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


The country poster book and the posters will be, upon approval of the authors, available for download after the conference at the conference website.
Flowchart of the pharmaceutical system in the in- and out-patient sector, 2015

**New pharmaceutical**

**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

**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.

**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:**
- Different mark up scheme at wholesale and pharmacy level
  - (Average wholesale mark-up 7.2%, Average pharmacy mark-up 19.6%)

**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
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

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.

Bibliography

1. Arutyunyan G., Topchyan H., Sahakyan A. Approaches to development of effective system for Pharmaceutical Price Regulation in Armenia, 4-th International Medical Congress of Armenia: «Together to Healthy Nation», July 2-4, 2015 Yerevan.
3. The results of evaluation of the availability of drugs on the basis of the analysis of retail prices and medicine pricing in the Russian Federation and on comparable markets of country-members of the CIS, the EU and the BRICS, M. 2013.
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

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

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

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

Minister of Health
- Cabinet approval required for medicines costing more than AUD20 million per year

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

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

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

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

**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**
  - **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**

**PRICING at ex-factory price level**

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

- **Pricing Committee**
  - **Task:** 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**
  - **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)

- **Main Association of Austrian Social Insurance Institutions (HVB)**
  - **Task:** Decision on the reimbursement status
  - **Criteria:** Eligibility for reimbursement; pharmacological, medical therapeutic, pharmacoeconomic criteria

- **Pharmacy Price Information (PPI) service at the Austrian Public Health Institute (GÖG)**
  - **Task:** Supporting the Austrian Medicines and Medical Devices Agency by providing data on pricing and reimbursement policies

**OUT-PATIENT**

- **Prices negotiations**
  - **Tendering**

**IN-PATIENT**

- **Hospital purchasing body**
  - **(individual hospital pharmacist or joint purchasing body)**
    - **Task:** Price negotiations or tendering of medicines
    - **Criteria:** Depending on the product or on the market situation of the medicine

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

- **Federal Commission of regional decision makers / payers (BGK)**
  - **Task:** Decision on use of medicines

**REIMBURSEMENT**

- **Reimbursement Code “EKO” (100% reimb.)**
  - **National Reimbursement Code**
    - **Green Box**
      - For prescription of medicines no approval necessary
    - **Light Yellow Box**
      - Medicines for defined indications
    - **Dark Yellow Box**
      - Medicines with essential added therapeutic value
  - **Red Box**
    - Ex-ante approval of head physician necessary

- **Use in hospitals**
  - **Pharmaceutical and Therapeutic Committee in hospital (association)**
    - **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 essential 'head point of service' reflecting medical therapeutic, health economic and health care considerations.

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

**Contact:** ppri@goeg.at
**BELGIUM**
National Institute for Health and Disability Insurance (NIHDI)

FLOW CHART PHARMACEUTICAL SYSTEM (IN- & OUT-PATIENT SECTOR)

### MARKETING AUTHORIZATION
- **Minister of Public Health or EMA**
  - Task: decision on marketing authorization and registration
  - Criteria: quality-safety-efficacy
  - Advisory board (Federal Agency FAMHP): Medicines Committee

### PRICING
- **Minister of Economic Affairs**
  - Task: maximum price setting
  - Criteria: statutory pricing (external and internal price referencing)
  - Advisory boards (Federal Agency for Economic Affairs):
    - Price Committee for Pharmaceuticals (reimbursable)
    - General Committee for Price Setting (non-reimbursable)

### REIMBURSEMENT
- **Minister of Social Affairs**
  - Task: decision on reimbursement & reimbursement level
  - Criteria: product-specific / economic / patient-specific / disease-specific
  - Advisory boards (NIHDI):
    - Reimbursement Committee
    - Technical Board for radioisotopes

#### IN-PATIENT SECTOR
- **Chapter I**
  - Reimbursement if prescribed within authorized indications (SPC)
  - No additional restrictions on reimbursement
- **Chapter II**
  - Reimbursement for all common indications (based on generally applied recommendations for good practice)
  - Reimbursement does not depend on a prior authorization delivered by the sickness fund
  - Prescribing HP must respect the recommendations and keep certain documents in the patient file ("a posteriori" control)
- **Chapter III**
  - Solutions for perfusion / parenteral nutrition
  - Reimbursement if prescribed within authorized indications (SPC)
  - No additional restrictions on reimbursement
- **Chapter IV**
  - Reimbursement is subject to particular reimbursement conditions and depends on a prior authorization delivered by the sickness fund ("a priori" control)
- **Chapter IVbis**
  - Pharmaceuticals not authorized in Belgium – imported by pharmacist
  - Reimbursement is subject to particular reimbursement conditions and depends on a prior authorization delivered by the sickness fund ("a priori" control)

#### OUT-PATIENT SECTOR
- **Chapter I**
  - Reimbursement list (pharmaceuticals)
  - (in- & out-patient sector)
  - No additional restrictions on reimbursement
- **Chapter II**
  - Reimbursement for all common indications (based on generally applied recommendations for good practice)
  - Reimbursement does not depend on a prior authorization delivered by the sickness fund
  - Prescribing HP must respect the recommendations and keep certain documents in the patient file ("a posteriori" control)
- **Chapter III**
  - Solutions for perfusion / parenteral nutrition
  - Reimbursement if prescribed within authorized indications (SPC)
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- **Chapter IVbis**
  - Pharmaceuticals not authorized in Belgium – imported by pharmacist
  - Reimbursement is subject to particular reimbursement conditions and depends on a prior authorization delivered by the sickness fund ("a priori" control)

