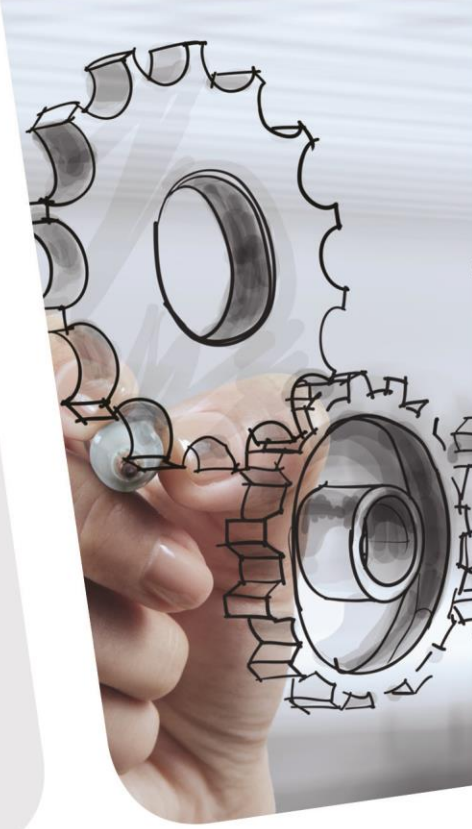
Gesundheit Österreich GmbH

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

4th PPRI Conference
Medicines access challenge - The value of pricing and reimbursement policies

Wednesday, 23 October 2019 - Thursday, 24 October 2019

Vienna, Austria



COUNTRY POSTER BOOK

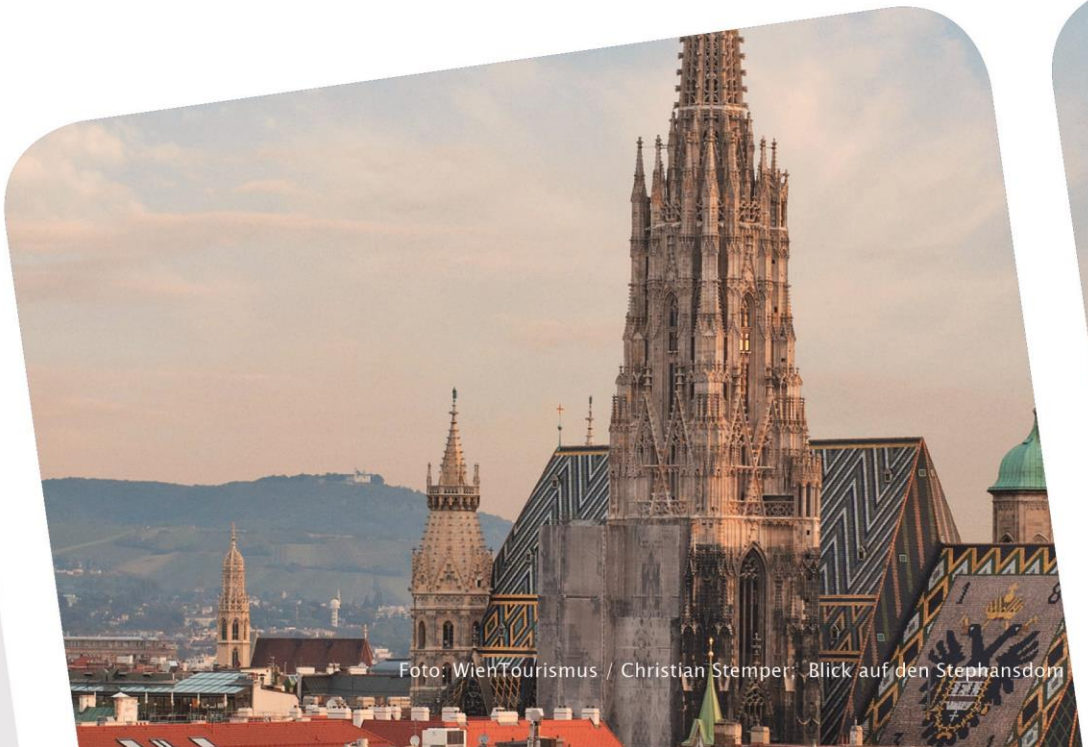
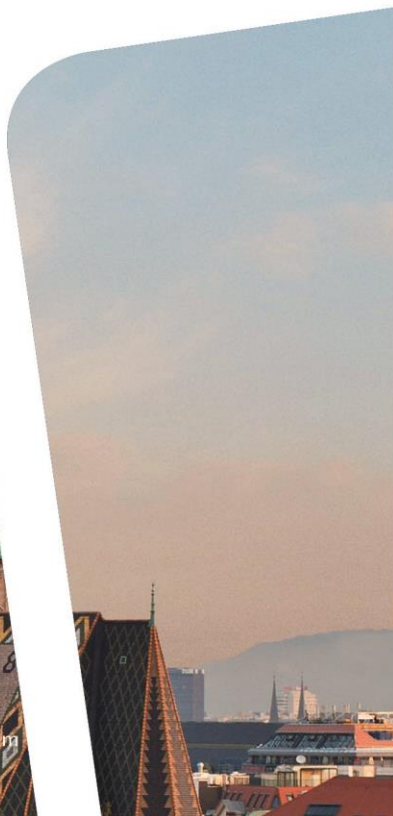


Foto: WienTourismus / Christian Stemper: Blick auf den Stephansdom



Contact: ppri@goeg.at

The country posters included in the country poster book were submitted to the conference organisers of the PPRI Conference 2019.

The printed version of the poster book (Version 17 October 2019) may not include all country posters that are displayed at the conference.

More information: https://ppri.goeg.at/ppriconference2019

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

Österreichische Sozialversicherung | Bundesministerium Arbeit, Soziales, Gesundheit und Konsumentenschutz | Gesundheit Österreich GmbH | PPRI Pharmaceutical Pricing and Reimbursement Information | WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

AUSTRIA

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

Total Population: 8.86 Mio. (2019)
GDP per Capita: 55,523 (PPP, current int. $, 2018)
Health Care Sector: social health insurance system
Health Expenditure per Capita: 5270.2 ($, PPP, 2017)
Health Expenditure in % of the GDP: 10.4 (2017)

PRICING at ex-factory level

Medicines applying for out-patient reimbursement

Medicines not in out-patient reimbursement but exceeding 750,000 Euro turnover a year at the expense of the Austrian health insurance funds

Statutory pricing

- **External Price Referencing (EU average)**
- **Generic price link**
  - **1st generic:** - originator -30 % - generic -28.65% of the lowered price of originator
  - **2nd generic:** - generic -18% of the price of 1st generic
  - **3rd generic:** - generic priced -15% of the price of 2nd generic - additionally, originator and all generics must be priced at the level of 3rd generic
- **Biosimilar price link**
  - **1st biosimilar:** - biological -30 % - biosimilar -11.4% of the lowered biological price
  - **2nd biosimilar:** - biosimilar -15% of the price of 1st biosimilar
  - **3rd biosimilar:** - biosimilar -10% of the price of 2nd biosimilar - additionally, originator and all biosimilars must be priced at the level of 3rd biosimilar

Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMASGK)

in consultation with

Pricing Committee

supported by

Pharma Price Information (PPI) service at the Austrian National Public Health Institute (GÖG) – checking pharmaceutical prices on request

Main Association of Austrian Social Security Institutions (HVB)

Negotiations and Managed Entry Agreements

Medicines not included in out-patient reimbursement

Free pricing

Price notification

Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMASGK)

Medicines purchased in the in-patient sector

Statutory pricing

Negotiations and tendering Managed Entry Agreements

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

PRICING at wholesale and pharmacy level

Whole salers — Statutory pricing

Maximum regressive wholesale mark-up scheme
(2 different schemes, one for Green + Yellow box products, one for the remaining)

Phar-macy — Statutory pricing

Maximum regressive pharmacy mark-up scheme
(2 different schemes: one for 'privileged' customers (e.g. health insurance funds) and one for private customers)

VAT: 10%

REIMBURSEMENT

OUT- PATIENT

100 % reimbursement
Co-payment: Prescription fee of €6.10 (2019) per prescribed item
(Exemptions from co-payments for vulnerable groups are in place)

Main Association of Austrian Social Security Institutions (HVB) in consultation with **Pharmaceutical Evaluation Board (HEK)**

Decision on inclusion in the out-patient positive list (Erstattungskodex - EKO) - Based on eligibility for reimbursement and **assessment** of the pharmacological, medical therapeutic, pharmacoeconomic value
New medicine to be listed must provide **additional benefit**

Positive list = EKO

- **Green Box**
  – Medicines qualifying for "automatic" reimbursement, broad use
  – For prescription of medicines no approval necessary
- **Light Yellow Box (RE2)**
  Reimbursable at defined conditions BUT ex-post control by chief medical officers of health insurance funds
- **Dark Yellow Box (RE1)**
  – Medicines with essential added therapeutic value at high cost;
  – Reimbursed at defined criteria after prior approval by chief medical officers of health insurance funds
- **Red Box**
  – When application is filed, medicine is included for a maximum duration of 180 days; if negative decision – delisting of the product from the Red Box
  – Reimbursable after prior approval by chief medical officers of health insurance funds

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

Basically not reimbursable. Medicines reimbursable on a case-by-case basis and prior approval by the chief medical officer of the of health insurance funds necessary

2020 = HVB will be moved to umbrella organization of the new Austrian Health Insurance Fund

IN - PATIENT

Public hospitals which receive public funds

Medicines are integrated in the **lump sums,** which are refunded to the hospitals according to diagnosis-orientated case groups (DRG).

Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMASGK)

in consultation with **Federal Health Commission (BGK)**

Definition and assessment of DRG groups (LKF) and medical services (MEL) and inclusion of medicines. Some oncology medicines, however, are defined as single medical procedures (Medizinische Einzelleistungen, MEL) and their utilisation is explicitly reimbursed.

FUNDING

State Health Funds (LGF)

The lump sums generated by eligible hospitals are billed to the Regional State Health Funds.
These are funded by several sources (Health Insurance Funds, States, Municipalities, Federal Health Agency, etc.)

Pharmaceutical formulary per hospital (owner)

Hospital/ Hospital owner association

in consultation with **Pharmaceutical and Therapeutic Committee in hospital (association)**

Pilot since 2018

Hospital Pharmaceutical Evaluation Board (Spitals-HEK)

Joint evaluation of high-cost medicines

İCBARİ TİBBİ SIĞORTA

SABAHA SAĞLAM ADDIMLAYAQ

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

AZERBAIJAN

Medicines access challenge – The value of pricing and reimbursement policies

Country profile

- Population: 10 million (2018) - ▲1%
- GDP: $46 billion (2018) - ▲1.4%
- Health expenditure – 7.6% GDP
- Health is a tax funded system
- Outpatient visits – 4.83 per person ▲ 2.4%
- Inpatient admission–64.7 per 1000 ▼ 0.3%

Roleplayers

The main roleplayers in drug pricing and reimbursement policies are Ministry of Health, Tariff Council, Analytical Expertise Center under the Ministry of Health, State Agency on Mandatory Health Insurance:

PRICE REGULATOR – TARIFF COUNCIL

- Method – external reference pricing
- Scope – state registered medicines (more than 11,000 drugs)
- Price control – Wholesale price and retail price

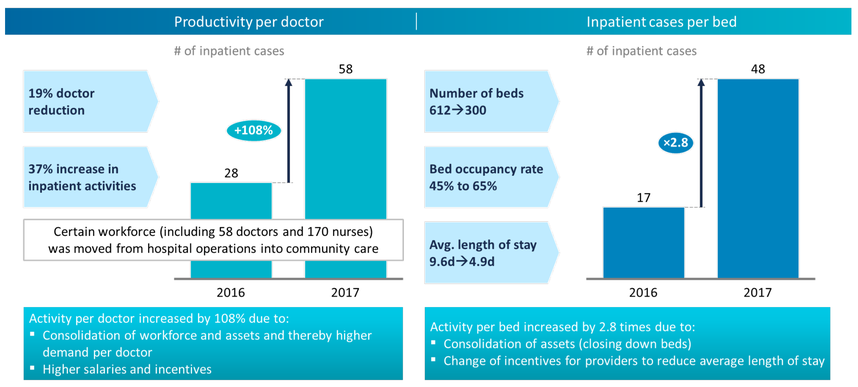
REIMBURSEMENT

MINISTRY OF HEALTH

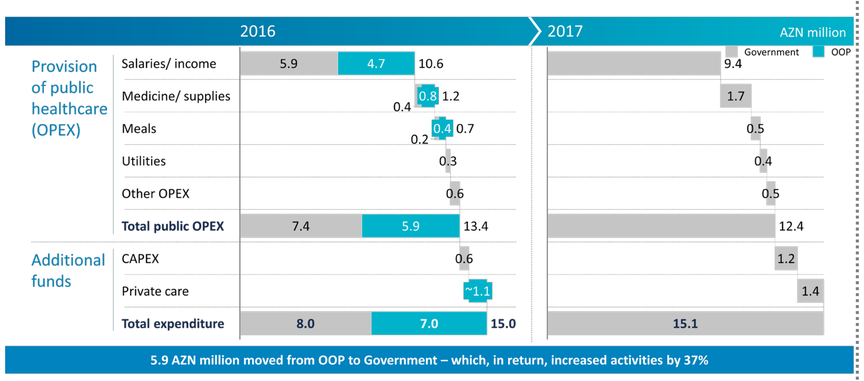
- Provide public hospitals.
- Operate state programs for selective disease to provide medicine.

STATE AGENCY ON MANDATORY HEALTH INSURANCE

- İmplement pilot project of mandatory health insurance.
- Medicine expenses increased more than 4 times in selected hospitals.
- From Jan. 1, 2020 compulsory health insurance is expected to cover whole country.



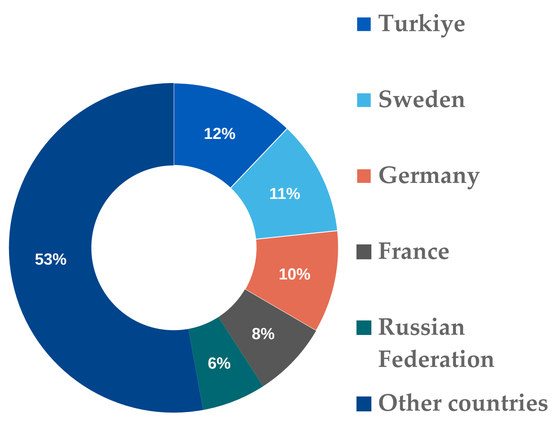
Productivity of workforce and utilization of assets increased significantly: Mingachevir case



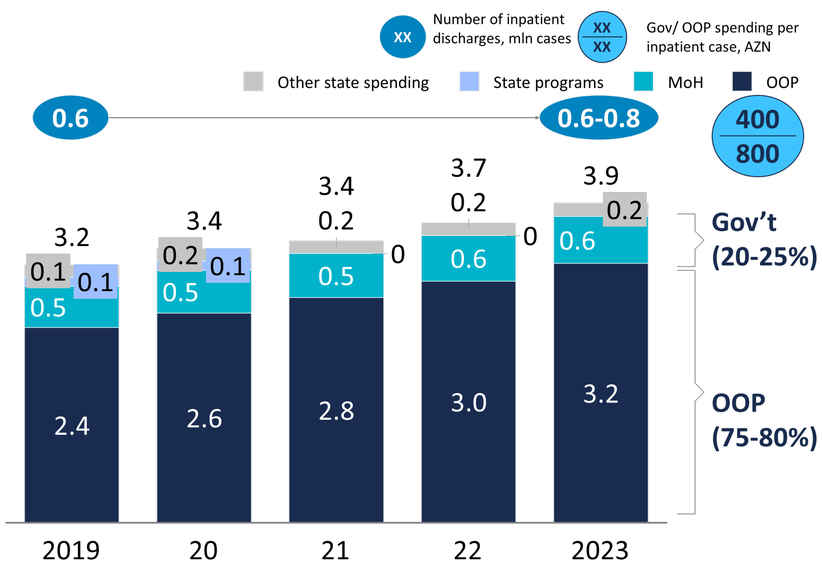
Effective healthcare expenditure in Mingachevir has not changed significantly but out-of-pocket expenditure was paid by the insurance which led to increase of activities by 37 percent

Data Analysis

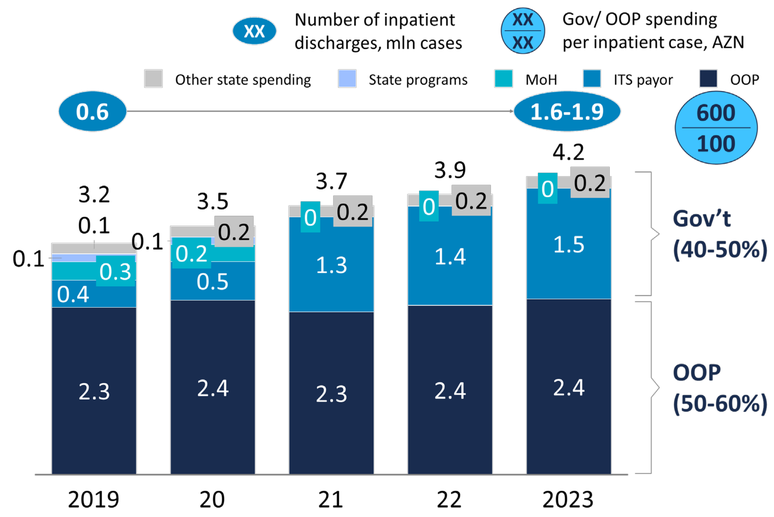
Medicine import statistics by country:



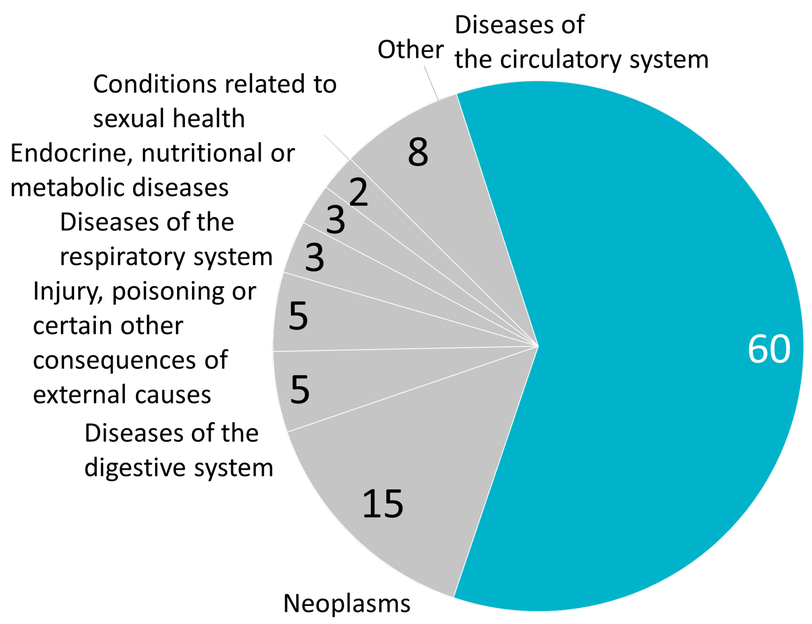
Health expenditure, bn AZN



Expected health expenditure after MHI implementation, bn AZN

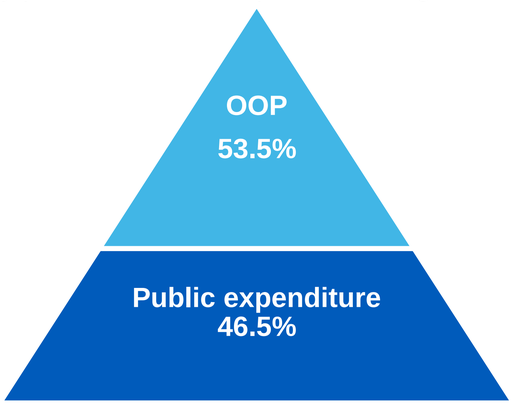


Deaths by cause, Azerbaijan 2016, %

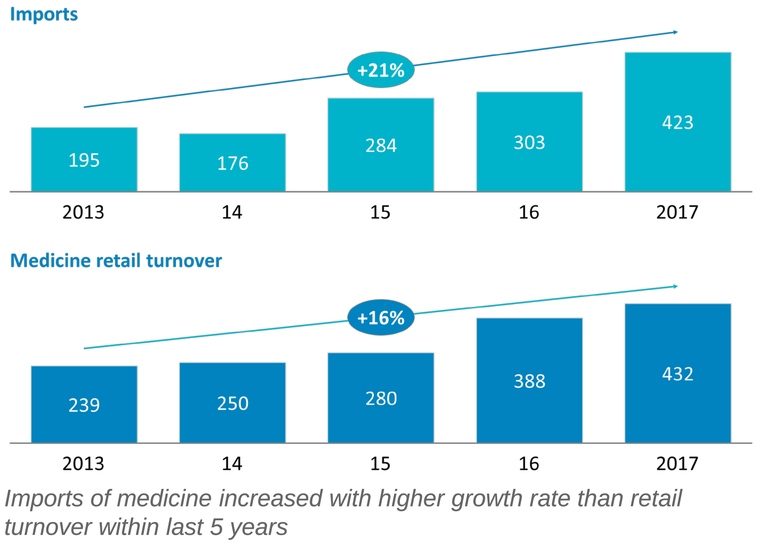


Results

Lessons learned from pilot project showed that utilization of medical services increase. It has impact on medicine use at hospital. The breakdown of total medicine cost (2018) by public and OOP expenditure is given below:



