3rd International PPRI Conference

Pharmaceutical Pricing and Reimbursement Policies
Challenges Beyond the Financial Crisis

Vienna, 12-13 October 2015

Country Poster Book

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

Gesundheit Österreich GmbH

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The country posters included in the country poster book were submitted to the conference organisers of the PPRI Conference 2015.

More information: http://whocc.goeg.at/Conference2015

The country poster book and the posters will be, upon approval of the authors, available for download after the conference at the conference website.

FONDI I SIGURIMIT TË DETYRUESHËM TË KUJDESIT SHËNDETËSOR

PPRI Pharmaceutical Pricing and Reimbursement Information

Albania

Flowchart of the pharmaceutical system in the in- and out-patient sector, 2015

New pharmaceutical

AUTHORISATION CLASSIFICATION

Ministry of Health (National Drugs and Medical Devices Agency)
Task: Decision on authorization and categorization
Criteria: Quality, safety, efficiency
Law No.105/2014, on Pharmaceuticals and Pharmaceutical Services

PRICING at ex-factory level

Ministry of Health - Drugs Prices Commission
Task: Decision on all drugs prices
Criteria: The lowest price in 5 countries of reference. The price of generic should not exceed 80% of brand's.

OUT-PATIENTS **IN-PATIENTS**

PRICING at wholesale and pharmacy level

Distributors

Wholesalers : Maximum mark-up 11% of the CIF/ex factory price divided between Importers 8% and distributors 3%.
Pharmacies: Maximum mark up 25% of the wholesaler price.
Recently changed by Council of Ministers Decision Nr. 53 dt.05.02.2014
VAT: standard rate is 20%, for all medicines is 0%

Rimbursed Drugs:
Diferent mark up scheme at wholesale and pharmacy level
(Average wholesale mark-up 7.2%, Average pharmacy mark-up 19.6%)

REIMBURSEMENT

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

Criteria: price referencing, cost effectiveness
List composition: 297 active principles, 1031 trade names
Reimbursement percentage: 50-100%
Exemption from co payment: 14 people categories

Public Hospitals

Wholesalers: Maximum mark up 6-8% of the CIF/ex factory price

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

Compulsory Health Insurance Fund
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

Approaches to Pharmaceutical Price Government Regulation in Armenia

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3rd international PPRI Conference
12 - 13 October 2015, Vienna

Introduction

Due to specific characteristics of Pharmaceutical market, medicine price regulation is not possible by only market mechanisms. Therefore, different schemes of Pharmaceutical Price Regulation have been implemented in EU countries, as well as in CIS member states (except Armenia and Tajikistan).

The new Law «On Medicines» of Republic Armenia is intended to provide the development and implementation of Pharmaceutical Price Regulatory system in Armenia.

Objectives

The main objective of this research is to develop recommendations for the synthesis of Pharmaceutical Price Regulation mechanisms based on the analysis of regulatory schemes currently applied to other countries.

Materials and methods

The medicine sales chain involves wholesale and retail phases represented as a system consisting of two «Input → Output» type modules (Figure №1).

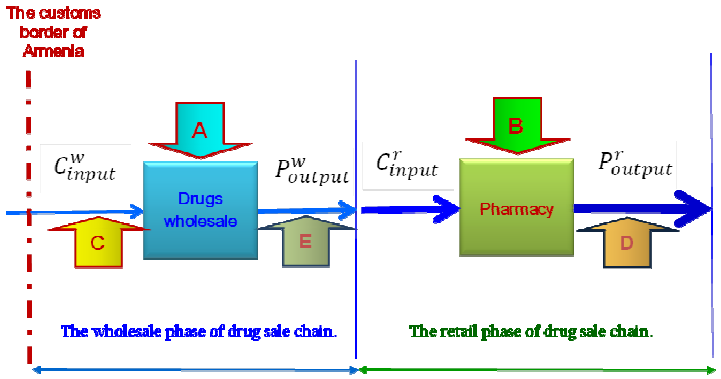

Figure N 1. The apportionment of regulatory influences of medicine prices.

Where:

C^w_{input} - is the cost of imported medicine per unit formed according to requirements of IAS 2 «Inventory» or its custom value formed on the border of Armenia,

P^w_{output} - is the wholesale price of imported medicine per unit,

C^r_{input} - is the cost of the medicine per unit purchased by pharmacy that is formed according to requirements of IAS 2 «Inventory»,

P^r_{output} - is the retail price of pharmacy,

D - is the regulatory influence on the retail price – D,

E - is the direct government regulation of wholesale price – E,

A - is maximum wholesale Mark-up – A,

B - is maximum retail Mark-up – B,

C - is regulatory influences on the wholesalers purchased medicines costs formation process – C.

Materials and methods

This system aims to restrain the growth of medicine prices, and as a starting point for assessing feasibility of this goal was analyzing the effects of possible influences on both inputs and outputs of the chain phases.

The designed «comprehensive model» of Pharmaceutical Price Regulation includes (may include) the integrity of possible regulatory influences currently applied to the systems of other countries.

The «comprehensive model», built using modular principle, enables to easily change (improve) each module entirely or its particular components.

Results

The analysis of all possible regulatory influences allows making approaches to the selection of the most effective set (vector) of possible regulatory influences included in the «comprehensive model». These approaches could serve as a basis for development and implementation of Pharmaceutical Price Regulation Scheme in Armenia.

Taking into account the peculiarities of Armenian pharmaceutical market, it is proposed to develop an effective and comprehensive Pharmaceutical Price Regulation Scheme including only three regulatory influences (tool), such as:

1. *To define the maximum wholesale Mark-up,*
2. *To define the maximum retail Mark-up,*
3. *To define basic cost for imported medicines by using external (internal) reference prices as a base.*

Conclusions

The designed «comprehensive model» involves the complex of all possible regulatory influences of medicine prices and could be used as an effective tool for:

- ❖ *carrying out analysis,*
- ❖ *developing Pharmaceutical Price Regulation systems.*

The research shows that maximum Mark-ups must be applied to both wholesale and retail phases of pharmaceutical market in Armenia, as well as the price regulation of wholesale phase only will not be effective.

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Australia[i]

Pharmaceutical pricing and reimbursement policies

National Medicines Policy

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford
- Medicines meeting appropriate standards of quality, safety and efficacy
- Quality use of medicines
- Maintaining a responsible and viable medicines industry

Reimbursement

Pharmaceutical Benefits Scheme (PBS)

National pharmaceutical public funding program

Community sector, private hospitals, public hospitals (most states and territories for outpatients and patients on discharge)

Pharmaceutical Benefits Advisory Committee (PBAC)

Cost-effectiveness analysis: Incremental Cost Effectiveness Ratio (ICER) compared to existing therapy

Recommendation

Minister of Health

Cabinet approval required for medicines costing more than AUD20 million per year

Funding of medicines

- Unrestricted benefits
- Restricted benefits for specific therapeutic uses
- Authority required benefits: requiring prior approval from the Department of Human Services

Post-market reviews

- To assess medicines utilisation and strengthen medicine pricing management
- Better targeting of medicines and avoidance of preventable wastage or inappropriate prescribing

Contribution of patients

18% of total PBS expenditure

- Co-payment per script
  AUD 37.70 for general beneficiaries
  AUD 6.93 for concessional beneficiaries
- Safety net thresholds (when reached, co-payment drops)
  AUD 1453.90 for general beneficiaries
  AUD 366 for concessional beneficiaries
- Special patient contributions
  Brand Premium and Therapeutic Group Premium

Remuneration of pharmacists

- 6th Community Pharmacy Agreement between the Australian Government and the Pharmacy Guild of Australia (2015-20120)
- Wholesaler mark-up: 7.52% for drugs < AUD1000
- Pharmacy dispensing fee: AUD 6.93
- Administration, Handling & Infrastructure (AHI) fee:
  from AUD3.49 to AUD70 depending on the price of the medicine

Pricing

Internal reference pricing

Medicines of similar safety and efficacy as existing listed medicines (cost-minimisation)

Value-based pricing

- Cost-effective medicines: no fixed ICER threshold
  less likely to be listed when ICER per Quality-Adjusted Life Year (QALY) > AUD75,000
- Pricing considers prices of alternative medicines, cost information, prices of medicines in comparable countries, financial impact on the medicine budget

Managed entry agreements

- Pricing arrangements that involve price or volume rebates, outcome agreements requiring patients to meet health targets for continued subsidy
- Managed access program: provisional funding of new medicines conditional on the later provision of favourable scientific evidence
  - Medicine with high and urgent unmet clinical need, would not otherwise be funded because of high clinical uncertainty and/or high cost

Medicines in public hospitals

- Shared Commonwealth and states and territories funding for global public hospitals expenditures
- Centralised hospital medicine formularies in some states
- Price negotiations and tendering at the hospital level or centralised at the state level in some states

Pricing reforms for generic medicines

- Establishment of two formularies for PBS medicines, known as F1 formulary (single brand listed) and F2 formulary (multiple brands or medicines interchangeable)
- Statutory price reductions
- Introduction of compulsory price disclosure by manufacturers
  - Reduction of listed prices to the level of the weighted average disclosed price

[i] Dr Agnes Vitry, agnes.vitry@unisa.edu.au, University of South Australia, Australia. October 2015

AUSTRIA

Pharmaceutical pricing and reimbursement policies 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 MEA Medizinmarktaufsicht)

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

Austrian Medicines and Medical Devices Agency — in consultation with — **BMG**: **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

The Austrian Medicines and Medical Devices Agency is also in charge of **pharmacovigilance**

VIGILANCE

PRICING at ex-factory price level

Federal Ministry of Health (BMG) — in consultation with — **Pricing Committee** — supported by — Pharma Price Information (PPI) service at the Austrian Public Health Institute (GÖG) – checking pharmaceutical prices on request

Medicines applying for out-patient reimbursement → Statutory pricing

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

Medicines not in out-patient reimbursement → Free pricing

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

PRICING at wholesale and pharmacy price level

Medicines distributed via

OUT- PATIENT

Wholesalers — Statutory pricing
Maximum regressive wholesale mark-up scheme set by **BMG** (2 different schemes, one for Green + Yellow box products, one for the remaining)

Pharmacies — Statutory pricing
Maximum regressive pharmacy mark-up scheme set by **BMG** (2 different schemes: one for 'privileged' customers (e.g. sickness funds) and one for private customers)

VAT: 10%
Co-payment (prescription fee of €5.55) for reimbursed medicines

IN - PATIENT

Price negotiations | Tendering

Statutory wholesale or pharmacy margins are not relevant, unless products are bought from wholesalers or community pharmacies.

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 (HEK)**

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

Reimbursable POM

National Reimbursement Code "EKO" (100% reimb.)

Green Box	Light Yellow Box	Dark Yellow Box
For prescription of medicines no approval necessary Price < EU average price	Medicines for defined indications Ex-post check of prescription behavior Max. EU average price	Medicines with essential added therapeutic value Ex-ante approval of head physician necessary Max. EU average price

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 (as decision also includes and depends on the price, period is 180 days); if negative decision – delisting of the product from the Red Box

Non reimbursable medicines

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

Only price notification

Medicines Commission

Task: Development of joint provision models for the in-patient and out-patient sector for high priced and specialized medicines. It is charged with establishing the eventual 'best point of service' reflecting medical-therapeutical, health economic and health care considerations.

Public hospitals which receive public funds

Federal Ministry of Health (BMG) — in cons. with — Federal Commission of regional decision makers / payers (BGK)

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

Medicines are integrated in the lump sums (with some exceptions) which can be generated for reimbursement of the procedure and diagnosis-orientated case groups (DRG) in hospitals.

Use in hospitals

Hospital/ Hospital owner association — in cons. with — Pharmaceutical and Therapeutic Committee in hospital (association)

Task: Decision on use of medicines

Pharmaceutical formulary per hospital (owner)

The financing of the medicines does not depend on the inclusion in a pharmaceutical formulary. Once included price negotiations/tendering start.

No co-payments for patients

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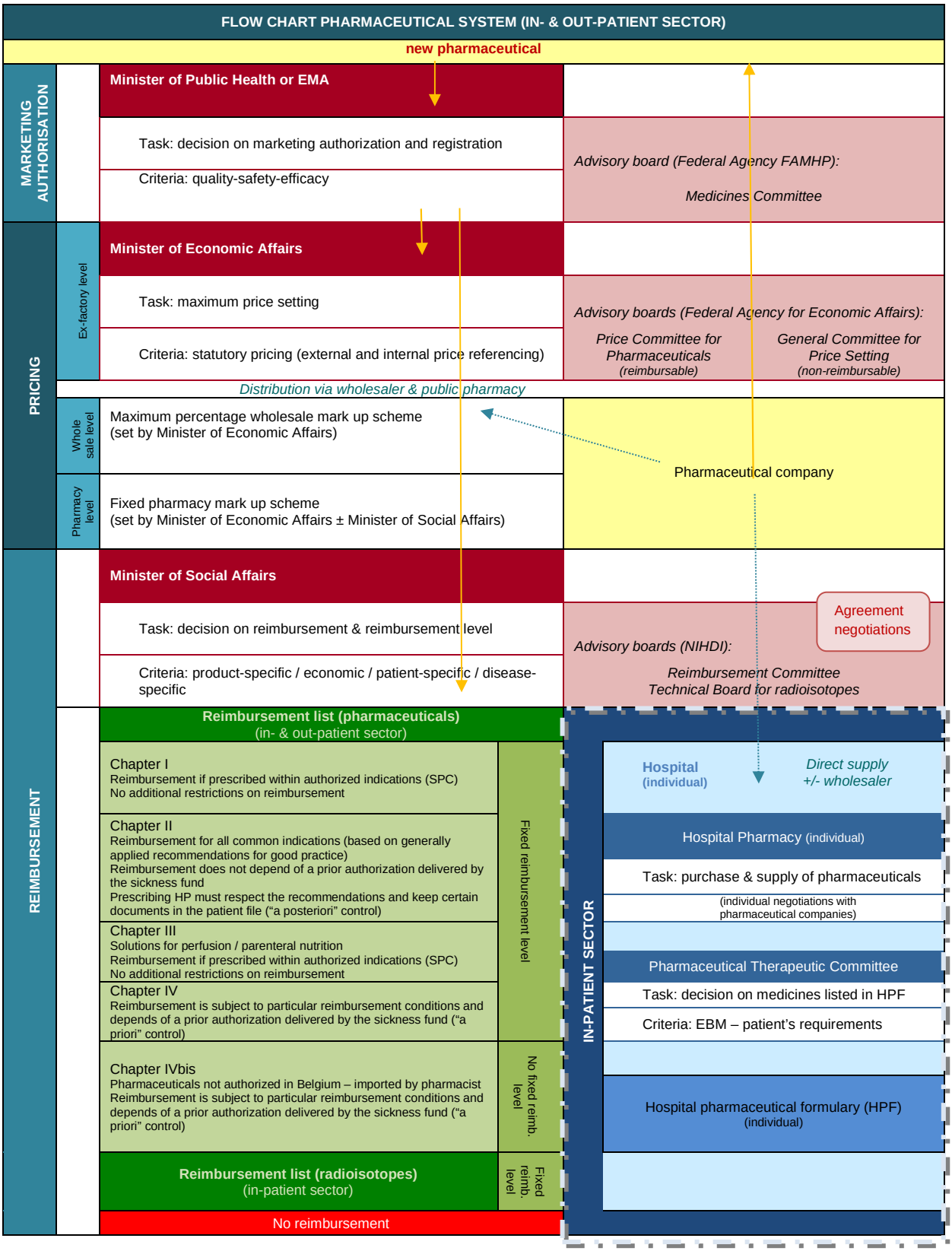
BELGIUM

National Institute for Health and Disability Insurance (NIHDI)



National Council on Prices and
Reimbursement of Medicinal Products

BULGARIA

Recent and planned developments in pharmaceutical policies 2015

DEVELOPMENTS

Changes in pricing

Changes in the Ordinance on the terms, rules and procedure for regulation and registration of prices for medicinal products in 2014 – in August and November.

Recent changes related to:

price changes (e.g. price cuts, price freezes, other price reductions)

- ✓ Freezing the registered prices of OTC products in August 201 4 for another eight months until December 31 st, 201 5 (Prices increase of OTC products was allowed only by the percentage of the inflation rate)

price reviews

- ✓ Price review of reimbursement medicinal products every six months (*single product in the international non-proprietary name*).
- ✓ Change in the period of price review of reimbursement medicinal products from six months to one year (*for others).*
- ✓ This requirement has come into force in August, 2014.

margin changes (wholesale, pharmacy)

There are no changes.

- ✓ Wholesale margins are 7%, 6% and 4% (but not more than 10 BGN) of the ex-factory price.
- ✓ Retail margins are 20%, 18% and 16% (but not more than 25 BGN) of the ex - factory price.

discounts / rebates (out-patient, in-patient), managed-entry agreements, clawback/payback system

- ✓ Since 2011 the National Health Insurance Fund can negotiates discounts from the reimbursement value of the out -patient medicinal products and in-patient oncology products

change in VAT on medicines

There is no change. The VAT in Bulgaria is 20 %.

other changes in pricing policies (e.g. change of reference countries in EPR)

- ✓ Reference countries – 17 (10 Basic and 7 additional)

  Basic countries - **RO, FR, LV, EL, SK, LT, PT, IT, SI, ES;**

  Additional countries – **BE, CZ, PL, HU, DK, FI, EE.**
- ✓ In November 2014, Finland and Denmark were included as additional countries for the purposes of ERP.
- ✓ Estonia as a basic country for ERP was replaced by Latvia as an additional country.

Changes in reimbursement

Changes in the Ordinance on the terms, rules and procedure for regulation and registration of prices for medicinal products in 201 4 – in August and November

Recent changes related to:

changes/modifications of reimbursement lists

- ✓ For the purposes of determining the value of payment for medicinal products included in the PDL for which there is a difference in the indications for treatment, the reference value can be calculated for vario us indications in the summary of product characteristics.

changes/modifications of reimbursement rates

There are no changes.

changes/modifications of co-payment

There are no changes.

other changes/modifications of the reimbursement system

- ✓ Since January 1st, 2015 the National Health Insurance Fund will have to pay for new molecules or indications for oncology included in the PDL in 2014. This payment process shall commence in the b eginning of every new year and shall cover the new molecules or indications for oncology included in the PDL in the previous year.

Planned changes:

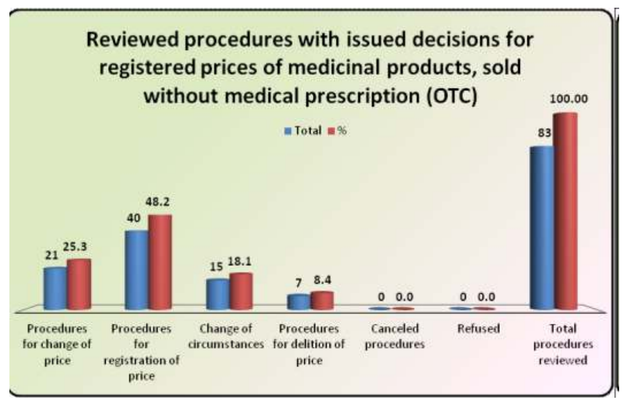
1. New regulation HTA (draft).
2. New regulation diagnosis reimbursement (draft).
3. Pay back and clow back (draft).

