ministry of Social Affairs and Health (Ulla Närhi)[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 30th 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

[1] Pharmaceuticals Pricing Board, Ministry of Social Affairs and Health, 00023 Government, lauri.pelkonen@stm.fi
[2] Ministry of Social Affairs and Health, 00023 Government, ulla.narhi@stm.fi

FRANCE

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

New medicine

AUTHORISATION/ CLASSIFICATION

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.

VIGILANCE

AFSSAPS is also in charge of **pharmacovigilance**

EVALUATION

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)

PRICING & REIMBURSEMENT

OUT-PATIENT

PRICING

Pricing Committee (CEPS)

Task: Price negotiations
Criteria: At ex-factory level, depending on ASMR

Task: Publication of ex-factory and retail price (distribution mark-ups regulated)*

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, pharmacoeconomic criteria

*Prices available at http://www.codage.ext.cnamts.fr/codif/bdm_it/index.php?p_site

Ministry of Health and Ministry of Finance

Task: Distribution mark-ups regulation
Criteria: Wholesalers, pharmacists margins

Ministry of Health

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

DISTRIBUTION

Pharmaceutical companies

Wholesalers

Hospital

Task: Decision on use of medicines

in cons. with

Pharmaceutical and Therapeutic Committee per hospital (owner)

Hospital purchasing body or union

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

in cons. with

Hospital pharmacy and/or pharmaceutical depot

Pharmaceutical formulary per hospital (owner)

Pharmacies

Hospitals

POST AUTHORISATION

French Health Products Safety Agency /
***Agence Française de Sécurité Sanitaire des Produits de Santé* AFSSAPS)**

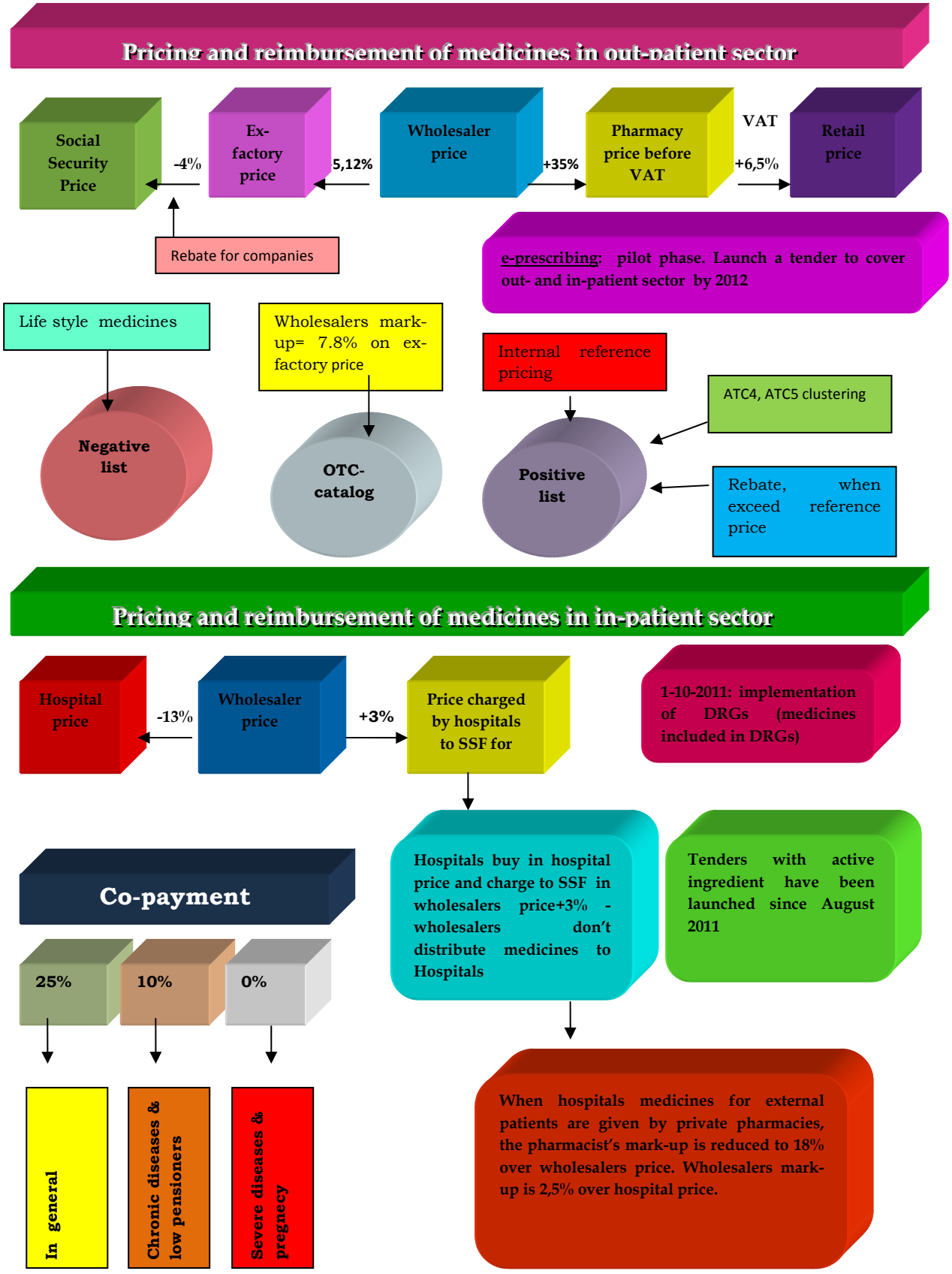
- Advertising control and distribution of Rational Drug Use Guidelines Commission
- Pharmacovigilance Commission

OUT-PATIENT IN - PATIENT

PPRI
Pharmaceutical Pricing and Reimbursement Information

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

AUTHORISATION/ CLASSIFICATION

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.

in consultation with **The Pharmaceutical Committee**

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

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

VIGILANCE

PRICING at wholesale leveland Reimbursment

Icelandic Medicine Pricing and Reimbursment Committee (IMPRC)

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

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

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

Reimbursemnet approval for all prescription drugs sorted by national code

Task: Decision on the reimbursement
Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria, price.
Transparency Directive 89/105/EEC

Pharmaceutical companies

University Hospital (LSH)

Pharmaceutical and Therapeutic Committee

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

PRICING Pharmacy level

Medicines distributed via

Wholesaler — Free mark up at Wholesale level

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

Task: Decision on use of medicines for in-patients in the hospital
Paid by Hospital

in cons. with **Hospital pharmacy**

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

in cons. with **State Trading Centre**

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

Hospital pharmacy and/or pharmaceuti cal depot

Public hospitals which receive public funds

REIMBURESMENT

General eimbursment

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.