Medicine imports and retail turnover



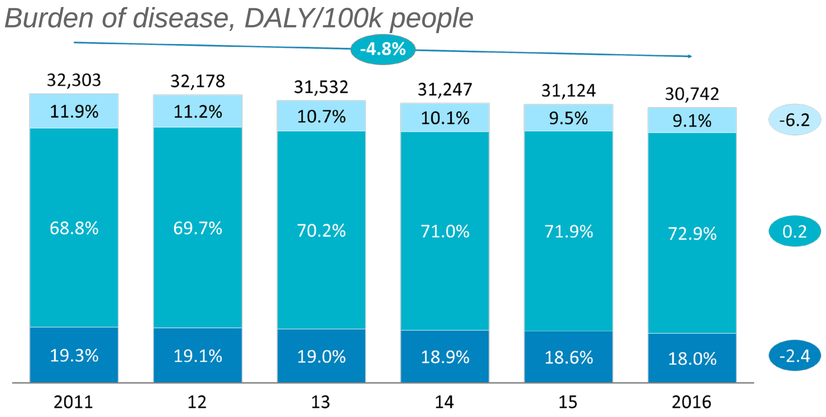
Imports of medicine increased with higher growth rate than retail turnover within last 5 years

List of diseases which medicine provided free by Ministry of Health

- ✓ vaccines
- ✓ multiple sclerosis
- ✓ oncology
- ✓ haemophilia
- ✓ chronic renal insufficiency
- ✓ diabetes
- ✓ prevention of AIDS
- ✓ tuberculosis
- ✓ mother-and-child health
- ✓ blood diseases

Burden of diseases

Burden of disease, DALY/100k people



Disability-Adjusted Life Year (DALY) has also improved by almost 5% since 2011 mainly due to improvements in communicable diseases but still higher than peer countries

References

1. The State Statistical Committee of the Republic of Azerbaijan – www.stat.gov.az
2. The Ministry of Health of the Republic of Azerbaijan – www.health.gov.az
3. World Health Organization – www.who.int
4. The Organisation for Economic Co-operation and Development – www.oecd.org
5. The World Bank – www.worldbank.org

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BELGIUM

National Institute for Health and Disability Insurance (NIHDI)

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

new pharmaceutical

MARKETING AUTHORISATION

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

Ex-factory level

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)

Wholesaler level

Maximum percentage wholesale mark up scheme
(set by Minister of Economic Affairs)

Pharmacy level

Fixed pharmacy mark up scheme
(set by Minister of Economic Affairs + Minister of Social Affairs)

Distribution via wholesaler & public pharmacy ⟷ Pharmaceutical company ⟷ *Direct supply to hospital +/- wholesaler*

REIMBURSEMENT

Minister of Social Affairs

Task: decision on reimbursement & reimbursement level

Criteria: therapeutic value, price, medical practice related to therapeutic & social needs, budget impact, pharmaco-economics

Advisory boards (NIHDI):

Committee on Reimbursement Medicines (CRM)
Technical Board for radioisotopes

Reimbursement list (pharmaceuticals)
(in- & out-patient sector)

Fixed reimbursement level

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 of 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 → *often through Managed Entry Agreements (MEA)*
Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the sickness fund ("a priori" control)

Chapter V
Reimbursement imposed by the Minister of Social Affairs

Chapter VIII
Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the sickness fund ("a priori" control) - after execution of an associated predictive test and linked to CIVARS (and PITTER register)

No fixed reimb. level

Chapter IVbis
Pharmaceuticals not authorized in Belgium – imported by pharmacist
Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the sickness fund ("a priori" control)

Reimbursement list (radioisotopes)
(in-patient sector)

Fixed Reimb level

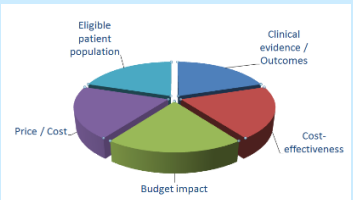
No reimbursement

Managed Entry Agreements

General Principles
- Agreements between NIDHI and a industry to achieve temporarily reimbursement
- To set a justifiable cost related to the expected added value and risk linked to uncertainty
- Based on budgetary & clinical conditions to gather of new or additional clinical evidence on the balance price/cost versus (therapeutic) value

Win-win-win
- Patients: (early) access to promising therapies
- Industry: access to the 'market'
- Payer: manage clinical uncertainties + budget

Key sources of Uncertainties



Types of agreements
- Financial MEA
- Performance / Value / Outcome based MEA
  - ➔ In Belgium all MEAs are coverage with evidence development
  - ➔ Behind financial deal often P4P-rationale (eg compensation for non-responders)

Direction for innovation
- New forms of MEAs (per therapeutic class or indication)
- New methods of negotiations (Horizon Scan, international collaboration)
- New approaches of payment models
- Evolution towards a demand-driven system with prioritization

Brazil

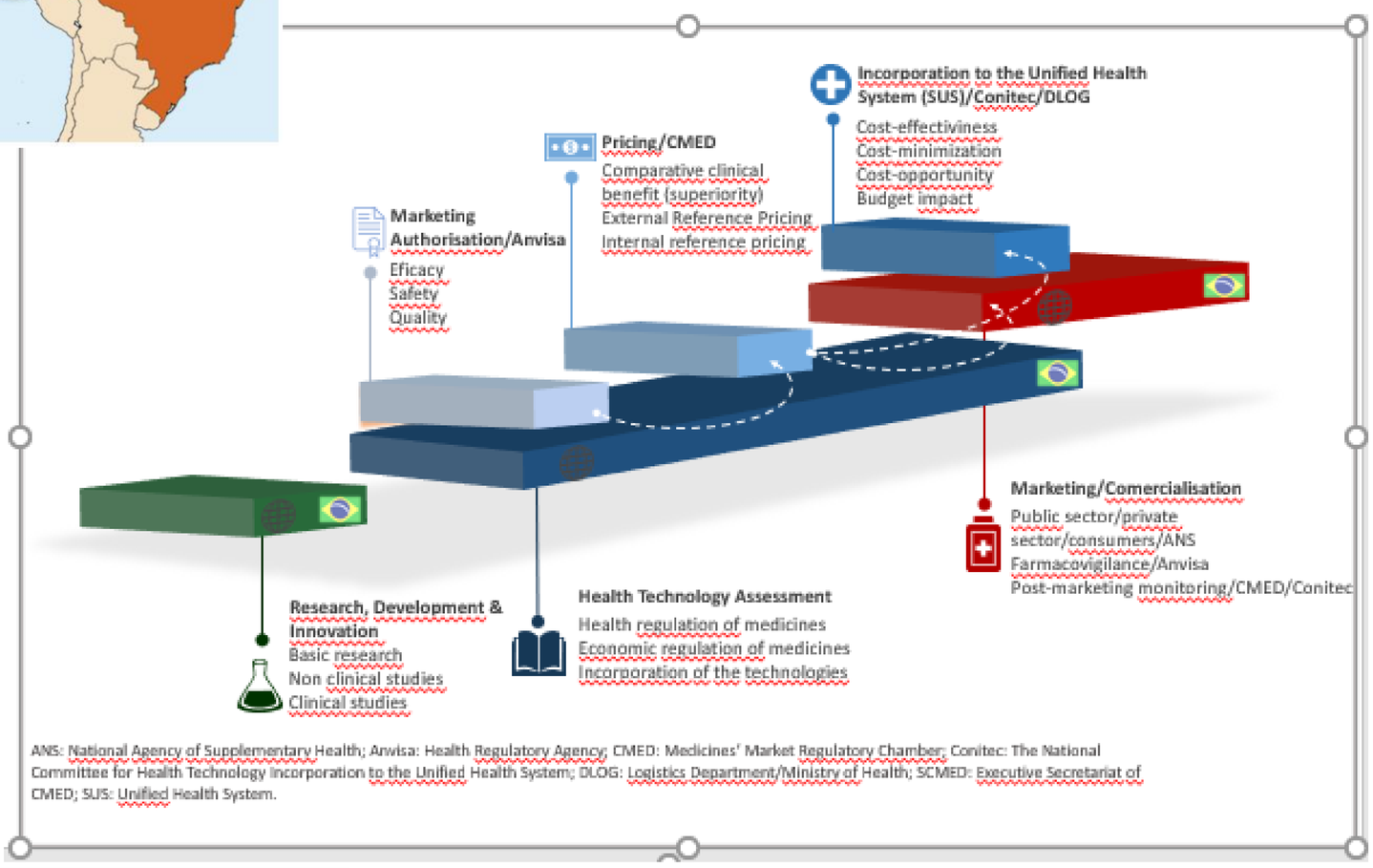
Pharmaceutical pricing and reimbursement policies

Adriana M. Ivama Brummell[1]; Misani A. Kanamota Ronchini[1]; Daniella Pingret Kipman[1]; Fernando de Moraes Rego[1]; J. Ricardo Santana[1];

[1]Medicines' Market Regulation Chamber Executive Secretariat (SCMED)/Brazilian Health Regulatory Agency (Anvisa), Brasília, Brazil; e-mail: Adriana.ivama@anvisa.gov.br

Total population (2016)	207,653,000
Gross national income per capita (PPP international $, 2013)	14,750
Life expectancy at birth m/f (years, 2016)	71/79
Probability of dying under five (per 1 000 live births, 2017)	15
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2016)	194/91
Total expenditure on health per capita (Intl $, 2014)	1,318
Total expenditure on health as % of GDP (2014)	8.3

Source: WHO (2019)



PRICING OF MEDICINES – PRIVATE AND PUBLIC SYSTEM

Medicines' Market Regulation Chamber (CMED) was established in 2003. It is a cross-government body with representatives from the Ministry of Health (President), the Presidency´s Office (Casa Civil), the Ministry of Economy and Ministry of Justice and Public Security and its Executive Secretariat at the Brazilian Health Regulatory Agency (Anvisa). The decision-making levels are the Ministerial Council, the Executive Technical Committee (CTE) and its Executive Secretariat (SCMED), a technical body for supporting the decision making and implementing its decisions and for monitoring the pharmaceutical market.[2]

Pricing mechanisms in Brazil are applicable to all medicines entering in the Brazilian market (out-patient and in-patient; public and private sector).

Pricing policies for medicines: The price authorisation by CMED is a mandatory requirement for all medicines entering in the Brazilian market. The pricing policy interventions include:

- price cap based on health technology assessment (HTA), using external reference pricing (ERP) (innovative medicines) and internal reference pricing (IRP) with generic medicines at 65% of the reference medicine prices;
- mandatory discounts for public procurement (PMVG): Price Adequacy Ratio (CAP) refers to a mandatory minimum discount, updated annually, that should be applied whenever medicines are procured by the public administration (Federal government, the States, the Federal District and the Municipalities). The CAP is applied to the Ex-factory Price - PF, resulting in the Maximum Government Selling Price (PMVG).
- annual prices adjustments: Adjustment ratios are calculated on the basis of three main factors: productivity factor, intra-sector relative price adjustment factor share and inter-sector relative price adjustment factor share;
- tax exemptions: these are the taxes on medicines: (i) Tax on transactions relating to the movement of goods and on the provision of interstate and intercity transport and communication services (ICMS); and (ii) contribution to the social integration and public equity programs (PIS/Pasep) and the contribution to the financing of social security (Cofins). The presumed credit grant of PIS/Pasep and Cofins is applied to prescription medicines from companies that adhere to the credit (positive list),
- Price list publicly available: updated electronic price lists are available online for outpatient medicines. Medicines for hospital use only don't have the prices published;[7]
- monitoring of the pharmaceutical market: there is an electronic system - Medicines' Market Monitoring System of Medicines (SAMMED) with mandatory annual communication of commercialisation data
- mechanisms of compliance and enforcement: non-compliant companies are fined (administrative law).
- Wholesale remuneration (e.g. margins): The distribution margin is 12% (informally negotiated);
- Pharmacy remuneration (e.g. margins): average margin between wholesaler and maximum consumer´s price (PMC): 38%

For more information: www.portal.anvisa.gov.br/cmed

MEDICINES IN THE PUBLIC SYSTEM

The National Committee for Health Technology Incorporation (CONITEC)

Provides therapeutic assistance and health technology incorporation into the Brazilian Public Health System (SUS). The purpose of CONITEC (part of the MoH's structure) is to advise the MoH in their duties related to the incorporation (uptake), disinvestment or alteration of health technologies by SUS, as well as the development or changes in Clinical Protocols and Therapeutic Guidelines (PCDT).

Medicines are provided free of charge at the Unified Health System (SUS) (out-patient and in-patient)

Positive list / formulary

Brazil has positive lists of medicines to be provided in the Unified Health System (SUS): National List of Essential medicines (Rename) and Clinical Protocols and Therapeutic Guidelines - PCDT

Timeframe: The decision-making period of 180 days (extendable for an additional 90 days);

Criteria: includes evidence-based analysis, taking into account aspects such as technology efficacy, accuracy, effectiveness and safety, as well as comparative economic benefit assessment and costs in relation to existing technologies (marketing authorisation at Anvisa is a requirement for the technology to be evaluated for incorporation into the Unified Health System).

For more information: http://conitec.gov.br/en/about-conitec

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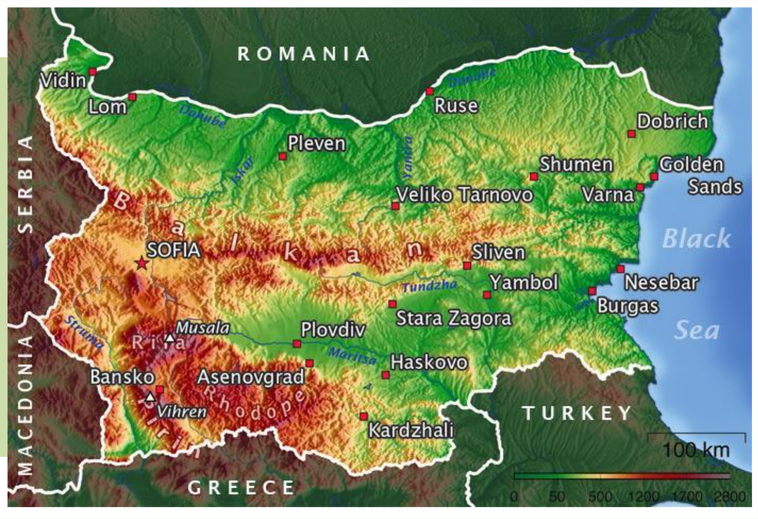
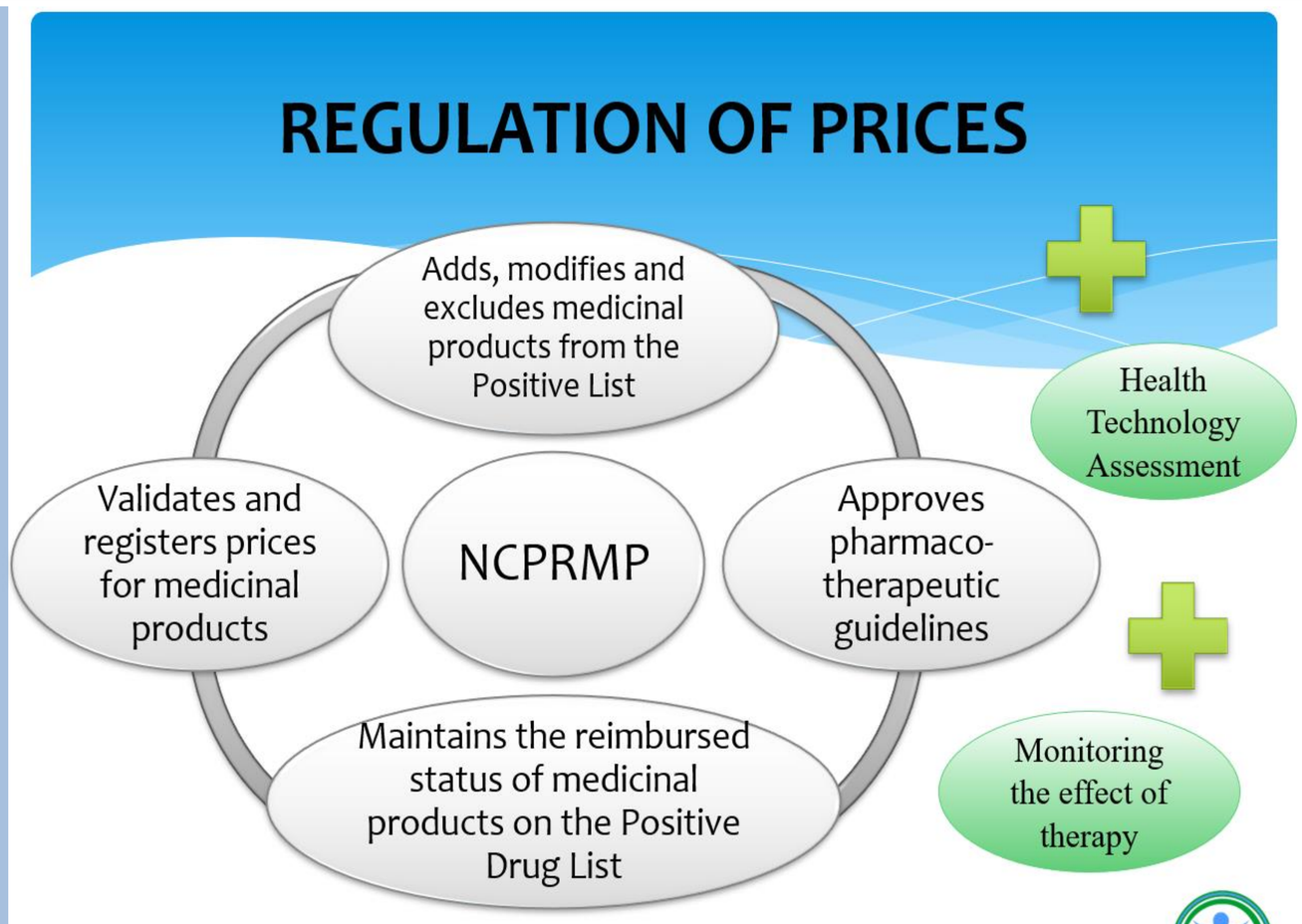
BULGARIA
National Council on Prices and Reimbursement of Medicinal Products

Population: 7.2 M
GDP per capita: 8472 €
Health expenditure:
8.2% GDP (2016)

BDA, NHIF, NCPRMP



PRICING



Pricing regulation applies for all medicinal products (**MP**) subject to medical prescription.