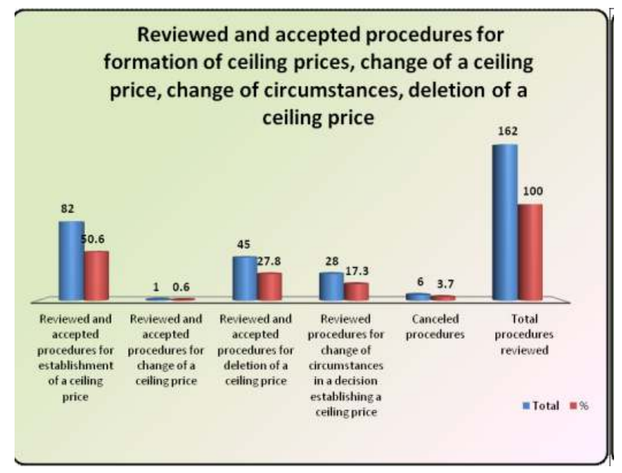
Other changes

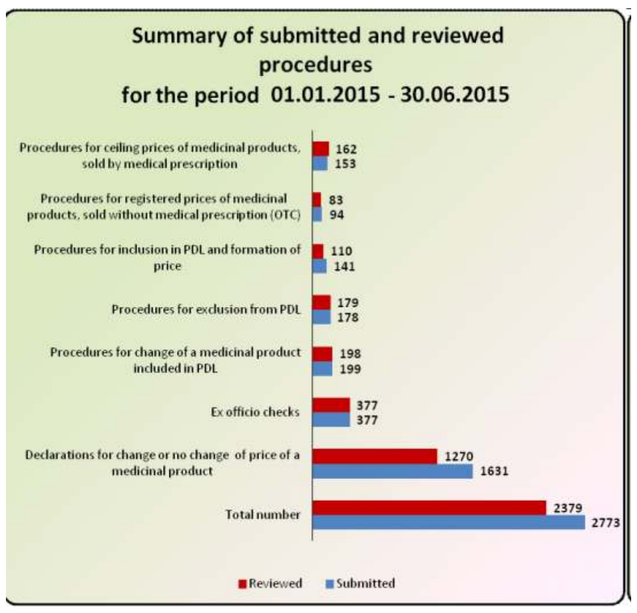
- ✓ *There are no changes.*

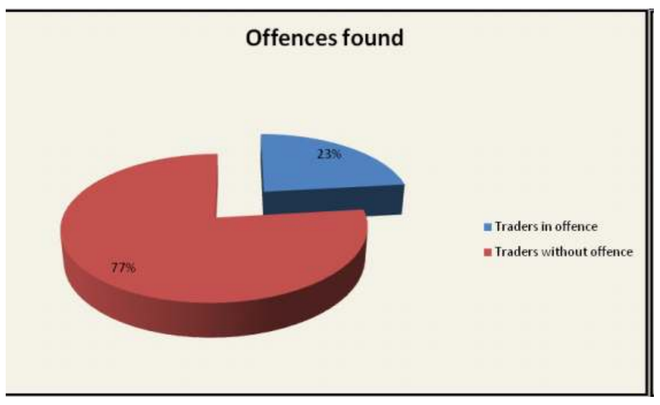
EX OFFICIO CHECKS MADE FOR ESTABLISHMENT OF CHANGE OR NO CHANGE OF PRICE FROM ALL CHECKS OVER THE LAST SIX MONTHS

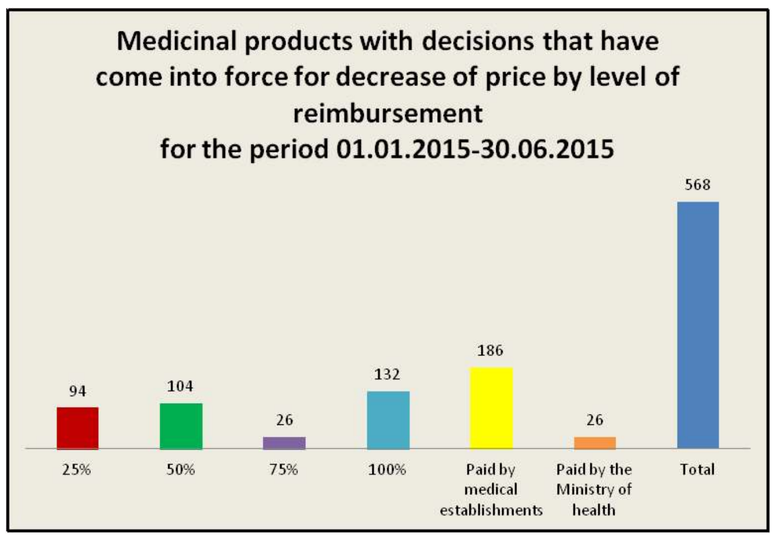
Checked prices of medicinal products in reference member countries	Found a lower price than manufacturing price in Bulgaria	Reference country	Found lowest price/pcs	%
		Greece	11	*11,22*
		Slovakia	36	*36,73*
		Romania	3	*3,06*
		Spain	20	*20,41*
		France	5	*5,10*
		Denmark	1	*1,02*
		Finland	0	*0,00*
		Slovenia	2	*2,04*
		Italy	5	*5,10*
		Estonia	0	*0,00*
		Hungary	0	*0,00*
		Portugal	3	*3,06*
		Lithuania	0	*0,00*
		Belgium	0	*0,00*
		Poland	0	*0,00*
		Latvia	10	*10,20*
		Czech Republic	2	*2,04*

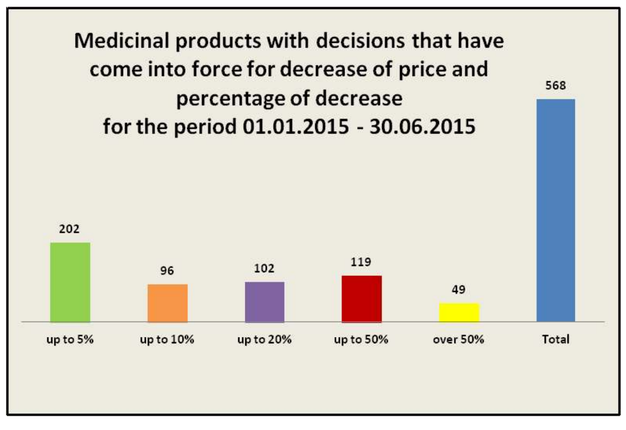


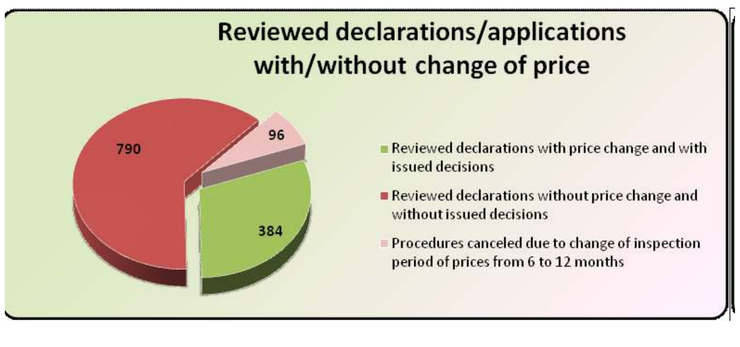


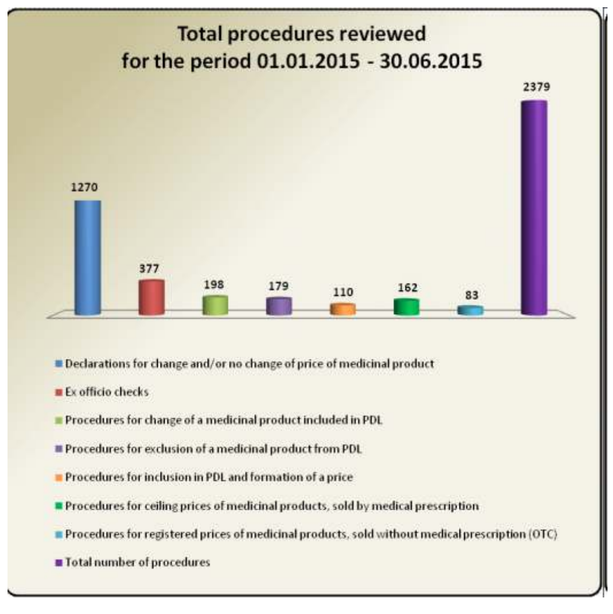












Patented Medicine Prices Review Board | Conseil d'examen du prix des médicaments brevetés

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WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

CANADA

Pharmaceutical pricing and reimbursement policies / in- and out-patient sectors

Health Canada – Drug Approval

Grants the authority to market new drugs in Canada once they have met the regulatory requirements for **safety, efficacy and quality.**

PRICING factory gate level

The Patented Medicine Prices Review Board (PMPRB)

Regulates the price of all **patented** medicines sold in Canada to ensure that they are **not excessive.**

Reviews the prices charged to **wholesalers, hospitals and pharmacies.**

Drug prices are compared to prices of similar drugs in a therapeutic class and/or to prices in seven comparator countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. Drug products are categorized by degree of innovation: breakthrough; substantial, moderate, or slight/no improvement. Yearly price increases are limited to changes in the Consumer Price Index.

IN-PATIENT

All drugs administered in hospitals are fully funded by the Medicare system at no cost to patients under the *Canada Health Act*.
Canadian hospitals operate under fixed budgets, and procure drugs typically through purchasing programs that establish group contracts for set prices. The hospital then buys directly from the manufacturer at the contract price.

OUT-PATIENT

Prescription drug costs in Canada are covered by a blend of public and private drug plans, as well as out-of-pocket payers.

PUBLIC (42.0%)*

Each of the 10 Canadian provinces and 3 territories provide public coverage with a focus on seniors, lower-income earners or those with high drug costs in relation to their income. Federal coverage is provided for veterans, First Nations and Inuits, Royal Canadian Mounted Police and the armed services.

PRIVATE (35.8%)*

Most employers provide private drug insurance for working-age beneficiaries and their dependants.

Out-of-pocket (22.2%)*

Individuals not covered by a public or private plan, or those with deductible or co-payment costs.

*Source: Canadian Institute for Health Information, 2014

PRICING

pan-Canadian Pharmaceutical Alliance (pCPA)

Since 2010, provincial and territorial governments have implemented individual policies aimed at reducing the price of generic drugs. More recently, through the pCPA initiative, they have been working together to achieve greater value for brand-name and generic drugs. Through these policies and the pCPA initiative, the prices of generic drugs have been reduced to levels as low as 18% of the reference brand-name prices.

Brand-name drugs

The pCPA conducts joint provincial/territorial negotiations and enters into confidential Product Listing Agreements (PLAs) for brand-name drugs for publicly funded drug plans. These negotiations are based on the health technology assessments conducted by the national review processes: Common Drug Review (CDR) or Pan-Canadian Oncology Drug Review (pCODR). As of June 30, 2015, 74 joint negotiations have been completed.

Generic drugs

The pCPA also conducts joint negotiations for top-selling generic drugs, benefiting all Canadians. As of April 2015, 14 commonly-used generic drugs have been reduced to 18% of their brand-name prices. Ongoing negotiations are focused on reducing the prices of an additional 4 drugs by April 2016.

Brand-name drugs

Private plans do not negotiate the prices of brand-name drugs collectively and do not benefit from the discounts/rebates available for public plans.

Generic drugs

The generic prices that are negotiated by the pCPA are available to both the private and out-of-pocket markets.

Wholesale and pharmacy markups

About half of the provinces/territories regulate wholesale margins, while others are unregulated. Most public and private drug plans reimburse a pharmacy markup. For public drug plans, the markup ranges from 4% to 8.5% of the drug ingredient cost.

Wholesale and pharmacy markups

No policies exist. These may be negotiated by individual insurers (e.g. Preferred Pharmacy Networks).

REIMBURSEMENT

The Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR)

Through the pCODR and CDR processes, the Canadian Agency for Drugs and Technologies in Health (CADTH) evaluates the clinical, economic, and patient evidence for cancer drugs (pCODR) and other drugs (CDR). Based on these evaluations, CADTH provides reimbursement recommendations and advice to Canada's federal, provincial, and territorial public drug plans (with the exception of Quebec), as well as to the provincial cancer agencies. The recommendations are not binding but are considered by the public drug plans when making formulary listing decisions.

Therapeutic reference price systems (RPS) are not commonly used in Canada.

Patient eligibility and cost-sharing

These vary widely according to the plan design. Some public plans provide income-based coverage, while other focus on seniors and lower-income earners. Cost sharing structures also vary depending on the plan design, with a blend of deductibles, co-insurance and/or co-payments.

Private plans generally cover all prescription drugs, although private formulary plans do exist, in which case, private drug plans make their own listing decisions.

Cost-sharing

Cost-sharing structures take the form of co-insurance, co-payments, deductibles, and maximums. Recent concerns over the long-term sustainability of private plans in Canada have resulted in an increased use of cost management mechanisms, such as mandatory generic substitution, greater use of managed formularies, prior authorization and multi-tiering (promoting the use of more cost-effective medicines), preferred pharmacy networks, increased cost sharing, pooling of high-cost beneficiaries, and the elimination of retiree benefits, among others.

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CHINA

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

PHARMACEUTICAL Supply Chain

Registration & Manufacturing	Dispensing	Utilization
Measures on the Administration of Drug Registration (Since October 2007)	13,000 wholesalers	Pharmaceutical market expanded 16.1% annually in recent years
5,000 pharmaceutical manufacturers now in China, mainly produce generic drugs and traditional Chinese medicines.	341,000 retail stores 554,000 rural drug supply outlets	Hospitals prescribe and dispense about 80% of total medicines, the remaining 20% by community drug stores (pharmacies)
After experiencing several quality issues, the government concentrated on the strict implementation of the Good Manufacturing Practice (2011 new GDP) to assure product quality.	950297 pharmacies (2012) at hospitals, primary health departments and professional public health departments	Hospital pharmaceutical revenue accounts for 41.1% of hospital total revenue in 2012

PRICING Management

Three types of prices determination model

(Maximum retail prices)

Product Type	Characteristics	Management Department
State-priced products	National medical insurance catalogue	National Development and Reform Commission (NDRC)
Local government-priced products	Local medical insurance catalogue	Provincial or municipal price control
Other products	Self-paying medicines	Mmanufacturers

Dispensing place

COMMUNITY PHARMACY

Self-pricing below price caps. However, with violent competition among chain pharmacies, the retail prices are always much lower than that of hospital pharmacies, especially for generics.

17% VAT

HOSPITAL PHARMACY

Before entering catalogues for hospital procurement, all the medicines are subject to tenders for provision in each province or municipality

Hospital pharmacies could add 15% from procurement price as profit and no VAT.

REIMBURSEMENT for out- or in-patient and insurance programs

Three main health insurance programs in China

Characteristic	New Rural Cooperative Medical Scheme (NCMS)	Urban Employee-Basic Medical Insurance (UEBMI)	Urban Residents-Basic Medical Insurance (UR-BMI)
Date started	2003	1998	2007
Populations	Rural residents	Urban employed	Children, students, elderly, disabled, other non-working urban residents
Coverage (95% in 2011)	98.3% (805 million, 2012)	265 million (2012)	271 million (2012)
Expenditures	92.292 billion RMB (13.6 billion USD) (2009)	201.6 billion RMB (29.6 billion USD)	6.7 billion RMB (985 mill USD)
Source of revenues	308 RMB/per capita (2012)	8% of employee wages: "6+2": 6% payroll tax on employers and 2% employee contribution	Average 245 RMB for adults, 113 RMB for minors (pilots 2008)
Positive list	About 1000 chemical and traditional Chinese medicines (determined by provincial government)	2151 including 1164 chemicals, 987 traditional Chinese medicines and others (2009). 503 kinds of Class-A medicines could be totally reimbursed, and other Class-B only partially reimbursed.	

OUT- PATIENT

50.3% drug consumption (2012)

Setting quotas for subsides per month; Special subsides for some chronic diseases

Different subsides for different insurance programs and diseases

IN - PATIENT

41.1% drug consumption (2012)

Patient visits: 10% at private hospitals in 2014

Government investment in health-care plans to increase from 5.36% of total GDP in 2012 to 7.6% in 2020. Out of pocket for patients' co-payment in 2012 was 34.4%

COLOMBIA

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

New medicine

AUTHORISATION/ CLASSIFICATION

INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos)

Task: Decision on authorization and registration
Criteria: Quality, safety, efficacy (Act 677/1995)

Medicines Review Commission
Biologicals Review Commission

Ministry of Health and Social Protection / INVIMA / Decentralized Health Authorities

Task: Decision on dispensing requirements and if a medicine fulfills the criteria of medicines
Criteria: Act 100/1993, Act 677/2005, Act 715/2000, Act 1122/2000, Act 1438 de 2011, Act 909/2004

INVIMA is also in charge of **pharmacovigilance**

VIGILANCE

PRICING at wholesale level

Ministry of Health and Social Protection (MinSalud)

in consultation with

National Commission of Medicines and Medical Devices Prices – Intergovernmental Body

Statutory pricing

Free pricing

Price notification to MinSalud

External Reference Pricing System (ERPS)[1]

Internal Reference Pricing System (IRPS)[1]

Identification of relevant markets (active pharmaceutical ingredients and dosage form). 2. Analysis of market power in each relevant market using the Hirschman-Herfindahl index (HHI). 3. Setting-up of an international reference price (IRP) for each relevant market, using available information of wholesale prices of 17 countries from the Americas, Europe and Australia.

Criteria: Act 04/2013

The IRPs obtained were incorporated into the estimate of Payment's Unity by Capitation (known as Unidad de Pago por Capitación – UPC), where the observed prices of the active ingredients concerned were replaced by the IRP obtained. Nine therapeutic classes until now.

Criteria: Technical Report, Minsalud, 2014.

Price negotiations

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

in cons. with

Tendering

Health insurers
Hospitals
Pharmacies

INPATIENT SECTOR

CAPITATION OR RISK PREMIUM

MinSalud

in cons. with

Health Technolgy Assessment Institute (IETS)

Task: Definition and assessment of inclusion of medicines to the national benefit package.

Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria

MinSalud

Task: estimate of Payment's Unity by Capitation (known as Unidad de Pago por Capitación – UPC), observed prices of the national benefit package medicines make part of this estimation.

Criteria: The UPC is the capitation or risk premium of the health benefit package, obtained by a risk adjustment with demographic variables (sex, age and geographic zone).

Co-payments for patients based on financial contribution capacity to the system

INPATIENT SECTOR

Contributory Regime (CR): covers workers and their families with monthly incomes above a minimum monthly amount

Subsidized Regime (SR): covers those identified as being poor through a proxy means test. monthly amount

Public Hospitals

Health Insurers
Private Hospitals

Institutional Pharmaceutical and Therapeutic Committees

Task: Decision on use of medicines. The financing of the medicines does not depend on the inclusion in a pharmaceutical formulary.

REIMBURSEMENT

Non National Benefit Package Medicines

Reimbursement on individual application possible:
Prescribers and people access to medicines by this way, includes judicial exceptions and exceptional approval of Scientific and Therapeutic Institutional Committees

No co-payments for patients

1. Glossary of Pharmaceutical Terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Contact: acosta-angela@javeriana.edu.co

Hrvatski zavod za zdravstveno osiguranje — Croatian Health Insurance Fund

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

CROATIA

Pharmaceutical pricing and reimbursement policies in the in- and out- patient sector

AUTHORISATION

Agency for Medicinal Products and Medical Devices of Croatia

Decision on national authorization and registration

HALMED

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MRP and DCP procedures

AUTHORISED

QUALITY, SAFETY, EFFICACY

Pricing policies for medicines included on the reimbursed lists – wholesale price + VAT 5%

Pricing and reimbursement process are public on HZZO's web site: http://www.hzzo.hr/zdravstveni-sustav-rh/trazilica-za-lijekove-s-vazecih-lista/

Ministarstvo zdravlja
Za zdravlje. Zajedno.

= Ministry of Health

STATUTARY P&R

- Ordinance establishing the criteria for **wholesale pricing** of medicinal products and the method for reporting wholesale prices
- Ordinance establishing the criteria for inclusion of medicinal products in **the reimbursment lists** of CHIF (HZZO)

MAH - proposal → HZZO – Division for drug - verification of documentation → Commitee for medicines opinion → HZZO Management board decision

PRICING

External price referencing

= annual price calculation (average price) for all medicinal products on lists

New medicines for lists:
Pharmacoeconomic analysis, Budget impact analysis

- **Original products**: up to 100% of AP
- **Me-too products**:

-up to 100% of AP
-reimbursement price: up to 90% of the price of cheapest similar product on the list in Croatia

- **Biosimilars:**

-up to 85% price of AP
-every each and other:
up to 90% of the cheapest biosimilar on the list

- **Generic products**:

-first generic: up to 70% of the original product price
-every each and other:
up to 90% of the cheapest generic on the lists

Internal price referencing

- Clusters formed at ATC levels 3-5
- Comparisons in major part DDD based, clinical expirience dose, dose in SCP
- Reference price=cheapest molecule with 5% of volume in last 3 months

REIMBURSEMENT

Osnovna lista lijekova

2009. INN 704 packages 2070
2015. INN 807 packages 3513

A list – basic list
all drugs are covered by mandatory insurance

B list – suplementary list
Drug price: part covered by mandatory insurance + part covered by co-payment

Dopunska lista lijekova

2009. INN 155 packages 326
2015. INN 302 packages 775

the OUT - PATIENT sector

LJEKARNA

e-Prescriptions
prescribing criteria are defined for certain indications

Medicines distributed via Wholesalers and Pharmacies

the IN - PATIENT sector

Hospital Pharmacies

Statutary pricing
Rp. – medicines on A list (basic list) - 100% covered by national reimbursement
Rp. – medicines on B list (supplementary list) with patient co-payment

+ service charge paid for dispensing

- No co-payment for patient in hospitals
- Statutary pricing + Price negotiations + Tendering (Volume +pay-back agreements, Pay per performance …)
- Medicines are intergrated in the sums which can be generated for reimbursement of the procedure and diagnosis-oriantated case groups (**DRG**)
  - ✓ except drugs which are paid separately:

List of particularly expensive drugs (new innovative / orphan drugs)
-Committee in hospital – decision on use of these medicines

CYPRUS REPUBLIC

MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

CYPRUS

PHARMACEUTICAL SERVICES MINISTRY OF HEALTH

1475 NICOSIA

Tel.: 22442237 webmail address http://www.moh.gov.cy/phs

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

OUT- PATIENT & IN - PATIENT

PRICING

Pricing policies refer to the private sector

There is no discrimination between in and out patient sector

External price referencing.