#### Agreements
- Direct supply +/- wholesaler
- Hospital Pharmacy (individual)
- Hospital (individual)
- Pharmaceutical Therapeutic Committee
  - Task: decision on medicines listed in HPF
  - Criteria: EBM – patient’s requirements
- Hospital pharmaceutical formulary (HPF)
  - (individual)

### Distribution Channels
- Distribution via wholesaler & public pharmacy
- Pharmaceutical company

### Agreement negotiations
- (individual negotiations with pharmaceutical companies)
Recent and planned developments in pharmaceutical policies 2015

BULGARIA

### Changes in pricing

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

**Recent changes related to:**
- Price changes (e.g., price cuts, price freezes, other price reductions)
- Reviewing the registered prices of OTC products in August 2014 for another eight months until December 31, 2014. (Prices increase of OTC products was allowed only by the percentage of the inflation rate)
- Retail margins are 20%, 18% and 16% (but not more than 10 BGN) of the ex factory price.
- Wholesale margins are 7%, 6% and 4% (but not more than 25 BGN) of the ex factory price.
- Change in VAT on medicines
- There is no change.
- The VAT in Bulgaria is 20%.
- Freezes, other price reductions)
- Recent changes related to:
  - Clawback/payback system
  - There are no changes.
  - Change in VAT on medicines
  - There is no change.
  - Other changes/modifications of reimbursement lists
    - 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 very new year and shall cover the new molecules or indications for oncology included in the PDL in the previous year.

**Recent changes related to:**
- Change in VAT on medicines
  - There is no change.
  - 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 very 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 close back (draft).

**Other changes:**
- There are no changes.

### Changes in reimbursement

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:**
- 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 each indication in the summary of product characteristics.

**Changes/modifications of reimbursement rates**
- 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 very 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 close back (draft).

Other changes
- There are no changes.
### 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.**

<table>
<thead>
<tr>
<th>PRICING</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The Patented Medicine Prices Review Board (PMPRB)</td>
<td>Regulates the price of all patented medicines sold in Canada to ensure that they are <strong>not excessive.</strong> Reviews the prices charged to wholesalers, hospitals and pharmacies. Drugs 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.</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>PUBLIC (42.0%)*</th>
<th>PRIVATE (35.8%)*</th>
<th>Out-of-pocket (22.2%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Most employers provide private drug insurance for working-age beneficiaries and their dependants.</td>
<td>Individually, not reimbursed by a public or private plan, or those with deductible or co-payment costs.</td>
</tr>
</tbody>
</table>

**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, benefitting 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.

**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.

**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.

**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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*Source: Canadian Institute for Health Information, 2014*
CHINA
Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

Registration & Manufacturing

Measures on the Administration of Drug Registration (Since October 2007)
5,000 pharmaceutical manufacturers now in China, mainly produce generic drugs and traditional Chinese medicines.

After experiencing several quality issues, the government concentrated on the strict implementation of the Good Manufacturing Practice (2011 new GDP) to assure product quality.

Dispensing

13,000 wholesalers
341,000 retail stores
554,000 rural drug supply outlets

Utilization

Pharmaceutical market expanded 16.1% annually in recent years
Hospitals prescribe and dispense about 80% of total medicines, the remaining 20% by community drug stores (pharmacies)
Hospital pharmaceutical revenue accounts for 41.1% of hospital total revenue in 2012

PRICING

Three types of prices determination model
(Maximum retail prices)

COMMUNITY PHARMACY

Self-pricing below price caps. However, with violent competition among chain pharmacies, the retail prices are usually 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.

Three main health insurance programs in China

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>New Rural Cooperative Medical Scheme (NCMS)</th>
<th>Urban Employee-Based Medical Insurance (UEBMI)</th>
<th>Urban Residents-Based Medical Insurance (UR-BMI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date started</td>
<td>2003</td>
<td>1998</td>
<td>2007</td>
</tr>
<tr>
<td>Populations</td>
<td>Rural residents</td>
<td>Urban employed</td>
<td>Children, students, elderly, disabled, other non-working urban residents</td>
</tr>
<tr>
<td>Expenditures</td>
<td>92.292 billion RMB (13.6 billion USD (2009))</td>
<td>201.6 billion RMB (29.6 billion USD)</td>
<td>6.7 billion RMB (985 mill USD)</td>
</tr>
<tr>
<td>Source of revenues</td>
<td>308 RMB/per capita (2012)</td>
<td>8% of employee wages; 6% payroll tax on employers and 2% employee contribution</td>
<td>Average 245 RMB for adults, 113 RMB for minors (2008)</td>
</tr>
<tr>
<td>Positive list</td>
<td>About 1000 chemical and traditional Chinese medicines (determined by provincial government)</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

REIMBURSEMENT

for out- or in-patient and insurance programs

OUT-PATIENT

50.3% drug consumption (2012)
Setting quotas for subsidies per month; Special subsidies for some chronic diseases

IN-PATIENT

41.1% drug consumption (2012)
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%

Patient visits: 10% at private hospitals in 2014

Setting quotas for subsidies per month; Special subsidies for some chronic diseases
Different subsidies for different insurance programs and diseases
COLOMBIA
Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

1. Glossary of Pharmaceutical Terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies
Contact: acosta-angela@javeriana.edu.co
CROATIA

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

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/здравствeni-sustav/hr/lezavice-s-vazeci-lista/

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 reimbursement lists of CHIF (HZZO)

MAH proposal

HZZO – Division for drug verification of documentation

Committee for medicines opinion

HZZO Management board decision

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 experience dose, dose in SCP
- Reference price-cheapest molecule with 5% of volume in last 3 months

Osnovna lista lijekova

2009, INN 754 packages 2070
2015, INN 807 packages 3513

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

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

Dopunska lista lijekova

2009, INN 155 packages 236
2015, INN 302 packages 775

E-Prescriptions prescribing criteria are defined for certain indications

Medicines distributed via Wholesalers and Pharmacies

Statutory 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

Hospitals

- No co-payment for patient in hospitals
- Statutory pricing + Price negotiations + Tendering (Volume + pay-back agreements, Pay per performance …)
- Medicines are integrated in the sums which can be generated for reimbursement of the procedure and diagnosis-oriented case groups (DROG)

except drugs which are paid separately:

List of particularly expensive drugs (new innovative / orphan drugs)

Committee in hospital – decision on use of these medicines
Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

**OUT-PATIENT & IN-PATIENT**

Pricing policies refer to the private sector.