External reference pricing - the lowest manufacturer's price in 10 countries (*BE, EL, ES, FR, IT, LV, LT, RO, SK, SI*).

Free pricing is applied for OTC products.

<u>Wholesale remuneration (e.g. margins)</u>
Regulated regressive margins – 7%, 6% and 4% depending on manufacturing price.

<u>Pharmacy remuneration (e.g. margins)</u>
Regulated regressive margins – 20%,18% and 16% depending on manufacturing price.

VAT is 20% standard for all products.

<u>Regulatory changes</u> since April 1, 2019

- ✓ ***Change of number of the reference countries;***
- ✓ ***The price of biosimilar product in PDL is not higher than 80% of the ex-factory price set for the reference biological product.***

REIMBURSEMENT

<u>HTA:</u> NCPRMP
- MP that belong to a new INN in the PDL, must be evaluated for HTA;
- MP included in the PDL for which an extension of the therapeutic indications has been requested and for which have not yet been paid for, must be evaluated for HTA;

<u>Requirements and conditions for inclusion in PDL:</u>
- The INN, to which the MP or combination belongs to, is paid for the same therapeutic indication in at least 5 of the following 17 countries: BE, EL, DK, EE, ES, IT, LT, LV, PL, PT, RO, SK, SI, HU, FI, FR, CZ;
- Presence of at least one positive HTA from France, Germany, the United Kingdom, or Sweden;
- Discount agreements with NHIF and framework agreements with MH;

<u>Monitoring of Therapeutic effect:</u>
- MP for which no evidence of therapeutic effectiveness has been provided and/or the cost-benefit ratio is unfavourable, are included in the relevant Annex to the PDL with an obligation to monitor the effect of therapy;
- The NCPRMP has an obligation to determine the conditions and criteria for therapeutic monitoring, health care facilities, and the estimated number of patients.

COVERAGE / REIMBURSEMENT

Reimbursement/Coverage in the out-patient sector
<u>Annex 1 of PDL</u> – 2213 medicines
Payer institution - NHIF

<u>Reference price system (RPS) of cluster of substitutable medicines:</u> yes, MP grouped in ATC level 5 and 4.
<u>Internal reference pricing</u> by INN and pharmaceutical form.
Cheapest product being the reference value.
<u>Co-payment</u>
4 levels of reimbursement –25%, 50%, 75% and 100%.
For 100% reimbursed products, NHIF pays 2 BGN per prescription to the pharmacy.
High cost MP are subject to restricted prescription and special requirements set by NHIF.

Reimbursement/Coverage in the in-patient sector

<u>Annex 2 and 3 of PDL</u> - 2794 medicines
Payer institutions - hospitals, Ministry of Health, NHIF.

- ✓ localised tenders by hospitals,
- ✓ centralised tenders for MP, paid by MH.

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

CANADA

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Pharmaceutical Pricing and Reimbursement Policies in the in- and out- patient sector

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**

Population: 37.6 Million
GDP per capita: CA$58,498 (2017)
Healthcare spending per capita: CA$6,839 (2018)
Share of healthcare spending on drugs: 15.7% (2018 forecast)

Pricing – National Level

The Patented Medicine Prices Review Board (PMPRB)

Regulates the price of all patented medicines sold in Canada to ensure that they are not excessive.
Reviews the prices charged to wholesalers, hospitals and pharmacie at the factory gate level.
Currently, drug prices are compared to prices of similar drugs in a therapeutic class and/or to prices in comparator countries. Drug products are categorized based on their degree of therapeutic improvement: breakthrough; substantial, moderate, or slight/no improvement. Yearly increases are limited to changes in the Consumer Price Index.
In August 2019, the Government of Canada introduced amendments to the *Patented Medicines Regulations* allowing for important changes to the regulatory process. Changes include:

- **An updated schedule of comparator countries** - The new framework includes countries with similar consumer protection priorities, economic wealth and marketed medicines as Canada.
- **Additional price regulatory factors** - The new regulatory framework adds new the factors that include the medicine's value to and financial impact on consumers in the health system.
- **Changes in reporting requirements** - The new framework requires the actual price obtained by the patentee to be reported to the PMPRB, taking into account any adjustments. This includes reporting the confidential rebates and discounts that manufacturers negotiate.

IN-PATIENT

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

OUT-PATIENT

Prescription drug costs are not covered by Medicare in Canada, but are covered by a blend of public and private drug plans, as well as out-of-pocket payers.

PUBLIC (42.7%)*	PRIVATE (35.6%)*	OUT-OF-POCKET (21.8%)*
Each of the 10 Canadian provinces and 3 territories provide coverage with a focus on seniors, lower-income earners and those with high drug costs in relation to their income. Federal coverage is provided for veterans, First Nations and Inuit, Royal Canadian Mounted Police and the armed services.	Most employers provide private insurance for working age beneficiaries and their dependants.	Individuals not covered by a public or private plan, or those with deductibles and co-payment costs.

*Source: Canadian Institute for Health Information, 2017 forecast

Public Reimbursement

HTA

Canadian Agency for Drugs and Technologies in Health (CADTH) and l'Institut national d'excellence en santé et services sociaux (INESSS)

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 plans (with the exception of Quebec), as well to the provincial cancer agencies. The recommendations are not binding, but are considered by the public drug plans when making formulary listing decisions.
In 2017, CADTH updated its Guidelines for the Economic Evaluation of Health Technologies. Manufacturer submissions should now include cost-utility analysis or a justification for their absence. CADTH also implemented a new streamlined its Health Technology Assessment (HTA) process for biosimilars that is expected to reduce the review period for these drugs to 3 months.
In the province of Quebec, the Institut national d'excellence en santé et services sociaux (INESSS) assesses the clinical advantages and costs of health technologies, medications and interventions used in the fields of health care and social services. It issues recommendations concerning adoption, use and coverage by the public plan of health technologies and services.

Pricing

Pan-Canadian Pharmaceutical Alliance (pCPA)

Starting in 2010, Canada's provincial territorial and federal governments have come together through the pan-Canadian Pharmaceutical Alliance (pCPA) to collectively negotiate the prices of brand name and generic drugs as a way to achieve greater value for publically funded programs.

Brand-name drugs

The pCPA enters into confidential Product Listing Agreements for brand-name dugs for publically funded drug plans. These negotiations are based on the health technology assessments conducted by a national review process: Common Drug Review (CDR) or the Pan-Canadian Oncology Drug Review (pCODR). As of August 31, 2019, 314 joint negotiations have been completed.

Generic drugs

In January 2018, the pCPA reached an agreement with the Canadian Generic Pharmaceutical Association to lower the price of the nearly 70 most commonly discpensed prescription generic drugs in Canada to either 10% or 18% of the equivalent brand-name drug.

Wholesale and pharmacy markups – Public and Private

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

CZECH REPUBLIC

State Institute for Drug Control
(SÚKL - pricing and reimbursement)
Šrobárova 48, Prague 10, 100 41,
Czech Republic
posta@sukl.cz, +420 272 185 111

Total population: 10 668 641 (August 2019)
GDP per capita: 19 555,5 E (2018)
Organisation of the health care sector – social health insurance system
Health expenditure per capita = 2 502 USD (2018, OECD)
Health expenditure in % of the GDP = 6, 2 % (2018, OECD)

Source: data.oecd.org; czso.cz

PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES

PRICING

OUT-PATIENT

State Institute for Drug Control (SÚKL)
- Decision on pricing and reimbursement (administrative proceeding – fixed terms and conditions)
- Act No. 48/1997 Coll., Act on Public Health Insurance (pricing + reimbursement)
- 75 days for decision (price/reimbursement) / 165 (price + reimbursement)

Ministry of Health (MoH)
- Appeal authority (can change the decision made by SÚKL)
- Ministerial regulation (pricing)

Statutory pricing

2 types of price regulation (Reimbursed medicines)
- Ministerial regulation (MoH)

Maximum margin
- Deregulated price (Ministerial decision)
- Degressive scheme (37 % - 2 %)
- Both wholesale and pharmacy

Maximum ex-factory price
- Regulated both max. price + max. margin

Maximum pharmacy retail price
Ex-factory price + Margin + VAT (10 %)

Free pricing → **OTC**

External price reference (EPR)
(EU excl. BG, CZ, EE, IT, DE, AT, RO, EL, CY, MT)
- average of 3 lowest ex-factory prices

Application for the determination of the maximum price (ex-factory)

Price agreements – ex-factory price based (PA)
(if lower than EPR)

Internal price reference (IPR)
(if lower than EPR + PA)

IN-PATIENT

Health Insurance Funds (HIFs)
- Payers of reimbursed medicines
- Party to administrative proceedings run by SÚKL
- 1 HIF (60 % market share) + 6 smaller ones (40% market share)

Individual hospital purchase
- Price biding, tendering, joint purchases

Directly controlled health facilities (MoH)
- Since 2019 each facility has to reveal purchase price of medicines to the MoH

Hospital only medicines
- Fully reimbursed - Act No. 48/1997 Coll.
- Have to apply for the max. price (SÚKL)

List of hospital only medicines
- Publicly available (www.sukl.cz)

COVERAGE / REIMBURSEMENT

HTA PROCESS

PARTIES TO ADMINISTRATIVE PROCEEDING (MAH and HIFs)
- Submission of HTA dossier
- Comments to evaluation reports
- Appeal

→ **SÚKL**
- Administrative proceeding:
  - Evaluation of HTA dossier
  - Decision

⇢ **MoH**
- Appeal proceeding

Level of reimbursement

Application for the determination of the level and condition of reimbursement)
- Standard procedure

External price reference (EPR)
(lowest EU price + availability in the CZ)

Cost of medicines with the same effectiveness
(vs. EPR)

Price agreements (ex-factory + reimbursement-based)
(if lower than previous)

30-day procedure (voluntary)
- Generics and biosimilars
- New package sizes

First generic product
- 40 % lower price + reimbursement

Second originator
- 15 % lower price + reimbursement

First biosimilar product
- 30 % lower price + reimbursement

Evaluated criteria
- Therapeutic benefit
- Cost - effectiveness
- Budget impact
- Medical need
- Safety
- Guidelines

List of reimbursed medicines
- Publicly available (www.sukl.cz)
- 9 927 medicines (1. 10. 2019)

Positive list
No co-payment
- Each HIF can have its own (in fact there are 2)
- Contains least costly medicines from selected ATC groups
- Financial bonus for doctors who prescribe medicines from positive list
- 35 medicines included

Co-payment
Max. price – Max. reimbursement
- 5 000 CZK/year (~ 192 EUR)
- Only the lowest co-payment for the medicine with the same active substance and pharmaceutical form accounted for

Vulnerable groups (limited co-payment)
- Seniors over 65 + children under 18 years – max. 1000 CZK/year (~ 38 EUR)
- Seniors over 70 years - max. 500 CZK/year (~ 19 EUR)

Financial limit for medicines
- Based on agreement between hospital and HIF

No co-payment in hospitals

Hospital formularies
- Individual for each hospital

Reimbursement for medicines

Separately billed medicines
- Reported together with provided medical care

Hospital budget
- Special budget for the most common medicines

Part of provided medical care
- Medicine is billed as a part of medical performance

Since 2014, the fee for one day stay in hospital was cancelled (100 Kč ~ 4 EUR)
- Was not socially fair, no cap for longer stays

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

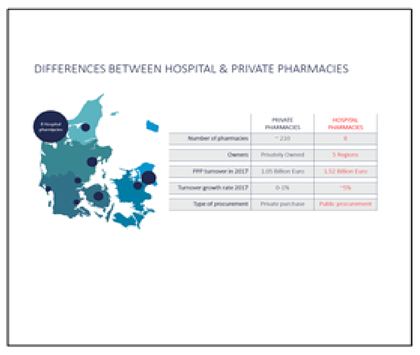
PPRI
Pharmaceutical Pricing and Reimbursement Information

AMGROS

Denmark

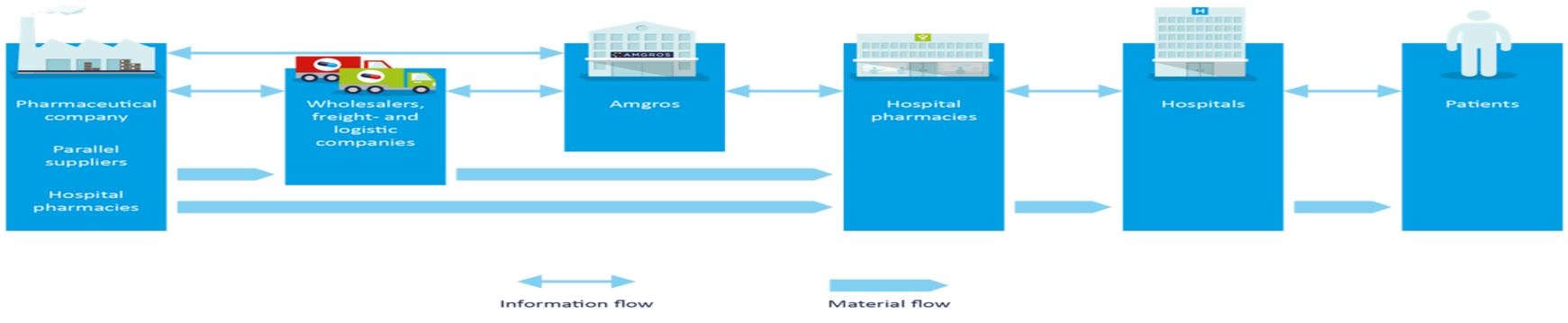
Ministry of Health – Rasmus Hølge Hazelton (rhh@sum.dk)
The Danish Medicines Agency – Diana Lauritzen (dila@dkma.dk)
Amgros – Trine Ann Behnk (tab@amgros.dk) & Dorthe Bartels (dbs@amgros.dk)

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



	OUT- PATIENT	IN - PATIENT
PRICING	In the out-patient sector the Danish Medicines Agency (DMA) are the competent authorities for pricing and reimbursement.	In the in-patient sector the national procurement organisation AMGROS I/S are the competent authority for procurement of pharmaceuticals to hospitals at national level
	• Free pricing on pharmaceuticals • Pharma supplier companies can do biweekly pricing changes, with notification to DMA • High competition by the system biweekly pricing have resulted in some of lowest priced generics at European level In addition, a price cap agreement exists, between the Ministry of Health, Danish Regions and The Danish Association of the Pharmaceutical Industry. Result is a cut of 15 % on list price level for pharmaceuticals used in the in-patient sector. In out-patient prices can not be increased. Pharmacy remuneration are 8.2% + 5,46 DKK of the pharmacy purchasing price ex. VAT (25 %)	• The Danish hospitals procure medicines via EU legislated tenders, managed and owned by AMGROS I/S in a national centralized procurement setting • Tenders are either with one or more winners, and criteria can both be qualitative in combination with price or price alone • Prices are confidential retail prices to hospital pharmacies and within the EU tender legislation context • Key focus is to secure supply to the hospitals in Denmark and to have fair competition on prices In addition, a price cap agreement exists, between the Ministry of Health, Danish Regions and The Danish Association of the Pharmaceutical Industry. Result is a cut of 15 % on list price level for pharmaceuticals used in the in-patient sector. **HTA process:** The funding model is defined by a combination of the clinical added value and the health Economical analysis, followed by a negotiation with the supplier of the medicine, resulting in a contract. The contract can either be defined as a single supplier contract or performed as a procurement contract with bids.

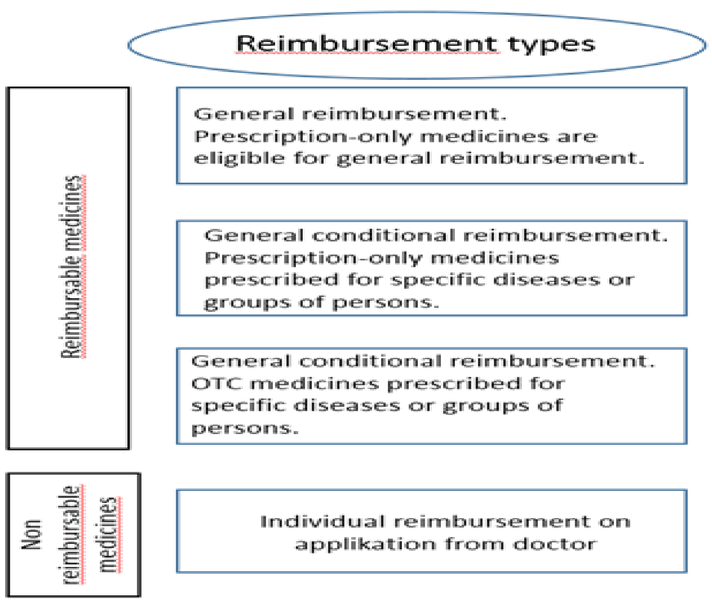
Distribution chain at hospitals in Denmark:



REIMBURSEMENT	The Reimbursement Committee advises the DMA on which products that is reimbursed. The Danish Regions are the payer of the reimbursement. The regions are publicly funded. There are three types of reimbursement, which are listed below.	The Medicine Council evaluates- with armlength principle to AMGROS I/S – incoming applications for the reimbursement. Reimbursement is based on the positive decision from Medicine Council in Denmark. If a positive reimbursement is achieved, implementation in the hospitals will be taken place after a tender or contract agreement on national level through AMGROS I/S as procurement body. In the formularies at hospital level, the decisions on which medicines to choose and use will be highlighted. All hospital treatments are full reimbursed for the patients. All new medicines and indications apply for a SoC decision through the medicine council, prior to contracting or procurement.

Annual personal expenditure on reimbursable medicine before deduction of reimbursement	Reimbursement for persons over the age of 18	Reimbursement for persons under the age of 18
0-131 €	0%	60%
131 – 218 €	50%	60%
218 – 471 €	75%	75%
In excess of 471 €	85%	85%
In excess of 2.554 € (Under the age of 18 3.137 €)	100%	100%

In-patient sector reimbursement types & in-patient sector pilot scheme for conditional reimbursement



VIEW NOW

Pilot scheme for conditional reimbursement on terms of risksharing

Pharmaceuticals with a risk of first-line use, even though it should not be the case, are not eligible for general or conditional reimbursement.

Only pharmaceuticals where the risk is economic could be a part of the pilot scheme.

Two products have been chosen to be a part of the pilot scheme. Brilique 60 mg for AMI and Skilarence for psoriasis.

DMA have estimated the patient population which fulfil the clause for the pharmaceuticals. The companies have to reimburse the expenses for the patient population which exceed the estimated population.