Price revisions take place annually. A re- calibration of the pricing method is performed biennial.

Wholesale remuneration

The wholesale prices include the wholesaler margins and distribution costs. A 3% mark-up is added to the EPR price to cover the cost of importing pharmaceuticals

Pharmacy remuneration

The Pharmacy margins reach 37% on wholesale price for the medicines of € 0-50, 33% for the medicines of €50.01 – 250 and 25% for the medicines of > € 250. The price revision only apply to medicines with wholesale prices greater than €10 Liberalisation of OTC prices

Pharmacists also receive a flat fee of €1.00 per prescription

VAT

A 5% VAT is added to the price

Reforms

Prices reduction

12 of January 2015: Prices revision was performed → Average price reduction of 15,51%, for 1968 medical products

29th of June 2015: Across the board price cut of 8.5% on the wholesale price. The price cut referred solely to medicines with wholesale prices greater than €10

Pricing under the authority of the Ministry of Health.

REIMBURSEMENT

Absence of reimbursement system

About 80% of the population has access to state-financed, public healthcare free of charge, others have to pay a fee or rely on the private healthcare sector. Medicines funded by the state are procured centrally by the Ministry of Health via tender and supplied through the public sector. Other medicinal products are supplied by private actors, according to the Ministry of Health regulations in line with EU regulation.

Hospital formulary provides contemporary information about medicines available from public hospitals and health care centers.

CZECH REPUBLIC

State Institute for Drug Control

Regulation and reimbursement of pharmaceuticals in the in- and out-patient sector

AUTHORISATION/ CLASSIFICATION

State Institute for Drug Control* (SUKL, Czech medicines agency) or *European Commission (European Medicines Agency)

Task:
If a product meets criteria for pharmaceuticals, a decision on marketing authorization is issued. This decision includes information on classification for supply and dispensing requirements

Criteria:
Quality, safety, efficacy (Directive 2004/27/EC) and Czech Act on Pharmaceuticals

***SUKL* is also in charge of pharmacovigilance and GMP/GDP inspections**

VIGILANCE

PRICING ex-factory level

State Institute for Drug Control

Task: Calculation of price for medicines if reimbursement has been applied for (IN/OUT-PATIENT)

Criteria: External price referencing, internal price referencing, price agreements

Ministerial Decision on deregulated ATC

Price notification for medicines with deregulated price (IN/OUT-PATIENT)

"Free pricing"

***SUKL* is also in charge of price controls**

PRICE CONTROL

PRICING Wholesale/Pharmacy level

Wholesalers

Wholesale mark up of reimbursed products is limited by Ministerial Decision (1 scheme, see pharmacies) IN/OUT-PATIENT

Pharmacies

Maximum regressive mark up scheme set by ***Ministry of Health*** (Ministerial Decision). 1 scheme: combines wholesale and pharmacy mark-ups for reimbursed products. IN/OUT-PATIENT

REIMBURESMENT

State Institute for Drug Control

Task: Decision on the level and conditions of reimbursement

Criteria: External price referencing, internal price referencing, comparison of therapeutic effectiveness, safety, compliance and cost effectiveness and other relevant factors

Administrative procedure

Parties:

pharm. companies (MAH)

Consultation:

medical associations

H

Individual hospital purchase (hospital pharmacy)

Task: Bid pricing. Obligatory tenders (Act on Public Procurement) for non-private hospitals.

Criteria: Depending on the product or on the market situation of the medicine

Pharmaceutical formulary per hospital (owner)

Ministry of Health

Task: Definition and assessment of DRG groups. DRG reimbursement of acute bed care since 2008

Insurance funds

Task: Decision (agreements with hospitals) on use of specific medicines

Act on Public Health Insurance

List of items with reimbursement

Hospital only medicines (reimbursed)

OUT-PATIENT | IN-PATIENT

Denmark

The Ministry of Health +45 72269000 sum@sum.dk
Danish Health and Medicines Authority +45 72227400 sst@sst.dk

Flowchart of the pharmaceutical system

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 (Ha), OTC for limited free sale (Håndkøb, Hx) and OTC for general free sale (Frihandel, Hf)

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 PPP.
No permanent price control. Prices are set freely.
DKMA publishes the consumer price and reimbursement price.

The companies can change prices every two weeks
Prices are subject to subsequent control by the Danish Competition Council.

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 or groups of persons

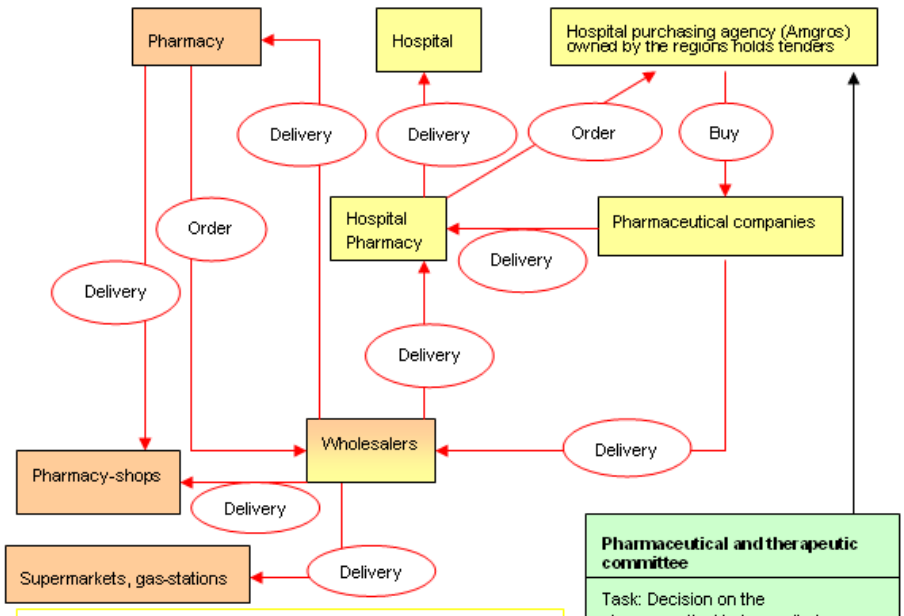
General conditional reimbursement. OTC pharmaceuticals prescribed for specific diseases or groups of persons

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).

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

SOTSIAALMINISTEERIUM

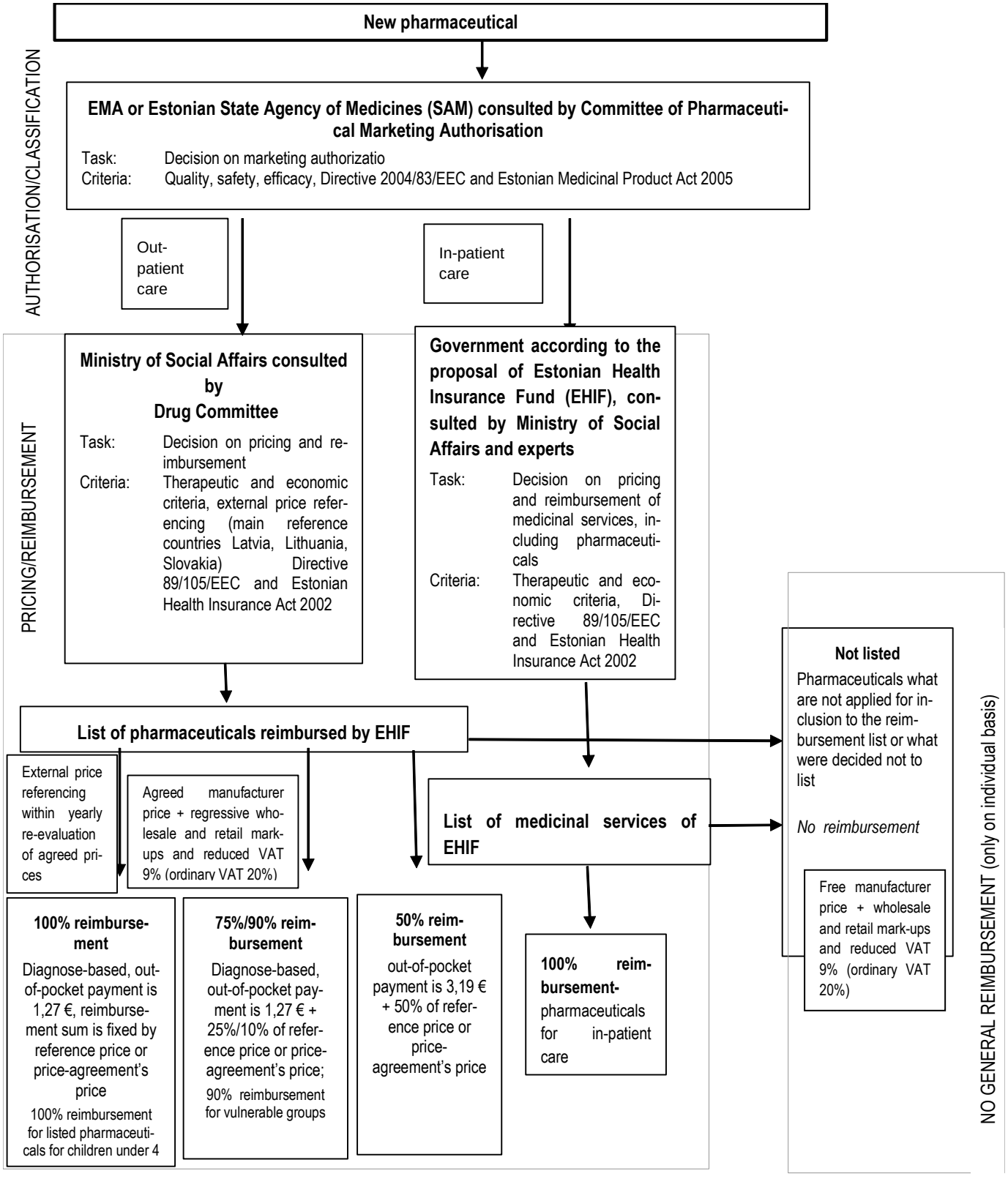
WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

ESTONIA

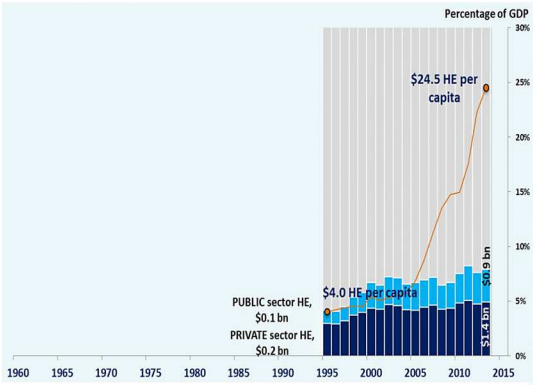
Ministry of Social Affairs (+372 6269 301, info@sm.ee)

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

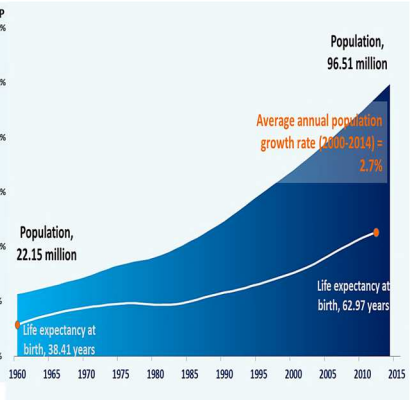


Ethiopia

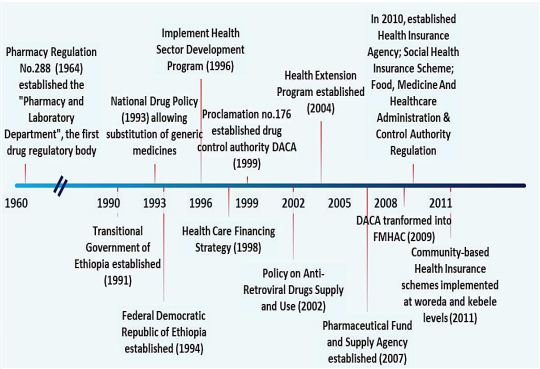
HEALTH EXPENDITURE INDICATORS



DEMOGRAPHY



HEALTH SYSTEM AND HTA DEVELOPMENT



SYSTEM IN 2015

Health legislation and financing	
Health system	Currently developing a three tiered system: Existing **public sector** provides tax- and donor-funded, mostly free, access to basic health care for the low-income formal sector workers, informal sector workers, the unemployed and the poor. Bismarck-type worker health insurance plans, called **Social Health Insurance (SHI)** will be mandatory for employees of formal sectors when launched. It covers 11% of total population. The government is currently piloting voluntary health insurance scheme called **community-based health insurance** for the rural & urban informal sector. The government provides financial incentives (25% of premium) to encourage uptake. At completion of roll out, the scheme aims to cover 85% of the Ethiopian population.
Main health legislation	**National Health Policy (1993)** recognizes access to essential medicines/technologies as part of the fulfilment of the right to health, with an emphasis on rural populations. **National Drug Policy (1993)** allows provision of essential medicines, generic substitution at pharmacy level, rights for local manufacturing and medicines importation, and other medicines related policies. **Health Care Financing Strategy (1998)** introduced health care reforms which included implementing revenue retention and use at health facility level, systematizing a fee-waiver system for the poor, standardizing exemption services, and setting user fees. **Health Extension Program (2004)** defined 16 free essential health services. **Regulation 191 (2010)** established the Ethiopian Health Insurance Agency. **Regulation 299 (2013)** established Food, Medicine, Health Care Administration and Control Authority with the authority to regulate the pharmaceutical sector.
Government role	Federal Ministry of Health (**FMoH**) develops national policy, laws, guidelines, standards and operational protocols. Regional Health Bureaus (**RHB**) implement national policy, regional laws standards, and operational guidelines, protocols and supervises hospital service delivery. Woreda Health Offices (**WorHO**) manage and coordinate operation of primary health care units in districts and neighbourhoods (kebele).
Financing	General tax revenue (for public) and donor and NGO funds for health services and medicines. Otherwise mostly out of pocket payments.
Private insurance	There are more than 10 private health insurance companies operating in Ethiopia. However, the benefit packages and coverage through these companies are not known from public sources.
Organization of and payment for health care services	
Hospital	In 2015, there were 224 hospitals: 68 private, 156 State-owned and 9 NGO supported hospitals. Public hospitals are allowed to open and operate a private wing to improve health workers' retention, provide alternatives and choices to private health service users, and generate additional income for health facilities.
Primary care	In 2015, there were 3,800 health centres and more than 15,000 health posts (all public) to deliver primary care. About 85% of the healthcare provision is provided by public healthcare facilities, while the remaining 15% is provided by the private sector. Private healthcare mainly focuses in the urban areas, where less than 15% of the population lives.
Pharmacy	Supply of medicines in the public and not-for-profit sector is provided by pharmacy unit/dispensary at each health care facility, city councils, and the Red Cross Society of Ethiopia, respectively. The private sector has three types of supply organisation: pharmacies run by pharmacy degree graduates, drug shops run by pharmacy diploma graduates or equivalent, and rural drug vendors run by nurses, health assistants, technicians.
Aspects of decision making for covering technologies and services	
Regulatory	The Food, Medicine and Healthcare Administration and Control Authority (**FMHACA**) is responsible for revising the **National List of Medicines** and regulatory functions in health, food, and medicine. The Pharmaceuticals Fund and Supply Agency (**PFSA**) handles supply chain management of the public sector.
Benefits package	Insurance beneficiaries are entitled to access inpatient, outpatient, delivery, and generic drugs included in **Ethiopian Health Insurance Agency Drug List**. The benefit package and medicines lists are developed with the support from WHO. There is no government regulation on pharmaceutical pricing or a system for pharmaco-economic evaluation.
Pricing	**Health services**: Public hospitals receives annual budget from Ethiopian Health insurance agency for inpatient services based on "department based grouping" which includes the cost of medicines; payments for hospital outpatient services are fee-for-service and the costs of medicines are reimbursed separately; Health centres receive annual budget based on capitation (inclusive of medicines cost. **Medicines:** PFSA manages procurement pricing. Generally, public sector pricing includes a 25% mark-up and is tax-exempted. Some medicines are exempted from standard policy (e.g. diabetes medicines have no mark-up, Cancer medicines have 50% reduction on standard mark-up). The government reimburses the costs of 690 medicines with 5% patient contribution. Health Program Medicines (e.g. HIV/TB, malaria, reproductive health) are supplied free of charge to patients. Private sector prices are highly variable.
Quality	FMHACA assesses quality of therapeutic goods at registration. Frequency of monitoring on quality of services and health goods is unknown. Post marketing surveillance of medicines is conducted annually.
Utilisation and budgetary manage-ment	**Centralised:** Ministry of Finance and Economic Development allocates tax revenue and donor fund to health budget. It monitors expenditures for drugs, medical supplies, and equipment at Federal level. **Decentralised:** At the regional level, health care budget is allocated by regional bureau of finance and economic development and delivery are augmented by donor funds or programs. NGOs support medicine supply by running their own programs and importing drugs, supplies, and medical equipment. Some NGOs distribute these goods to affiliated health institutions. Parastatal organizations cover medical expenses of their employees through direct reimbursement, providing health services through their own clinics and dispensaries, and purchasing health insurance for employees.
Monitoring and data governance	**Expenditure:** Ministry of Finance and Economic Development, Regional Health Bureaus regularly collects data; Donor and NGO reports for individual projects provide additional information. **Quality and safety of health technologies & services:** FMHACA manages data on Product Registration, Licensing, & Quality Assessment **Data and communication infrastructure:** Integrated Pharmaceutical Logistics System established in 2009, is used for recording and reporting at different levels of the supply chain.
Stakeholder participation	Donors are involved in financing of medicines. The Health Sector Development Program governance structure allows the participation of donors at each level (policy and technical level)

FINLAND

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Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

	OUT-PATIENT	IN-PATIENT

PRICING	**Pricing in the out-patient sector**
	Non-reimbursable pharmaceuticals can be priced freely
	Statutory pricing for reimbursable pharmaceuticals
	– Pricing procedures include:
	  o external price referencing
	  o internal price referencing
	  o health economic evaluations
	
	For generics: price linkage and reference pricing (RPS)
	
	Wholesale remuneration not controlled
	
	Pharmacy remuneration
	– Statutory regressive mark up
	– Different mark ups for prescription and non-prescription products
	
	VAT
	– Standard rate 24%
	– Reduced rate for medicines 10%
	
	Reforms valid from Jan 2016
	Generics:
	– Price of the first generic must be 50% (now 40%) lower than price of the originator. For packages including devices, −40% is still valid.
	– Price of the originator included in RPS has to be lowered nine months after generic entry into RPS (new regulation).
	– Mandatory price info of the lowest priced product in RPS by pharmacies.
		Pricing in the in-patient sector
		
		Price negotiations or tendering of pharmaceuticals.
		
		Each hospital has its own pharmaceutical formulary.