There is no discrimination between in and out patient sector.

External price referencing.

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

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

Prices reduction

Pricing under the authority of the Ministry of Health.

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

**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

**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

**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

**Ministerial Decision on deregulated ATC**

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

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

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

“Free pricing”

**Administrative procedure**

**Parties:**
pharm. companies (MAH)

**Consultation:**
medical associations

**List of items with reimbursement**

**OUT-PATIENT**

**IN-PATIENT**

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

**Price control**

**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**

**Hospital only medicines (reimbursed)**

**List of items with reimbursement**
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

European Medicines Agency (EMA) or Danish Medicines Agency (DMAA).
Task: Decision on authorization and registration

Danish Medicines Agency
Task: Categorizes pharmaceuticals into POM, prescription-only OTC (P), OTC for limited free sale (Håndkab, H) and OTC for general free sale (Frank, F)
Criteria: Safety, suitability for self-medication, etc. (Danish Medicines Act, No. 1180 of 12 December 2005 and Executive Order on Prescriptions, No. 159 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 81 of the Danish Medicines Act, No. 1180 of 12 December 2005 and Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/GWP/1035/98)

Pricing: It is free. However, the DMAA has to be notified of the PPR.
No permanent price control. Prices are set freely.
The companies can change prices every two weeks.

Flowchart:

- **OUTPATIENT SECTOR**
- **INPATIENT SECTOR**

DMAA 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. 54 of 26 June 2003 and Executive Order, No. 140 of 17 March 2005 on Reimbursement

Reimbursement types:
- General reimbursement
- Prescription-only pharmaceuticals subject to reimbursement
- 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
- Individual reimbursement on application from doctor

Distribution:
- Pharmacy
- Hospital
- Hospital purchasing agency (Agoerx)

Order
- Distribution
- Hospital Pharmacy
- Pharmaceutical companies

Delivery
- Pharmacy
- Hospital
- Supermarkets, gas stations

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

Pharmaceutical and therapeutic committee
Task: Decision on the pharmaceuticals to be included in hospital pharmaceutical formulary
Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

New pharmaceutical

EMA or Estonian State Agency of Medicines (SAM) consulted by Committee of Pharmaceutical Marketing Authorisation
Task: Decision on marketing authorisation

Out-patient care

In-patient care

Government according to the proposal of Estonian Health Insurance Fund (EHIF), consulted by Ministry of Social Affairs and experts
Task: Decision on pricing and reimbursement of medicinal services, including pharmaceuticals

List of pharmaceuticals reimbursed by EHIF

Not listed
Pharmaceuticals what are not applied for inclusion to the reimbursement list or what were decided not to list
No reimbursement

List of medicinal services of EHIF

Free manufacturer price + wholesale and retail mark-ups and reduced VAT 9% (ordinary VAT 20%)

100% reimbursement
Diagnose-based, out-of-pocket payment is 1.27 €, reimbursement sum is fixed by reference price or price-agreement's price
100% reimbursement for listed pharmaceuticals for children under 4

75%/90% reimbursement
Diagnose-based, out-of-pocket payment is 1.27 € + 25%/10% of reference price or price-agreement's price; 90% reimbursement for vulnerable groups

50% reimbursement
out-of-pocket payment is 3.19 € + 50% of reference price or price-agreement's price

100% reimbursement - pharmaceuticals for in-patient care
Ethiopia

**HEALTH EXPENDITURE INDICATORS**

<table>
<thead>
<tr>
<th>Year</th>
<th>Public sector</th>
<th>Private sector</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>22.15 billion</td>
<td>0.86 billion</td>
<td>23.01 billion</td>
</tr>
</tbody>
</table>

**DEMOGRAPHY**

- **Population**: 23.52 million
- **GDP per capita**: $243.6

**HEALTH SYSTEM AND HTA DEVELOPMENT**

- **System in 2015**

**Health legislation and financing**

- **Government role**: Federal Ministry of Health (FMoH) develops national policy, laws, guidelines, 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 (WHO) 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 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.

- **Pricing**: Health services: Public hospitals receive 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. Medicines 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. Parishal 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.