FINLAND

Pharmaceuticals Pricing Board
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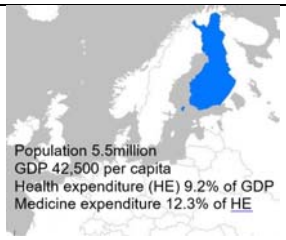
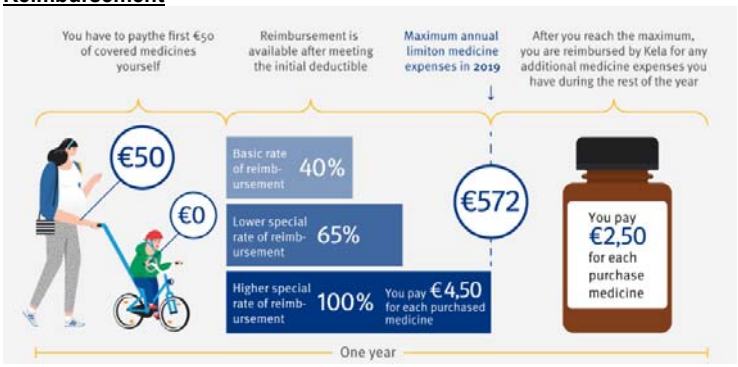


Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

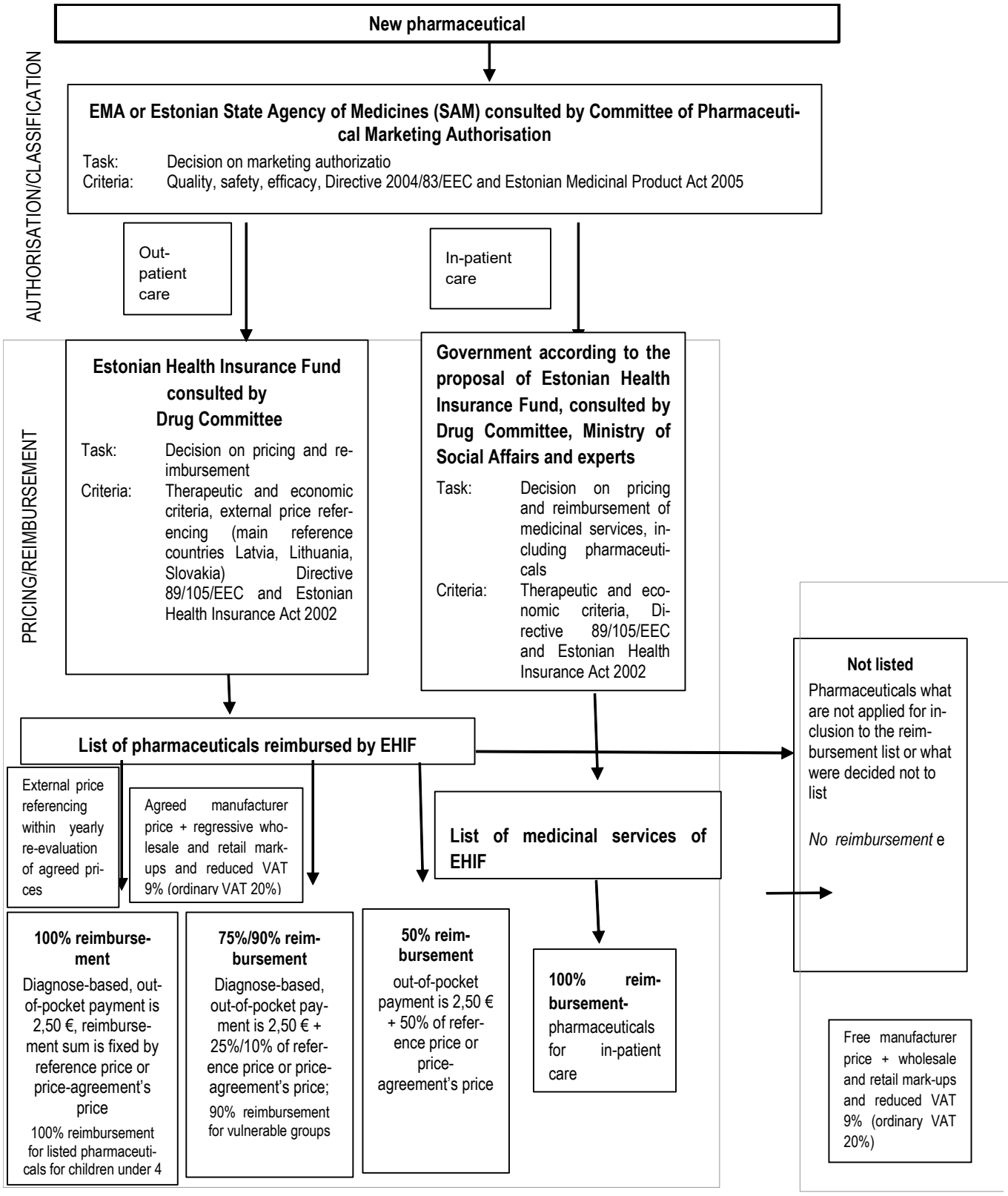
	OUT-PATIENT	IN-PATIENT
	Competent authorities **Pharmaceuticals Pricing Board (**subordinated to the Ministry of Social Affairs and Health) confirms reimbursement status and a wholesale price of medicinal products, clinical nutritional preparations and basic ointments that are reimbursable by the Health Insurance Act. **Social Insurance Institution (Kela)** administers the drug reimbursement system.	**Competent authorities** Hospital districts owned by municipalities. Procurement is typically done by procurement pools (e.g. responsibility areas of university hospitals).
PRICING	**Pricing** Non-reimbursable pharmaceuticals can be priced freely. **Statutory pricing (at wholesale price level) for reimbursable pharmaceuticals.** Pricing procedures include: o External price referencing o Internal price referencing o Health economic evaluations For generics: price linkage, generic substitution and reference pricing (RPS) For biosimilars: price linkage Decisions valid max 5 years; for new active substance max 3 years. **Wholesale remuneration:** Not controlled **Pharmacy remuneration:** Statutory regressive mark-up separately for prescription and non-prescription pharmaceuticals **VAT:** Standard rate 24%, reduced rate for medicines 10% **Reforms valid from Jan 2017:** o wholesale price of the 1st biosimilar must be at least 30% lower than price of the originator. o RPS: extended to parallel imported products, "price corridor" narrowed to €0.50. o Managed-entry agreements (MEA) allowed (temporary legislation valid until end of 2019; new proposal: until end of 2025).	**Pricing** Price negotiations or tendering of pharmaceuticals. Each hospital has its own pharmaceutical formulary.
REIMBURSEMENT	**Reimbursement**  **Reference price system (RPS):** Generic reference price groups: same active substance, quantity and pharmaceutical form, closely corresponding package size **Mechanisms for vulnerable groups:** Better reimbursement rate for pharmaceuticals used for chronic and severe diseases (Special reimbursements) **Recent reforms** • Reimbursement rate of type II antidiabetics (A10B) reduced from 100% to 65%. • Annual co-payment ceiling lowered from €608 to €572.	**Reimbursement** Hospital pharmacies issue medicines only to their own wards and departments. Pharmaceuticals used in hospitals are included in the patient's daily charge.

Estonian Health Insurance Fund

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

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



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

(Case study, Egypt)

Nany Keshk, Mohammed Alsebai

PRICING IN AND OUT – PATIENT

COVERAGE / CEIMBURSEMENT

Out-patient (clinics and hospitals)

In-patient (Public hospitals& primary care units)

Ministry of Health & Population (MOHP)

Egyptian Drug Authority --> NODCAR, NORCB, and CAPA

CAPA

The final decision-making body

Pricing in the out-patient sector

Pricing in the in-patient/hospital sector

Currently, each drug has 2 prices. The first is the mandated price for the Egyptian market, which is based on international reference pricing (**IRP**); the second is the price on the tender drug list. Both prices are set by **CAPA**, one by its pricing unit and the second price by its procurement department.

The Pricing Unit to regulates not only the ex-factory price, but also the distribution margin be shared between wholesalers and pharmacies in payment for logistic and capital costs of distribution.

The private sector has its own set of regulations and standards. Some are the same as those for the public sector and some may differ. Private insurers and providers negotiate prices with drug manufacturers, but are not involved in the drug evaluation process.

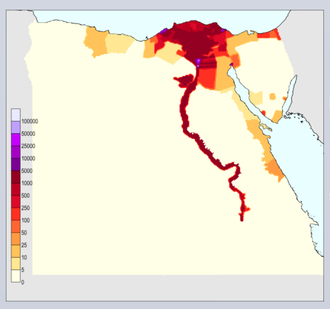
For the mandated market price, the drug manufacturers recommend prices for new medicines. These prices are reviewed by the pricing committee. The recommended price is approved or reduced according to the lowest price-referenced country for the referenced product. The referenced product is then applied to the branded drug.

Out-patient sector

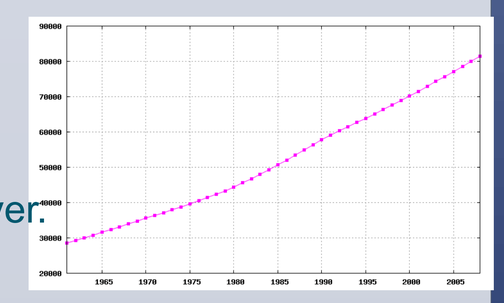
In-patient sector

Private health expenditure covers 95.7 % of the total health expenditure

The private sector includes several private insurance organizations as well as a network of outpatient clinics and hospitals.. The private sector has its own set of regulations and standards. Some are the same as those for the public sector and some may differ. Private insurers and providers negotiate prices with drug manufacturers, but are not involved in the drug evaluation process.



Population in Egypt:
98 M (2018)
10% Abroad
90% Along the Nile River.



Public health expenditure consists of recurrent and capital spending from government (central and local) budgets, external borrowings and grants (including donations from international agencies and nongovernmental organizations), and social (or compulsory) health insurance funds. It covers the provision of health services (preventive and curative), family planning activities, nutrition activities, and emergency aid designated for health but does not include provision of water and sanitation. Of the total population, 51 % is covered by a public health service, public health insurance or social insurance, or other sickness funds.

The plan is to re-institute the role of the HIO as the provider of insurance and care for all Egyptians. The increased premiums and co-payments for universal coverage take into account the employee's salary range and the rise in healthcare services and prices. The CCO operates in specific governorates and contracts with other entities to provide care.

Estonian Health Insurance Fund

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

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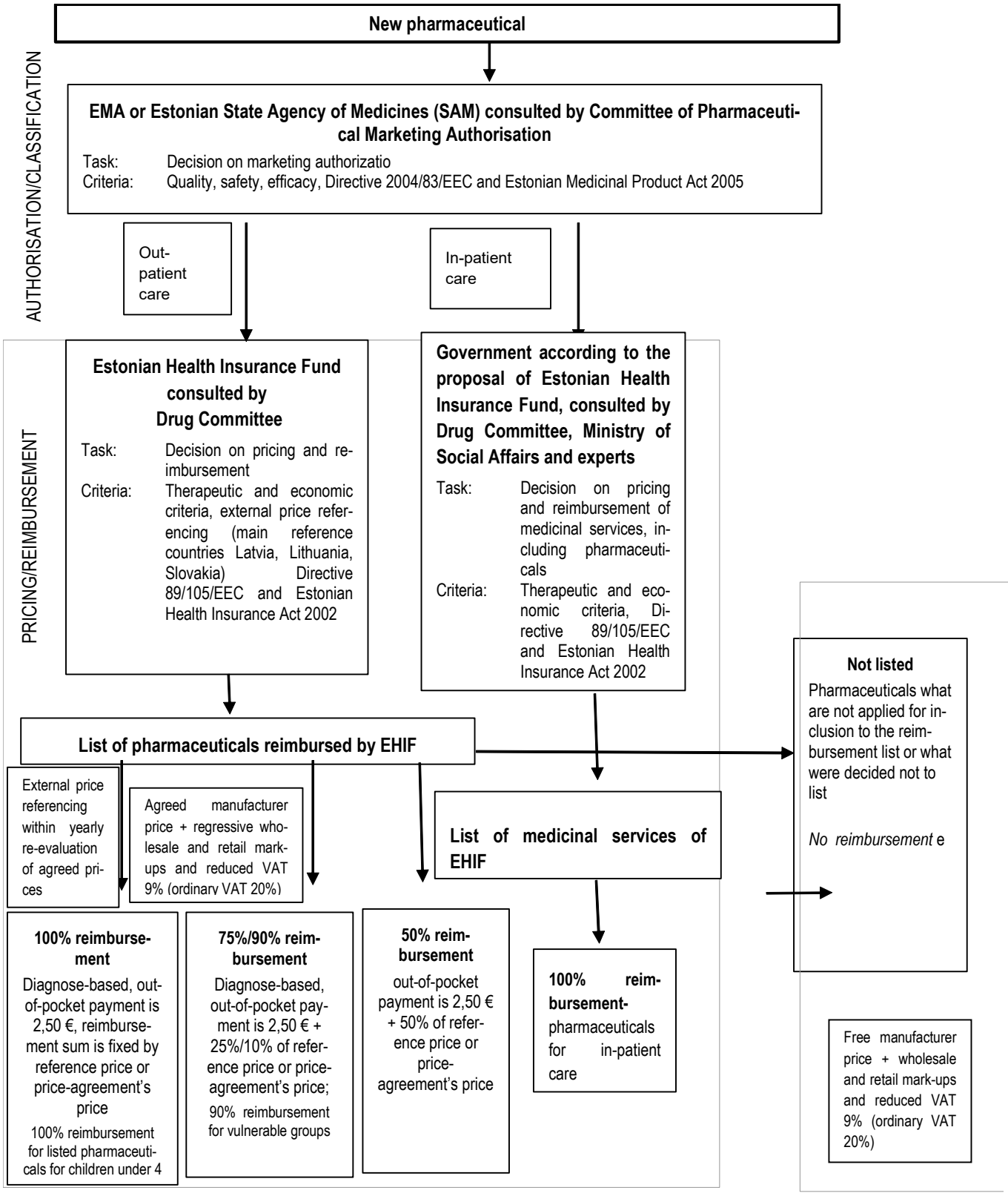
Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector



FINLAND

Pharmaceuticals Pricing Board
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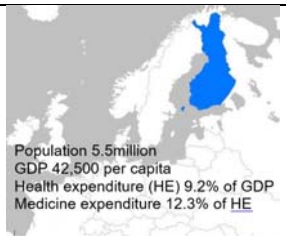

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

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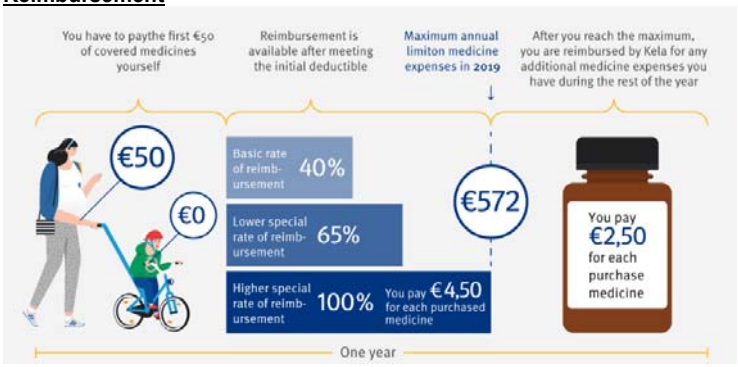
REIMBURSEMENT	**Reimbursement**  **Reference price system (RPS):** Generic reference price groups: same active substance, quantity and pharmaceutical form, closely corresponding package size **Mechanisms for vulnerable groups:** Better reimbursement rate for pharmaceuticals used for chronic and severe diseases (Special reimbursements) **Recent reforms** • Reimbursement rate of type II antidiabetics (A10B) reduced from 100% to 65%. • Annual co-payment ceiling lowered from €608 to €572.	**Reimbursement** Hospital pharmacies issue medicines only to their own wards and departments. Pharmaceuticals used in hospitals are included in the patient's daily charge.

FRANCE

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

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

AUTHORISATION

European Medicines Agency (**EMA**) or French Health Products Safety Agency (**ANSM**)

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

Only medicines requesting to be reimbursed are assessed

EARLY ACCESS SCHEMES

Scheme name	Regulatory status
Temporary use authorisation (ATU) Temporary use recommandation (RTU)	Coverage before a Marketing authorisation (MA)
ATU for new indication (post-ATU direct) ATU for new indication (ATU EIT)	Coverage after a MA

ASSESSMENT

French National Authority for Health (**HAS**)

Task: Clinical assessment (for all drugs requested to be reimbursed) and economic assessment (only if supposely innovative and/or annual gross revenu > 20 M€ and/or organisational impact)
Criteria: - Clinical assessment : medical value (**SMR**); added-medical value (**ASMR**); target population; comparators; use conditions
- Economic assessment : incremental cost-effectiveness ratio (**RDCR**)

P&R CRITERIA

Reimbursement criteria

Reimbursement rates are driven by SMR

SMR important	65 %
SMR moderate	35 %
SMR weak	15 %
SMR insufficient	0%

Drugs treating severe and chronic disease (ALD) and in-patient drugs are covered 100 %

Pricing criteria

Pricing decisions are mostly driven by ASMR

ASMR I	major added value	price > comparators
ASMR II	important added value	price > comparators
ASMR III	significant added value	price > comparators
ASMR IV	minor added value	price = comparators
ASMR V	no added value	price < comparators

PRICING

OUT-PATIENT

Pricing Committee (**CEPS**)

Task: Price negotiation
Criteria: set by law (Art. L162-16-4 Social Security Code)
- Added medical value (ASMR)
- Economic assessment
- Comparators prices
- Sales forecast
- Use conditions

ERP is used only for innovative medicines (ASMR I, II and III) and a valid economic assessment
ERP basket is composed by Germany, Italy, Spain and the UK

IN-PATIENT

Lists of authorised medicines in hospital

Drugs over-DRGs or dispensed at the hospital for out-patient use → Pricing Committee (**CEPS**)

Task: Price negotiation
Criteria: Same as out-patient

Drugs included in the DRGs → Hospital purchasing body or union

Task: Price negotiation and/or tendering
Criteria: Depends on the product or the market situation

REIMBURSEMENT

Sickness funds union (UNCAM)

Task: Reimbursement rate
Criteria: Reimbursement rate (15%, 35%, 65%) based on SMR
Drugs treating severe and chronic disease (ALD) are covered 100 %

Ministry of Health

Task: Positive list and publication

Ministry of Health

Task: Positive list and publication
Hospital drugs are covered 100%

SPECIFIC PRICING

GENERICS
Originator:
-20% at generics marketing

Generics: - 60% vs originator price

BIOSIMILARS
Originator:
-20% at biosimilars marketing

Generics: - 40% vs originator price

PARALLEL IMPORT
-5% vs originator

GENERICS
Both originator and generics :
-40 % vs originator price

BIOSIMILARS
Both originator and biosimilars :
-30 % vs originator price

PARALLEL IMPORT
-5% vs originator

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

PRICING

out - patient sector

POM (reimbursed/non reimbursed) | **OTC**

↓

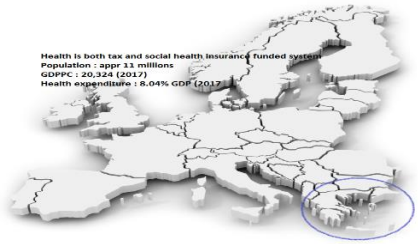
National Organization for Medicines (EOF)

↓

Statutory Pricing

↓

Task: annual review of prices; Retail price, Wholesaler price, Ex-factory price; sunset clause **Criteria**: External Reference Pricing (average of the two lowest prices in Eurozone, increases of prices up to 10% under certain conditions); Generic price is set at the 65% of the originator price	**Task**: annual review of prices; indicated retail price **Criteria**: External Reference Pricing (average of the two lowest prices in Eurozone or even one, increases with no restrictions)
Retail price = ex-factory + regressive wholesale and pharmacy margins (%) by price ranges + VAT (6%, 13% or 24%)	**Indicated retail price** = ex-factory + VAT (6%, 13% or 24%)



in - patient sector

POM to be purchased by hospitals + OTC

↓

National Organization for Medicines (EOF)

↓

Task: Setting the maximum hospital price	=	ex-factory – 8.74%

ASSESSMENT

Assessment and Reimbursement Committee	Negotiation Committee	Assessment and Reimbursement Committee	Minister of Health

Technology
Medicines

Assessment
- Clinical benefit
- Relative effectiveness
- Cost-Effectiveness
- Budget impact

Price Negotiation

Final opinion-appraisal
Reports and recommendation for use

Final Decision
Inclusion or not to the reimbursement list

REIMBURSEMENT

EOPYY

Task: healthcare services provision

3 Levels of Reimbursement
25%: in general
10%: chronic diseases

- 0%: Some Chronically ill and patients with paraplegia, tetraplegia
- Patients belonging to low income/vulnerable groups
- Women during pregnancy and lactation

Internal Reference Pricing
The reference price in ATC4 level is the weighted average generic price with the lowest-cost daily dose (the generics taken into account need to represent 20% of the total sales volume in the last 6 months of the given cluster).