Individual reimbursement

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.

Regional Hospitals

in cons. with **Pharmaceutical and Therapeutic Committee per hospital**

Task: Decision on use of medicines in specific hospitals

Pharmaceutical formulary per hospital

OUT- Patient

IN - Patient

ITALY

AIFA- Italian Medicines Agency

AUTHORISATION

EMA OR AIFA

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

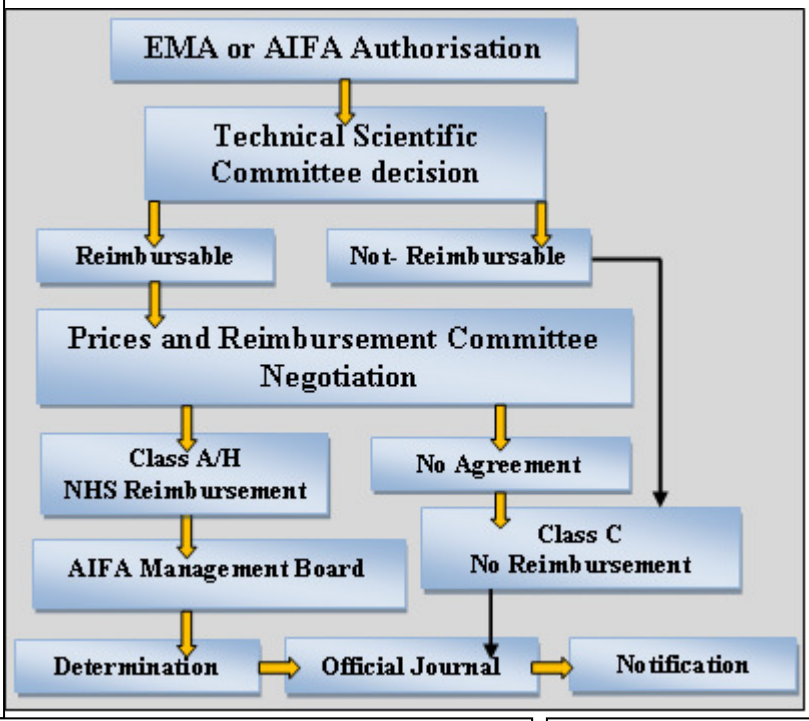
Criteria: quality, safety and efficacy have to be evaluated for a marketing authorisation (Directive 2001/83/EC), Law 219/2006.

PRICING AND REIMBURSEMENT

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 (CTS). The current reimbursement medicine classification is: Class A (totally reimbursed by the NHS) and Class C (not reimbursed by the NHS).



AIFA

Criteria:

- therapeutic value and impact on target population,
- other country international prices,
- pharmaceutical expenditure ceiling planning,,
- budget impact,
- cost/efficacy and pharmacoeconomic analysis

(according to CIPE Deliberation n. 3/2001).

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 discharged 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

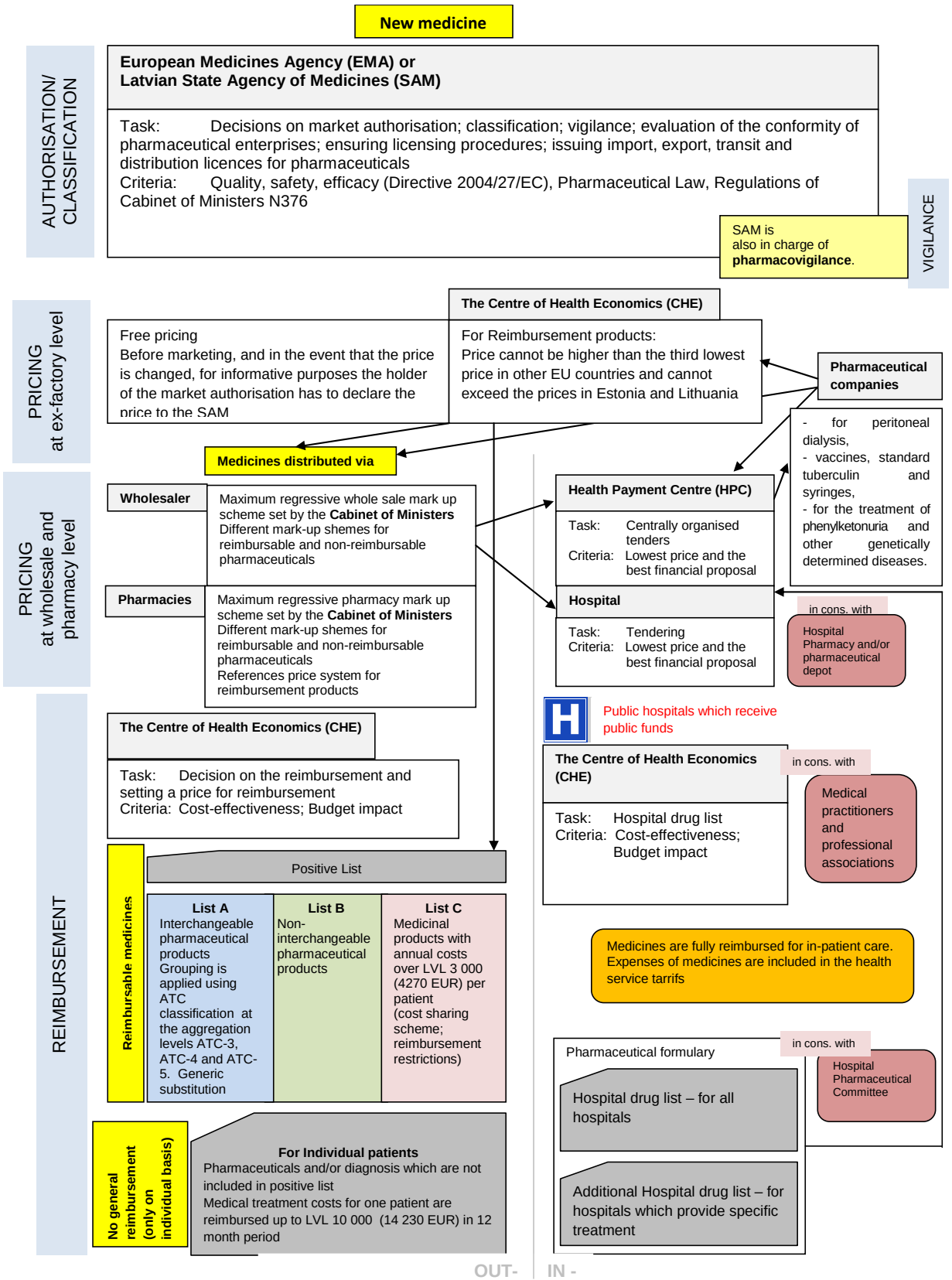
In-patient pharmaceutical pricing is negotiated by AIFA, but Pharmaceutical Companies must grant rebates to hospitals according to those medicines listed on the Hospital Pharmaceutical Formulary (HPF). Tenders may be provided at Regional level, or may be directly managed by hospitals bargaining their 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 (RHPF) and the National Pharmaceutical Formulary (NPF).