- **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).
## Pharmacological Pricing and Reimbursement Policies in the In- and Out-Patient Sector

### Pricing in the Out-Patient Sector

- **Non-Reimbursable Pharmaceuticals** can be priced freely.
- **Statutory Pricing for Reimbursable Pharmaceuticals**
  - **Pricing Procedures** include:
    - External price referencing
    - Internal price referencing
    - 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

- **Generic**
  - 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 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

### 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

In 2016, additional savings of €50 million (about 4%) on reimbursement costs must be generated. Measures to reach that have not yet been published.
The pharmaceutical system in France in the in- and out-patient sector

**New medicine**

### Authorisation/Classification
- **European Medicines Agency (EMA)** or **French Health Products Safety Agency / Agence nationale de sécurité du médicament et des produits de santé (ANSM)**
  - Task: Decision on authorization and registration

### Vigilance
- **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.
  - 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 Committee (CEPS)**
  - Task: Price negotiations
  - Criteria: At ex-factory level, depending on ASMR +/- RDCR
  - Publication of ex-factory and retail price (distribution mark-ups regulated)

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

#### IN-PATIENT
- **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

### Reimbursement
- **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

### Distribution
- **French Health Products Safety Agency / Agence nationale de sécurité du médicament et des produits de santé (ANSM)**
  - Task: Distribution mark-ups regulation
  - Criteria: Wholesalers, pharmacists margins

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

### Pharmaceutical companies
- Wholesalers
- Pharmacies
- Hospitals
- Pharmacological and Therapeutic Committee per hospital
  - Task: Decision on use of medicines

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

**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 occurrence.

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

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

**EML with Recommendations for Reimbursement**

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

**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

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

**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.
Pricing and reimbursement of medicines in the in- and out-patient sector

**Social Security Price**
-9%

**Ex-factory price**
-4.67% (<200€)
-1.48% (>200€)

**Wholesale price**
from +2.00% to +30.00%

**Pharmacy price before VAT**
+6.0%

**VAT**
+6.0%

**Retail price**

**High Cost Drugs purchased by EOPYY’s Pharmacies**

**Life style medicines**
-Wholesalers mark-up= 5.4% on ex-factory price

**OTC-catalog**

**Positive list**

**Internal reference pricing & Reimbursement Price**

**ATC4, ATCS clustering**

**Co-payment/Rebate when exceed reimbursement price**

**Negative list**

**Pricing and reimbursement of medicines in in-patient sector**

**Ex-factory**
+8.74%

**Hospital Price**
+5%

**Price charged by hospitals to EOPYY**

**Hospitals buy in hospital price-5% plus volume rebate and charge to EOPYY in Hospital Price+5%**

**1-30-2011: implementation of DRGs (medicines included in DRGs)**

**Tenders with active ingredient have been launched by National Procurement Committee**

**Co-payment**

- 25%
- 10%
- 0%

**In general**

**Chronic diseases & low pensioners**

**Severe diseases & pregnancy & high cost drugs**

**High Cost Drugs are dispensed through EOPYY’s pharmacies, Hospital Pharmacies and Private Pharmacies. When dispensed by private pharmacies under specific requirements the same profit margins are applicable, but the MAH has to return to EOPYY the excess expenditure from dispensing by EOPYY’s pharmacies.**
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 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 (V.28.) Legal framework for price setting
- Decree of the Ministry of Health 5/2007 (II.24.) wholesale and pharmacy mark-up, price margins
- Act XCVIII of 2008 on the Safe and Economic Supply and Distribution of Medicines and Therapeutic Medical Devices

Links
http://www.oeo.hu/cyphg
http://www.oeo.hu/iramos/gyogyaszkeresko
http://www.oeo.hu/feleso_menu/szakmai_oidletak/publikus_forgalmi_adatok/gyogyaszforgalmi_adatok

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.
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

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.

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

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

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.

Wholesaler
Free mark up at Wholesale level

Pharmacies
Maximum mark up set by the Icelandic Medicine Pricing and Reimbursement Committee (2 different steps: one for a 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

Icelandic Medicine Pricing and Reimbursement Committee (IMPRC)

- Task: Decision on reimbursement status of hospital/high cost medicines
- Criteria: Price relative to efficacy

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

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
- Criteria: No co-payment for patients
- Criteria: Pharmaceutical formulary per hospital

Sept. 2015
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, Belgium, 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 Assessment 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 Drug 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
   ACI: 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 Arixiban

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)

Reimbursement Costs: 1999 to 2014

Development of pharmaceutical expenditure in the last 5 available years

GMS, DPS and LTI include pharmacy fees

Expenditure on High Tech Drugs

Expenditure on the scheme was €486 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) €14.00 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, Malignant Illness (Under 16yrs of age), Spinal Bilidets 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: Pharmacy and Poisons Board (PPB)


Reforms: Establishment of a Food & Drugs Authority and Pharmacy Council (underway)
- Draft Policy and Bill are being developed to implement this reform

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Public Sector</th>
<th>Faith-Based (FBO)</th>
<th>Private Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection (for financing)</td>
<td>MOH - National Medicines &amp; Therapeutics Committee (NMTC)</td>
<td>NO legal requirement for FBO or private sector to apply the national EML</td>
<td>However, the FBO sector largely aligns with the KEMSA - may make some modifications (e.g. when EML is considered out of date) • Adapted by Mission for Essential Drugs &amp; Supplies (MEDS), Formulary Committee</td>
</tr>
<tr>
<td>Formulary (for procurement)</td>
<td>Kenya Medical Supplies Authority (KEMSA) formulary (extracted from the KEMSA &amp; based on available funds)</td>
<td>Adapted from KEMSA based on annual review of requirements of FBO facilities. May also supply non-formulary items (ad-hoc pricing)</td>
<td>Individual hospitals may develop formularies as a tool for internal cost control</td>
</tr>
<tr>
<td>Pricing policies for medicines</td>
<td>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 &amp; child health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAT</td>
<td>Kenya Revenue Authority (KRA): NO VAT on medicines - but importers have to seek exemption for each consignment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturers</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procurement Agent</td>
<td>KEMSA: a state agency</td>
<td>MDES: A non-profit trust established by the churches</td>
<td>Individual wholesalers (local or international). No law on wholesale vs retail business</td>
</tr>
<tr>
<td>Procurement method(s)/Legislation</td>
<td>Generic procurement is applied routinely by KEMSA &amp; MEDS</td>
<td>No law applies but Kenya National Pharmaceutical Policy (KNPP 2012) supports/encourages generic procurement</td>
<td>Mostly brand-name</td>
</tr>
<tr>
<td>Wholesale Remuneration/Legislation</td>
<td>Public health medicines issued for free to facilities (all sectors) (paid by govt. unit or donor) through KEMSA &amp; MEDS. Agreed fees for distribution (via wholesaler)</td>
<td>Restricted tender to pre-qualified suppliers (international/national). Pooled procurement with other FBOs (e.g. Uganda, Zambia) - select items. No applicable legislation</td>
<td>Direct procurement by facilities &amp; retailers as feasible. No applicable legislation</td>
</tr>
<tr>
<td>Pharmacy remuneration (Retail pricing)</td>
<td>NO law/guidance on pricing/margins to patients (all sectors). No legal requirement to pass price benefits onto patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dispensing/other fees</td>
<td>Not applicable - public officers cannot charge patients fees</td>
<td>Not applicable - FBO staff are salaried - no extra charges to patients</td>
<td>No legislation on dispensing fees. Average mark-up 30%</td>
</tr>
</tbody>
</table>