REIMBURSEMENT	**Reimbursement in the out-patient sector** **Positive list** **Reference price system (RPS)** – Since 2009 – Generic reference price groups: same active substance, quantity and pharmaceutical form, closely corresponding package size **Co-payments** Basic reimbursement 65% Lower special reimbursement 35% Higher special reimbursement €3 per purchase After reaching the annual limit to co-payments (€612 in 2015) €1.5 per purchase **Mechanisms for vulnerable groups** Better reimbursement rate for patients with chronic and severe diseases **Reforms valid from Jan 2016** – Implementation of an €45 annual threshold to be paid in full by a patient before receiving reimbursements. Concerns only patients aged 18 years or more. – Basic reimbursement increased to 40% (now 35%). – Need of restricted reimbursement in RPS re-evaluated and abolished if redundant nine months after generic entry into RPS. – Two-year time limit in the criteria for special reimbursement status abolished.	**Reimbursement in the in-patient sector** Hospital pharmacies issue medicines only to their own wards and departments. Pharmaceuticals used in hospitals are included in the patient's daily charge.

In 2016, additional savings of €50 million (about 4%) on reimbursement costs must be generated. Measures to reach that have not yet been published.

FRANCE

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

New medicine

PPRI Pharmaceutical Pricing and Reimbursement Information

AUTHORISATION/ CLASSIFICATION

European Medicines Agency (EMA)
or
French Health Products Safety Agency / *Agence nationale de sécurité du médicament et des produits de santé* (ANSM)

Task: Decision on authorization and registration
Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Public Health Code

French Health Products Safety Agency / *Agence nationale de sécurité du médicament et des produits de santé* (ANSM)

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

ANSM is also in charge of **pharmacovigilance**

EVALUATION

French National Authority for Health / *Haute Autorité de santé (HAS)*

Task: Health technology assessment and medico-economic assessment (only for innovative drugs)
Criteria: - HTA : Clinical benefit and therapeutic interest (SMR), level of improvement of clinical benefit (ASMR)
- Medico-economic: incremental cost-effectiveness ratio (RDCR)

PRICING & REIMBURSEMENT

OUT-PATIENT

PRICING

Pricing Committee (CEPS)

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

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%)

Ministry of Health and Ministry of Finance

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

IN - PATIENT

REIMBURSEMENT

List of authorised medicines in hospital

Drugs on the top of DRGs

Drugs included into the DRGs

PRICING

Pricing Committee (CEPS)

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

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

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

Pharmacies

Pharmaceutical and Therapeutic Committee per hospital

Task: Decision on use of medicines

Hospitals

POST AUTHORISATION

French Health Products Safety Agency /
***Agence nationale de sécurité du médicament et des produits de santé* (ANSM)**

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

OUT-PATIENT

IN - PATIENT

GHANA

Ghana National Drugs Programme, Ministry of Health and +233302661670, gndp@ghndp.org
Medicines Transparency Alliance Ghana, +233504529867, info@metaghana.net
WHO Country Office for Ghana

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

New Medicines

Process as outlined below applies to all medicines. Single source medicines may go through price negotiation, prior to listing on the health insurance medicines list.

SELECTION

FDA Registration
To review the safety profile of the medicine and to provide the FDA registration number and classification

National Medicines Selection Committee
To make decisions on the application of the medicine for clinical use

Evidence Summaries Subgroup
To review the evidence for cost-effectiveness of the medicine or other health technology

Stakeholder Consensus and Ministerial Approval

STG
To provide guidance on treatments for diseases of common occurance

EML
To list essential medicines by levels of care
- National Health Insurance Medicines List
- Emergency Medicines List

Stakeholder consensus on EML with levels of care

Ministerial Approval
To provide political support for the STGs and EML and endorse as national policy

PRICING

EML with Recommendations for Reimbursement

National Health Insurance Medicines List (NHIML)
To determine prices for reimbursement under the public social health insurance scheme

Mix of pricing strategies in New Pricing Policy

VAT Exemption Policy
on selected medicines and pharmaceutical manufacturing inputs

Evidence to inform policy
Informed by Evidence from
-Previous price surveys
-Price and availability data from public, private and mission sectors
-Price and availability data for child medicines from public, private and mission sectors
-Price component analysis
-ABC analysis

NHIA Benefits Package (defined by Government policy in consultation with stakeholders)

REIMBURSEMENT

G-DRGs
Ghana Diagnosis Related Groups guiding reimbursements for services

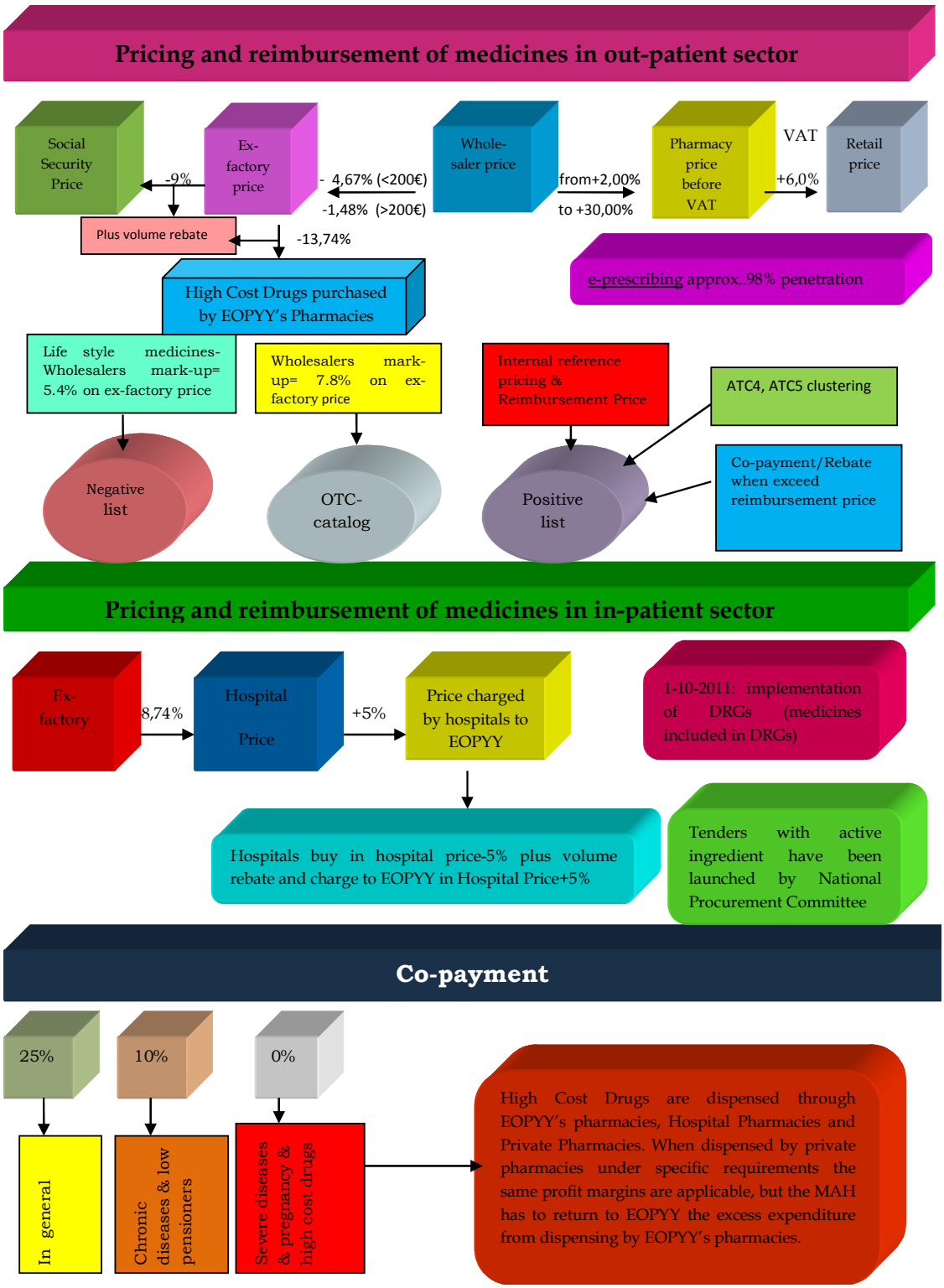
Exemptions
To finance services provided under exemption policies e.g. Maternal Exemption Policy

Capitation
To finance services under Provider Payment Mechanisms

Patients (clients or beneficiaries) receive services and medicines at several levels of care (with referrals if necessary) via the three modalities above.
Patients only pay for services and medicines not covered by insurance.

GREEK HEALTHCARE ORGANIZATION FOR THE PROVISION OF HEALTHCARE SERVICES (EOPYY)

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



Litsa Panagiota, Kani Chara, Kourafalos Vasileios
Vienna, 12-13 October 2015 for PPRI conference

HUNGARY

Pharmaceutical pricing and reimbrsement polices in the in- and out-patient sector

Pricing

Pricing regulations apply for only reimbursed drugs in the in- and out-patient sectors. Free pricing prevails outside the reimbursement system. VAT: 5% for all medicines

Pricing in the out-patient sector

Pricing at ex-factory level

- *External reference pricing:* EU 28 + Switzerland + Norway + Iceland
- *Internal reference pricing* - therapeutic groups and active substance groups with fixed prices

  This applies for generic drugs and drugs with similar efficacy.

  Maximum amount of reimbursement for each drug in the group is based on the lowest priced medicine (with a minimum required DOT turnover).

  Required cut down prices for generic drugs:

  1st generic drug – 40%,

  2nd generic drug – 20%,

  3rd generic drug – 10%,

  4-6th generic drugs – 5%,

  afterwards 0,3 Euro Cent.

  Biosimilar drugs: yearly tendering process, the cheapest medicine is required to prescribe for the new patients. Required cut down prices for biosimilar drugs: 1st – 30%; 2nd – 10%; 3rd – 10%
- *Sales representative registration fee* ~ 3100 EUR/capita/year
- *Cost-effectiveness requirement for innovative medicines*

  (ICER ≤ 2-3 x GDP per capita)

Pricing at wholesale level

- *Strictly regulated regressive margins*

  8% - 6,5% - 5% - 4,4%, depends on the ex-factory price
- *Statutory pricing* according to Decree of the Ministry of Health 5/2007

Pricing at pharmacy level

- *Strictly regulated regressive margins*

  27% - 23% - 20% - 18%, depends on the wholesale price
- *Co-payment* - Patients should pay 1 EUR for 100% reimbursed drugs
- *OTC products have free pricing*
- *Statutory pricing according to Decree of the Ministry of Health 5/2007*

Pricing in the in-patient sector

- *Centralised or hospital tendering* is required for some medicines

  High-cost oncology and biological drugs (item-based reimbursement)

  Separate budget for haemophilia and HCV infection

  Tenders are valid for 1-3 year.
- *Pharmaceutical companies* may offer discounts to hospitals or to NHIFA (National Health Insurance Fund Administration).

Main acts

- Decree of the Ministry of Health 32/2004 (IV.26.) Legal framework for price setting
- Decree of the Ministry of Health 5/2007 (I.24.) wholesale and pharmacy mark-up, price margins
- Act XCVIII of 2006 on the Safe and Economic Supply and Distribution of Medicines and Therapeutic Medical Devices

Links

http://www.oep.hu/pupha

http://www.oep.hu/iframes/gyogyszerkereso

http://www.oep.hu/felso_menu/szakmai_oldalak/publikus_forgalmi_adatok/gyogyszer_forgalmi_adatok

Reimbursement

Reimbursement in the out-patient sector

Positive list

Positive list publicly available for reimbursed drugs.

Reimbursement categories

- *Without restrictions* – normative reimbursement

  25%, 55% and 80% reimbursement provided to patients
- *With restrictions* – binded to therapeutic indication and specialization

  50%, 70%, 90%, 100% reimbursement provided to patients
- *Special medicines* for haemophilia and HCV infection

  100% reimbursement provided to patient
- *Vulnerable groups*

  Named patient program:

  Fairness reimbursement for seriously ill persons without reimbursed therapy or in off-label indications. Decision is based on individual cases.

  Patients with Prescription Exemption Certificate:

  Fairness reimbursement for socially indigent persons. Decision is based on individual cases.

Special requirements

- *Generic drugs and drugs with similar efficacy are labelled to therapeutic or active substance groups*
- *Price volume agreements on medicines*

  ~ This provides a secure cap for budget overspending for certain drugs or indications.

  ~ Simple payback on every unit sold

  ~ Outcome contract which stipulates that the Marketing Authorization Holder (MAH) pays back a pre-determined amount, if the real-life effectiveness of the product falls behind the clinical efficacy on which its reimbursement dossier has been based.
- *Reimbursement payback for all pharmaceutical companies*

  ~ overspending-based payback in case of defined budget deficit
- *Reimbursement payback for all wholesale companies*

  2,5% payback
- *Statutory 20%* payback on sales revenue
- *Statutory 10% additional payback* on sales revenue for drugs being reimbursed for 6 years without competitors

Reimbursement in the in-patient sector

- *high-cost oncology and biological drugs (item-based reimbursement)* 100% reimbursement category for expensive medicines that are used in hospitals. Reimbursements of these drugs are binded to therapeutic indication and paid directly by the Health Insurance Fund Administration.
- There is no *co-payment* for hospital medicines.
- *The diagnoses-related group* (DRG) system covers all the costs of acute hospital care, including pharmaceuticals.

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

Iceland

Icelandic Medicine Pricing and Reimbursement Committee
Telephone: +354 553 9000 e-mail: verd@lgn.is

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 authorization and registration
Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Icelandic Medicines 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 medicinel fulfills the criteria of medicines
Criteria: Directive 92/56/EEC, Icelandic Medicines Act, prescription ordinance etc.

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

VIGILANCE

PRICING wholesale level

Icelandic Medicine Pricing and Reimbursement Committee (IMPRC)

Task: Calculation of Nordic average price for general medicines
Criteria: External price referencing

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

Task: Calculation of Nordic lowest price for hospital/high cost medicines
Criteria: External price referencing

Wholesaler | Free mark up at Wholesale level

PRICING Pharmacy level

Pharmacies

Maximum mark up set by the **Icelandic Medicine Pricing and Reimbursment Committee** (2 different steps: one for a 11% plus 5,86 € fixed fee and the second step 2% with 13,86 € fixed fee (depending on Wholesale price).

VAT: 24%

University Hospital

Tenders or Negotiated Procedure regarding medications, for all hospitals in Iceland are organized by the University Hospital

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

REIMBURSEMENT

General reimbursment

Icelandic Medicine Pricing and Reimbursement Committee (IMPRC)

Task: Decision on the reimbursement status

Criteria: Reimbursement in the Nordics,
Price is relative to efficacy and in comparisons to already reimbursed drugs,
Budget impact

National Reimbursement Code set by the Ministry of Health paid by the National Insurance.

Fully reimbursed – no copayment by patient
Some medicines for patient who are terminally ill, patients with kidney problems and for patient with psychiatric problems

Co-payment system
Co-payment is a proportion of the annual usage
Step-wise increase in co-payment by the Health Insurance up-to a full reimbursement

Individual reimbursement

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

Icelandic Medicine Pricing and Reimbursement Committee (IMPRC) in cons. with **University Hospital and Health Insurance**

Task: Decision on reimbursement status of hospital/high cost medicines
Criteria: Price relative to efficacy
Budget impact
Clinical evaluation done by the University Hospital
Clinical guidelines done by the University Hosptial
Evaluations within fixed budget done by the Health Insurance

Fully reimbursed – no copayment by patient
Hospital and some high cost medicines

Use in hospitals

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

Task: Decision on use of medicines

No co-payment for patients

Pharmaceutical formulary per hospital

Sept. 2015

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

PPRI
Pharmaceutical Pricing and Reimbursement Information

IRELAND

Pharmaceutical System in Ireland

Pricing of Pharmaceuticals

The IPHA (Irish Pharmaceutical Healthcare Association) Agreement continues at the moment with a guiding reference to prices in specified EU Member States – Austria, Belguim, Denmark, Finland, France, Germany, Netherlands, Spain and United Kingdom. However, the statutory foundation for Pricing rests in the Health (Pricing & Supply of Medical Goods) Act 2013 which introduced Reference Pricing.

New Chemical Entities

NCE are referred for a Health Technology Assesment to assist HSE decisions.

Product Approval

Approved products are added to the Reimbursable List. This includes the GMS and Community Drugs Schemes and also High Tech Arrangements.

Medicines Management Programme

In 2013 the multi-disciplinary Medicines Management Programme headed by the National Medicines Information Centre (NMIC) and the National Centre for Pharmacoeconomics (NCPE) in collaboration with the HSE-Primary Care Reimbursement Service (HSE-PCRS) was established.

Aims of the MMP include

- Ensuring that patients have access to the essential medicines that they need
- Facilitating more cost-effective prescribing with initiatives in relation to high-cost medicines
- Ensuring value for money in relation to medicines and
- Enhancing evidence based prescribing and optimising patient safety through a reduction in medication related adverse events.

Preferred Drugs Initiatives

The Preferred Drugs Initiative, which identifies a single 'preferred drug' within a therapeutic drug class, offers prescribers useful guidance on selecting, prescribing and monitoring a drug for a particular condition. For each Preferred Drugs evaluation, useful **'Prescribing Tips and Tools'** and 'Information for patients' are also available to download.

1. Preferred Drugs for PPIs and Statins
   PPI = Lansoprazole,
   Statin = Simvastatin
2. Preferred Drugs for SSRIs and SNRIs
   SSRI = Citalopram
   SNRI = Venlafaxine
3. Preferred Drugs for ACE Inhibitor and ARBs
   ACE Inhibitor – Ramipril
   ARB = Candesartan
4. Preferred Drugs for Urinary Incontinence & Overactive Bladder = Tolterodine ER
5. Preferred Drugs for Oral Anticoagulants = Warfarin and where Warfarin is not suitable Apixaban

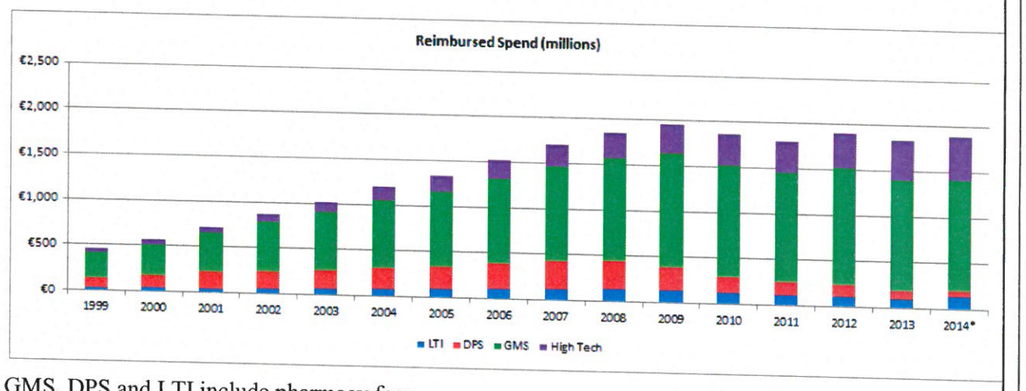
Prescribing and Cost Guidance

Focus primarily on the associated costs of particular treatments, as well as providing useful information for prescribers and other healthcare professionals regarding the prescribing, monitoring and reimbursement of these treatments.

1. Prescribing & Cost Guidance for Inhaled Medicines for Asthma and Chronic Obstructive Pulmonary Diseases (COPD)

Development of pharmaceutical expenditure in the last 5 available years

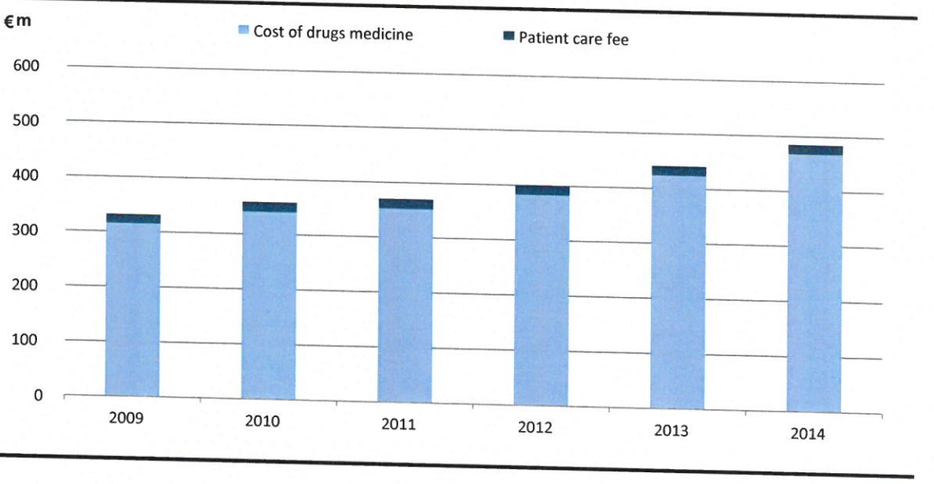
Reimbursement Costs: 1999 to 2014



GMS, DPS and LTI include pharmacy fees

Expenditure on High Tech Drugs Expenditure on the scheme was €485 million in 2014, representing almost 50% increase when compared with 2009. While the patient care fee has remained relatively stable at around €17 million a year, expenditure on drugs and medicines has increased from €315 million in 2009 to €468 million in 2014.