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

LATVIA

The Centre of Health Economics. 22 Duntes Street, Riga, Latvia, www.vec.gov.lv

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



Republic of Macedonia

Faculty of Medical Sciences, University "Goce Delecev" in Stip

Bistra Angelovska (bistra.angelovska@ugd.edu.mk), Verica Ivanovska (verica.ivanovska@ugd.edu.mk)

The pharmaceutical system in the Republic of Macedonia in the in- and out-patient sector

Pricing policies for medicines

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 – ereased 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)

Reimbursement

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
- Modifications in the Law on Health Care Insurance and related Rules (2007-2011)
- Introduction of Reference pricing system (2007)

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

out and in patient

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
- Modifications in the Law on Health Care Insurance and related Rules (2007-2011)
- Introduction of Reference pricing system (2007)

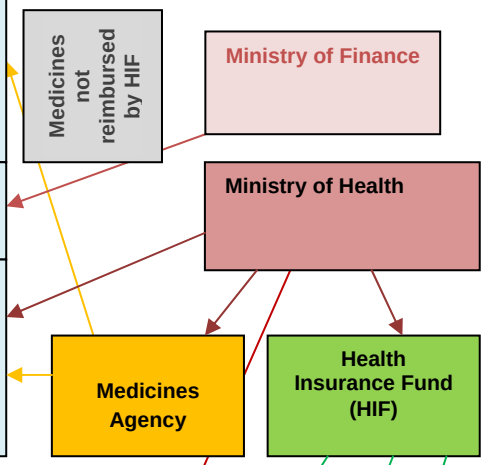
out-patient sector

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)

in-patient sector



Pharmaceutical Pricing and Reimbursement in Mexico*

PPRI Pharmaceutical Pricing and Reimbursement Information

National Institute of Public Health, Mexico

Market authorization

National Medicines Regulatory Authority
(Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS)

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

Private sector — 65% volume market share, 80% value market share

Reimbursement

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

Each institution decides on its own list

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)

Price regulation

Patented medicines

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

Price negotiation only applies to patented medicines

Generic medicines

Generic medicines

Patented medicines

Price regulation only applies to patented medicines

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

Patented medicines

Procurement

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)

About 20% mark-ups

Medicines

Dispensing

No copayment

Medicines

NO VAT on medicines

Medicines

About 20% mark-ups

Medicines

Pharmacies or outlets in public institutions

Retail pharmacies
(about 23,500 in total)

- Free of charge
- Only with institutional Rx
- Only for medicines included in the reimbursement list
- No substitution permitted
- Prescribing by generic name

Medicines

Rx

80% of total pharmaceutical expenditure is out-of-pocket

Medicines

- With and without Rx
- POM regulation not enforced (except antibiotics and controlled medicines)
- Prescribing by generic name or generic plus brand name
- No substitution permitted if brand name specified on Rx

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

Prescribing

Rx — **Physicians working in public sector**

Rx — **Physicians working in public and private sector**

Rx — **Physicians working in private sector**

Pharmaceutical companies (around 100 manufactures)

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

Consulted data source: González Pier E, Barraza Lloréns M. Trabajando por la salud de la población: Propuestas de política para el sector farmacéutico. Versión para el diálogo. Ciudad de México: Funsalud. 2011.