**Reforms:** The most desirable & comprehensive reforms relate to overhaul of the healthcare financing architecture – particularly the policy and institutional arrangements (see below)
**Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector**

<table>
<thead>
<tr>
<th>OUT- PATIENT</th>
<th>IN - PATIENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pricing in the out-patient reimbursement</strong></td>
<td><strong>Pricing in the in-patient sector (Public hospital)</strong></td>
</tr>
<tr>
<td><strong>Statutory pricing</strong></td>
<td><strong>Negotiations Committee under the Ministry of Health</strong></td>
</tr>
<tr>
<td>Pricing policies for reimbursable medicines</td>
<td>Price negotiations</td>
</tr>
<tr>
<td>External price referencing: Declared manufacturer price is compared with 85 % of the average manufacturer prices in reference countries (8 countries)</td>
<td>Expensive hospital medicines included in the List of Centrally Procured Medicines and Medical Devices (centrally purchased by the NHIF)</td>
</tr>
<tr>
<td>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</td>
<td>Free to patient</td>
</tr>
<tr>
<td>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</td>
<td>Hospital medicines not included in the List of Centrally Procured Medicines and Medical Devices</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>REIMBURSEMENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRICING at ex-factory level</strong></td>
</tr>
<tr>
<td><strong>Pricing in the out-patient reimbursement</strong></td>
</tr>
<tr>
<td><strong>Statutory pricing</strong></td>
</tr>
<tr>
<td>Pricing policies for reimbursable medicines</td>
</tr>
<tr>
<td>External price referencing: Declared manufacturer price is compared with 85 % of the average manufacturer prices in reference countries (8 countries)</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PRICING at wholesale level</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statutory pricing</strong></td>
</tr>
<tr>
<td>Wholesales Regressive margins</td>
</tr>
<tr>
<td>Pharmacies Regressive margins</td>
</tr>
<tr>
<td>VAT: 5% for reimbursable medicines, 21% for non-reimbursable medicines</td>
</tr>
<tr>
<td>All hospital medicines</td>
</tr>
<tr>
<td>Statutory margins are not relevant, unless products are from community pharmacy</td>
</tr>
<tr>
<td>VAT: 5% - reimbursed medicines</td>
</tr>
<tr>
<td>21% - not reimbursed medicines</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>REIMBURSEMENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reimbursement in the out-patient sector</strong></td>
</tr>
<tr>
<td>Positive list (500 active substances included on positive list) Reference price system (RPS) ATC 5 &amp; 4 level (Lowest price of medicine in reference group)</td>
</tr>
<tr>
<td>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)</td>
</tr>
<tr>
<td>Mechanisms for vulnerable groups 100 % reimbursed rate for all reimbursed medicines for children, disable patients</td>
</tr>
<tr>
<td>Reforms</td>
</tr>
<tr>
<td>MEA: price volume, expenditure cap, risk sharing</td>
</tr>
<tr>
<td>E-prescriptions system</td>
</tr>
<tr>
<td><strong>Reforms</strong></td>
</tr>
<tr>
<td>price negotiations with manufactures or wholesalers strategy for the acquisition of patented expensive hospital drugs</td>
</tr>
</tbody>
</table>
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*

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

- **Public sector**  
  40.1% volume market share  
  18.5% value market share

- **Private sector**  
  59.9% volume market share  
  81.5% value market share

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

**Secondary and tertiary care reimbursement list**  
(Catalogo de medicamentos)

**Primary care reimbursement list**  
(Cuadro básico)

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

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

**Institutional procurement agencies**

- **Branded originator medicines**  
  0.9% volume share  
  38.7% value share

- **Generic medicines**  
  99.1% volume share  
  61.3% value share

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

- **Generic medicines**  
  74.2% volume  
  49.6% value

- **Branded originator medicines**  
  25.8% volume  
  50.4% value

**Wholesalers**  
(about 20 in total)

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

- **Retail pharmacies**  
  (about 25,000 in total)
  16.8% Pharmacies in supermarkets
  21.8% Independent pharmacies
  NO VAT on medicines

- **Consumers and patients**  
  (by 2012, 53.7% of the patients paid for their medicines)
  81% of total pharmaceutical expenditure is out-of-pocket