High Tech Drug Costs 2009/2014



New Initiatives in 2014/2015

- **Core Lists for each of the Long Term Illness (LTI) conditions**
- **Expanding eligibility to include free GP Services to all under age 6 years and over 70 years**
- **Cycle of Care – Type 2 Diabetes**
- **Online browser for annual dataset submission Asthmatic Patients**

Key

GMS – General Medical Services Scheme – This provides for people who are unable without undue hardship to arrange general practitioner medical and surgical services to receive a medical card for free general medical services. Medicinal Items are prescribed from a specified Reimbursement List. Prescription Fee applies.

DPS – Drugs Payment Scheme – This is a co-payment scheme for people who do not have a Medical Card – an individual or family has now to pay no more than (currently set at) €144.00 in a calendar month for approved drugs, medicines and appliances.

LTI – Long Term Illness Scheme – Drugs and Medicines are provided free of charge to patients who suffer from any of the 16 listed Illnesses – Mental Handicap, Hydrocephalus, Cerebral Palsy, Muscular Dystrophy, Haemophilia, Diabetes Mellitus, Diabetes Insipidus, Epilepsy, Multiple Sclerosis, Parkinsonism, Cystic Fibrosis, Phenylketonuria, Acute Leukaemia, Mental Illness (Under 16yrs of age), Spinal Bifida and Conditions arising from the use of Thalidomide

High Tech – For the supply and dispensing of High Tech medicines through Community Pharmacies.

HSE – Health Service Executive

Pharmaceutical Pricing and Reimbursement Policies in the In- and Out-patient Sectors in Kenya

Ministry of Health, Afya House, Cathedral Road, Box 30016-00100, Nairobi, Kenya +254 20 2717077 www.health.go.ke
Mbindyo R[1], Cheruiyot S[2], Siyoi F[3], Forshaw C[4]
(1) WHO Country Office – Kenya, (2) Ministry of Health - Kenya, (3) Pharmacy & Poisons Board – Kenya and (4) DANIDA Health Sector Programme Support - Kenya

AUTHORIZATION & CLASSIFICATION

Ministry of Health: Pharmacy and Poisons Board (PPB)

Task: Decides on Marketing Authorization and Categorization (Scheduling) Criteria: Quality, Safety & Efficacy Law: Pharmacy and Poisons Act, Cap. 244/1957

Reforms: Establishment of a Food & Drugs Authority and Pharmacy Council (underway)

- Draft Policy and Bill are being developed to implement this reform

PRICING

Aspect	Public Sector	Faith-Based Sector (FBO)	Private Sector
Selection (for financing)	MOH - National Medicines & Therapeutics Committee (NMTC) Task: Updating Kenya EML & Guidelines Criteria: Cost-effectiveness (using WHO Model List as basis) Law: No law on EML development/use	NO legal requirement for FBO or private sector to apply the national EML.	
		However, the FBO sector largely aligns with the KEML - may make some modifications (e.g. when EML is considered out of date) • Adapted by Mission for Essential Drugs & Supplies (MEDS) Formulary Committee	Some private hospitals use KEML for procurement & prescribing - mostly as a cost- effectiveness tool (not mandatory)
Formulary (for procurement)	Kenya Medical Supplies Authority (KEMSA) formulary (extracted from the KEML & based on available funds)	Adapted from KEML based on annual review of requirements of FBO facilities. May also supply non-formulary items (ad-hoc pricing)	Individual hospitals may develop formularies as a tool for internal cost control
Pricing policies for medicines	NO explicit pricing policy for medicines countrywide. However, indirect pricing approaches are pre-determined through the applicable procurement and supply system, which is linked to financing arrangements • Some medicines for priority health programmes are provided for free by the Government (through KEMSA) to **ALL** sectors. Target conditions: HIV, TB, malaria, immunization, maternal & child health		
VAT	Kenya Revenue Authority (KRA): NO VAT on medicines - but importers have to seek exemption for each consignment **Law**: *Value Added Tax Act (Cap. 476)*		
Manufacturers	No regulation of ex-factory prices. Prices usually depend on the procurement agent and the procurement methods they apply (as below). Tendering is the most common approach.		
Procurement Agent	KEMSA: a state agency **Law**: *KEMSA Act No.20 of 2013*	MEDS: A non-profit trust established by the churches	Individual wholesalers (local or international). No law on wholesale vs retail business
Procurement method(s)/ Legislation	Generic procurement is applied routinely by KEMSA & MEDS No law applies but Kenya National Pharmaceutical Policy (KNPP 2012) supports/encourages generic procurement		Mostly brand-name
	Open tender (mandatory), international if necessary for adequate competition. **Law:** *Public Procurement & Disposal Act 2005* (Cap 412A) (Procurement prices are published online for transparency)	Restricted tender to pre-qualified suppliers (international/national). Pooled procurement with other FBOs (e.g. Uganda, Zambia) - select items. No applicable legislation	Direct procurement by facilities & retailers as feasible. No applicable legislation
Wholesale Remuneration/ Legislation	Public health medicines issued for free to facilities (all sectors) through KEMSA & MEDS. Agreed fees for distribution (paid by govt. unit or donor)		No wholesaler role in public health medicines.
	Cost + 8% mark-up. Partial cost recovery (e.g. staff costs paid directly by Government). NO applicable law and NO price referencing	Cost + regressive mark-up (5 -22%). Full cost recovery (availability & prices usually higher than KEMSA) No price referencing	Average mark-up 25%. Discounts of 2-3% for prompt /reliable (cash) payment.
Pharmacy remuneration (Retail pricing)	NO law/guidance on pricing/margins to patients (all sectors). No legal requirement to pass price benefits onto patients However, facilities are expected to pass on the full benefit of any free medicines provided by Government		
	'Course-of-treatment' pricing common in public & FBO facilities.		Cost + mark-up (each med.)
	NO legislation on pricing to patients. Waivers may apply for some patients	Waivers may apply (for approx. 10% who cannot afford to pay)	No waivers, discounts common
Dispensing/ other fees	Not applicable - public officers cannot charge patients fees	Not applicable. FBO staff are salaried - no extra charges to patients	No legislation on dispensing fees. Average mark-up 30%

Pricing in the out-patient sector

Uninsured: Medicines paid out-of-pocket if accessed through a health facility. The final patient price depends on the sector (e.g. public/private/FBO)

No policies/mechanisms at the **interface** between out- and in-patient sectors. However, any government-subsidized medicines are also subsidized in all sectors

Pricing in the in-patient sector

In all sectors, the **uninsured** pay out-of-pocket for the full cost of hospitalization (including medicines). No special pricing arrangements apply for in-patient medicines.

REIMBURSEMENT

Reforms: The most desirable & comprehensive reforms relate to overhaul of the healthcare financing architecture – particularly the policy and institutional arrangements (see below)

Aspect	Public	Private
Institutions	National Health Insurance Fund	Private insurers (#20 approx.)
Task	Collection & disbursement of mandatory health insurance contributions	Provision of health insurance services
Law	*NHIF Act No 9 of 1998*	Operate independently – only governed by a general insurance regulator (prudential compliance)
Benefits overview	NHIF reimburses the full cost of treatment (inpatient & outpatient) in over 400 accredited **Public**, **FBO** and **some private** health providers across the country	Reimburse the full cost of treatment (inpatient & outpatient)
Exclusions	NHIF does not exclude any disease	Private insurers may have exclusions
Medicines Coverage	No special provisions on medicines coverage; No positive/negative lists	No provisions on medicines coverage; No positive/negative lists
Provider selection	Each insurance provider independently determines 1) eligibility criteria for providers and accredits them to offer services; and 2) the reimbursement rates for services and products. Some private providers have pursued international accreditation	
Coverage	Overall insurance coverage is only 17% (primarily NHIF); No specific provisions for medicines	

Reimbursement in the out-patient sector

Both NHIF & Private insurers reimburse full cost of prescribed medicines (up to specified spending limits). For private providers, the NHIF rebate is so low that drug costs are not considered.

Reimbursement in the in-patient sector

No positive or negative lists. The full cost of medicines is reimbursed for in-patients (up to specified spending limits).

It is likely that the retail costs of drugs in Kenya are inflated with margins at each resale level, set at a minimum of 30% by law, with entrenchment of middle men, i.e. wholesalers, also by law. This has a net effect of keeping prices high in retail pharmacies, which is where most people purchased medicines due to persistent stock outs in public facilities.

REFORMS

- Establish legal mandates for the following national stewardship functions and establish public (state) institutions to execute them:
  - Regulate pricing and reimbursement and ensure overall economic regulation in the sector - **Health benefits & tariffs regulator**
  - Regulate the quality of care and accredit qualifying eligible health facilities (public, FBO, private) - **Care quality regulator**
  - Mandate evidence-based therapeutics guidance (including essential lists) as statutory tools for prioritizing public financing - ***HTA agency***
- The MOH is spearheading the development of a healthcare financing policy and strategy. A critical aspect (currently missing) is coherent pricing and reimbursement policies, which should prioritize generic prescribing and the application of evidence to guide decisions. Advocacy is ongoing towards embedding the above stewardship structures into the health financing policy reforms.

LITHUANIA

National Health Insurance Fund under the Ministry of Health of the Republic of Lithuania

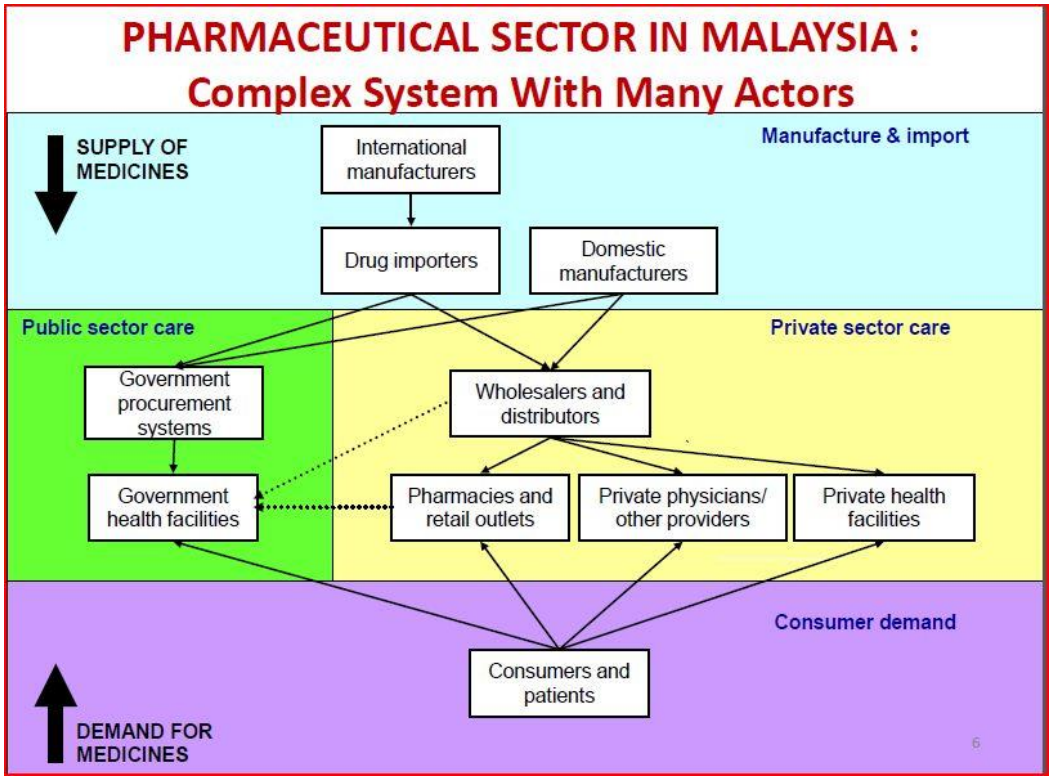
(+37052364100, vlk@vlk.lt)

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

	OUT- PATIENT	IN - PATIENT
PRICING at ex-factory level	**Pricing in the out-patient reimbursement** Statutory pricing Pricing policies for reimbursable medicines External price referencing: Declared manufacturer price is compared with 95 % of the average manufacturer prices in reference countries (8 countries) The first generic is required to be priced 50% below the originator. The second and the third follower required to set their prices 15% lower than the cheapest product and the following ones need to be cheaper The first biosimilar is required to be priced 30% below the originator. The second and the third follower required to set their prices 10% lower than the cheapest product and the following ones need to be cheaper	**Pricing in the in-patient sector (Public hospital)** **Negotiations Committee** under the Ministry of Health Price negotiations Expensive hospital medicines included in the List of Centrally Procured Medicines and Medical Devices (centrally purchased by the NHIF) Free pricing Hospital medicines not included in the List of Centrally Procured Medicines and Medical Devices
PRICING at wholesale and pharmacy level	Statutory pricing Wholesales Regressive margins Pharmacies Regressive margins VAT: 5% for reimbursable medicines, 21% for non-reimbursable medicines	Tendering Price negotiations Expensive hospital medicines included in the List of Centrally Procured Medicines and Medical Devices All hospital medicines Statutory margins are not relevant, unless products are from community pharmacy VAT: 5% - reimbursed medicines 21% - not reimbursed medicines
REIMBURSEMENT	**Reimbursement in the out-patient sector** Positive list (500 active substances included on positive list) Reference price system (RPS) ATC 5 & 4 level (Lowest price of medicine in reference group) Percentage co-payment 10%, 20%, 50% of reimbursed rate, depends on severity of the disease (the more severe, the higher the reimbursement rate), 100% reimbursed medicines has co-payment until 1.5 EUR (depends on retail price, exception Insulins) Mechanisms for vulnerable groups 100 % reimbursed rate for all reimbursed medicines for children, disable patients Reforms MEA: price volume, expenditure cap, risk sharing E-prescriptions system	**Reimbursement in the in-patient sector** Expensive hospital medicines included in the List of Centrally Procured Medicines and Medical Devices (26 active substances) Out-patient list also relevant for in-patient sector Medicines are integrated in the lump sum (with some exceptions) which can be generated for reimbursement Hospital formularies are not centralized Pharmaceutical formulary per hospital No co-payment in hospitals Reforms price negotiations with manufactures or wholesalers strategy for the acquisition of patented expensive hospital drugs

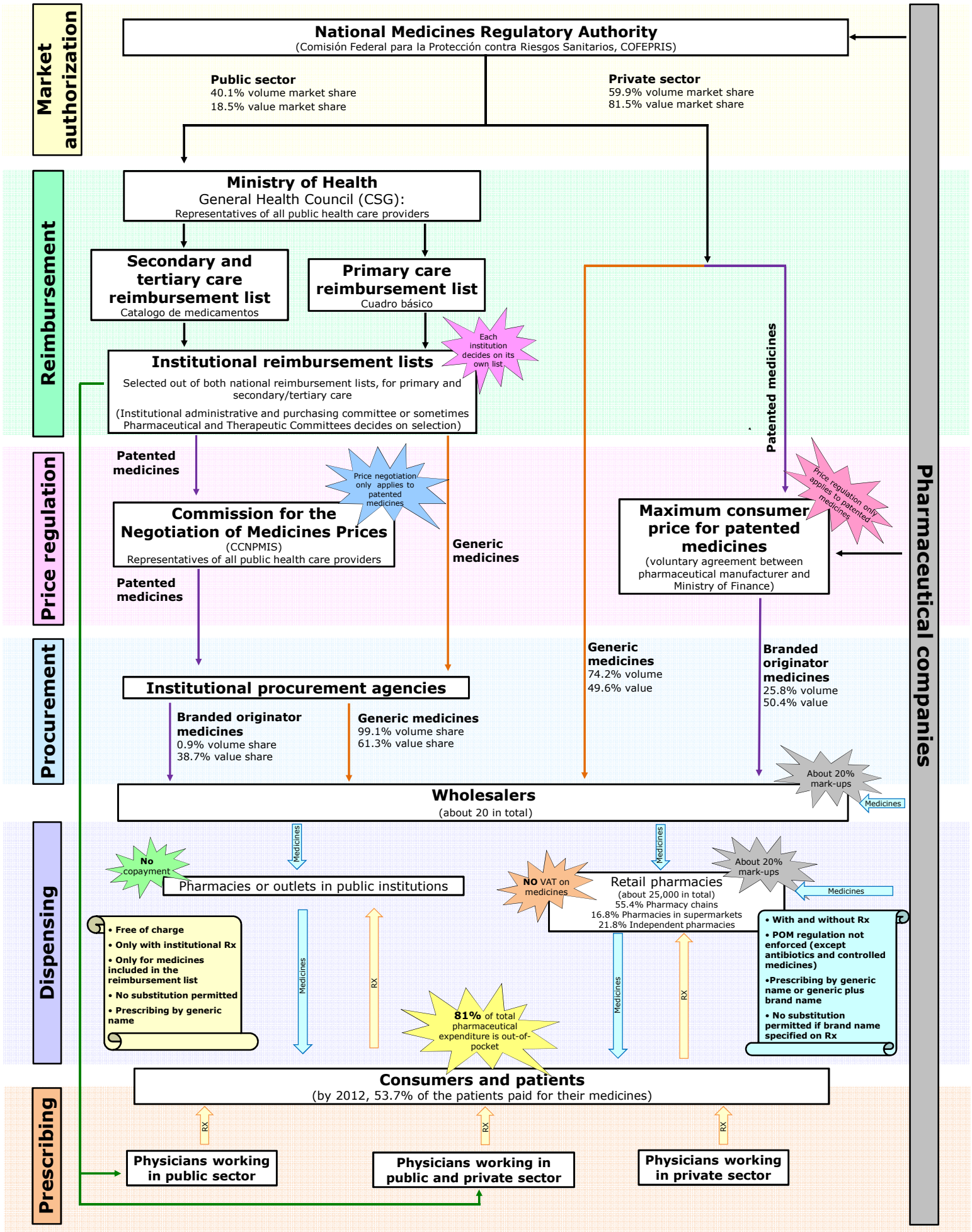
MALAYSIA

Kementerian Kesihatan Malaysia & University Technology MARA, Yahaya Hassan, Noorizan Abd. Aziz, Nur Liyana Zainal Bahrin, Nur Wahida Zulkifli, Azlan Ahmad. Tel:603-32584647; Email: nurwahidazulkifli@gmail.com



- **Malaysian's healthcare system consists of GOVERNMENT and PRIVATE institutions.**
- **As for government healthcare facilities, they are functioning through a SUBSIDISATION SYSTEM. Government will subsidise the cost incurred for the healthcare treatment of the patients. Our public need to pay just a small amount as registration fees while the rest will be borne by government. The subsidy comes from country's revenue and taxpayers' money.**
- **As for the government healthcare institutions, they have been operating using a NATIONAL DRUG FORMULARY and every institution conduct their service based on the allocation given by the government. The allocation were given based on certain criteria such as number of bed, specialty services offered and number of patients enrolled.**
- **As for the private institutions, costs incurred during treatment are solely under the PATIENTS' RESPONSIBILITY. They might opt for payment under company's coverage, personal insurance scheme or from their out-of pocket money.**
- **As for current practice, our public healthcare institutions have not been any of the reimbursement policy.**

Pharmaceutical Pricing and Reimbursement in Mexico*



*Elaborated by Veronika J Wirtz, National Institute of Public Health, Mexico; September 2011. Updated by Yared Santa-Ana-Tellez, Utrecht University, The Netherlands; September 2015

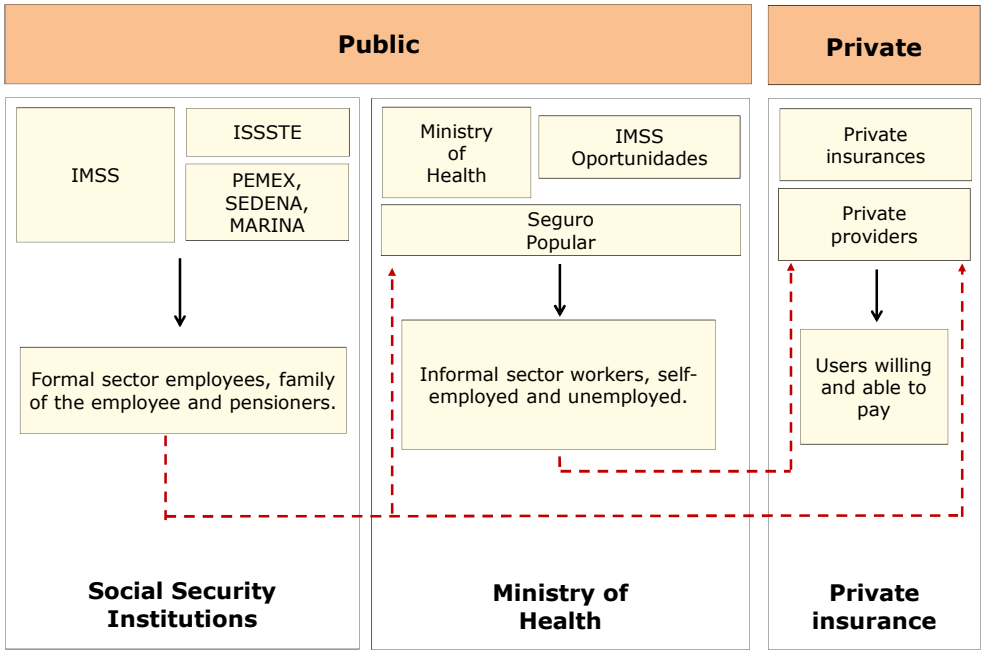
Consulted data sources:
González Pier E, Barraza Lloréns M. Trabajando por la salud de la población: Propuestas de política para el sector farmacéutico. Versión para el diálogo. Ciudad de México: Funsalud. 2011.
Fundación Mexicana para la Salud. Descripción del sector farmacéutico en México, 2012. Ciudad de México: Funsalud. 2013

Mexican Health System Structure

Health care provided by segmented networks, each institution employs its own staff, without synergies and high duplication. Employment status determines the health provider.