Contact: veronika.wirtz@insp.mx

Ministerie van Volksgezondheid, Welzijn en Sport

The Netherlands

Ministry of Health, Welfare and Sport

AUTHORIZATION/ CLASSIFICATION

EMA or Medicines Evaluation Board (CBG)
Task: Decision on authorization and registration
Criteria: Quality, safety, efficacy (Directive 2004/27/EG or Medicines Act

Medicines Evaluation Board (CBG)
Task: Decision on prescription and dispensing requirements
Criteria: Directive 92/26/EEG and Medicines Act

Ministry of Health
Task: Calculation of maximum prices
Criteria: external price referencing; Medicines Pricing Act (WGP)

PRICING

Z-index
publication price list (taxe)

Pharmaceutical companies

Pharmacies
remunerated according to taxe-price (pharmacy purchase price)

Wholesaler
mark ups not regulated

VAT: 6% (all kinds of medication)

Dispensing fee: average €7,90 per prescription

REIMBURSEMENT

Ministry of Health
Task: Final decision on reimbursement status
Criteria: advice from CVZ

Health Care Insurance Board (CVZ)
Task: advice on reimbursement
Criteria: medical therapeutic, pharmacoeconomic

Dutch Health Care Authority (NZa)
Task: set tariffs for healthcare providers; maintain list of high-cost and orphan medicines for hospitals

Reimbursement System (GVS)
positive list for reimbursed medicines

reimbursement limit
therapeutically interchangeable medicines

Co-payment when the price is higher then the reimbursed limit.

fully reimbursed
unique medicines, proven clinical benefit and cost-effectiveness

optional: conditions for reimbursement (only reimbursed when used for specified indications)

not reimbursed: most OTC's and a small number of POM

Hospital
Task: decision on use of medicines
Criteria: clinical benefit, user-friendly, costs

Regional purchasing groups
task: purchasing of medicines (tendering)

Pharmaceutical formulary per hospital

- most medicines paid for out of hospital budgets (via DRGs)
- extra financial compensation from health care insurer for medicines on NZa list of high-cost medicines and orphan medicines
- no copayments for patient

OUT- PATIËNT

IN- PATIËNT

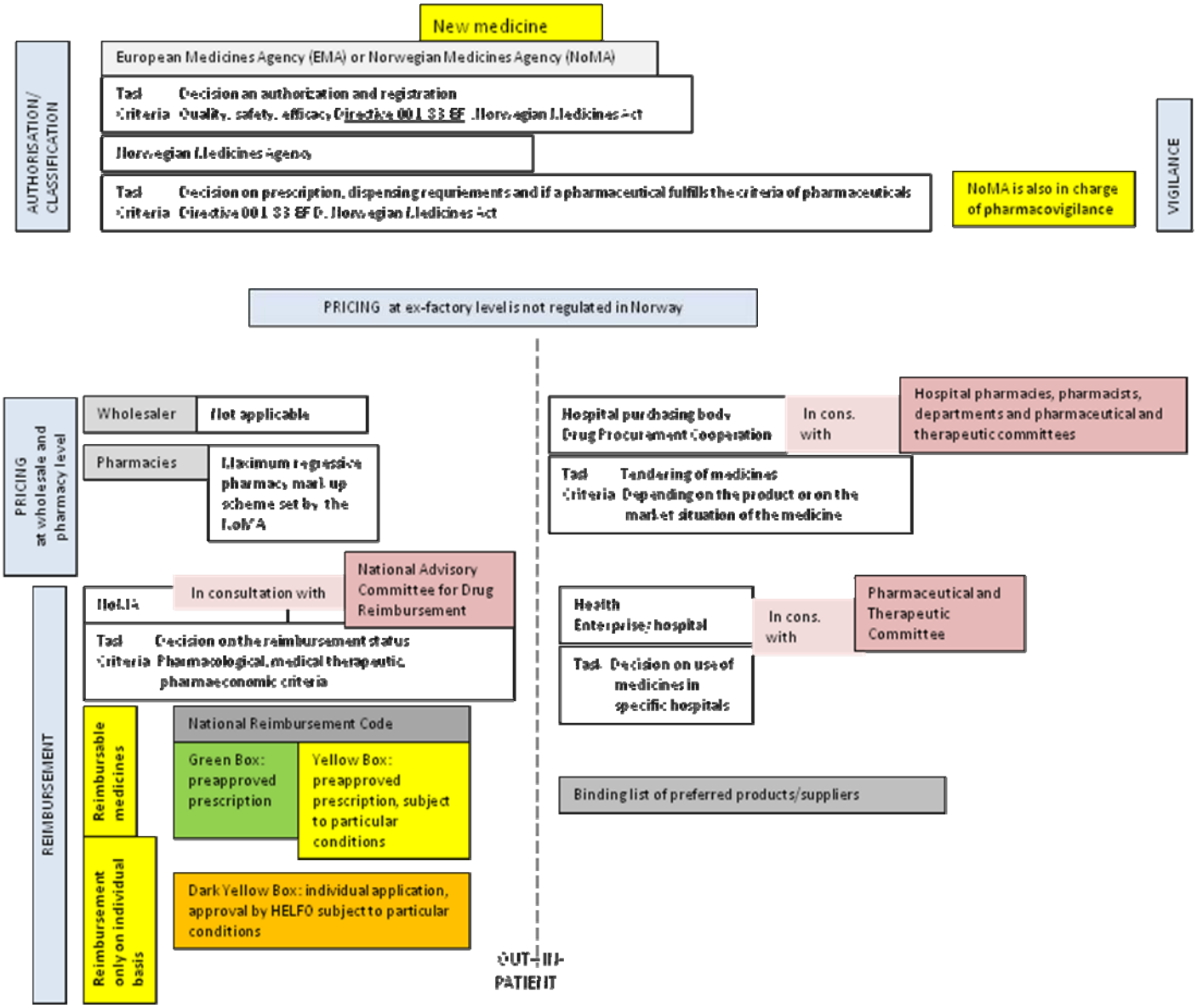
Statens legemiddelverk
Norwegian Medicines Agency

PPRI
Pharmaceutical Pricing and Reimbursement Information

NORWAY

Statens legemiddelverk / Norwegian Medicines Agency

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



PORTUGAL

Ministério da Saúde

infarmed – Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

AUTHORISATION/ CLASSIFICATION

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**

VIGILANCE

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)

Statutory Pricing

GENERICS
- Internal Reference Pricing
- <=35% reference medicine price
- If ex-factory price of reference medicine <10€, the difference applied is 20%

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

OTC not reimbursed

Pharmaceutical companies

Task: Establish OTC price

Criteria: Decree-Law n.º 134/2005, 16th August

Free Pricing

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

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

Applied only to Public hospitals

POM (except restrict) + **OTC**

Pharmaceutical companies

Task: Establish the price of medicines for use in hospitals
Criteria: No regulatory framework

Free Pricing

SPMS

Task: Public Procurement
Criteria: European Directives 2004/17/CE and 2004/18/CE
Price is an important decision factor

Tendering

HOM and restrict POM

INFARMED

Task: Evaluate the added value of new HOM and restrict POM
Setting a maximum price and an annual budget for NHS Hospitals
Criteria: Decree-Law 195/2006, 3rd October

Statutory Pricing

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).