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

*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

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

Reimbursement decision making in the Mexican public sector

1. Safety and Effectiveness
   - Health Technology
   - National Medicines Regulatory Authority (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS)
   - Is the Health Technology effective and safe?
     - Yes → Approval
     - No → Non Approval

2. Cost-Effectiveness for Public Sector
   - Is the Health Technology Cost Effective?
     - Yes → Inclusion in National List
     - No → Exclusion from National List
   - General Health Council Positive List Commission integrated by Ministry of Health
     - IMSS, ISSSTE, PEMEX, SEDENA, DIF, MARINA

3. Affordability for Public Sector
   - Affordability of health technologies
     - Yes → Inclusion to Institutional positive list
     - No acquisition → No
   - Commission for the Negotiation of Medicines Prices (CCNPMIS)
     - regulates the acquisition prices only for patented/single source medicines

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

Elaborated by Yared Santa-Ana-Tellez, Utrecht University, The Netherlands; Fernando Alarid, University of Minnesota, and Boel Rivera-Dropaza, Mexican Institute of Social Security, Mexico September 2015
Consulted data sources: OECD (2015), OECD Economic Surveys: Mexico, OECD Publishing...
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 enterprises

- Pharmacies in the dispensaries 4%
- Privat pharmacies 5%
- Medical assistance enterprise in rural…
- Storehouses
- Local producers 1%

Distribution of pharmacies

- The number of the pharmacies 1993

Pharmacies in the dispensaries 4%
Privat pharmacies 5%
Medical assistance enterprise in rural…
Storehouses
Local producers 1%

The number of the population per pharmacie 1785

The number of the population
- Urban ari - 1380
- Rural ari - 3352

Medicine market share

- Essentials – 26.6%
- Originals – 14.6%
- Generics – 85.5%
- Rx – 69.7%
- OTC – 29.4%

Authorization of medicines

<table>
<thead>
<tr>
<th>Year</th>
<th>Local (MDL)</th>
<th>Imported (MDL)</th>
<th>Total (MDL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>1109</td>
<td>4685</td>
<td>5794</td>
</tr>
<tr>
<td>2011</td>
<td>1160</td>
<td>5073</td>
<td>6233</td>
</tr>
<tr>
<td>2012</td>
<td>1143</td>
<td>6233</td>
<td>7376</td>
</tr>
<tr>
<td>2013</td>
<td>1177</td>
<td>6209</td>
<td>7386</td>
</tr>
<tr>
<td>2014</td>
<td>1132</td>
<td>6061</td>
<td>7193</td>
</tr>
<tr>
<td>2015</td>
<td>912</td>
<td>4722</td>
<td>5634</td>
</tr>
</tbody>
</table>

Evolution of the manufacturers prices for medicines

<table>
<thead>
<tr>
<th>Year</th>
<th>National currency (MDL)</th>
<th>Currency (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>+6.9</td>
<td>+5.65</td>
</tr>
<tr>
<td>2011</td>
<td>+5.65</td>
<td>+2.15</td>
</tr>
<tr>
<td>2012</td>
<td>+0.09</td>
<td>-1.12</td>
</tr>
<tr>
<td>2013</td>
<td>-0.36</td>
<td>-5.37</td>
</tr>
<tr>
<td>2014</td>
<td>-2.47</td>
<td>-4.67</td>
</tr>
<tr>
<td>2015</td>
<td>-10.38</td>
<td></td>
</tr>
</tbody>
</table>

Pharmacotherapeutic groups included in the Reimbursement program

<table>
<thead>
<tr>
<th>Pharmacotherapeutic group</th>
<th>INN</th>
<th>Pharmacotherapeutic group</th>
<th>INN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular agents</td>
<td>19</td>
<td>Drugs used in diabetes</td>
<td>7</td>
</tr>
<tr>
<td>Digestives</td>
<td>5</td>
<td>Epidermolyis bullosa</td>
<td>5</td>
</tr>
<tr>
<td>Endocrine therapy</td>
<td>3</td>
<td>Autoimmune disease</td>
<td>3</td>
</tr>
<tr>
<td>Drugs used in asthma therapy</td>
<td>4</td>
<td>Ophthalmic diseases</td>
<td>4</td>
</tr>
<tr>
<td>Treatment and prophylaxis agents used in children (0-5 years)</td>
<td>12</td>
<td>Prophylaxis of iron deficiency anemia and folic acid deficiency during pregnancy</td>
<td>2</td>
</tr>
<tr>
<td>Cystic fibrosis</td>
<td>2</td>
<td>Misenia gavis</td>
<td>1</td>
</tr>
<tr>
<td>Anti-epileptics</td>
<td>6</td>
<td>Multiple sclerosis</td>
<td>1</td>
</tr>
<tr>
<td>Parkinson’s disease</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nervous system</td>
<td>11</td>
<td></td>
<td>87</td>
</tr>
</tbody>
</table>

The rate of compensation

<table>
<thead>
<tr>
<th>Group</th>
<th>50%</th>
<th>70%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular agents</td>
<td>6.7%</td>
<td>26%</td>
<td></td>
</tr>
</tbody>
</table>

Differentiated value added tax

<table>
<thead>
<tr>
<th>Purchase price (MDL)</th>
<th>Final margin</th>
<th>Wholesale margin</th>
<th>Pharmacy margin</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 30,00</td>
<td>&lt; 40 %</td>
<td>&lt; 15 %</td>
<td>&lt; 25 %</td>
</tr>
<tr>
<td>30,01- 60,00</td>
<td>&lt; 37 %</td>
<td>&lt; 12 %</td>
<td>&lt; 25 %</td>
</tr>
<tr>
<td>60,00 – 120,00</td>
<td>&lt; 26 %</td>
<td>&lt; 10 %</td>
<td>&lt; 16 %</td>
</tr>
<tr>
<td>120,01 – 240,00</td>
<td>&lt; 21 %</td>
<td>&lt; 8 %</td>
<td>&lt; 13 %</td>
</tr>
<tr>
<td>&gt;240,00</td>
<td>&lt; 16 %</td>
<td>&lt; 5 %</td>
<td>&lt; 11 %</td>
</tr>
</tbody>
</table>