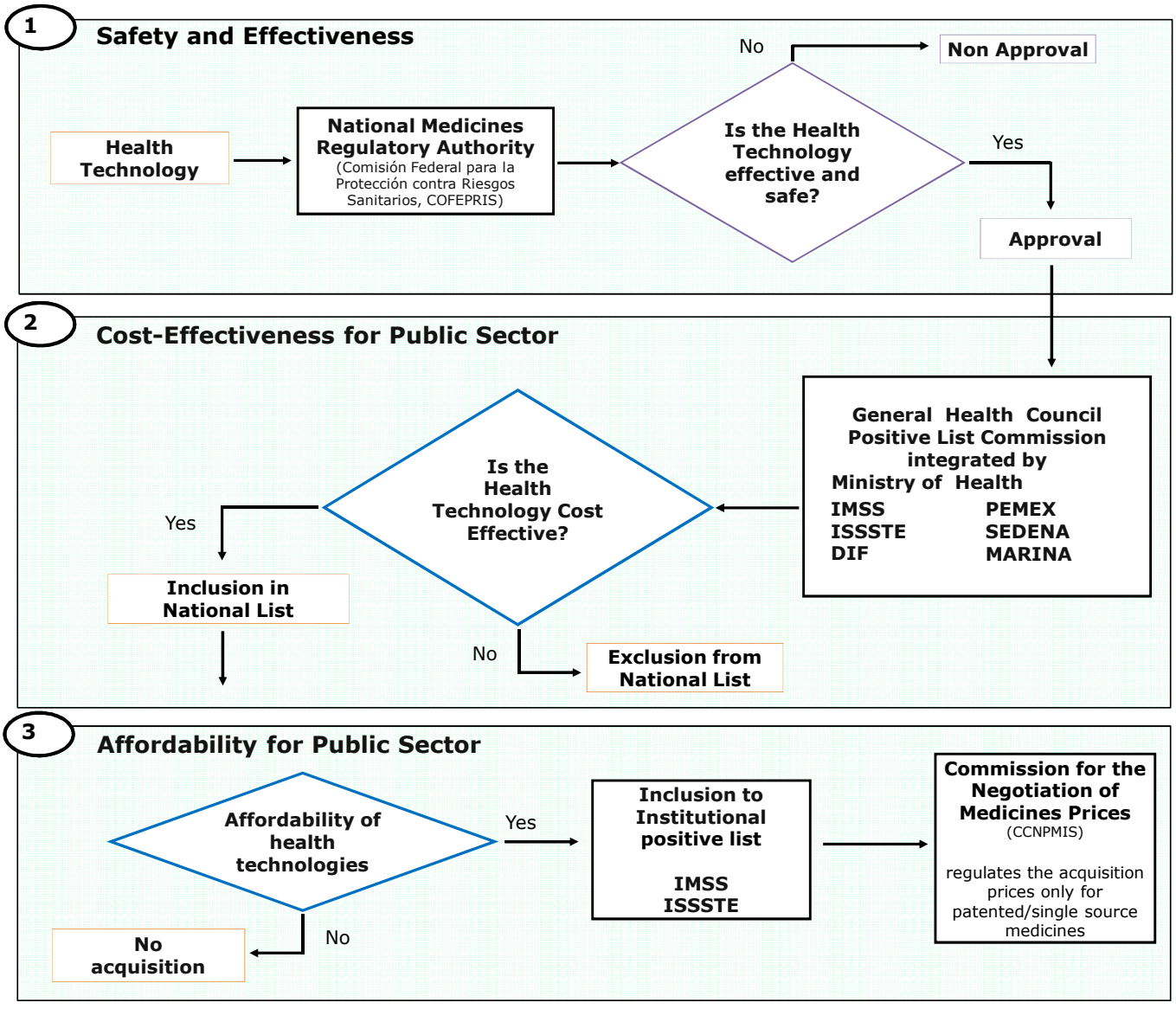
The largest providers are:

- Instituto Mexicano de Seguridad Social (IMSS), for people in formal employment.
- Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE), for civil service employees.
- Seguro Popular covers remaining families



Mexican Health System organization, diagram based on Gómez Dantés, 2011

Reimbursement decision making in the Mexican public sector‡



‡Elaborated by Yared Santa-Ana-Tellez, Utrecht University, The Netherlands; Fernando Alarid, University of Minnesota, and Itzel Rivas-Oropeza Mexican Institute of Social Security, Mexico September 2015

Consulted data sources:
OECD (2015), OECD Economic Surveys: Mexico , OECD Publishing. http://dx.doi.org/10.1787/eco_surveys-mex-2015-en
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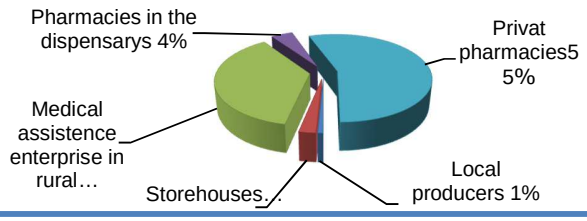
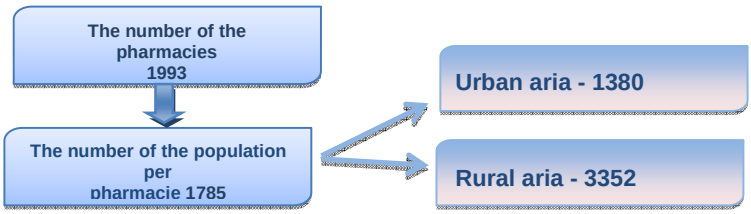
Pharmaceutical system in the Republic of Moldova

The Republic of Moldova is a landlocked country in Eastern Europe, bordered by Romania to the west and Ukraine to the north, east, and south. It declared independence in 1991 as part of the dissolution of the Soviet Union. Moldova is a member state of the United Nations, the Council of Europe, the World Trade Organization (WTO), the Organization for Security and Cooperation in Europe (OSCE), the GUAM Organization for Democracy and Economic Development, the Commonwealth of Independent States (CIS) and aspires to join the European Union. Its population is 3 557 634.

Types of the pharmaceutical enterpises

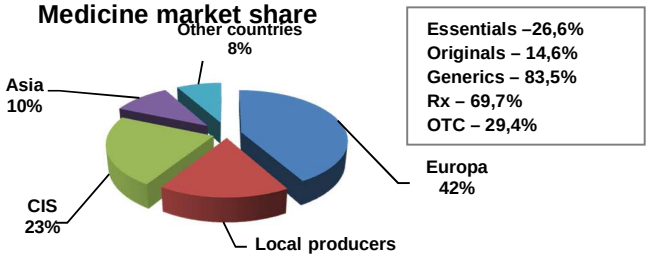


Distribution of pharmacies



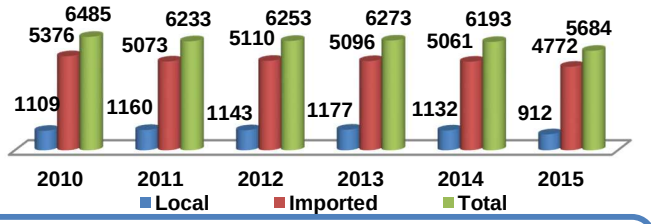
- The most of the pharmaceutical enterprises are located in the urban area.
- Rural area is assured by the pharmaceutical services through medical assistant sections.
- The suppliers (45) importe the medicines from 57 countries. They provide the hospital sector (state procurements) and private pharmacies.
- The local producers cover 17% of the pharmaceutical market. 26% from their portfolios are essential medicines. The most representative groups are D, J, A, C, N and R. Moldavian producers export their medicines in 11 countries.

Medicine market share



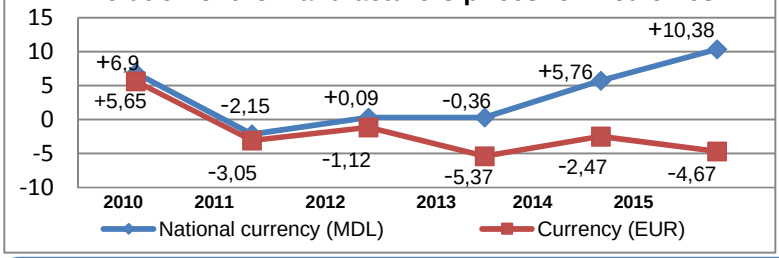
Essentials –26,6%
Originals – 14,6%
Generics – 83,5%
Rx – 69,7%
OTC – 29,4%

Authorization of medicines



- For the registration of the medicine the applicant shall submit the dossier in CTD format.The procedure for issuing the certificate of the registration of the drug lasts 210 days.
- The medicines quality is checked by theLaboratory for Quality Control, which is certified according to ISO 9001: 2008. It performs subsequent control, selective to products manufactured according to GMP standards and series-by-series for non-GMP drugs.

Evolution of the manufacturers prices for medicines



Differentiated value added tax

Purchase price (MDL)	Final margin	Wholesale margin	Pharmacy margin
0 – 30,00	< *40 %*	< *15 %*	< *25%*
30,01- 60,00	< *37%*	< *12%*	< *25%*
60,00 – 120,00	< 26 %	< 10 %	< 16 %
120,01 – 240,00	< 21 %	< 8 %	< 13 %
>240,00	< 16 %	< 5 %	< 11 %

Annotation: The average exchange rate in August - 1 EUR = 21,1864 MDL, but on 25 September - 22.6684 MDL

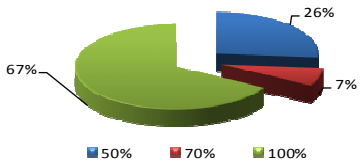
- The medicines prices are regulated by the Government. Prices for all types of medicines (Rx and OTC) are declared annually by the producer/manufacturer. The price accepted for registration must comply the following requirements:

1) is the average price of the lowest three prices of the reference countries: Romania, Greece, , Serbia, Croatia, Czech Republic, Slovakia, Lithuania and Hungary;
2) generic medicine price does not exceed 75% of the original medicine;
3) medicine price that can not be found in the reference countries must be equal to the average of International Non-proprietary Name (INN) recorded in the Regisrer.

Annotation: Although the prices measured in a foreign currency fell, they raised in the national currency due to the MDL depreciation.

- For drugs from warehouses and pharmacies are established differentiated value added tax. This law was implemented since the 1st of October.

The rate of compensation



Pharmacotherapeutic groups included in the Reimbursement program

Pharmacotherapeutic group	INN	Pharmacotherapeutic group	INN
Cardiovascular agents	19	Drugs used in diabetes	7
Digestives	5	Epidermolysis bullosa	5
Endocrine therapy	3	Autoimmune disease	3
Drugs used in asthma therapy	4	Ophthalmic diseases	4
Treatment and prophylaxis agents used in children (0-5 years)	12	Prophylaxis of iron deficiency anemia and folic acid deficiency during pregnancy	2
Cystic fibrosis	2	Mistenia gavis	1
Antiepileptics	6	*Multiple sclerosis*	1
Parkinson's disease	2		
Nervous system	11	**Total**	**87**

- The methodology of reimbursement of medicines was implemented for the first time in 2005.
- Since 2013 all medicines without GMP Certificate have been excluded from the List of reimbursement of medicines.
- At the moment, the List of reimbursement of medicines includes 87 INN (584 medicines). The list contains drugs from 16 pharmacotherapeutics groups.
- The procedure for inclusion in the list of the reimbursement medicines recently has been changed. The submission of dossiers by producers.
- The approval decision belongs to the Council (Minister of Health, Medicines and Medical Devices Agency, National Health Insurance Company, etc.), which sets the rate of the compensation (10-100%).

Ministerie van Volksgezondheid, Welzijn en Sport

The Netherlands

Ministry of Health, Welfare and Sport

AUTHORIZATION/CLASSIFICATION

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

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

PRICING

Out patient

Pharmaceutical companies
• Determine list price

Ministry of Health
• Calculation of maximum prices using external reference pricing (Medicines Pricing Act)
• Reference basket: UK, France, Belgium and Germany
• Option to negotiate price for selected medicines

Wholesaler
• Mark up not regulated

Z-index
Publication price list (taxe)

Pharmacies
• remunerated according to taxe-price (pharmacy purchase price)
• 6% VAT for all medicines

In patient

Dutch Health Care Authority (NZa)
• Determines tariff for healthcare providers
• Determines special tariff for high cost drug and orphan medicines (add-on)

Hospital
• Negotiate with pharmaceutical companies on prices
• In some cases using regional purchasing groups (tenders)
• Apply for special tariff

REIMBURSEMENT

Out patient

Ministry of Health
• Final decision on reimbursement status based on formal appraisal and advice from the Health Care Institute (ZINL)
• Option to negotiate terms of reimbursement for selected medicines
• Option to conditionally reimburse medicines pending additional research on effectiveness / cost effectiveness

National Health Care Institute (ZINL)
• Advice on reimbursement for all out-patient medicines
• In some cases advice on reimbursement for in-patient products
• Appraisal criteria: necessity, efficacy, cost-effectiveness, feasibility.

Reimbursement System (GVS)
• Positive list for reimbursed medicines
• Internal reference pricing for therapeutic equivalent products (set limit)
• Co-payment: if price is higher than the maximum price or the group price (IRP)
• If registered for specific indication or sub-set of patients reimbursement can be limited
• No reimbursement: most OTC and small number of POM

Health insurers
• Reimbursement if medicine is on positive list
• Generics: therapeutic substitution, preference policy

In patient

Reimbursement system:
• Hospital budget
• Reimbursement using DRGs
• Additional compensation for high cost medicines
• No co-payments for patients
• Negotiation between health insurers and hospital on tariff for reimbursement

Hospital
• Individual decision on procurement of medicines

Health insurers
• Reimbursement if medicine is determined to be in line with the current established medical science and medical practice

Statens legemiddelverk
Norwegian Medicines Agency

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI
Pharmaceutical Pricing and Reimbursement Information

NORWAY

Norwegian Medicines Agency (+47 22 89 77 00, post@noma.no)

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

OUT-PATIENT SECTOR

PRICING at ex-factory level is not regulated in Norway

PRICING at pharmacy level

Pharmacies

Maximum pharmacy purchasing price and pharmacy mark -up scheme set by the **NoMA**

REIMBURSEMENT

NoMA

In consultation with

National Advisory Commi ttee for Drug Reimbursement

Task: Decision on the reimbursement status
Criteria: Pharmacological, medical therapeutic, pharmaeconomic criteria

National Reimbursement Code

Reimbursable medicines

Preapproved prescription

Preapproved prescription, subject to particular conditions

Reimbursement only on individual basis

Individual application, approval by HELFO subject to particular conditions

IN-PATIENT SECTOR

Regional Health Authorities

Commissions evaluations from:

Norwegian Medicines Agency

Cooperate/align decisions on reimbursement of costly medicines.

Evaluates cost-effectiveness of selected in-patient medicines.

Hospital purchasing body: Drug Procurement Cooperation (LIS)

In consultation with:

Hospital pharmacies, pharmacists, depart-ments and pharmaceutical and therapeutic committees

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

Health Enterprise/hospital

In consultation with:

Pharmaceutical and Therapeutic Committee

Task: Decision on use of medicines in specific hospitals

List of preferred products/suppliers

PERU

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

New medicine

AUTHORISATION/ CLASSIFICATION

Ministry of Health
National Medicines Authority - Dirección General de Medicamentos Insumos y Drogas (DIGEMID)

Task: Decision on authorization and registration
Criteria: Quality, safety, efficacy (Law 29459)

National Medicines Authority - Dirección General de Medicamentos Insumos y Drogas (DIGEMID)

in consultation with **Pharmacology Committee**

Task: Decision on prescription, dispensing requirements and if a medicine fulfills the criteria of medicines
Criteria: Law 29459 and directives.

The DIGEMID is also in charge of **pharmacovigilance**

VIGILANCE

PRICING at ex-factory level

Pharmaceutical companies

Wholesaler
Mark up not regulated

VAT: 18% (all kinds of medication)
exempt from customs duty medicines for cancer, HIV and diabetes (0%)

PRICING at wholesale and pharmacy level

OUT- PATIENT | IN - PATIENT

Medicines distributed via

VAT: 18% (all kinds of medication)
exempt from customs duty medicines for cancer, HIV and diabetes

Wholesalers — Free Mark up at wholesale level.

Pharmacies — Free Mark up at pharmacies.
Pocket payments covered

Pocket payments: 29.8% (Uninsured)

Observatorio de Precios de Medicamentos (OPM)

Task: increased affordability of drugs through price transparency
Criteria: informed consumer prices, discount brands and generic, location of pharmacies

Price negotiations | Tendering

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 increased by 25%
Criteria: Depending on the product or on the market situation of the medicine

Free pricing

Security Social EsSalud
Task: Free coverage in hospital
Criteria: patient must be contributor to the social security fund

Comprehensive Health Insurance-SIS
Task: Free coverage in hospital
Criteria: patient must be previously affiliated insurance

Health strategies
Task: Free coverage in hospital
Criteria: patient must be diagnosed with disease: HIV, TBC, malaria or other diseases of interest to public health

REIMBURSEMENT

Reimbursable

Ministry of Employment | **Ministry of Health (MINSA)**

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

Ministry of Employment | **Ministry of Health (MINSA)**

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

Public hospitals which receive public funds

Use in hospitals

Hospital/ Hospital owner association — in cons. with **Pharmaceutical and Therapeutic Committee in hospital (association)**

Task: Decision on use of medicines

Pharmaceutical formulary per hospital (owner)

The financing of the medicines does not depend on the inclusion in a pharmaceutical formulary. Once included price negotiations/tendering start.