High Cost Medicines
High cost medicines are dispensed through EOPYY's pharmacies and Hospital Pharmacies (purchased at hospital price minus 5%) with exemption from cost-sharing.

PAYMENT

EOPYY

Task: reimbursement of medicines to community pharmacies

Task: reimbursement of high cost medicines dispensed through EOPYY's pharmacies

Ministry of Health

Task: reimbursement of medicines for in-patients and of high cost medicinal products for outpatients in public sector

Close budgets

Community Pharmacies and EOPYY: There is an annual budget cap for medicines dispensed through private pharmacies and EOPYY (excluding high cost medicines for hospital use) (2018: 1,945 billion€)

Hospital expenditure (public) : There is an annual budget cap for medicines dispensed purchased by public hospitals (2018: 550 million€)

LEGISLATION

1. Law 4512/2018 (Official Gazette A' 5/17.01.2018): articles 247-256 set the rules of HTA and Negotiation Committee)
2. Law 4583/2018 (Official Gazette A'212/18.12.2018): article 212 sets one price review per year
3. Law 4600/2019 (Official Gazette 43/09.03.2019): article 161 sets the new country basket and the average of the two lowest prices in Eurozone.

AUTHORS

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HUNGARY

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

Pricing

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

Pricing in the out-patient sector

Pricing at ex-factory level

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

  This applies for generic drugs and drugs with similar efficacy.

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

  Required cut down prices for generic drugs:

  1st generic drug – 40%,

  2nd generic drug – 20%,

  3rd generic drug – 10%,

  4-6th generic drugs – 5%,

  afterwards 0,3 Euro Cent.

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

  (ICER ≤ 2-3 x GDP per capita)

Pricing at wholesale level

- *Strictly regulated regressive margins*

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

Pricing at pharmacy level

- *Strictly regulated regressive margins*

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

Pricing in the in-patient sector

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

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

  Separate budget for haemophilia and HCV infection

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

Main acts

- Decree of the Ministry of Health 32/2004 (IV.26.) Legal framework for price setting
- Decree of the Ministry of Health 5/2007 (I.24.) Wholesale and pharmacy mark-up, price margins
- Deree of the Government 452/2017 (XII. 27.) Reimbursement of medicinal products
- Act XCVIII of 2006 on the Safe and Economic Supply and Distribution of Medicines and Therapeutic Medical Devices

Links

http://www.neak.gov.hu/pupha

http://www.neak.gov.hu/gyogyszerkereso

http://www.neak.gov.hu/felso_menu/szakmai_oldalak/publikus_forgalmi_adatok/gyogyszer_fgyogyszer_forgalmi_adatok

Reimbursement

Reimbursement in the out-patient sector

Positive list

Positive list publicly available for reimbursed drugs.

Reimbursement categories

- *Without restrictions* – normative reimbursement

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

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

  100% reimbursement provided to patient
- *Vulnerable groups*

  Named patient program:

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

  Patients with Prescription Exemption Certificate:

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

Special requirements

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

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

  ~ Simple payback on every unit sold

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

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

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

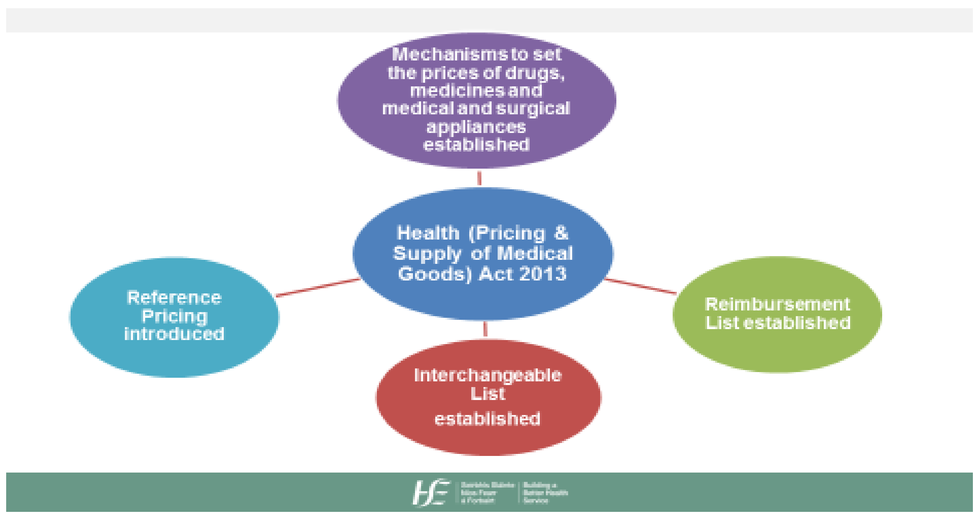
Reimbursement in the in-patient sector

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

PHARMACEUTICAL SYSTEM IN IRELAND

Pricing and Reimbursement of Medicines

Health (Pricing and Supply of Medical Goods) Act 2013

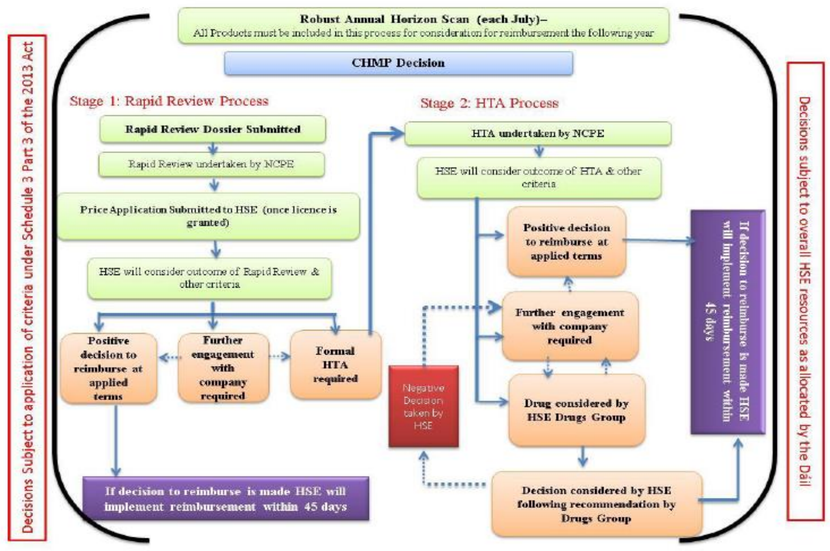


IPHA (Irish Pharmaceutical Healthcare Association) Agreement 2016

- Applies to medicines reimbursed via the Community Drug Schemes (including High Tech Arrangements) and Public Hospitals
- Revised basket of countries since previous agreement agreed: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK
- Ceiling Price set by reference to the average of same basket of 14 countries
- Prices realigned annually (downwards only)
- Rebates on sales to be paid annually (currently 5.5%)

Principles and Processes for the Assessment of New Medicines in Ireland (IPHA Agreement 2016 Schedule 1)

- Companies to submit annual Horizon Scan
- Rapid Review Dossier +/- Full Health Technology Assessment Dossier
- At all stages of the decision-making process the Health Service Executive (HSE) will subject each medicine to an assessment of affordability in accordance with the 2013 Act

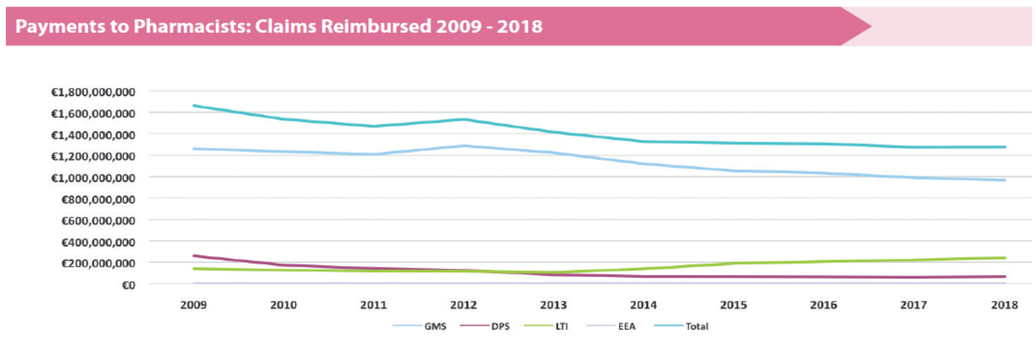


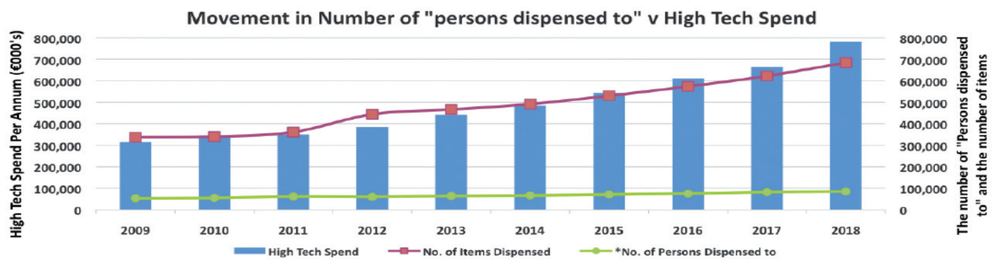
Medicines Management Programme

Aims to promote safe, effective and cost effective prescribing via a number of activities:

- 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.
- Prescribing Tips and Tools, which offer clear, concise guidance on the prescribing and monitoring of these drugs for their licensed therapeutic indications.
- 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 prescribing, monitoring and reimbursement.
- Managed access processes for some reimbursable medicines.

Spend on Medicines 2009-2018





Recent Changes in Pricing and Reimbursement

Changes in Pricing

- Between June and August 2019, the HSE completed a review of reference prices previously set for interchangeable medicinal products as per the criteria listed in Section 24 of the Health (Pricing and Supply of Medical Goods) Act 2013. A total of 60 interchangeable groups were reviewed during this period. In addition, 6 interchangeable groups were subject to the setting of a new reference price.
- Between May and July 2019, the HSE engaged with suppliers of medicines to conduct a Price Realignment exercise (downwards only) in accordance with Sub-Clause 5.2 of the 2016 IPHA Agreement. Realigned prices were published on the HSE website and came into effect on 1st July 2019.

Changes in Reimbursement

- The requirement for prior reimbursement approval for non first-line standard oral nutritional supplements (ONS) came into effect on 1st July 2019.
- Rheumatology, Dermatology and Gastroenterology medicines were added to the the High Tech Hub from 1st June 2019. The High Tech Hub Ordering and Management System, which was rolled out nationally in March 2018, was developed to streamline administration of the High Tech scheme for pharmacists and to provide enhanced visibility of stock management and spending on this scheme to the HSE.

Other Developments

- In May 2019, the Medicines Management Programme completed the evaluation process for the identification of the best-value biological (BVB) medicines for TNF-α inhibitors on the High Tech Drug Scheme.
- A Pilot project is ongoing to expand the treatment of Hepatitis C from hospital-based to community-based services.
- Preparing for Brexit - The Department of Health, the Health Products Regulatory Authority (HPRA) and the HSE are implementing a comprehensive and coordinated set of preparations to ensure continuity of health services and continued supply of medicines and medical devices in the event of a 'no deal' Brexit.
- The prescription charge for medical card holders will be reduced by 50 cent (to €1.50 per item for people under the age of 70 and to €1 per item for people over the age of 70) from July 2020.
- The monthly threshold for the Drugs Payment Scheme will be reduced by €10 (to €114) from September 2020.
- The medical card weekly income threshold for people over the age of 70 will be increased by €50 for a single person (to €550) and by €150 for a couple (to €1,050) from September 2020.
- The Government intends to expand free GP care to children under the age of 8 and free dental care for children under the age of 6 from September 2020.
- From 1st June 2019, HSE Primary Care Eligibility and Reimbursement Service (PCERS) assumed governance for the processing of all new and review Long-Term Illness (LTI) applications.
- The HSE Technology Review Committee for Rare Diseases, appointed in June 2018, is continuing activities in 2019. This Committee reviews proposals received from industry or expert groups in Ireland for funding of new products for rare diseases, or expanded indications for existing products or related predictive laboratory tests for rare diseases. It is also responsible for providing contributions to the development of clinical guidelines for relevant Orphan Medicinal Products (OMPs).

Corporate Pharmaceutical Unit, HSE, Primary Care Reimbursement Service, Exit 5, M50, Finglas, Dublin 11. D11XKF3
CPU website: https://www.hse.ie/eng/about/who/cpu

MINISTRY OF HEALTH For a healthier life
PPRI Pharmaceutical Pricing and Reimbursement Information
WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Population :9 Million **GDP per capita PPP**: 36250$(2017)
Health Expenditure: 7.6 % of GDP (2018)
Health expenditure per capita: 2953$(2018)

ISRAEL, Ministry of Health

Pharmaceutical Pricing and Reimbursement Policies in the In-and Out-Patient Sector

PRICING

The Ministry of Health is the competent authority for pricing in the in-and-out-patient sector

Israel sets maximum prices for **all listed drugs**: Prescription drugs, OTC and GSL, whether the drug is reimbursed or not.

The public retail price = Wholesaler price + pharmacist margin + VAT

Since January 1st, 2019 - A number of changes were made in the Price Control Order of Prescription Drugs:

- **Innovative & Biosimilar drugs** - Maximum price is the average of the lowest three quoted wholesale prices among the following countries: England, Germany, Holland, France, Belgium, Spain and Hungary.
- **Generic drugs or Innovative drugs with generic alternatives** - Prices are fixed at the price-level on the determining day of the previous year (01.07.2018). If a company wants to set a higher price for a particular product, it must be approved by the Ministry of Health.
- **Regressive Pharmacist Margin** :

Purchase package price (ILS)	Pharmacist's margin (%)
Up to 38.00	37
38.01-94.00	34.5
94.04-193.00	25
193.01-1750	17.5
1750 and above	10

- **Exchange rate**: If the average exchange rate of the Euro will rise or fall above 3% between publication of the annual price list, at January 1st, and the end of the following May, the price list will be updated by the amount of said change on July 1st. The change is limited to no more than 5%.
- **VAT**: The standard VAT for all commodities: 17% for all kind of medicines

Pricing in the in-patient sector

Medications given in hospitals are provided to patients in the framework of the general rates set by the Ministry of Health's maximum price list, usually according to the type of procedure (PRG) or according to the price per day of hospitalization. A minority of drugs are under consignation agreement between the HMOs and hospitals, mainly oncologic drugs.

COVERAGE / REIMBURSEMENT

Reimbursement in the out-patient sector

- Reimbursements in Israel are determined by a public committee composed of physicians, HMOs, MOH, MOF and public representatives. Each year after a long and difficult evaluation, this committee decides on drugs, medical tests and technologies that are added to the positive list (aka the public health basket).

  In 2018 the list of drugs in the public health basket increased by approximately 135 new medications / indications / non-pharmaceutical medical technologies - at an added cost of 460 million NIS. In 2019, the list increased by approximately 88 new medications / indications.
- The reimbursement system is based mainly on active ingredients (molecule) and medical indication.
- The National Health Insurance Law states that the HMOs may offer their members additional health care plans, known as "supplementary insurance". Each HMO provides its patients with basic medical services (the basic basket of services) as well as plans that include additional health services (AHS).
- The health basket provided by the HMOs is a list of medical services that the HMOs are legally obliged to provide to their insured, including: hospitalization, examinations, treatments, medicines and medical equipment. The list can be found in the Second Schedule to the National Health Insurance Law and in the National Health Insurance Order (Medications in the Health Services Basket).
- Reimbursement of medicines that are not included in the reimbursement list or in the HMOs own list: HMOs are not obligated to fund treatment not included in the healthcare basket (positive list). Applicants requiring treatment not included in the basket, have the option of appealing to their health plan's exceptions committee. The exceptions committee is composed of a number of health fund employees, some of which are doctors. The purpose of the committee is to consider requests for assistance beyond that which is required by law, and it has the authority to consider and decide regarding the provision of services that are not included in the healthcare basket for policyholders.
- Co-**payment** - Patients pay co-payment for drugs starting from a min. of 17 NIS, to 10%-15% of the public maximum price list including VAT. In addition, there are quarterly ceilings and discounts for certain populations such as the elderly, patients who suffer from chronic illness (HIV, CF, Cancer, tuberculosis, etc).

Reimbursement in the in-patient sector

- Hospitals are not limited by the National Health basket. They must provide the best health treatment and the necessary drugs whether included in the basket or not.
- HMOs are permitted to dictate service providers to patients - subject to reasonable distance, availability and other clinical considerations.