Annotation: The average exchange rate in August - 1 EUR = 21.1864 MDL, but on 25 September - 22.6684 MDL

- 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 the Laboratory 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.
- The medicines 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 Regiser.
- 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 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 (554 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%).
**The Netherlands**

**Ministry of Health, Welfare and Sport**

### 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)

### 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.

- **In patient**
  - **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

### 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

### Health insurers

- Reimbursement if medicine is on positive list
- Generics: therapeutic substitution, preference policy

### 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
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 pharmacy level

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

NoMA
Task: Decision on the reimbursement status
Criteria: Pharmacological, medical therapeutic, pharmaco-economic criteria

National Advisory Committee for Drug Reimbursement

Reimbursable medicines
National Reimbursement Code
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.

Hospital purchasing body: Drug Procurement Cooperation (LIS)
Hospital pharmacies, pharmacists, departments 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
Pharmaceutical and Therapeutic Committee

Task: Decision on use of medicines in specific hospitals

List of preferred products/suppliers

PRICING at ex-factory level is not regulated in Norway
Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

**New medicine**

**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)**

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

**Pharmacology Committee**

**Wholesaler**

- Mark up not regulated

**Pharmaceutical companies**

**Medicines distributed via**

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

**Wholesalers**

- Free Mark up at wholesale level.

**Pharmacies**

- Free Mark up at pharmacies.
- Pocket payments covered

**VAT:**

- 18% (all kinds of medication)
- Exempt from customs duty medicines for cancer, HIV and diabetes

**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

**Pricing at wholesale level**

**Pricing at ex-factory level**

**OUT-PATIENT**

**Hospital purchasing body**

- (individual hospital pharmacist or joint purchasing body)
- Task: Price negotiations or tendering of medicines increased by 25%
- Criteria: Depending on the product or on the market situation of the medicine

**Hospital pharmacy and/or pharmaceutical depot**

**Price negotiations**

**Tendering**

**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

**Pricing at wholesale and pharmacy level**

**Pocket payments:**

- 29.8% (Uninsured)

**VAT:**

- 18% (all kinds of medication)
- Exempt from customs duty medicines for cancer, HIV and diabetes (0%)

**Ministry of Health (MINSA)**

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

**Non reimbursable medicines**

- Pocket payments

**Public hospitals which receive public funds**

**Use in hospitals**

- Hospital/Hospital owner 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**
POLAND

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

**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

**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 – 5%

medicines, medical devices VAT – 8% FSMP VAT – 5% or 8% or 23%

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

**POM (except HOM) + OTC reimbursed**

- **National medicines agency (INFARMED)**
  - **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)

**OTC not reimbursed**

- **Pharmaceutical companies**
  - **Task:** Establish OTC price
  - **Criteria:** Decree-Law n.º 134/2005, 16th August

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

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

**POM to be purchased by hospitals + OTC**

- **Shared Services of Ministry of Health (SPMS)**
  - **Task:** Public Procurement
  - **Criteria:** European Directives 2004/27/CE and 2004/18/CE
  - Price is an important decision factor

**Additional *reimbursement and additional conditions***

- **Applied only to Public hospitals**
  - **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)

**NATIONAL HEALTH TECHNOLOGY ASSESSMENT SYSTEM (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**

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

- **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: 90%)
  - C: 60% (D: 60%)

**Specific Scheme**

- **Product Specific**
  - Based on therapeutic classification

**Generics**

- From the 57% 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

**Population Group Specific**

- Extra reimbursement (15%) for pensioners

**Disease Specific**

- Defined pathologies e.g., HIV, Alzheimer disease

**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

**OUT-**

- **Use in Hospitals**
  - **National Formulary**
  - **In consultation with**

**IN-**

- **Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic Committee**
  - **Task:** Decision on use of medicines in the hospital
  - **Criteria:** Ministerial Dispatch n.º 1083/2004

PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES IN THE IN- AND OUT-PATIENT SECTOR

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

<table>
<thead>
<tr>
<th>External reference pricing system</th>
</tr>
</thead>
</table>
| 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) |

<table>
<thead>
<tr>
<th>Reimbursement criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Measures for all drugs</th>
</tr>
</thead>
</table>
| Internal reference pricing system for interchangeable drugs (ATC 5) since 2003  
- Pricing and managed entry agreements: discounts (reduction of price), rebates (material discount), price-volume agreements, payback 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) |

**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)  

<table>
<thead>
<tr>
<th>Approaches for rational prescribing</th>
</tr>
</thead>
</table>
| 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 care providers is planned for the year 2015.  
- Audits focused mostly on prescribing restrictions  
- Education (polypharmacy, antibiotics, etc.) |

<table>
<thead>
<tr>
<th>Pharmacies:</th>
</tr>
</thead>
</table>
| 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. |
### 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.