Negotiations

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

REIMBURSEMENT

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

General Scheme
4 levels reimbursement : A(90%); B (69%); C (37%); D (15%)

Product Specific
Based on therapeutic classification

Specific Scheme

Population Group Specific
extra reimbursement (15%)for pensioners

Disease Specific
Defined pathologies e.g. HIV, Alzheimer disease

Generics
From the 5th generic reimbursed , price <5% of the PRP whose generic application is valid, regardless its decision

Internal Pricing Referencing
Reference price – average of 5 lowest PRP at the market (including non-generics) in each Homogeneous Group (HG);
Reimbursement –
<5% of the lowest generic price, with at least 5% of market share, in each HG

Compounds Medicines
Annual list, reimbursed at 30% of its price

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.

Additional financing

- Special financing of medicines to HIV treatment.
  Criteria: Medicines and medical procedures to HIV patients are subsidized according to the predicted the number of new HIV patients
- Medicines for specific conditions and dispensed in hospitals to out-patient with no co-payment
  Criteria: medicines reimbursed at 100% for hospital only dispensing
- Chronic Kidney disease (comprehensive price)

USE IN HOSPITALS

National Hospital Formulary

in consultation with

Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic Committee

Task: Decision on use of medicines in the hospital

Criteria: Order n.º 1083/2004

Pharmaceutical formulary (Addendum) per hospital

DISTRIBUTION

Pharmacies Extensions | **Community pharmacies** | **Internet** | **OTC Dispensaries**

OUT-PATIENT

IN -

ROMÂNIA
MINISTERUL SĂNĂTĂȚII
DIRECȚIA POLITICA MEDICAMENTULUI
Strada Cristian Popișteanu nr. 1-3, 010024, București,
☎ (004021) 307.25.50 • FAX: (004021) 307.25.48

PPRI
Pharmaceutical Pricing and Reimbursement Information

ROMANIA

The Pharmaceutical System in Romania in the In- and Out-patient Sectors

PRICING

Ex-factory Price

POM: External referencing

External reference pricing is based on the lowest price from within a basket of 12 EU countries:
AT, BG, BE, CZ, DE, GR, HU, IT, LT, PL, SK, ES)
Prices established by MOH

OTC: Unregulated

Prices are not controlled by the MOH

Wholesale and Retail Price

Wholesale mark-ups
Regressive mark-up schemes for wholesale price and pharmacy price

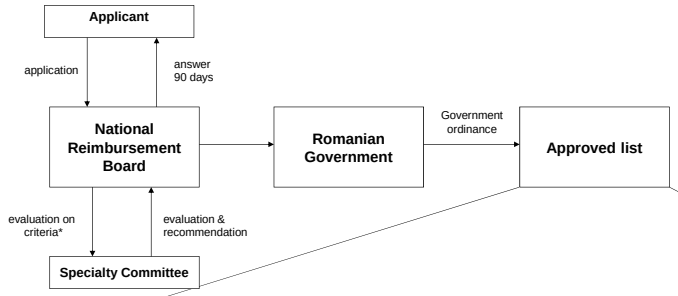
Ex-factory Price (RON)	Wholesale mark-up
Up to 50	14%
50-100	12%
100-300	10%
Over 300	30 RON

Wholesale price (RON)	Max pharmacy mark-up
Up to 25	24%
25-50	20%
50-100	16%
100-300	12%
Over 300	35 RON

+

9% VAT
for all medicines (POM & OTC)

REIMBURSEMENT DECISION



***Reimbursement inclusion criteria:**

INN reimbursed in at least 3 of the EU Member States for at list a year, 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;
2a) Known INN, with new indication clinically superior to current standard therapy;
2b) Known INN, with new indication , at least as effective as current standard therapy, if price is lower than the price of current standard therapy;
3a) INN with a superior safety profile compared with the known INNs for the same therapeutic indication;
3b) INN with a safety profile at least equal to the known INNs for the same therapeutic indication, if price is lower than the price of current standard therapy;
4. combinations of two or more INNs with at least the same therapeutic benefit, at a price at most equal with the sum of individual .

REIMBURSEMENT

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 POM's, with some exceptions for special categories of patients.
There are three sublists:

National Health Insurance House

manages the

National Health Fund

including budget for medicines

Sublist A
90% reimbursed from the level of cheapest product in the group (ATC level 3-4)
Includes essential medicines, typically generics.

The grouping is done into clusters of ATC levels 4-5. 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 B
50% reimbursed from the level of cheapest product in the group (ATC level 3-4)
Typically includes original medicines.

The grouping is done into clusters of ATC levels 4-5. 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% reimbursed list
includes several sections which are managed differently

Section C1
Medicines uses in ambulatory care for specified diseases (mainly severe and chronic): hepatitis, psychiatric disorders, dementia, blood malignancies etc.

100% reimbursed from the level of cheapest product within the INN

Section C3
Medicines reimbursed for special groups of persons: children, unemployed students, pregnant women and young mothers

100% reimbursed from the level of cheapest product within the INN

Section C2
Medicines reimbursed under National Treatment Programs delivered **through hospitals**: HIV/AIDS, certain malignancies, TB, multiple sclerosis, diabetes, renal disease, osteoporosis, hepatitis B/C, transplantation

No longer zero copayment!