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ITALY

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

Total population: 60,359,546
GDP per capita: 41,626 USD
Health Care Sector: NHS
Health Care Expenditure per capita: 3,428 USD
Pharmaceutical spending per capita: 601 USD

New medicine

AUTHORISATION

European Medicines Agency (EMA) for Centralized procedure

OR

Italian Drugs Agency (AIFA) for
- National procedure
- Mutual recognition and decentralized authorization procedure

In consultation with

Technical Scientific Commission (CTS) with the co-operation of experts belonging to the National Institute of Health (ISS) and of other experts of well-known experience belonging to the Italian academic and health community

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

Marketing authorization (Autorizzazione all'immissione in commercio, AIC)

PRICING – EX FACTORY LEVEL

Balduzzi Decree – 13 sept 2012, n°158 : C-Non Negotiated (CNN) – those drugs that obtained the AIC through the centralized, mutual recognition, decentralized and national procedure as well as of parallel import, **are automatically classified into the C-NN group waiting for the Company to present a possible request for different classification and price negotiation through an ad-hoc dossier** (CIPE resolution of 1 Feb 2001, n°3)

AIFA and its technical-advisory commissions are responsible for the definition of the reimbursement and supply regime for all authorized medicines as well as the negotiation with the pharmaceutical companies of the prices of those medicines charged to the NHS

Several examples of Management Entry Agreements (MEAs)

Reimbursable pharmaceuticals (Class A/H)

Price is set through **a contracting process** between **AIFA** and **pharmaceutical Companies**.
The contracting process is made of 4 steps:

1. The Company presents price & reimbursement request by submitting a dossier to AIFA. The request has to follow the Guidelines published by the Agency;
2. The Scientific Technical Commitee (CTS) expresses a binding opinion on the therapeutic value of the drug, its *place in therapy* and supply regime, as well as its eventual innovativeness;
3. The Pricing and Reimbursement Commitee (CPR) evaluates the dossier and, when necessary, convenes the Company for the negotiation;
4. In case of positive opinion on the reimbursement, the negotiation result is submitted to AIFA Board of Directors for the definitive assessment

AIFA decides the allocation

The request for classification is contextual to negotiation. Negotiation is foundamental for the drugs' disbursement by the NHS

Non - Reimbursable pharmaceuticals (Class C)

Free pricing by pharmaceutical companies

Class C drugs can be sold to the citizens either against the presentation of a medical prescription
(Class C with prescription) or directly dispensed without prescription

Price negotiation criteria
(CIPE resolution of 1 Feb 2001, n°3):
- Positive ratio/cost efficacy
- Risk/benefit ratio
- Economic impact assesment on NHS
- Cost of the therapy more favorable than products
- Estimate of the market shares that can be acquired
- Comparison with prices and consumptions of other EU countries

II-patient (H): pharma company must grant rebates (at least 50%) to hospitals for those medicines listed on the Hospital Pharma Formulary (HPF)

Tenders

Positive opinion o the drug by CTS at regional and local health authority level before hospital use
[VETO POSSIBILITY]

Results are published in the **Official Journal of the Italian Republic (Gazzetta Ufficiale)**

Th only regulatory provision applicable to non-reimbursable medicinal products must be traced in article 13 of the RD 03/03/1927 which provided for the right of the pharmacist for a margin not less than 25% of the price to the public

PRICING – WHOLESALE & PHARMACY LEVEL

WHOLESALER	Maximum margin of PRP net is 3%	Law n. 662/96, modified by the law n. 122/2010
PHARMACIES	Maximum margin of PRP net is 30.35%. Pharmacy claw-back linked to pharmacy turnover and medicine price.	

+ VAT: **10%**

AIFA carries out a monitoring action on prescription-only medIcines, verifying compliance with two conditions:
-the price of the medicine can be increased every two years (in odd years);
-the increase cannot exceed the programmed inflation

By 2008, the price of **not-prescription medicines** at all price levels is totally free. AIC's holder is obliged to communicate to AIFA the increasing variations over the maximum ex-factory price applied to distribution

REIMBURSEMENT

IN-PATIENT (Class H)	OUT-PATIENT (Class A)
Positive list	Hospital Pharmaceutical formulary
-No patient copayment for medicines dispensed in hospital -Most medicines, included into the HPF are part of the National reimbursement list (class A), but the HPF may also include some not reimbursed medicines (class C), according to the Hospital specialization	- Patient **fixed co-payment ("ticket")** and **prescription fee** (it changes/exists or not according to the region) -**Exceptions** from co-payment for particular social groups, pregnant women, aged etc.

Reference Price System ATC 5

100% reimbursement

But… authorities can decide to put restrictions in place for certain products or product classes, which are known as "note AIFA"

*A fund for **innovative medicines** & a fund for **innovative cancer medicines**, 500 million endowment each, have been established in 2017 (Legge di bilancio).*
*Innovativeness criteria: **medical need**, **added therapeutic value** and **quality of evidence**. Innovativeness and benefits have a maximum duration of 36 months*

For more information please visit the site of the Italian Drugs Agency (AIFA) at https://www.aifa.gov.it/ or scan the QR code

National Health Service
Republic of Latvia

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

LATVIA

National Health Service (NHS), phone +37167043700, email nvd@vmnvd.gov.lv

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

	OUT- PATIENT	IN - PATIENT
PRICING	**Pricing in the out-patient sector** Pricing policies for medicines *Non-reimbursable medicines:* free pricing at manufacturer price level. For informative purposes the holder of the market authorisation has to declare the price to the State Agency of Medicines. *Reimbursable medicines:* price is regulated at wholesale price level. Internal and external price referencing is applied, managed entry agreements are in place. Wholesale remuneration Regressive wholesale mark-up scheme is applied to all medicines (different mark-up schemes for reimbursable and non-reimbursable pharmaceuticals). Pharmacy remuneration Regressive pharmacy mark-up scheme is applied to all medicines (different mark-up schemes for reimbursable and non-reimbursable pharmaceuticals). VAT Standard VAT rate is 21%, VAT rate for medicines 12%. Reforms Managed entry agreements allowed by the legislation (in 2012). Price linkage rules introduced for the followers in the Positive list (30% for the first one, 10% for the next two and 5% for the following ones) (in 2011). Wholesale mark-ups decreased for reimbursable medicines with manufacturer price EUR 142,28 and higher (in 2011). VAT on medicines increased from 5% to 10% (in 2009) and to 12% (in 2011).	**Pricing in the in-patient sector** Pricing policies for medicines Suppliers of hospital pharmaceuticals are mostly wholesalers and wholesale prices are used as hospital prices. Centralised procurement is organised by the NHS for the purchase of the following pharmaceuticals and medical devices: (1) peritoneal dialysis, (2) vaccines, standard tuberculin and syringes (3) parenteral chemotherapy medicines (4) and the treatment of phenylketonuria and other genetically- determined diseases. Health care institutions themselves organise the procurement of pharmaceuticals and medical devices that are not purchased centrally. Hospital pharmaceuticals are purchased according to the Public Procurement Law. Procurement is the sole pricing policy for pharmaceuticals and medical devices used in hospitals. Procurement is mainly organised by using open tendering procedures. Minor purchases are made after requesting quotes. Wholesale remuneration Regressive wholesale mark-up scheme set by the Cabinet of Ministers is applied to all medicines. VAT Standard VAT rate is 21%, VAT rate for medicines 12%.
REIMBURSEMENT	**Reimbursement in the out-patient sector** Positive / negative list Positive list with 1747 medicines, 265 medical devices (on 01.10.2019.). Reference price system (RPS) RPS was gradually implemented since 01.07.2005. Grouping is applied using ATC-4 and ATC-5 levels. Co-payment Fixed co-payment EUR 0.71/prescription for pharmaceuticals which are 100% reimbursed. Patient co-pays 25% or 50% of the price of the cheapest medicine in the case of 75% and 50% reimbursement and also pays the price difference when more expensive, not the reference (cheapest) product is prescribed. Mechanisms for vulnerable groups For children up to age 18 and low income persons the pharmaceuticals included in the Positive list are 100% reimbursed except when more expensive, not the reference (cheapest) product is prescribed, patient pays the price difference. Prescription-only medicines, that are not included into Positive list, are reimbursed for children up to 24 months of age (reimbursement rate 50%) and for pregnant women and women within 70 days of postnatal period (reimbursement rate 25%). Reforms In 2009 the reimbursement rate was decreased to 75% for diagnoses with 90% reimbursement and to 50% for diagnoses with 75% reimbursement. After that for some groups of diagnoses the	**Reimbursement in the in-patient sector** Reimbursement of medicines Medicines are fully reimbursed for in-patient care. Expenses for medicines are included in the payment rates for health care services. The expenses of certain high-cost pharmaceuticals are paid separately. Hospital formularies *Basic Hospital Pharmaceutical Formulary (HPF)* is used in all hospitals financed from the State budget. 1137 medicines of different INNs, pharmaceutical forms and strengths (pack size in HPF is not specified) are included in basic HPF. *Additional HPF* is detailed in each individual hospital and is relevant to the profile of the health care institution. Co-payment in hospitals Medicines are fully reimbursed for in-patient care.

reimbursement rate was increased (for cardiovascular diseases from 50% to 75% in 2011; for Crohn's disease an ulcerative colitis from 50% to 75% in 2015, to 100% in 2018; for hepatitis B and C from 75% to 100% in 2016; for psoriasis from 75% to 100% in 2018; for sarcoidosis from 50% to 100% in 2018; for Hypersensitivity pneumonitis and pulmonary diseases from 50% to 100% in 2018; for disorders of mineral metabolism from 75% to 100% in 2018; for Huntington and Motor neuron disease from 50% to 100% in 2018; for Alzheimer disease, Dementia and mental disorders due to brain damage and dysfunction from 50% to 75% in 2019; for Schizotypal, Persistent delusional and Acute and transient psychotic disorders from 50% to 75% in 2019; for Mental retardation from 50% to 100% in 2019;). New diagnoses covered by the reimbursement system (artificial fertilization and infertility in 2012; immunodeficiencies, Primary pulmonary hypertension, other urticarial, Osteogenesis imperfecta, Lung transplant status in 2018; Personality and behavioural disorders due to brain disease, damage and dysfunction, Depressive episode and Mild mental retardation in 2019;). Reimbursement of prescription-only medicines, that are not included into Positive list, for children up to 24 months of age (reimbursement rate 50%) and for pregnant women and women within 42 days (since 2012) and 70 days (since 2019) of postnatal period (reimbursement rate 25%). 100% reimbursement of pharmaceuticals included in the Positive list for children up to age 18 (since 2014). Parenteral chemotherapy medicines switch to centralized procurement from 2019. HTA evaluation went to State Agency of Medicines from 01.07.2019.	

LIETUVOS RESPUBLIKOS
SVEIKATOS APSAUGOS MINISTERIJA

PPRI
Pharmaceutical Pricing and Reimbursement Information

LITHUANIA

Ministry of Health of the Republic of Lithuania (+370 5 268 5110, ministerija@sam.lt)

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

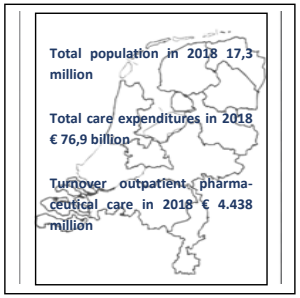
	OUT- PATIENT	IN - PATIENT
	Ministry of Health is responsible for policy and legal regulation of pricing and reimbursement NHIF is responsible for implementation of pricing and reimbursement	Ministry of Health is responsible for the List of Centrally Procured Medicines and Medical Devices NHIF is responsible for procurement procedure
PRICING	**Only one producer in LT market** • External price referencing -manufacturer price is compared with the average manufacturer prices in 3 EU countries where the price is lowest • The first generic 30% cheaper the originator. • The first biosimilar 15% cheaper the originator **Two or more producers** • No ERP, competition • Copayment cap -20% of reimbursed price or 4,71 Eur • All strengths in one cluster • New patient get cheapest product in pharmacy Linear wholesaler margins Linear pharmacy margins VAT: 5% for prescription medicines "Wise list" project as a best practice for rational use of pharmaceuticals	**Expensive hospital only used medicines** • The List of Centrally Procured Medicines and Medical Devices (centrally purchased by the NHIF) • Price is set after negotiations **Other hospital medicines and medical devices** • Procured via Central Procuring Organization • Via separate public competition procedure Statutory margins are not relevant, unless products are from community pharmacy VAT: 5% for prescription medicines, 21% for non-prescription medicines
	HTA process: New HTA system in process of implementation. ICER value under discussions	
COVERAGE / REIMBURSEMENT	**Reimbursement in the out-patient sector** Positive list (550 active substances included on positive list) Internal reference price system (RPS) in groups of 2 or more producers at ATC 5 & 4 level (Lowest price of medicine in reference group) 100% reimbursement rate for all medicines Co-payment „cap" per package Mechanisms for vulnerable groups since July1, 2020 No co-payment for patients elder 75 No co-payment for low income patients Cheapest product with the same INN for new patient **Reforms:** E-pharmacy	**Reimbursement in the in-patient sector** Expensive hospital medicines included in the List of Centrally Procured Medicines and Medical Devices (31 active substances) Medicines are integrated in the remuneration for the service sum (with some exceptions) Hospital formularies are not centralized Pharmaceutical formulary per hospital No co-payment in hospitals **Reforms:** Hospital pharmacy has a possibility to sell reimbursed medicines for patients which are in the day care unit (example: chemotherapy)

The Netherlands

Ministry of Health , Welfare and Sport

Ministerie van Volksgezondheid, Welzijn en Sport

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



PRICING

	OUT- PATIENT	IN - PATIENT
	Ministry of Health Welfare and Sport is the **competent authority** for pricing and reimbursement. The Health Care Institute assesses the NCE's but the Minister takes the decision for approval. Everyone who lives or works in the Netherlands is obliged to have a basic insurance and is a payer.	**Hospitals and the health insurers** (in accordance with the national basic health insurance package) are the **competent authorities** for pricing and reimbursement in the in-patient/hospital sector. Everyone who lives or works in the Netherlands is obliged to have a basic insurance and is a payer.
	Pricing in the out-patient sector	**Pricing in the in-patient/hospital sector**
	Pricing policies for medicines Internal Reference Pricing External Reference Pricing Preference Policy (generic substitution)	Pricing policies for medicines The insurer and the hospital sign a contract on the basis of **DRG's**. Due to competitive contracting between hospitals and insurers most prices are confidential except list prices. **Add-on (high cost medicines)**: If a medicine costs € 1000,-- or more, a reimbursement of the actual list price can be requested by the hospital. **Price negotiations** on national level.
	Pharmacy remuneration Prescription remuneration	
	VAT 9%	VAT 9%
	Reforms Change in ERP basket (Germany out and Norway in (2020))	

HTA process: outpatient drugs: positive list: market authorization -> HTA -> reimbursement decision by Minister -> reimbursement

Inpatient: direct reimbursement -> HTA if annual budget exceeds 10 millions

COVERAGE / REIMBURSEMENT

	OUT- PATIENT	IN - PATIENT
	Medicines are not covered by public funds	
	Coverage / reimbursement in the out-patient sector	**Coverage / reimbursement in the in-patient sector**
	Positive / negative list Yes	Reimbursement of medicines According the Health Insurance Law
	Reference price system (RPS) of cluster of substitutable medicines: Yes, since 1991	Hospital formularies no
	Request after registration (EMA or CBG) of the manufacturer NCE → Assessment Health Care Institute Survey Health Care Institute → Admission of the NCE / Rejection of the NCE generics List 1A (clusters) (832 clusters with 746 ATC5 level medicines) List 1B (359 ATC5 level medicines)	
	Co-payment Product co-payment: if a price of a product is higher than the reimbursement limit. Co-payment out-patient medicines in 2018 € 43 million (€ 14 million has not been refunded because of a repayment arrangement of the manufacturers). The patient's out-of-pocket payments on medicines is maximized at € 250,00 per patient per year	Co-payment in hospitals no
	Reforms Revision of the Internal Reference Pricing System. We haven't decided yet what we are going to do but it has to be finished in 2022	No reforms

Government of the Republic of Moldova
Ministry of Health, Labor and Social Protection

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

REPUBLIC OF MOLDOVA

Ministry of Health, Labor and Social Protection 2 Vasile Alecsandri str.
National Health Insurance Company, 46, Vlaicu Pircalab str.
Medicines and Medical Devices Agency, 2/1, Korolenko str.
State University of Medicine and Pharmacy "Nicolae Testemitanu", 22 N. Testemitanu

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

PRICING at ex-factory level (price ATC 5)

All type of medicines (Rx and OTC) authorised and included in the State Medicines Nomenclature

Bureau of Price, from Medicines and Medical Devices Agency → **National Manufacturer Price Catalogue**

Task: Average price of the lowest three prices of the 9 reference countries: Romania, Greece, Bulgaria, Serbia, Croatia, Czech Republic, Slovakia, Lithuania and Hungary; if there are not at least 3 prices in the reference countries, the price compares to 2 or 1 price existing;
Generic medicine price does not exceed 75% of the original medicine;
Criteria: External reference pricing.

The manufacturer price of medicines is approved for a period of one year, calculated from the date of issuing the Agency order.
The price is declared by the applicant in the national currency (Moldavian lei) and foreign currency.
If there is no price information in the reference countries, the manufacturer price for medicines is compared with:
a) the price in the country of origin;
b) the average of the lowest three prices on the catalogues in the countries where the medicine is placed on the market;
c) the average of the price in the country of origin and the average of the price of the medicines entered on the date of assessment of the dossier in national price catalogues;
d) the average import price for the previous years for the given pharmaceutical product, if it has been imported.

OUT- PATIENT

PRICING at wholesale and retail (pharmacy) level

Pricing in the out-patient sector

Medicines distributed via wholesale and pharmacy, regressive mark-up

Purchase price (MDL)	Final margin	Wholesale ark-up	Pharmacy mark-up	For reimbursed medicines Pharmacy mark-up
0-30,00	≤40%	≤15%	≤25%	≤15%
30,01-60,00	≤32%	≤12%	≤20%	≤15%
60,01-120,00	≤26%	≤10%	≤16%	≤15%
120,01-240,00	≤21%	≤8%	≤13%	≤13%
>240,01	≤16%	≤5%	≤11%	≤11%

Annotation: The average exchange rate for 2018:
1 EUR = 19.8442 MDL

VAT for all types of medicines: 8 %

REIMBURSEMENT

Reimbursement in the out-patient sector

Council of reimbursed medicines from mandatory health insurance funds

Task: Decision on reimbursement status and rate of International Non-proprietary Name.
Criteria: eligibility for priority diseases, efficiency, safety, comparative effectiveness, pharmacoeconomic criteria.

Section I

- **List of medicines for sustained (long-term) treatment in ambulatory care**
- **Reimbursed rate:**
  - 100% (full price);
  - 50%, 70% and 30% from median retail price (collected from 50 community pharmacies);
  - 1 free (100% covered) trade name (with lowest price), for all INN reimbursed.
- **91 INN for:**
  - *Cardiovascular diseases*; *Digestive diseases; Endocrine diseases* (inclusive Diabetes mellitus (100%); *Bronchial asthma*; *Anaemias* in pregnant women (100%); *Some diseases of children up to 18 years* (100%); *Epilepsy* (100%); *Parkinson diseases* (100%); *Psychical diseases* (100%); *Some autoimmune diseases* (100%); *Some rare diseases* (100%) etc.

Section II

- **List of medicines for episodic treatment in the day hospital/day care room, procedures room and at home treatment, of diseases commonly found in the practice of family physician**
- **Reimbursed rate:**
  - 100% (full price) for children up to 18 years;
  - 70% from median retail price (from 50 community pharmacies).
  - 1 free (100% covered) trade name (with lowest price), for all INN reimbursed.
- **57 INN for (52 INN for adults and children + 5 INN only for children):**
  - *Respiratory system diseases*: Pneumonia; Chronic bronchitis; COPD, Bronchial asthma; *Digestive system diseases*: Chronic hepatitis; Fibrosis and liver cirrhosis; Chronic pancreatitis, Ulcerative disease; *Mental diseases*: Multiple sclerosis; Myelopathy; Cerebrovascular disease; Encephalopathy; *Osteoarticular diseases*: Rheumatoid arthritis; Reactive arthritis; Psoriatic arthritis; Gout; Back pain; *Endocrine diseases*: Diabetes mellitus + diabetic neuropathy; Diabetes + angiopathies; Diabetic Nephropathy; *Infection diseases*: Acute Respiratory Viral Infection (on children).

IN - PATIENT

Pricing in the in-patient sector

Center for Centralized Public Procurement in Health

Tendering | **Price negotiation**

Task: Tendering or price negotiation of medicines. Pharmacotherapeutic Committees of public health facilities and medical institutions determine the need for medicines for the planned period (the next year), taking into account the Institutional Pharmacotherapeutics Formulary, dosage, pharmaceutical form of medicines, clinical protocols approved by MoH, the amount needed to treat one patient, stocks of drugs in institutions, and provide this information to Center. In accordance with the lists of medicines, depending on the value of contracts, appointment, features of procurement and use of medicines, the Center's working group applies one of the public procurement procedures.
MoH determine the necessary amount of medicines for National vertical and special Programs.
Criteria: Requirements for each batch of medicines are evaluated separately: quality, efficiency, delivery time, payment terms and price. The tender prices are benchmarked against the registered price in the National Catalogue.