No co-payments for patients

Non reimbursable medicines

Pocket payments

Non reimbursable medicines

POLAND

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

AUTHORISATION/ CLASSIFICATION

New medicine

European Medicines Agency (EMA) OR
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Prod-

Task: Decision on authorization and registration, qualification to prescription
Criteria: Quality, safety, efficacy, pharmacovigilance

PRICING / REIMBURSEMENT

OUT- PATIENT

IN - PATIENT

Ministry of Health
The drug has to be available in Poland before the reimbursement application is submitted

Medicines/Medical devices/FSMP applying for out-patient reimbursement

Medicines applying for out-patient reimbursement (chemotherapy or therapeutic program)

new clinical indication (do not reimbursed yet)
the same procedure for original/generic/hybrid/biosimilar product

reimbursed clinical indications (generic)

formal evaluation

HTA evaluation (clinical and economical)

Price negotiations (Economic Commission)
product price in EU countries + EFTA countries are supporting information

decision of the Minister of Health

Medicines distributed via

Wholesalers	Wholesale mark-up – 5% Pharmacies regressive mark-up medicines, medical devices VAT – 8 % FSMP VAT – 5% or 8% or 23%
Pharmacies	

Tendering (involving wholesalers and manufacture's wholesalers)

Maximum mark-up (5% + 8% VAT)

100% → medicines for specific indications (treatment of malignant tumors, psychotic disorders, mental retardation or developmental disorders, infectious diseases epidemic of the specific hazard for the population), war veterans, medicines and FSMP used in pharmaceutical programmes, oncology chemotherapy; in-patient sector are free of charge)

Fixed rate (app. EUR 0.75), 70%, 50% → rate depends on the disease duration (up to 30 days or more than 30 days) with correlation to the cost of treatment and the minimum wage

The Act of Reimbursement does not define the originator drug. The law defines the reimbursement INN in specific clinical indication. In case the next drug with the same INN (the next application form) in the same specific clinical indication is applying, its manufacturer is obliged to propose a price decrease of at least 25% in comparison to the first drug.
After the expiry of the period of market exclusivity, the official price must be reduced by at least 25%.

The pricing procedures is only for reimbursement products.

Medicine do not available in Poland, and without authorization and registration

Application for individual access made by doctor/regional/national consultant – decision during 30 days
Application for individual reimbursement made by patients – decision during 30 days

Ministry of Health, Katarzyna Kurek (+48 22 63 49 377, k.kurek@mz.gov.pl)

PORTUGAL

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INFARMED - National Authority of Medicines and Health Products, I.P.
3rd international PPRI Conference, 12 - 13 October 2015, Vienna

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

PRICING

POM (except HOM) + **OTC** reimbursed → **National medicines agency (NFARMED)**

Task: Retail price of medicines; annual review of prices; exceptional revision of prices

Criteria: Decree-Law n.º 97/2015, 1st June; Ordinance n.º 195-C/2015, 30th June
External Price Referencing (medium prices SP, FR,SI)

Statutory Pricing

GENERICS
•Internal Reference Pricing
1st generic:
•<=50% reference medicine price; If ex-factory price of reference medicine <10€, the difference applied is 25%
Other generics:
•Price of the reference medicine 2 years before the request of price for the 1st generic

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

Public Retail Price (PRP) = ex-factory price +
Regressive Wholesaler and Pharmacy margins (fixed and %) by price ranges +
Special Tax earmarketed for INFARMED +
VAT (6%)

OTC not reimbursed → **Pharmaceutical companies**

Task: Establish OTC price

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

Free Pricing

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

Applied only to Public hospitals

POM to be purchased by hospitals + OTC

Shared Services of Ministry of Health (SPMS)

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

INFARMED

Task: Setting a maximum price
Criteria: Decree-Law n.º 97/2015, 1st June; Ordinance n.º 195-C/2015, 30th June

Tendering / **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

In general: Hospital price = ex-factory price + VAT (6%)
(Margins are not relevant, unless products are bought from wholesaler or community pharmacy)

NATIONAL HEALTH TECHNOLOGY ASSESSMENT SYSTEM (SiNATS)

SiNATS

-**Technology**: Medicines + Medical Devices + Other Technologies
-**Assessment**:
  a) Relative Effectiveness (Added Therapeutic Value)
  b) Cost-Effectiveness (Economic Value)
  c) Other dimensions of the technology value (including affordability)
-**Decisions**:
  a) Price
  b) Financing/reimbursement
  c) Control and cost limitation
  d) Risk sharing
  e) Additional monitoring of use
-Re-assessment of technologies on the market (ex-post evaluation) – New paradigm
-Participation in the European HTA system

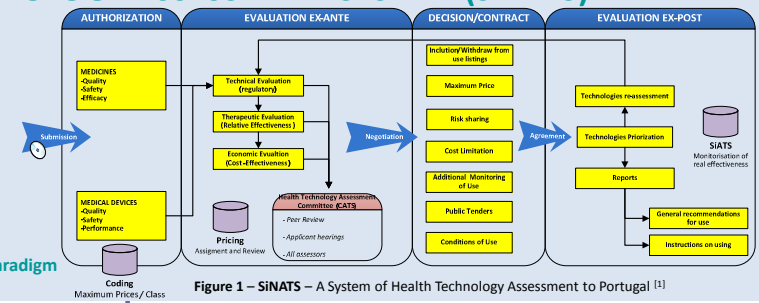

Figure 1 – SiNATS – A System of Health Technology Assessment to Portugal [1]

REIMBURSEMENT

Ministry of Health or INFARMED (currently power delegation on generics, biosimilars and reimbursement delist)

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

Criteria: Decree-Law n.º 97/2015, 1st June; Ordinance n.º 195-A/2015, 30th June

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

Biosimilars
Price <=80% biologic medicine reference price

Ministry of Health through ACSS (Central Administration of the Health System) and Regional Health Administrations

Task: Financing hospital level of activity , including use of medicines, through Diagnosis-related Groups (DRG). There's a National Formulary with guidelines for the rational use of medicines taking HTA into account and covering both outpatient and inpatient

Special financing of medicines to HIV/ HCV treatment.
Criteria: Medicines and medical procedures to HIV patients are subsidized according to the predicted the number of new HIV patients/ Central financing for HCV treatment

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)

Additional financing

USE IN HOSPITALS

National Formulary

in consultation with

Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic Committee

Task: Decision on use of medicines in the hospital

Criteria: Ministerial Dispatch n.º 1083/2004

OUT- IN - PATIENT

[1] Martins, J; Rodrigues, J; Antunes, M; Ferrador, F; Ramos, I; Ramos, R; Santos, C; Caldeira, S; Castro, J; Arriegas, M; Dias Almeida, P; Mota-Filipe, H; Castro Alves, E; "SiNATS - Criar o Futuro", (2014).

RUSSIA

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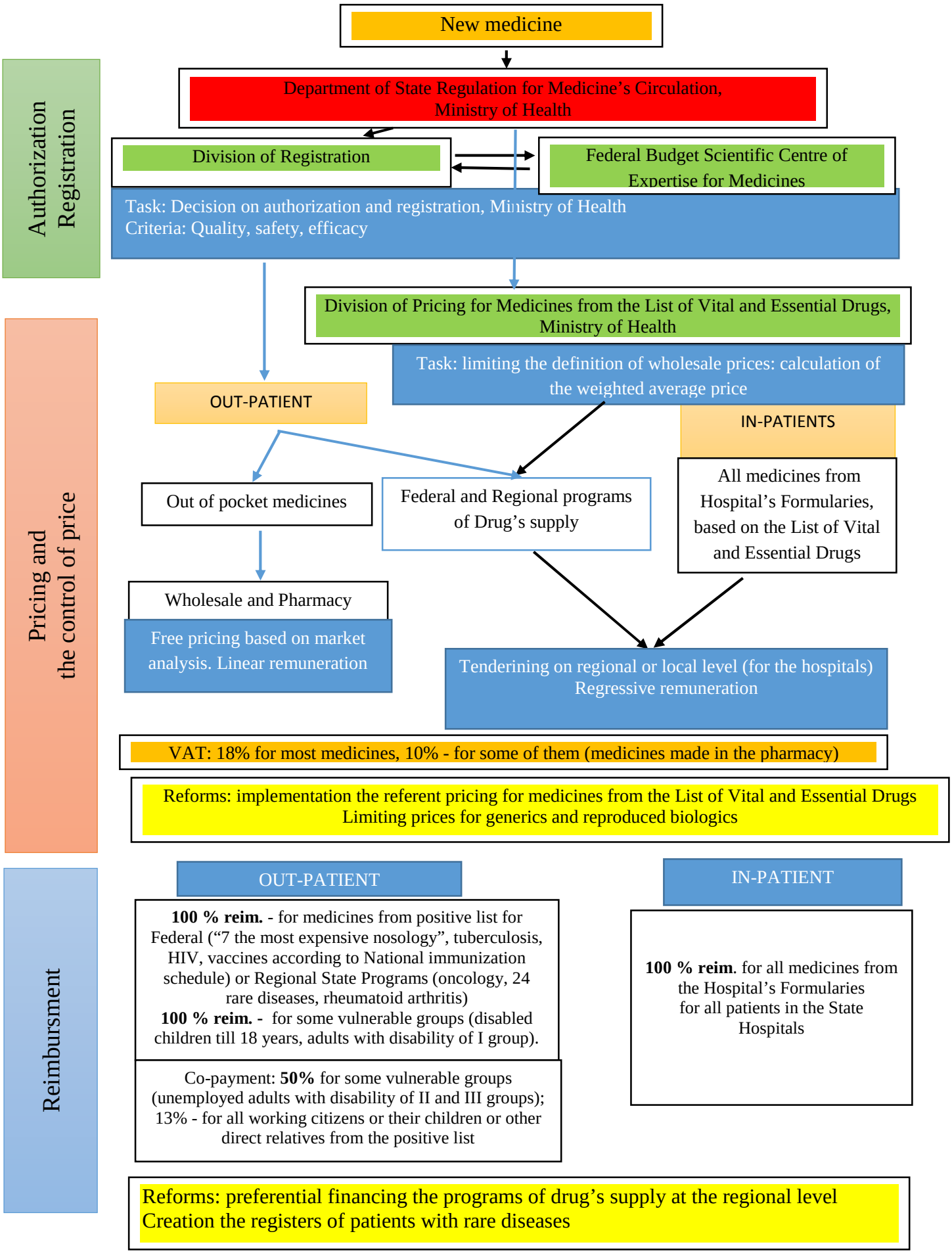


Zavod za zdravstveno zavarovanje Slovenije
Health Insurance Institute of Slovenia
www.zzzs.si

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI
Pharmaceutical Pricing and Reimbursement Information

SLOVENIA 2015

Health Insurance Institute of Slovenia

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

PRICING

Responsible institution: Agency for Medicinal Products and Medical Devices
Legal basis:
- Medicinal Products Act
- Rules on price setting for medicinal products for human use

Maximum allowed prices are set for prescription medicinal products (originators and generics), financed or intending for financing from public funds - List of highest recognised values

External reference pricing system
- Reference countries: Austria, France, Germany, ex-factory prices for calculations
- Price setting (comparison originator, generic)
- Price structure: ex-factory price + wholesale margin + pharmacy fee + VAT
- Setting of higher prices (exceptionally)

REIMBURSEMENT

Responsible institution Health Insurance Institute of Slovenia
Legal basis:
- Health Care and Health Insurance Act
- Rules of classification of medicinal products for human use on the list

Reimbursement criteria: Public health priorities, Clinical criteria, Therapeutic value, Relative effectiveness, Economic criteria, Pharmacoeconomic analysis, Budget impact analysis, Ethical criteria (orphans), Data and evaluations from reference sources
Reimbursement committee

FINANCING

Measures for all drugs
Internal reference pricing system for interchangeable drugs (ATC 5) since 2003
Reference pricing for therapeutic drug groups (clusters, ATC 4 or 3) since 2013
Pricing and managed entry agreements: discounts (reduction of price), rebates (material discount), price-volume agreements, pay-back agreements, performance-based (outcome-based) agreements
Prescribing restrictions
Prescription drugs
Positive list: 100 % or 70 % covered by compulsory HI, the rest is paid by voluntary co-insurance or by patient,
1.799 medicines (458 INN)
Intermediate list: 10 % covered by compulsory HI, the rest is paid by voluntary co-insurance or by patient,
933 medicines (198 INN)
Exceptions: vulnerable groups (children, young people in education, and patients with certain diseases): 100 % reimbursement for positive list; for socially vulnerable people the voluntary co-insurance is paid by the government.
Ampulated drugs
List B (91 expensive medicines separately paid to hospitals for treatment for in-patients, most of them ATC B or L)
List A (30 medicines separately paid to all providers for out-patients including home treatment)

OTHER ACTIVITIES

Health Technology assessment
- There is no HTA body
- The pharmacoeconomic analysis and budget impact analysis have to be included in the application dossier for reimbursement for the drugs with the planned budget impact of 500.000 EUR in the first 3 years
- The explicit Incremental Cost-Effectiveness Ratio (ICER) threshold is set at 25 000 EUR/QALY (1.5 GDP/capita)

Approaches for rational prescribing
- In 2011, a project on the quality of prescribing by general practitioners was initiated - a set of 8 quality indicators has been made available on the ZZZS web site
- In 2012, a project "Pharmacotherapy groups and clinical pharmacist – consultant" was introduced by ZZZS:
  - The clinical pharmacist consultant has a weekly afternoon practice in the Community Health Center for the admission of patients, for the review of therapies, and for patient counseling.
  - Once a month, the pharmacist's clinic takes place in homes for the elderly.
  - Regular meetings are held every second month for sharing expertise and experiences. In particular, these meetings focus on specific drug groups and polypharmacy study case reports prepared by the Pharmacotherapy groups, which consist of up to 15 physicians and 1 clinical pharmacist consultant.
- For physicians and pharmacists, on-line access to the data about the drugs dispensed to each individual person has been established. An e-prescription system for primary health care providers is planned for the year 2015.
- Audits focused mostly on prescribing restrictions
- Education (polypharmacy, antibiotics, etc.)

Pharmacies:
- A fee is paid to pharmacies for their services.
- Maximum duration of repeat dispensing is 3 months for the maximum quantity of the drug and 1 year in total. However, all drugs with the price of more than 150 Euro per pack have to be issued monthly.

SOUTH AFRICA

National Department of Health

Civitas Building

Cnr. Thabo Sehume Street and Struben Street

Pretoria, Gauteng

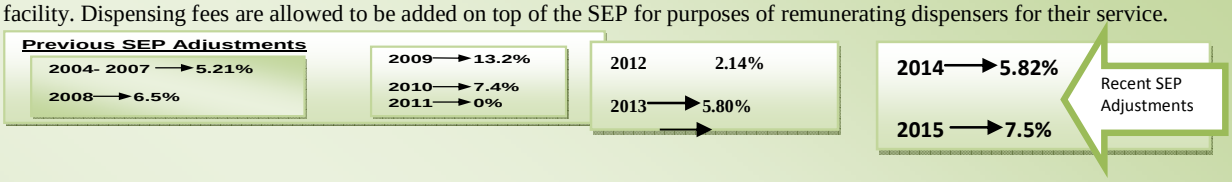
The pharmaceutical system in South Africa in the in- and out-patient private sector

Pricing in the out-patient sector

Pricing policies for medicines

Health care in South Africa varies from the most basic primary health care, offered free by the state, to highly specialized, hi-tech health services available in the both the public and private sector. The State contributes about 40% of all expenditure on health and is under pressure to deliver services to about 80% of the population. The middle class minority South Africans that utilize private sector services contribute monthly premiums to medical aid schemes of their choice. These schemes serve as funders of the private sector health system. The National Drug Policy, Medicines and Related Substances Act, Pharmacy Act, Health Act, and Pricing Regulations contain regulatory measures which control the sale of medicines in South Africa. Pharmacists and qualified dispensing practitioners can dispense any medicine that is registered 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 medicines, after getting permission from the South African Pharmacy Council and the Nursing Council.

Private sector pricing of medicines: The Single Exit Price (SEP) is the selling price for every medicine registered for human use and sale in private sector facilities. The SEP should never change until the medicine reaches the dispensing point e.g pharmacy or dispensing doctor facility. Dispensing fees are allowed to be added on top of the SEP for purposes of remunerating dispensers for their service.



Single Exit prices (SEP) only change after approval is sought and granted by the National Department of Health. SEPs are made available to everyone at no cost. No rebates, discounts or incentive schemes are allowed in South Africa. SEP reviews are determined and announced by the Minister of Health annually. **Public sector pricing of medicines**: The bulk of public health-sector funding comes from National Treasury with some patients only charged a small fee at certain facilities. Medicines for supply to State (government/ public) facilities are procured on tender. The National department of Health ensures that contracts are secured with successful bidders (pharmaceutical manufacturers). Agreed upon medicine prices are communicated to respective officials responsible for pharmaceuticals in the nine South African provinces.

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 Fee :DF

Dispensing fees are regulated at a maximum and they can be discounted by the dispenser.

Dispensing pharmacists and other licensed dispensing professionals are allowed to charge a dispensing fee on top of the SEP. Dispensing fees for pharmacists have four tiers (See Table 1) and non pharmacists dispensing fees differ (See table 2). Dispensing fees are set as maximum fees. The dispensing fee paid by the consumer is dependent on the price of the medicine i.e. the SEP (See tables below). The pharmacy mark up or dispensing fee is the only mark up allowed on the price that leaves the manufacturer site, regardless of which wholesaler transported the medicine (s) to the pharmacy or any retailer. 1 USD = 13.36 ZAR (October 2015)

Table 1: CURRENT PHARMACISTS DF

TIERS	SEP BANDS	DISPENSING FEE %	DISPENSING FEE Rand Value
Tier 1	R0 - R90.51	46%	7.44
Tier 2	R90.52 - R241.41	33%	19.86
Tier 3	R241.42 - R844.95	15%	63.19
Tier 4	R844.96+	5%	149.91

Table 2: CURRENT NON-PHARMACIST D.F.

TIERS	SEP BANDS	DISPENSING FEE %	DISPENSING FEE Rand Value
Tier 1	R0 - R112	30%	0.00
Tier 2	➢ R112 +	0%	33.60

VAT

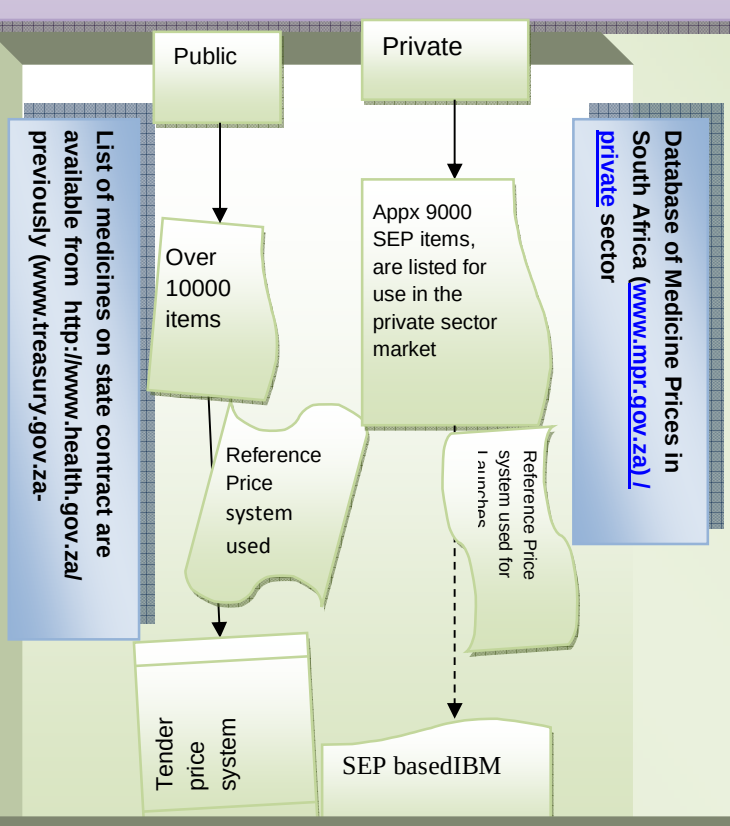
In South Africa, Vat is 14% for all commodities including medicines. Tax incentives given to the pharmaceutical industry are within the domain of the Department of Trade and Industry. These arrangements are not part of the Department of Health's mandate and therefore not covered in the Department of 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 were published in February 2013. Compliance with the guidelines is voluntary. The Department of Health intends to make these guidelines **mandatory**.

International Benchmarking: South Africa has chosen Spain, New Zealand, Australia, South Africa and Canada as benchmark countries.

Reimbursement in the out-patient sector



Co-payments

Copayments are charged to medical aid scheme members that do not comply with their scheme rules when purchasing medicines. PMB rules determine the nature of the rules for compliance.

The medical aid scheme option chosen by the patient also determines the extent of the copayment.