Since september 2011, a new scheme is in place, which still covers 100% of the price of medicines, *unless* there are generics (in which case, only the *least expensive generic* is reimbursed 100%).

OUTPATIENT SECTOR

MEDICINES IN HOSPITAL

Funding of public hospitals
Through National House of Health Insurance (CNAS)

National Health Programmes

Several medical services including medicines (see **C2**)

DRG

Financing by solved case.
Hospitalised patients benefit from free medication according to the therapeutic needs

MINISTRY OF HEALTH

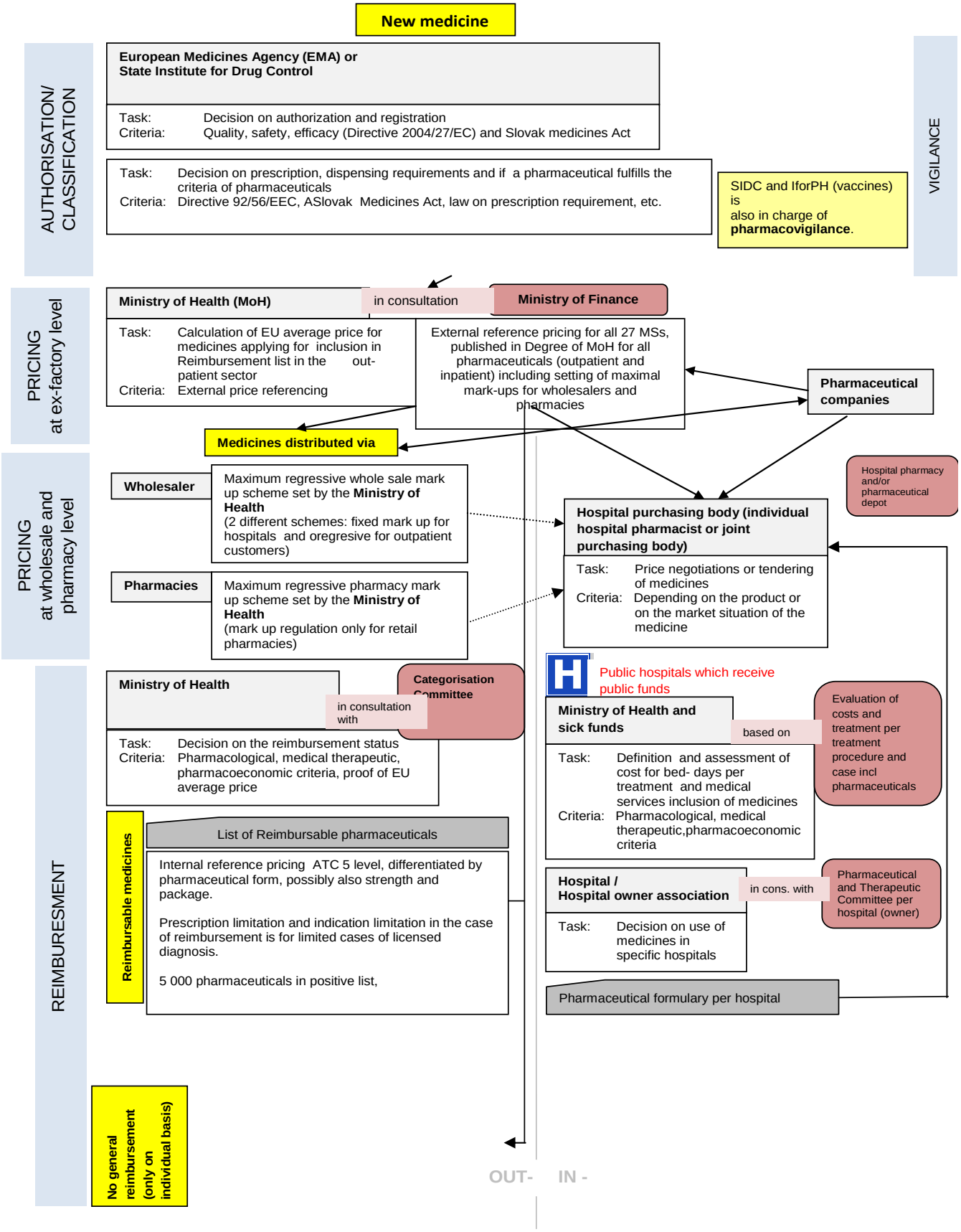
finances the National Health Programmes from own budget, in addition to the National Health Fund

The budget of the National Health programmes is managed by the

NATIONAL HEALTH INSURANCE HOUSE

Bogdan Grigore, MD., Pharmaceutical Policy Directorate, Ministry of Health, ROMANIA

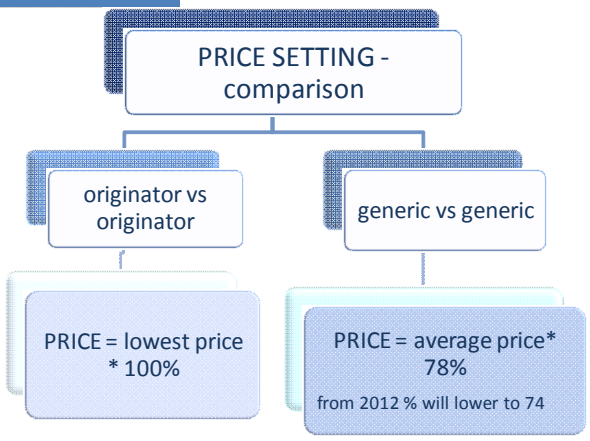
Slovakia – Flowchart of the pharmaceutical system , 2010