VAT for all types of medicines: 8 %

Reimbursement in the in-patient sector

Institutional Pharmacotherapeutic Committees

Task: Decision on introduction of medicines in the needed for procurement list of medicines
Criteria: eligibility for diseases, efficiency, safety, cost criteria. VEN and ABC analysis.

The hospitals purchase the medicines from the winning bidder. The cost of medicines is included in the DRG price. High cost medicines are reimbursed separately by the National Health Insurance Company (surfactant, chemotherapeutics). Insulin analogues are reimbursed by MoH.
Hospital formularies
Pharmacotherapeutic Formulary, List of Essential Medicines, and National Clinical Protocols are the basis for hospitals to develop their institutional needs for central procurement.

No co-payments for patients

Changes in Pricing and Reimburesment

- ***Planed to introduce the final price in Catalog*** *(need to change the incoterms from EX-works to Cip price)*
- ***Planed to increase the number of INN of reimbursement list,*** *also to increase the forms and doses of existing INN that are already reimbursed*
- ***Planned to elaborate a new EML with fusion of three Commtte:*** *for reimbursement list of medicines, essential medicines, and pharmacotherapeutic formulary list in one, with a common criteria and mechanisms for including, examining and evaluating medicines.*
- ***Planed to elaborate new National Price Catalogue*** *with new maximum price at the community pharmacy level.*
- ***Planed to*** *elaborate a National practical guidelines on HTA for medicines listing in National Essential list of medicines .*

Republic of Korea

Health Insurance Review & Assessment Service (HIRA)

EUNYEONG PARK(eypark@hira.or.kr), JIHYE KIM(christina@hira.or.kr), MYOJEONG KIM(myojeong@hira.or.kr)

- **total population : 51,826,059(2018)**
- **GDP per capita : $33,346.3 (2018)**
- **organisation of the health care sector : National Health Insurance (NHI)**
- **Current expenditure on health per capita : 3191.6 USD(ppp) (2018) (% of Government/compulsory schemes : 59.8%)**
- **Current expenditure on health in % of the GDP : 8.1% (2018)**
- **Pharmaceutical expenditure per capita : 634 USD(ppp) (2017)**

Recent developments in pharmaceutical policies 2019
Special Topic : post management of listed drugs

Health Insurance Review & Assessment Service

PRICING SYSTEM

- **(Drug Pricing System)** Since December 2006, the Korean government has employed the "positive list system"
- **(Listing)** In order for drugs to be listed in the NHI drug formulary, pharmaceutical companies must apply for listing process to HIRA. If the pharmaceutical companies want to higher reimbursement price than the existing price in the NHI drug formulary, then they have to submit an economic evaluation report to HIRA. Clinical effectiveness and cost-effectiveness are core criteria for listing decision. In case of orphan drugs, then they can be exempt from the submission of the economic evaluation report.
- **(Pharmaceutical Expenditures and Drug Coverage)** Recently, Pharmaceutical expenditures and total health expenditures covered by NHI has been increasing. As of January 1, 2019, the total number of listed drugs are 20,901 items.

- **(Follow-up Management of listed drugs)** There are three types of follow-up management schemes on a regular and periodic basis.

Drug Price Adjustment according to Actual Transaction Survey	Pre-contract Price Reduction due to Expending Coverage	Negotiation Linked with Volume
• Investigating actual drug prices transacted between healthcare institutions and pharmaceutical companies • Reflect the actual prices on deciding list prices	• Adjust Prices according to predicted expenditures increases for expending coverage (max 5%)	• Adjust Prices if the volume of a drug hae exceeded the volume forecasted at the time of the first negotiation(max 10%)

POST MANAGEMENT

- **(Post –Evaluation Method For Equivalent Drugs)** Preparing a fiscal soundness plan for the sustainablity of health insuarance
- **(Conceptual Framework)** Developing a comprehensive drug re-evaluation system that includes both financial impact and clinical benefit

Finance-based Post-Evaluation	Performance-based Post-Evaluation
• Price Comparison of Excluded Countries - Foreign System & Price Survey • Evaluation for Old Drugs - Status of Foreign & Domestic	• Literature Review - Systematic Review - Evaluation Using Value Framework • RWE based Evaluation

※ These policies are developed referred to **National Health Insurance Plan(2019-2023)**
: (Appropriate management of pharmaceuticals) Mid-to long-term strategy & improvement of financing structure for application of National Health Insuarance benefits based on analysis

Statens legemiddelverk
Norwegian Medicines Agency

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

NORWAY

4th PPRI Conference, 23-24 October 2019, Vienna

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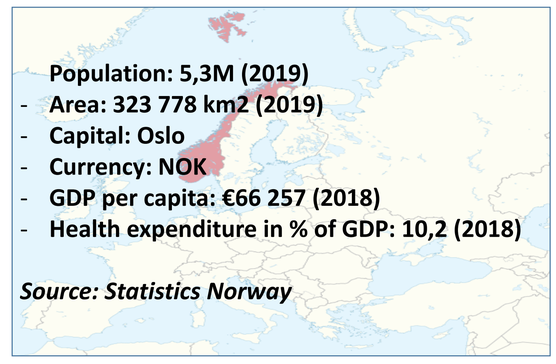
PPRI
Pharmaceutical Pricing and Reimbursement Information



Pharmaceutical pricing and reimbursement policies in the primary care- and specialist care sector

PRICING

PRIMARY CARE SECTOR

Norwegian Medicines Agency (NoMA)
Responsible for pricing and general reimbursement

Norwegian Health Economics Administration (HELFO)
Responsible for individual reimbursement

PRICING POLICIES

Statutory pricing for all registered prescription-only medicines (POMs).
Free pricing for unlicensed medicines, veterinary medicines and OTCs.

Maximum price regulation at pharmacy purchase price (PPP) level. Price is set based on external reference pricing (ERP).
Country basket: **SE, FI, DK, DE, UK, NL, AT, BE, IE**. Price set as mean of the 3 lowest unit prices.
75% of POM-market is price re-evaluated annually, using ERP and IRP.

REMUNERATIONS

NoMA regulates pharmacy mark-up: combination of regressive percentage and mark-up per pack:
- 2% on PPP plus
- €3 per pack
- Additional 0,5% for cooled goods and €2 per pack for narcotics (01.july 2019)

Wholesale remuneration is not regulated.

REFORMS

- Generic substitution
- Stepped price regulations for substances with generic competition (2005)

SPECIALIST CARE SECTOR

Norwegian Drug Procurement Cooperation (LIS)
Performs price negotiations and tenders

Regional Health Authorities (RHAs)
Responsible for financing/reimbursement

PRICING POLICIES

Maximum price regulation (PPP) for all prescription-only medicines as a roof + **tendering/price negotiations** (ex-manufacturer prices).

LIS performs tenders on most pharmaceuticals financed by the hospitals. The tendering is performed mainly on behalf of the hospitals, and in some cases prices are negotiated.

REMUNERATIONS

The Regional Health Authorities or sometimes hospitals can set pharmacy mark-up freely up until maximum pharmacy mark-up.
Wholesale distribution and mark-up is based on two tenders on behalf of the four RHAs.

REFORMS

- Centralizing procurement for the RHAs
- Increased use of price negotiations
- Sustainability demands embedded in tender processes
- Nordic tenders and price negotiations

25% VAT on all pharmaceuticals

HEALTH TECHNOLOGY ASSESSMENT PROCESS

Horizon scanning report
NoMa

Health technology assessment
NoMa
Three criteria for priority setting:
- Utility for patient
- Resource use
- Severity of disease

Price negotations
Norwegian Hospital Procurement Trust

Reimbursement decision National Insurance Scheme
NoMa

Reimbursement decision hospitals
Decision Boards

Decision Board: CEOs of the 4 RHAs + patient representative

REIMBURSEMENT

National Insurance Scheme (NIS)
Provides reimbursement for primary care sector

General reimbursement

Criteria:
- Severe disease
- Need for ≥ 3 months of medication per year
- Three criteria for priority setting are met

Individual reimbursement

Criteria:
- Products available for general reimbursement do not provide sufficient effect/cause unacceptable adverse reactions
- Patient differs from the patient group assessed for general reimbursement

CO-PAYMENT

39% co-payment, maximum €52 per prescription. Co-payments are included in the cost-ceiling scheme (2019: €238). Exceptions for co-payments, e.g.:
- Low-income pensioners
- Children under 16
- Treatment of contagious diseases

REFORMS

- HTA mandatory for general reimbursement medicines since 2002 and for all new medicines since 2018

RHAs
Provides reimbursement in publicly funded hospitals

Reimbursement policies

Pharmaceutical expenditure in publicly funded hospitals is covered by the hospital budgets.

In each of the four RHAs, a hospital medicines committee works out a limited list of medicines; an advisory list to guide the hospitals choice of medicines.

CO-PAYMENT

No co-payments for medicines used in specialist care treatment.

REFORMS

- Financing of several medicines that often are dispensed in public pharmacies but prescribed by hospital specialists (Health enterprise-prescriptions) has been allocated from primary care (NIS) to specialist care (RHAs). Process is still ongoing.
- HTA mandatory for all new medicines since 2013

PORTUGAL

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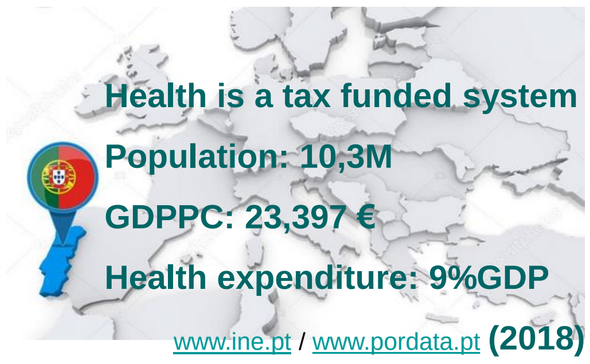
INFARMED - National Authority of Medicines and Health Products, I.P.
PPRI Conference, 23 – 24 October 2019, Vienna



www.ine.pt / www.pordata.pt (2018)

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

PRICING

Out-patient

POM (except HOM) → **National medicines agency (Infarmed)**

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

Criteria: External Price Referencing (**average** prices ES, FR, IT, SI)

Statutory Pricing

- **GENERICS**: Price Capping •Generic price ≤50% originator price; If ex-factory price of originator <10€, the difference applied is 25%
- **PARALLEL IMPORT**: <5% PRP of the 'considered medicines' and essential similar medicines
- **NOTIFIED PRICES**: For non reimbursed/ non reimbursable POM. **Possibility** of price increase up to 10% per year (max. 2.5€)

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

OTC non reimbursed → **Pharmaceutical companies**

Task: Establish OTC price

Free Pricing

Wholesale and pharmacy margins are not regulated VAT (6%)

In-patient: Applied only to Public hospitals

POM to be purchased by hospitals + OTC → **National medicines agency (Infarmed)**

Task: Setting a maximum price (**lowest** price ES, FR, IT, SI)

SPMS

Task: Centralised public procurement for a list of specified medicines and public procurement for other medicines
Criteria: Price is an important factor

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).

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

NATIONAL HEALTH TECHNOLOGY ASSESSMENT SYSTEM (SiNATS)

SiNATS

Technology
Medicines + Medical Devices + Other Technologies

Assessment
a) Relative Effectiveness (Added Therapeutic Value)
b) Cost-Effectiveness (Economic Value)
c) Other dimensions of the techonology value (including affordability)

DATS (HTA Department) **CATS (HTA Committee)** For new INN and Therapeutic indication

Contract negotiation
a) Price
b) Financing/reimbursement
c) Control and cost limitation
d) Risk sharing
e) Additional monitoring of use

Decision
Reports and recommendations for use

Re-assessment of technologies on the market (ex-post evaluation)

REIMBURSEMENT

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

Task: Decision on reimbursement; reassessment; exclusion and sunset clause

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

Product Specific
Based on therapeutic classification

Specific Scheme

- **Population Group Specific** extra reimbursement (15%) for pensioners
- **Disease Specific** Defined pathologies e.g. HIV, Alzheimer disease

Generics
Out-patient
From the 5th generic reimbursed, price <5% of the PRP whose generic application is valid, regardless its decision
In-patient
≤70% originator medicine

Internal Reference Pricing
Out-patient
Reference price – average of 5 lowest PRP at the market (including non-generics) in each Homogeneous Group (HG) ; not higher than the most expensive generic in each HG
Reimbursement –
<5% of the lowest generic price, with at least 5% of market share, in each HG.

Biosimilars
In and Out-patient
Price ≤ 80% biological medicine's originator price
Price ≤70% if biosimilar is ≥5% market share

Economic advantage
In and Out-patient
If equivalent to comparator: Price ≤90%

PAYMENT

Ministry of Health through ACSS (Central Administration of the Health System)

Task: Reimbursement of medicines to Community Pharmacies based on reimbursed dispensed medicines

Task: Financing hospital level of activity , including use of medicines, through Diagnosis-related Groups (DRG). Hospitals are funded prospectively through contracting of services (contracting programs) between ACSS, Regional Health Administrations and each Hospital, which includes:

Additional financing

- Special financing of medicines to HIV/ HCV treatment. **Criteria:** Medicines and medical procedures to HIV patients are subsidized according to the predicted number of new HIV patients/ Central financing for HCV treatment
- Medicines for specific conditions and dispensed in hospitals to out-patient with no co-payment **Criteria:** medicines reimbursed at 100% for hospital only dispensing
- Comprehensive price (e.g. chronic kidney disease)

USE IN HOSPITALS

in consultation with

National Formulary

Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic Committee

Task: Decision on use of medicines in the hospital

Legislation: Decree-Law n.º 97/2015, 1st June; Ordinance n.º 195-C/2015, 30th June; Ordinance n.º 195-A/2015, 30th June; Decree-Law n.º 134/2005, 16th August; Ministerial Dispatch n.º 1547-B/2016; European Directives 2004/17/CE and 2004/18/CE; Ministerial Dispatch n.º 1083/2004

Република Србија

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

REPUBLIC OF SERBIA

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

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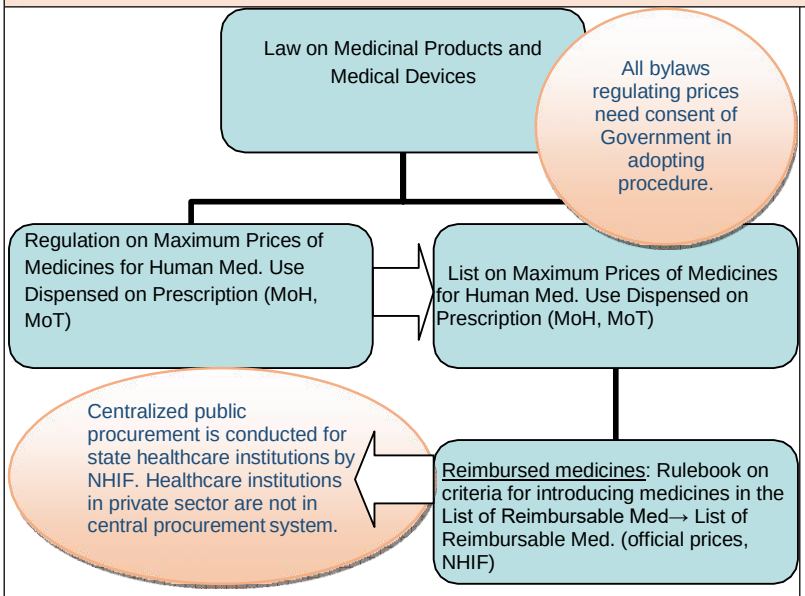
Population: 6.9 mil (3.6 mil female, 3,4mil male)
GDP: 5226 €/cap. (SORS, 2017.)
Total health expenditure of GDP: 8.8% (Institute for Publ. Heath of Serbia, 2015.)
Health care insurance: mandatory and voluntary. Mandatory health insurance is provided by National Health Insurance Fund

PRICING

Authorities competent for price setting: **Ministry of Health (MoH), Ministry of Trade (MoT),** for all medicines for human medical use with marketing authorization and dispensed on prescription. **National Health Insurance Fund** (**NHIF),** for reimbursable medicines.



Reference price system
External
1° basket: Slovenia, Croatia, Italy;
2° basket: Estonia, Bulgaria, Romania, Lithuania, Latvia, Hungary…

Methodology of calculation is defined by Regulation on Maximum Prices.

Margins are regulated by Regulation on Maximum Prices:
Wholesale margins: 6%

Retail margins:
Non-reimbursable medicines: regressive, depending on price level.
Reimbursable medicines: up to 12%

Challenges in process of prices policy changing:
1. More efficient procedures of price settings.
2. Insuring the affordability of medicines and continual supply.

REIMBURSEMENT

List of reimbursed medicines: yes; List A, List A1, List B, List C and List D.
2542 registered medicines on the list (710 INNs, 2017.)- Nearly 55% of all medicines with MA. List D: non-registered medicines (220 on the list).
Reference price system (RPS): yes; the lowest price in reference countries + additional mechanisms for price decreasing (next added generics decrease price of existing medicines in INN at least by 10%).
Managed Entry Agreements (volume cap and cross-product types for placing new medicines on reimbursement list).
Centralized public procurement (since 2014; project supported by World Bank).

Reimbursement of medicines in the out-patient sector

List A and A1 and List D-partly (medicines dispensed in public pharmacies).
Procurement: centralized, by proprietary name of medicine.
Co-payment: yes.
A List: 50, 00 RSD (0.4 €)/pack.
A1 List: 10%-95% of retail price
Mechanism for vulnerable groups:
Law on Health Insurance and Rulebook on List of Reimbursable Medicines stipulate vulnerable groups free of co-payment for medicines on A List.

Reforms and challenges:
1. Improving mechanisms in order to get better affordability of medicines
2. Improvement in procurement system in order to strengthen the competitiveness among manufacturers.

Reimbursement of medicines in the in-patient sector

According to Financial Plan NHIF – amount of money allocated for hospital medicines.
All medicines for in-patient use **(List B, List C and List D-partly)** are procured by NHIF – **open centralized procedure of procurement, INN procurement.**
Co-payment in hospitals: no.