Pricing in the in-patient sector

Pricing policies for medicines

Implementation of pricing policies is similar for the in-patient sector and out-patient sector, 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

The determination of whole sale mark-ups is not dependent on whether medicines are for in-patient or out-patient sector. Agreements between service providers of logistical services and manufacturers determine the different levels of wholesale mark-ups (referred to as the Logistics Fee in the private sector).

Pharmacy mark-ups

Efficiency in service provision and pricing levels differ significantly between private and private facilities. Otherwise the same principles apply to in-patient and out-patient sectors in both the state and private facilities.

VAT

14% as described above.

Reforms

International Benchmarking & Pharmaco economic Assessments.

Mechanisms for vulnerable groups

Children under five years, pregnant mothers, psychiatric patients and the elderly are offered healthcare free of charge at public institutions.

Where public private partnerships exist between State and private facilities, free services e.g. vaccination etc. are offered in private facilities

Sweden

Dental and Pharmaceutical Benefits Agency (TLV)

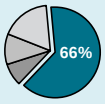
Pharmaceutical pricing and reimbursement policies

OUT-PATIENT

IN-PATIENT

PRICING

Pricing of pharmaceuticals in the benefit scheme



66% of sales are within the benefits scheme (TLV; 2014). Companies apply to TLV in order to enter a product into the reimbursement scheme. By using the Value Based Pricing method, TLV determines whether the pharmaceutical, at a given price and effect, is cost-efficient and can be reimbursed. TLV decides both the pharmacy purchasing and retail price. Recently, TLV proposed a revised construction of the pharmacy margin, to better fit a changing market with increasing volume of high-cost pharmaceuticals. TLV decides neither ex-factory price, nor the wholesalers' margin.

Pricing policies for reimbursed pharmaceuticals

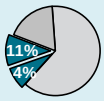
High cost pharmaceuticals. A new form of collaboration between county councils, pharmaceutical companies and TLV has been developed to establish national recommendations and a plan for coherent introduction of new high-cost pharmaceuticals. A result of this collaboration may lead to a risk sharing agreement between the county councils and the pharmaceutical companies.

Pharmaceuticals subject to competition. A tender auction system is applied to determine the available product at the lowest price for off-patent and interchangeable pharmaceuticals. The winning product in each group is the preferred product the following month. More than half of all dispensed packages are part of the system, and constitute one fifth of total expenditure for the benefit scheme.

Pharmaceuticals not subject to competition and older than 15 years are imposed with a price reduction of 7.5%. This reduction was optional during 2014; however, as of 2015 it is enacted by law.

Pharmaceutical reviews. Reviews of pharmaceuticals approved for the benefit scheme are performed by TLV in therapeutic areas where there is reason to question whether the pharmaceuticals still provide sufficient cost-efficient use.

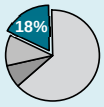
Pricing of pharmaceuticals not included in the benefit scheme



15% of sales are out-patient pharmaceuticals outside the benefit scheme, such as OTC (11%) and non-reimbursed Rx (4%). The price setting is unrestricted. The companies decide ex-factory price, the wholesaler decides the price to pharmacies and pharmacies set the retail price.

The standard VAT rate is 25%, and is applied to both OTC-pharmaceuticals and medical devices. There is no VAT on prescribed pharmaceuticals.

Pricing in the hospital sector



18% of pharmaceutical sales are made in the hospital sector.

Pharmaceuticals in the hospital sector are paid by 21 county councils providing healthcare. The county councils are responsible for the purchase of pharmaceuticals. The county councils are allowed to form partnerships and negotiate prices individually, or in clusters.

Drug and Therapeutic Committees within county councils act as advisory boards concerning the use, efficiency and cost of pharmaceuticals.

There is no VAT imposed on pharmaceuticals and medical devices purchased by the county councils.

REIMBURSEMENT

For pharmaceuticals included in the benefit scheme, the patient and the state share the costs of the pharmaceuticals. During a 12-month period, a patient pays the full amount of pharmaceuticals up to SEK 1 100 (€120). After paying SEK 2 200 (€240), the patient is fully subsidized. Between SEK 1 100 and SEK 2 200, the patient is subsidized 50%, 75% or 90%, depending on the accumulated costs.

Insulin, pharmaceuticals prescribed for preventing contamination of certain communicable diseases (i.e. HIV), and pharmaceuticals for persons lacking perception of their own state of illness, are always subsidized at 100%. There is a government proposal to offer children fully subsidized pharmaceuticals within the benefit scheme. At present time, children are included in the same benefit scheme as adults.

An adult patient pays a fee when visiting a hospital or primary care center. The maximum fee per patient is SEK 1 100 (€120) per year. Should the amount exceed SEK 1 100 (€120) during said period, the health care is fully subsidized. Patients pay a fixed fee for the medical appointment and no co-payment is required for pharmaceuticals used during a hospital stay.

TLV September 2015, www.tlv.se, +46-8-568 420 50. Contact: Peter Skiöld; peter.skiold@tlv.se

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

PPRI
Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Switzerland

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

New medicine

AUTHORISATION/ CLASSIFICATION

Swiss Agency Swissmedic

Task: Decision on authorization and registration
Criteria: Quality, safety, efficacy

Swiss Agency Swissmedic

The Swiss Agency of Therapeutic Products is also in charge of **pharmacovigilance**

in consultation with

Swissmedic Medicines Expert Commitee

Human Medicines Expert Commitee
Veterinary Medicines Expert Commitee

VIGILANCE

PRICING at ex-factory level

Federal Office of Public Health (FOPH) in cons. with **Federal Medicines Commitee (EAK)**

Medicines applying for out-patient reimbursement

Statutory pricing

Task: Price setting for medicines applying for inclusion in the positive list (SL) in the out-patient sector.

Criteria: External price referencing, internal price referencing (Therapeutic cross-comparison), weighting of EPR/IPR 2/3:1/3

Medicines not in out-patient reimbursement

free pricing

PRICING at wholesale and pharmacy level

Medicines distributed via

OUT- PATIENT

Wholesalers

Statutory pricing

Pharmacies

Statutory pricing

Maximum regressive wholesale/ pharmacy mark-up scheme set by **FOPH**
Joint mark-up for wholesale and pharmacy (plus fee for service remuneration for pharmacy).

For prescription-only medicines up to an ex-factory price of 880 francs a surcharge of 12% is imposed, for more expensive medicines the surcharge is 7%. In addition, a price-related surcharge is levied for every pack. For reimbursable OTC medicines a surcharge of 80% is imposed without a surcharge per pack.

VAT: reduced 2.5%

IN - PATIENT

Price negotiations

Statutory margins are not relevant.

SwissDRG AG

Task: Definition and assessment of DRG groups, calculation of cost weights for each category
Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria

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

Task: Price negotiations (Baserate) between hospitals and insurers within each canton, approval by cantonal governments

Criteria: economic criteria

The costs of drugs, as well as diagnostic and therapeutic services used in in-patient settings are included in the tariff. There are supplementary payments for e.g. high costs medicines. 45% of costs are covered by mandatory insurance and 55% by the cantons.

Use in hospitals

Hospital in cons. with Pharmaceutical and Therapeutic Committee in hospital /Hospital Pharmacy

Task: Decision on use of medicines

Pharmaceutical formulary per hospital (owner)

Co-payments for patients

REIMBURSEMENT

FOPH in cons. with **(EAK)**

Task: Decision on the reimbursement status
Criteria: efficacy, suitability and cost-effectiveness

Reimbursable

Positive list (specialties list):
Contains all reimbursable drugs
Reimbursement 90% - 100% of the formulary list price (retail prices) accepted.
Health insurer pays a share of the maximum price listed according to the deductible.
About 3000 medicines are included, more than 92% prescription-only medicines. OTC products also reimbursable.

FOPH is analysing the Impact of a reference pricing system for generics.

Deductible: The patient chooses a deductible according to which the level of monthly premiums is calculated. The higher the deductible, the lower the premium. Only when this is exceeded does the health insurer pay, although the insured person still has to pay 10% of costs up to a maximum of 700 francs himself.

Non reimburs-able medicines

Reimbursement of medications in individual cases
Application for the reimbursement of the cost of a medication in individual cases is possible if predefined conditions are fulfilled.

TURKEY

Turkish Medicines and Medical Devices Agency, Ministry of Health

Engin DOĞAN, MSc (engin.dogan@titck.gov.tr)

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

	OUT- PATIENT	IN - PATIENT
PRICING	**Pricing in the out-patient sector** Pricing policies for medicines Ex-factory prices for all pharmaceuticals. MoH is the only authorized body to determine on maximum price of pharmaceuticals. External reference pricing system is used. 5 reference countries (France, Greece, Italy, Portugal, and Spain). For original products, reference countries, importing and exporting countries are considered. Lowest price of these countries is the reference ex-factory price. Wholesale remuneration (e.g. margins) Statutorily regressive mark-ups for all pharmaceuticals. Changing from 9% to 2%. Pharmacy remuneration (e.g. margins) Statutorily regressive mark-ups for all pharmaceuticals. Changing from 25% to10%. VAT 8% VAT for all pharmaceuticals. Reforms – if applicable A new Council of Ministers' Decree dated July 10, 2015 for pricing of pharmaceuticals was announced, and a new euro-exchange rate was implemented.	**Pricing in the in-patient sector** Pricing policies for medicines All pharmaceuticals can be used in hospitals. So pricing procedure is same as out-patient sector. Hospital prices are either the ex-factory prices or wholesale prices, but purchasing prices for hospitals may be different. Four ways of purchasing medicines for hospitals: Open tendering, Tendering among predetermined competitors (procurement by invitation), Bargaining Negotiations, Direct purchase. Wholesale remuneration - if appl. in the in-patient sector Same as out-patient sector. Pharmacy remuneration - if appl. in the in-patient sector There isn't any pharmacy remuneration. VAT – if applicable Same as out-patient sector.
REIMBURSEMENT	**Reimbursement in the out-patient sector** Positive / negative list There is a positive list for out-patient medicines. The list dated June 5, 2015 contains 8382 pharmaceuticals to be reimbursed. Reimbursement price: The reimbursement price is different from the pharmacy retail price. Companies have to give mandatory discounts to Social Security Institution (SSI). It changes from 20% to 41% for original products, and 20% to 28% for generics. Co-payment There is a 10% co-payment for retired members of the SSI and their dependents and 20% co-payment for active workers and their dependents of the total amount of prescription. Also, there is an additional 3 TL (€ 0.88) payment per prescription up to 3 boxes of medicines and 1 TL (€ 0.29) for each extra box of medicine. Mechanisms for vulnerable groups An exemption list for chronic diseases. Reforms – if applicable In March 2015, Commission of Medical and Economical Assessment has been established by Social Security Institution (SSI) to assess imported medicines for reimbursement decisions. These medicines don't have marketing authorization in Turkey. They are imported from other countries on a patient by patient basis after getting permission from Ministry of Health. If a medicine is on the Imported Medicine List of SSI, they are reimbursed for each patient. The sub-commission will make recommendations to upper-commission (Pricing Commission of Health Services) for reimbursement decisions.	**Reimbursement in the in-patient sector** Reimbursement of medicines way of hospital funding / included in the hospital remuneration etc. Hospital formularies Each hospital has its own hospital formularies and procures the medicines. Other than out-patient medicines list, there is also hospital-only-medicines list for reimbursement. Both lists are used in hospitals. Co-payment in hospitals There aren't any co-payments for in-patients. Mechanisms for vulnerable groups – if applicable Same as out-patient sector. Reforms – if applicable SSI has started to reimburse chemotherapy medicines only in hospital since July 1, 2015.

PHARMACEUTICAL SYSTEM OF UKRAINE

<table>
<tr><td rowspan="2">AUTHORISATION</td><td>Ministry of Health of Ukraine
State Expert Centre of the MoH</td><td>State Administration of Ukraine on Medicinal products</td></tr>
<tr><td>Decision on authorization and registration
Development of the national list of Essential medicines (215 INN), List of the Medicines which are purchased for the means of the state and local budgets.
Maintenance if the List of the registered Medicines
List of the ex-factory prices
Price monitoring
Vigilance

Medicines necessary for antiterrorist operation may be imported without authorization in Ukraine</td><td>post-marketing quality control of medicines; licensing, GMP certification of manufacturers, licensing of pharmacies</td></tr>
<tr><td rowspan="2">PRICING
at ex-factory level</td><td>Ministry of Health of Ukraine
Ministry of Economics of Ukraine</td><td>State Inspection on Prices:</td></tr>
<tr><td>Customs fee 5 % (temporary measure, will be canceled since 2016)
VAT 7%
Pricing is regulated only on Medicines which are purchased for the means of the state and local budgets (over 1000 INN)</td><td>Price control</td></tr>
<tr><td rowspan="2">PRICING
at wholesale and pharmacy level</td><td colspan="2">OUT-PATIENT SECTOR</td><td>IN-PATIENT SECTOR</td></tr>
<tr><td>Wholesalers
Maximum wholesale markups for Essential Medicines (215 INN):
Maximum distribution price markup 10 %</td><td>Pharmacies
Retail markups are regulated for Essential Medicines (215 INN)
Maximum retail markup 25 %</td><td>Medicines which are purchased for the means of the state and local budgets:
TENDER Procedure
12 state programmes:
HIV/AIDS
Tuberculosis
Oncology
Transplantation
Orphan diseases
etc.

Procurements by international organization (WHO, UNICEF) – HIV/AIDS, Tb, vaccines – planned since 2015

Reference pricing is suspended since 01/07/2015</td></tr>
<tr><td rowspan="2">Reimbursement</td><td colspan="2">OUT-PATIENT SECTOR</td><td>IN-PATIENT SECTOR</td></tr>
<tr><td colspan="2">Groups of patients to whom the medicines are dispensed free of charge:
1. veterans of the World War II
2. veterans of labour
3. Chernobyl cleanup veterans
4. retired collective farmers, workers, public servants
5. children under 3 years
6. disabled children under 16 years
7. children under 18 years, who in 1988 had an illness on chemical inoxicative alopecia in Chernivtsi
8. adolescent girls and women with contraindication of pregnanc
Groups of patients to whom the medicines are dispensed at half-price:
1. disabled people of the I or II groups
2. children 3-6 years
3. rehabilitated victims of the political repressions
4. honorary donors of Ukraine or USSR
Medicines for the treatment in the out-patient sector are dispenced free of charge for the following diseases (totally – 34):
• Oncology
• Hematological diseases
• Diabetes (mellitus and insipidus)
Rheumatism
• Rheumatoid arthritis
• Syphilis
• Tuberculosis
• AIDS
• etc.</td><td>Pilot project on reimbursement of insulins – since 01/01/2016
All registered insulins (8 INNs = 110 branded names).
Reimbursement price = reference price (the procedure of reference price calculation will be developed by 01/12/2015)</td></tr>
</table>

United Kingdom

Department of Health, Cathleen Schulte, cathleen.schulte@dh.gsi.gov.uk, +44 20 7972 6539

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

PRICING

Out patient

Pricing policies for medicines
Maximum prices (manufacturer price/reimbursement price/NHS list price) of **branded medicines** are set in line with requirements of the voluntary Pharmaceutical Price Regulation Scheme (PPRS) or statutory regulations (the Health Service Branded Medicines (Control of Prices and Supply of Information)(No.2) Regulations 2008 and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007). Manufacturers are required to seek agreement on the proposed maximum price from the Department of Health prior to launch. Products containing a New Active Substance have freedom of pricing.

The 2014 PPRS operates until the end of 2018 through a cap on the vast majority of National Health Service spend on branded medicines. For any expenditure above the agreed level, companies in the PPRS make quarterly percentage payments to the Department of Health on their net sales. Companies which are not members of the voluntary scheme are subject to statutory regulations and are required to apply a 15% price cut to products that were on the market on 1 December 2013.

The prices of **generic medicines** are set by the market. Generic manufacturers have freedom of pricing subject to a maximum of the reference product at the point of patent expiry. Part VIII of the Drug Tariff lists the reimbursement price of many generic drugs in the community.

Wholesale remuneration
The reimbursement price includes margins for the wholesaler and pharmacist. These are not fixed, so it is not possible to derive the ex-factory price. Historically, the margin for branded medicines was nominally 12.5% off the NHS list price but, in practice, it varied as it was negotiated between the manufacturer and wholesaler. Changes to the way medicines are distributed e.g. Direct to Pharmacy (DTP) schemes or a restricted number of wholesalers mean that this average figure is no longer accurate for many medicines. In addition, Part II of the Drug Tariff lists medicines for which a discount is not deducted when reimbursing pharmacy contractors.

Pharmacy remuneration
Most new medicines are granted automatic full reimbursement following market authorisation and pricing approval. In the community, any product may be prescribed for a patient and it will be reimbursed on the NHS except for a small number on a negative list - Part XVIIIA of the Drug Tariff.

VAT
The NHS list price excludes VAT. Medicines supplied to hospitals and community pharmacies are subject to VAT at the standard rate (20%). Medicines dispensed by a community pharmacist against a prescription are zero-rated for VAT (which means that the patient pays no VAT and the pharmacy can recover the VAT paid when buying the medicines). Sales of over-the-counter (OTC) medicines are also subject to VAT at the standard rate.

Reforms
The Department of Health is currently running a 12-week public consultation on proposals to reform the statutory scheme regulations. More details on the Department's proposals can be found at:
https://www.gov.uk/government/consultations/pricing-of-branded-health-service-medicines

In

Pricing policies for medicines
As in the outpatient sector, maximum prices of **branded medicines** are set in line with requirements of the voluntary Pharmaceutical Price Regulation Scheme (PPRS) or statutory scheme. In addition, companies that are members of the PPRS have the option to propose a patient access scheme (PAS) in the context of a NICE appraisal of a medicine. A PAS is an arrangement agreed between the Department of Health (with input from NICE) and a company to improve the cost-effectiveness of a medicine without affecting the agreed maximum (list) price. There are a number of different types of PAS, but the most common and preferred model is a discount scheme.

Wholesale remuneration
Not applicable.

Pharmacy remuneration
Costs of medicines for in-patients are covered by a tariff price, which includes an element for medicines.

VAT
The NHS list price excludes VAT. Medicines supplied to hospitals are subject to VAT at the standard rate (20%).

Reforms
The Department of Health is currently running a 12-week public consultation on proposals to reform the statutory scheme regulations. More details on the Department's proposals can be found at:
https://www.gov.uk/government/consultations/pricing-of-branded-health-service-medicines

REIMBURSEMENT

Positive / negative list
There is no positive list. Most new medicines are granted automatic full reimbursement following market authorisation and pricing approval. In the community, any product may be prescribed for a patient and it will be reimbursed on the NHS except for a small number on a negative list (Part XVIIIA of the Drug Tariff).

Reference price system
The UK does not operate reference pricing.

Co-payment
From 1 April 2015 the prescription charge in England increased to £8.20 per item. Prescription charges do not currently apply in Wales, Scotland and Northern Ireland.

Mechanisms for vulnerable groups
No charges are paid by children under 16 (or full time students under 19), pregnant women, people aged 60 or over, people with certain medical conditions or people on low incomes. Overall, about 90% of prescription items are dispensed free. Those people who do pay charges and who need prescriptions regularly may buy a pre-payment certificate, which entitles them to free prescriptions for a fixed period. The cost of the pre-payment certificate is £29.10 for a 3-month and £104.00 for an annual certificate.

Reimbursement of medicines
Most new medicines are granted automatic full reimbursement following market authorisation and approval of the NHS list price by the Department of Health.

Hospital formularies
Formularies have been in place in the majority of NHS hospitals for many years, sometimes shared arrangements are in place. Each hospital will normally have their own formulary of active substances, and as a result, the formal and number of items on each list will vary significantly – as a minimum medicines approved by NICE are on this list. Generic substitution is normally practised with these lists, with the exception of products with narrow therapeutic indices and variable bioavailability. The formularies are continually updated, and depending on hospital policy, are overhauled every 1 to 2 years.

Co-payment in hospitals
Not applicable.

Mechanisms for vulnerable groups
Not applicable.

Reforms
In June 2014, the Health Secretary appointed Lord Carter to chair the NHS Procurement and Efficiency Board. In June 2015, the Department of Health published Lord Carter's independent, interim report which, among other areas, made recommendations for efficiencies in hospital pharmacy and medicines optimisation. Lord Carter's report is available at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/434202/carter-interim-report.pdf