PHARMACEUTICAL SYSTEM IN OUT-PATIENT SECTOR

PRICING IN THE OUT-PATIENT SECTOR IN SLOVENIA

Legal basis:	• Medicinal Products Act • Rules on price setting for medicinal products for human use
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



Reforms – planned:

Lowering of % used for price setting
Change of calculations for off-patent 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

REIMBURSEMENT IN THE OUT-PATIENT SECTOR

Legal basis:	• Health Care and Health Insurance Act • Rules on classification of medicinal products for human use on the lists
Responsible institution:	• Health Insurance Institute
Type of lists: POSITIVE INTERMEDIATE NEGATIVE	• Medicines classified on lists: prescription medicinal products, products prepared in pharmacy • Reimbursable lists: positive, intermediate • Decision of the Committee - measures ! • Number of medicines on positive list: 1.550 • Number of medicines on intermediate list: 550
Level of reimbursement:	• **POSITIVE LIST**: 100% or 75% , the rest is paid by voluntary health insurance or by patient • **INTERMEDIATE LIST**: 10%, the rest is paid by voluntary health insurance or by patient • **EXEMPTIONS**: vulnerable groups – children, young people in education, patients with certain diseases: 100% reimbursement for positive list

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

List of interchangeable medicinal products

List of interchangeable medicines	• Medicine is interchangeable within the group • Group is defined by active ingredient, strenght, pharmaceutical form • Decision of Drug Committee – measures! • Number of interchangeable medicines: 2.700
List of highest recognised values	• Includes only interchangeable medicines classifed 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

SOUTH AFRICA

National Department of Health

Civitas Building

Cnr. Struben Street and Andries Street

Pretoria

The pharmaceutical system in South Africa in the in- and out-patient private sector

Pricing in the out-patient sector

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

2004- 2007 → 5.21%

2008 → 6.5%

2009 → 13.2%

2010 → 7.4%

2011 → 0%

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 tired 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.

Dispensing fee structure for South Africa: The exchange rate between the SA Rand and the US dollar is approximately 1$ ~R7.5

The SEP is the price of the medicine i.e. the Single Exit Price: In the SEP there is ex manufacturer price,logistics fee (distribution fee) and Vat.

Dispensing Fee Tiers	SEP Range in rands	Dispensing Fee formula
Tier 1	R 0 - < R75.00	46% of SEP + R6.00
Tier 2	R75.00 - < R200.00	33%of SEP + R15.75
Tier 3	R200.00 -< R700.00	15%of SEP + R51.00
Tier 4	R700.00 -> R700.00	5% of SEP + R121.00

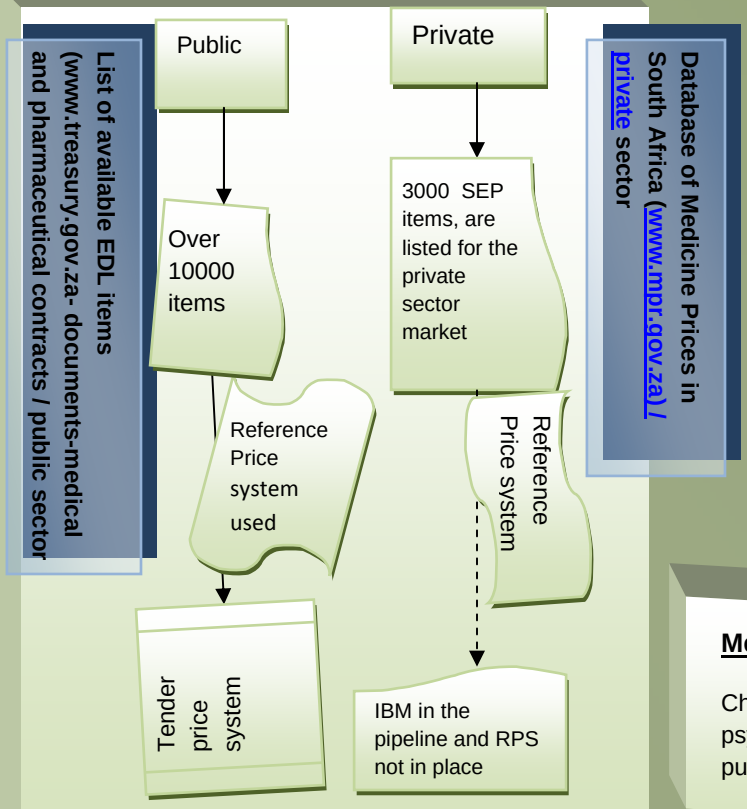
VAT

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 Pharmaceoeconomic 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 South Africa private healthcare sector is performed by medical aid schemes in South Africa. Each medical aid scheme implements regarding the reimbursement policies

Reimbursement in the out-patient 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.

Pricing in the in-patient sector

Pricing policies for medicines

Implementation of pricing policies at the in-patient sector is similar to that in the outpatient sector policies as described above, for the private sector. Affordability determines the amount paid by patients in the public sector. Some patient categories do not pay for health services in the public sector e.g. geriatrics, children under 5 and some psychiatric patients.

Wholesale mark-ups

In patient logistics fees or wholesale markups are determined similarly to the outpatient sector as described above.

Pharmacy mark-ups

In the private sector the system is the same for both inpatient and outpatient sectors as described above.

VAT

14% as described above

South Korea

SeongOk Kim (pipikso@yahoo.co.kr)

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

New Medicine

AUTHORIZATION /CLASSIFICATION

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)

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

REIMBURSEMENT

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)

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

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.