### Previous SEP Adjustments

<table>
<thead>
<tr>
<th>Year</th>
<th>Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004-2007</td>
<td>5.21%</td>
</tr>
<tr>
<td>2006</td>
<td>6.5%</td>
</tr>
<tr>
<td>2009-2010</td>
<td>13.2%</td>
</tr>
<tr>
<td>2010</td>
<td>7.4%</td>
</tr>
<tr>
<td>2011</td>
<td>0%</td>
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<tr>
<td>2012</td>
<td>2.14%</td>
</tr>
<tr>
<td>2013</td>
<td>5.80%</td>
</tr>
<tr>
<td>2014</td>
<td>5.82%</td>
</tr>
<tr>
<td>2015</td>
<td>7.5%</td>
</tr>
</tbody>
</table>

SEP reviews are determined and announced by the Minister of Health annually. SEP reviews 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 manufacturer 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 FEES

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)
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.

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.

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

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.

IN-PATIENT

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.

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.
Switzerland

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

**AUTHORISATION/CLASSIFICATION**

| 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**

**Swissmedic Medicines Expert Committee**

**Human Medicines Expert Committee**

**Veterinary Medicines Expert Committee**

**PRICING**

**at ex-factory level**

| Medicines applying for out-patient reimbursement |
| Statistical 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 |

**Federal Office of Public Health (FOPH)**

**Federal Medicines Committee (EAK)**

**PRICING**

**at wholesale and pharmacy level**

| Medicines distributed via |
| Wholesalers |
| Statistical 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). |
| Pharmacies |
| Statistical pricing |
| For prescription-only medicines up to an ex-factory price of 880 francs a surcharge of 12% is imposed, for more expensive ones 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% |

**REIMBURSEMENT**

| Reimbursable medicines |
| 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. |

| 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. |

**IN-PATIENT**

**Hospital purchasing body**

(task: decision on use of medicines)

| Criteria: economic criteria |

**Swiss DRG AG**

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

**OUT-PATIENT**

**Price negotiations**

| Statutory margins are not relevant. |

| Use in hospitals |

**Use in hospitals**

**Pharmaceutical formulary per hospital (owner)**

| Co-payments for patients |
### 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% to 10%.

**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 applicable in the in-patient sector**

Same as out-patient sector.

**Pharmacy remuneration - if applicable in the in-patient sector**

There isn’t any pharmacy remuneration.

**VAT – if applicable**

Same as out-patient sector.

### 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>
<thead>
<tr>
<th>AUTHORIZATION</th>
<th>Ministry of Health of Ukraine State Expert Centre of the MoH</th>
<th>State Administration of Ukraine on Medicinal products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision on authorization and registration</td>
<td></td>
<td>post-marketing quality control of medicines; licensing, GMP certification of manufacturers, licensing of pharmacies</td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>List of the ex-factory prices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vigilance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines necessary for antiterrorist operation may be imported without authorization in Ukraine</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PRICING at ex-factory level</th>
<th>Ministry of Health of Ukraine Ministry of Economics of Ukraine</th>
<th>State Inspection on Prices:</th>
</tr>
</thead>
<tbody>
<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></td>
<td>Price control</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRICING at wholesale and pharmacy level</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesalers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum wholesale markups for Essential Medicines (215 INN): Maximum distribution price markup 10%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retail markups are regulated for Essential Medicines (215 INN) Maximum retail markup 25%</td>
<td></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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OUT-PATIENT SECTOR</th>
<th>IN-PATIENT SECTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groups of patients to whom the medicines are dispensed free of charge:</td>
<td></td>
</tr>
<tr>
<td>1. veterans of the World War II</td>
<td></td>
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<tr>
<td>2. veterans of labour</td>
<td></td>
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<tr>
<td>3. Chernobyl cleanup veterans</td>
<td></td>
</tr>
<tr>
<td>4. retired collective farmers, workers, public servants</td>
<td></td>
</tr>
<tr>
<td>5. children under 3 years</td>
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<tr>
<td>6. disabled children under 16 years</td>
<td></td>
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<tr>
<td>7. children under 18 years, who in 1988 had an illness on chemical inoxicative alopecia in Chernivtsi</td>
<td></td>
</tr>
<tr>
<td>8. adolescent girls and women with contraindication of pregnancy</td>
<td></td>
</tr>
<tr>
<td>Groups of patients to whom the medicines are dispensed at half-price:</td>
<td></td>
</tr>
<tr>
<td>1. disabled people of the I or II groups</td>
<td></td>
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<tr>
<td>2. children 3-6 years</td>
<td></td>
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<tr>
<td>3. rehabilitated victims of the political repressions</td>
<td></td>
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<tr>
<td>4. honorary donors of Ukraine or USSR</td>
<td></td>
</tr>
<tr>
<td>Medicines for the treatment in the out-patient sector are dispensed free of charge for the following diseases (totally – 34):</td>
<td></td>
</tr>
<tr>
<td>1. Oncology</td>
<td></td>
</tr>
<tr>
<td>2. Hematological diseases</td>
<td></td>
</tr>
<tr>
<td>3. Diabetes (mellitus and insipidus)</td>
<td></td>
</tr>
<tr>
<td>4. Rheumatism</td>
<td></td>
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<tr>
<td>5. Rheumatoid arthritis</td>
<td></td>
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<tr>
<td>6. Syphilis</td>
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</tr>
<tr>
<td>7. Tuberculosis</td>
<td></td>
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<tr>
<td>8. AIDS</td>
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<tr>
<td>9. etc.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OUT-PATIENT SECTOR</th>
<th>IN-PATIENT SECTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot project on reimbursement of insulins – since 01/01/2016</td>
<td></td>
</tr>
<tr>
<td>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>
<td></td>
</tr>
</tbody>
</table>
Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

### Pricing policies for medicines

**Out patient**

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 at 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 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](https://www.gov.uk/government/consultations/pricing-of-branded-health-service-medicines)

### 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.

### Reforms