Price Review & Adjustment
- Price adjustment with criteria of pharmacoeconomics
- Price-volume agreement (in condition of price negotiation)
- Price survey and adjustment
- Price cut

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

DISTRIBUTION/ COPAYMENT

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

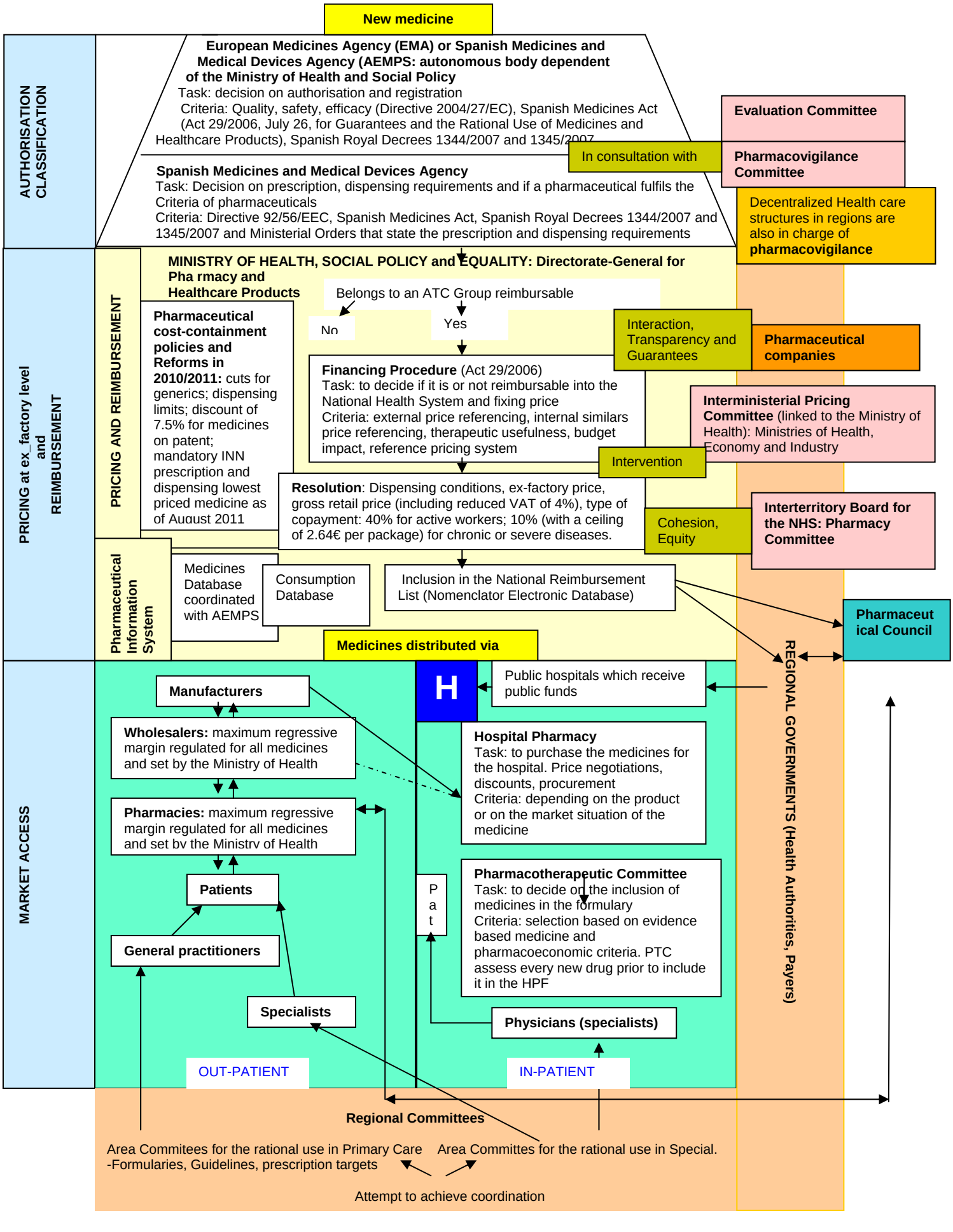
Co-payment for adult (6-64 year old) under National Health Insurance (NHI)Scheme (covers 97% of total population)
- Inpatient : 20% of cost (dispensing fee + drug cost)
- Outpatient : 30% of cost (dispensing fee + drug cost)
(From October 2011, 50% for outpatient, prescription issued by general hospitals and tertiary care hospitals for not severe cases such as cold, hypertension, diabetes, osteoporosis etc.)

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 5% (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)

MINISTERIO DE SANIDAD, POLITICA SOCIAL E IGUALDAD

PPRI Pharmaceutical Pricing and Reimbursement Information

SPAIN-Directorate General for Pharmacy and Healthcare Products
The pharmaceutical system in SPAIN in the in- and out-patient sector



TURKEY

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PPRI
Pharmaceutical Pricing and Reimbursement Information

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

New Medicine

Authorization

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

Authorization of Medical Products for Human use Commission

Technology and Pharmacology Commission

Price (ex-factory)

MoH GDPP Department of Pricing

Pricing Commission

Submission

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

Price (Retail)

Wholesaler
Regressive mark-ups

Pharmacy
Regressive mark-ups
+
8%VAT

Manufacturer

Supplies

Supplies

Supplies

Supplies

Hospital Purchasing Committee

Task: Prepare the terms of reference, buy the most suitable drug
Criteria: Price and compliance with the ToR

Reimbursement

Social Security Institution Reimbursement Commission

Medical and Economic Evaluation 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

Health Implementation Guide: Reimbursement Rules

List 2/A Outpatient Medicines

List 2/B Hospital Only Medicines

Advices

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.

Criteria: Safety, quality and efficacy. (Directive 2001/83/EC (as amended).

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

VIGILANCE

PRICING AND REIMBURSEMENT

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.

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.

IN-PATIENT

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.

DISTRIBUTION

Pharmaceutical companies

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

OUT-PATIENT

IN-PATIENT

Wholesalers

Wholesale margin not regulated – negotiated with pharmaceutical companies.

Community pharmacies

Pharmacy mark up not regulated – negotiated with wholesalers.

NHS Hospitals

Patients

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

Patients

No payment for NHS medicines.

NHS Prescription Services

Task: Reimburse pharmacies for dispensing NHS prescriptions.

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.