Reforms and challenges:
1. Ensuring stable supply of essential medicines
2. DRG for acute care- ongoing project (supported by WB)

Ministry of Health of the Slovak Republic

PPRI
Pharmaceutical Pricing and Reimbursement Information

Slovak Republic

Ministry of Health of Slovak Republic

Tel.: +421 2 593 73 111, e-mail: office@health.gov.sk

Total population: 5, 4 mil
GDP per capita: 33 923
Health expenditure per capita: 2 187, 8
Health expenditure in % of the GDP: 6, 7%
Pharmaceutical expenditure: 577, 4 US
Organisation of the health care sector: SHI

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

	OUT- PATIENT	IN - PATIENT
	Decision making institution: Ministry of Health (MoH) Payers: Health insurance company, insured patient	Decision making institution: Ministry of Health (MoH), Hospital Payers: Health insurance company
PRICING	**Pricing in the out-patient sector** Pricing policies for medicines **Pricing at ex-factory price level** Calculation of EU average price for medicines applying for inclusion in Reimbursement list in the out- patient sector **Pricing procedures**: External price referencing **Pricing at wholesale and pharmacy level** **Public Retail Price (PRP) = Ex-factor price+ Regressive wholesaler and pharmacy margin (fixed + %) + VAT (10%)** Wholesale remuneration Maximum regressive wholesale mark-up scheme set by the Ministry of Health (2 different schemes: fixed mark up for hospitals and regressive for outpatient customers) Pharmacy remuneration Maximum regressive pharmacy mark-up scheme set by the Ministry of Health (mark-up regulation only for retail pharmacies) VAT Standard rate 20% and reduced rate for medicines 10%	**Pricing in the in-patient/hospital sector** Pricing policies for medicines Hospital purchasing body (individual hospital pharmacist or joint purchasing body) negotiates and tenders price of medicine **Pricing at ex-factory price level** The maximum ex-factory price of hospital medicines is regulated by the Ministry of Health **Pricing procedures:** Public procurement, negotiation with the manufacturer or wholesaler Wholesale remuneration The maximum regressive wholesale mark-up is fixed. Radiopharmaceuticals- maximum regressive wholesale mark-up 10% Pharmacy remuneration There is no pharmacy margin applied in hospital sector VAT Standard rate 20% and reduced rate for medicine 10%.
COVERAGE / REIMBURSEMENT	**Coverage / reimbursement in the out-patient sector** Positive / negative list / formulary List of Reimbursable pharmaceuticals contains 4328 medicines Reference price system (RPS) of cluster of substitutable medicines Internal reference pricing: ATC 5 level, differentiated by pharmaceutical form, strength and package since December 2011 Co-payment Prescription fees: 0.17 Euro except non-reimbursed medicine, e- prescription Deductible: higher than 5% of the average monthly wage of an employee in the economy of the Slovak Republic for groups of socially vulnerable (disadvantaged) patients Reforms Prevalence 1:50 000 as the criterion of inclusion to List of Reimbursable pharmaceuticals. There is no need of HTA evaluation of medicines	**Coverage / reimbursement in the in-patient sector** Reimbursement of medicines Medicines funded from the hospital budget (based on bed-days per treatment and medical services inclusion of medicines). Evaluation of costs and treatment per treatment procedure and case inclusion of pharmaceuticals is a task of Pharmaceutical and Therapeutic Committee Hospital formularies The hospital pharmaceutical formulary is often individual per hospital (decentralised) Co-payment in hospitals Payment in hospitals is without patient participation

SLOVENIA

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JAZMP (Agency for medicinal products and medical devices of the Republic of Slovenia)

Slovenia
Total population: 2.084.301
GDP per capita: 22.083 EUR
Organisation of HC sector: social health insurance system
Health expenditure per capita: 1.689 EUR
Health expenditure in % of the GDP: 8,2 %
Pharmaceutical expenditure: 600 million EUR

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

PRICING

Responsible institution	JAZMP - Agency for Medicinal Products and Medical Devices
Legal basis	Medicinal Products Act, Rules on price setting for medicinal products for human use
General information	**Every MP financed/intended for financing from public revenues should have list price determined prior to market launch** Price structure: ex-factory element of price + wholesale margin + pharmacy fee + VAT

Medicinal products for human use:

MAP (maximum allowed price)	EHAP (exceptional higher allowed price)
Re-determined twice yearly for every MP on the market (N = cca. 4700) **External Reference Pricing model (RCs: AT, DE, FR)** MAPs are determined and regulated by calculation of administratively determined ex-factory element of price (PEC) which may not exceed maximal allowed value of PEC, to which regulated wholesale margin is added. Three approaches for calculation of MAP: - Original (innovative) MP - Biosimilars - Generic MP	EHAP possible in cases when MAP does not enable the authorization holders to supply the market (e.g. due to small market size) (N = cca. 900) Committee for the determination of EHAP. Determined for a period of up to 1 year, several times consecutively or intermittently HTA-elements (pharmacoeconomic analysis and relative therapeutic evaluation) are taken into account; no pharmacoeconomic analysis and relative therapeutic evaluation is needed when annual sales (for all presentations on the market) are below 50.000 € or if the medicinal product has a temporary MA and complies to an item on the national Essential or Indispensable Medicines lists

REIMBURSEMENT

Responsible institution	HIIS - Health Insurance Institute of Slovenia
Legal basis	Health Care and Health Insurance Act, Rules of classification of medicinal products for human use on the list
Reimbursement criteria	Public health priorities, Clinical criteria, Therapeutic value, Relative effectiveness, Economic criteria, Pharmacoeconomic analysis, Budget impact analysis, Ethical criteria (orphans), Data and evaluations from reference sources

Measures for all drugs
- Internal reference pricing system for interchangeable drugs (ATC 5) since 2003
- Reference pricing for therapeutic drug groups (clusters, ATC 4 or 3) since 2013
- Pricing and managed entry agreements: discounts (reduction of price), rebates (material discount), price-volume agreements, 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 MPs (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.

Hospital/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)

South Africa

Fatima Suleman, Discipline of Pharmaceutical Sciences, University of KwaZulu-Natal
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Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

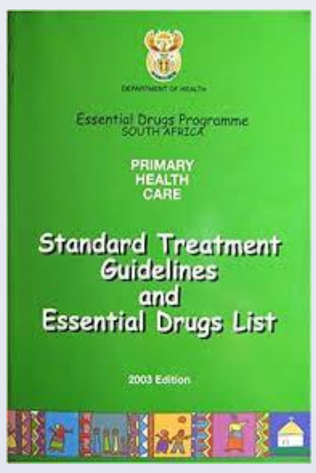
Pricing in the in and out-patient sector

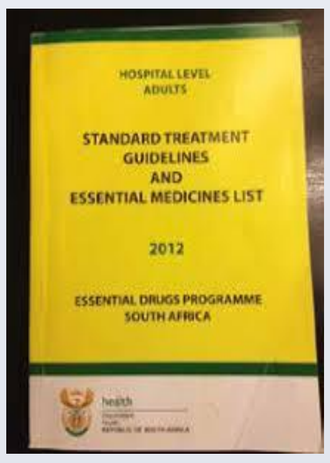
Public Sector

Quality of medicines good - Registration of medicines for South Africa – Medicines Control Council

Serves 80% of population – divided into Primary Health Care (free), Hospital Levels Care (Adult and Paediatric) and Tertiary Services. Medicines are obtained via competitive tender processes

Governed by Standard Treatment Guidelines and Essential Medicines Lists





Has about 10 000 medicines listed → Competitive tender processes employed for purchase → ERP system used as well

List of medicines on state contract are available from http://www.health.gov.za/ previously (www.treasury.gov.za-documents-medical and pharmaceutical

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

Medicines Selection by National Essential Medicines List Committee – Monitored by Provincial, District and Institutional Pharmacy and Therapeutics Committees

Private Sector

Serves about 20% of population; payment is through medical schemes or out-of-pocket.

Pricing governed by Single Exit Pricing policy; Dispensing Fee Policy and voluntary Pharmacoeconomic Guidelines – as per recommendation of Pricing Committee (PC) to Minister

Single Exit Price is the price at which a manufacturer must sell to all pharmacies and dispensing doctors, irrespective of volume sold.

Ex-Manufacturers Price + **Logistics Fee** + **VAT**

Components of the Single Exit Price

Value added tax (VAT) is added to all medicines sold, even though they are considered ESSENTIAL in the public healthcare sector.
Only Dispensing fee added to SEP at point of sale to patient

About 9000 medicines listed → ERP used at launch (unofficial) → SEP adjustments annually

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

Reforms

Guidelines on Pharmacoeconomic Assessment - 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 – currently under review.

Will need to be reassessed in the light of the proposed National Health Insurance proposal – pilot projects of private sector engagement in chronic medicine dispensing underway – amongst others

Reimbursement in the in and out-patient sector

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. NHI under debate currently

GOBIERNO DE ESPAÑA | MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

PPRI Pharmaceutical Pricing and Reimbursement Information

SPAIN

Ministry of Health, Consumer Affairs and Social Welfare

Directorate General (DG) of Services of the National Health System Basic Portfolio and Pharmacy

Email: cartera-farmacia@mscbs.es ☎ +34 915964015

Total population= 46,72 Millions (World Bank (2018)
GDP per capita (USD) =40,854.6 (World Bank (2018)
Organisation of health care sector = NHS
Health expenditure per capita= 2,389.89 USD (World Bank (2016)
Health expenditure in % of the GDP= 8.96% (World Bank (2016)
Pharmaceutical exp. (%current health exp.) = 22,3 %.(OECD 2016)

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

PRICING

The Ministry of Health, Consumer Affairs and Social Welfare (MoH) is the competent authority for pricing and reimbursement in the out-patient and in-patient sector. Payers are the regional governments and decisions are made by a Price & Reimbursement Committee (P&R committee), whose members are representatives of the MoH, as well as representatives of the Ministry of Finance and Civil Service, Ministry of Industry, Trade and Tourism, Ministry of Economy and Competitiveness, and of all Regional Governments health representatives.

Pricing in the out-patient sector and in-patient/hospital sector

Ex-factory price is established by the P&R committee for all reimbursable medicines (both out-patient and in-patient). External price referencing is used as supportive pricing policy. Policies for generic and biosimilars are in place. Conditional pricing is also applied (capping, MEAs). Reference price system (RPS) is also applied for out-patent price fixing. VAT for medicines is a reduced rate of 4%

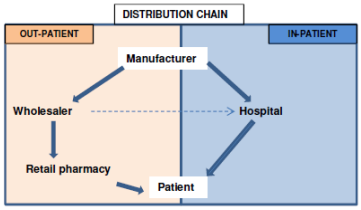
OUT- PATIENT

Wholesale remuneration
Ex-factory price ≤91.63 €, wholesale margin is 7.6% of the wholesale price. Ex-factory price >91.63 €, fixed wholesale margin of 7.54 €
Pharmacy margins
Ex-factory price ≤91.63 €, 27.9% of pharmacy retail price. Ex-factory price >91.63 € and ≤ 200 €, fixed pharmacy margin of 38.37 €/pack. Ex-factory price >200 € and ≤ 500 €, fixed pharmacy margin of 43.37 €/pack. Ex-factory price is >500 €, fixed pharmacy margin of 48.37 €/pack.

A pharmacy claw-back system has been in place since August 2000, with pharmacies making payments based on a percentage of their annual sales of reimbursable medicines at manufacturer prices

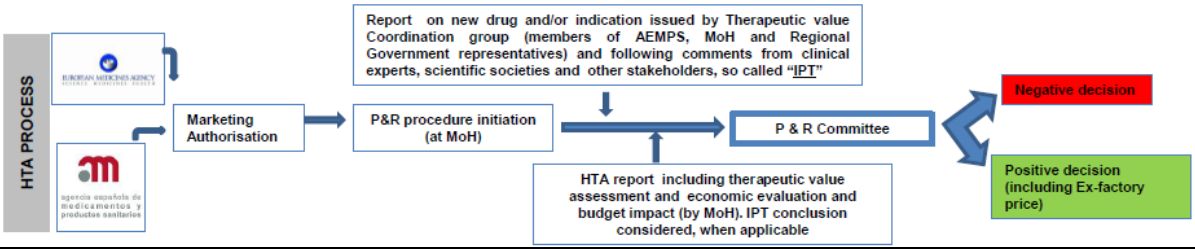
IN - PATIENT

Wholesale remuneration and pharmacy remuneration are not applicable in the in-patient sector
Tendering for medicines in the in-patient sector in addition to pricing policies is also applied.



Reforms: As cost-containment measures, mandatory discounts are in place. Discounts of 7.5% on originator medicines, 4% on orphan medicines and 15% for medicines reimbursed for more than 10 years and without a generic, granted jointed by manufacturers, wholesalers and pharmacies to the NHS for all reimbursable medicines since 2010. Exemption: Products included in the internal reference price system.

COVERAGE / REIMBURSEMENT



Coverage / reimbursement out-patient sector
There are both positive and negative lists. Medicines included in the positive list are updated monthly and available at:
http://www.mscbs.gob.es/profesionales/nomenclator.do

NEW: A new search tool informing on whether a medicine is reimbursed or not (including both out-patient and in-patient), is currently under development. Availability foreseen in November 2019.

Co-payment
60% of selling price of medicines for people earning ≥100,000 €/year; 50% for people earning ≥18,000 and <100,000 and 40% for the remaining employed citizens. Specific medicines for long term treatment have a reduced co-payment of 10% of the price with a maximum fee of 4.26 €/pack. Co-payment for retired people is 10% with a maximum monthly co-payment depending on earnings (6€, 18€ and 60€, respectively). Special vulnerable collectives are exempt from co-payment.

Coverage / reimbursement in-patient sector: In terms of coverage and reimbursement, consideration of in-patient medicines is given to drugs dispensed only in hospitals regardless of whether the patient is formally admitted or is ambulatory.

Co-payment:

There is full coverage of reimbursed medicines with no co-payment by patients in the in-patient sector

Sudan

National Health Insurance Fund, email pharmkal@hotmail.com

Baladya street, Mobile: +249912230757

- Total population: 40,199,543
- Health Insurance Coverage: 67.7% as of June 2019(272252777 individuals)

Pharmaceutical pricing and reimbursement policies in the public and private sectors sector

	Private sector	Public Sector
AUTHORIZATION	**National Medicines and Poisons Board(NMPB)** Enforcement of the Medicines and Poisons Act 2009	**National Medicines Supply Fund(NMSF)** -procurement, warehousing and distribution of medicines and other medical supplies to the public sector(NMSF Act in 2015) **National Health Insurance Fund** - Financing of medical services for insured population(NHIF Act 2016)
PRICING	**Originators(Innovators):** - **CIF price should not exceed 70% of its price published in BNF.** **The CIF price is agreed upon between the pricing committee and the importer.** **Imported generic medicines:** - **Generics from high income countries with stringent regulatory authorities, the CIF price up to 70% of originator registered in Sudan** - **From middle- income CIF 35-50%** - **From low-middle income countries CIF 20%** **Locally manufactured medicines:** - **15-20% top up of the cost** Distributers: Wholesalers: 15-20% mark-up Pharmacies: 20-25% mark-up	NMSF Mark-up 15% of the tender price after adding inland cost **Public pharmacies:** 20% of NMSF whole sale price regardless the location(NMSF beers the **cost of distribution)**
COVERAGE / REIMBURSEMENT	**NHIF:** social health insurance(67.7% population) **Medicines list:** includes 690 formulations **Reimbursement percentage:** 75%(co-insurance) **Prescribing guidelines** Private Insurance (2%) Different benefits packages Different copayments systems	**Free medicines: Federal Ministry of Health through NMSF** **Emergency medicines in hospitals: for the first 24 hours** **Essential medicines for children under five years** **Renal dialysis medicines** **Medicines for kidney and liver transplantation** **Oncology medicines and medicines used cardiac catheterization**

Sweden

Dental and Pharmaceutical Benefits Agency (TLV) +46-8 568 420 50

Pharmaceutical pricing and reimbursement policies

Tax funded national health care system

Population (2018): 10,175,000

GDP €/capita (2018): 46,300

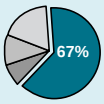
Health Care Sector Share of GDP (2017): 11%

OUT-PATIENT

PRICING

Pricing of pharmaceuticals on the benefit scheme

TLV is responsible for pricing and reimbursement of out-patient pharmaceuticals. The Board of Pharmaceutical Benefits decides on which new pharmaceuticals to include on the benefit scheme.



67% of pharmaceutical sales were within the benefits scheme in 2018. Pharmaceutical companies apply to TLV in order to list a product on the benefit scheme. TLV uses a Value Based Pricing method to determine whether a pharmaceutical, at a given price and effect, is cost-effective. TLV sets the pharmacy purchasing and retail price but not the ex-factory price and the wholesalers' margin.

Pricing policies for reimbursed pharmaceuticals

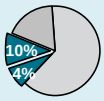
High cost pharmaceuticals. TLV, regions and pharmaceutical companies collaborate to establish national recommendations and coherent introductions of new high-cost pharmaceuticals. In 2018, 46 risk sharing agreements were established with a total expenditure of SEK 6.3b (approx. € 580 m), yielding a return of SEK 2.8b (€ 240 m) (44%). The return is divided 60/40 between the regions and the state.

Pharmaceuticals subject to competition. A tender auction system is applied on a monthly basis for off-patent and interchangeable pharmaceuticals to identify the product with the lowest price and its availability. The available product with the lowest price in each group is the preferred product the following month. About two thirds of all dispensed packages on the benefits scheme are subject to generic substitution and they constitute one fifth of the total expenditure.

Price reduction. Pharmaceuticals that are not subject to competition and are older than 15 years are imposed with a price reduction of 7.5%. These products are reviewed two times per year.

Pharmaceutical reviews. TLV performs reviews of pharmaceuticals, which are on the benefit scheme, in therapeutic areas where pharmaceuticals may no longer be cost-effective.

Pricing of pharmaceuticals not included on the benefit scheme



14% of pharmaceutical sales are outside the benefit scheme (over the counter (OTC) (10%) and non-reimbursed prescription pharmaceuticals (4%)). The price setting is unrestricted: 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 on both OTC pharmaceuticals and medical devices. There is no VAT on prescribed pharmaceuticals.

COVERAGE / REIMBUR.

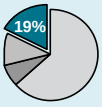
Patients and the state/regions share the costs of pharmaceuticals included on the benefit scheme. Over a 12-month period, patients pay the full amount of the pharmaceutical cost up to SEK 1 150 (€105) where a stepwise subsidy scheme begins. After reaching the high-cost ceiling of SEK 2 300 (€210) patients are fully subsidised.

Insulin, pharmaceuticals prescribed for preventing contamination of certain communicable diseases (e.g. HIV), and pharmaceuticals for persons lacking perception of their own state of illness are always fully subsidised. Pharmaceuticals on the benefits scheme are fully subsidised to children <18 years and contraceptives are subsidised to women <21 years of age.

IN-PATIENT

Pricing in the hospital sector

The 21 regions of Sweden provide healthcare and pay for pharmaceuticals in the hospital sector. The regions procure pharmaceuticals directly from the pharmaceutical companies.



19% of pharmaceutical sales are made in the hospital sector.

The regions have a Drug and Therapeutic Committee, which act as an advisory board on the use, efficiency and cost of pharmaceuticals. TLV provides HTA reports to support their decision-making process.

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

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

Source: The Swedish Association of Local Authorities and Regions, the Swedish eHealth Agency, EUROSTAT and TLV

TLV October 2019, www.tlv.se. Contact: Peter Skiöld; peter.skiold@tlv.se

TURKEY

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

Social Security Institution (SGK)
Canan DEMIR (cdemir4@sgk.gov.tr)
Hatice Demet CELIK (hdcelik@sgk.gov.tr)
Turkish Medicines and Medical Devices Agency (TİTCK)
Kagan ATIKELER (kagan.atikeler@titck.gov.tr)

Population: 82 Million (2018)

GDP per Capita: 9,311.4 $ (2018)

Health Care Sector: Social Health Insurance System

Health Expenditure in % of the GDP: 4.2% (2017)

Pharmaceutical Expenditure: 6,4 billion $ (2018)

AUTHORIZATION

Turkish Medicines and Medical Devices Agency (TİTCK) — **Tasks:** Decisions on authorization and ex-factory/retail prices.

Social Security Institution (SGK) — **Tasks:** Decisions on eligibility for reimbursement, reimbursement prices, reimbursement conditions and financing.

in coordination with → The Ministry of Treasury and Finance, Presidency of Strategy and Budget, academia, and representatives of professional associations

PRICING

OUT-PATIENT

Pricing in the out-patient sector

Reference Price (in Euro)

External RPS. The lowest price of 5 countries (France, Greece, Italy, Portugal and Spain). In addition, ex-factory prices of import/export countries are also taken into account.

× Fixed Exchange Rate

The reference price is converted into Turkish Lira (“TL”) at a fixed rate which is set in January of each year as 60% of the previous year’s annual average of the Euro.

= Ex-Factory Price (in TL)

+Wholesaler Mark-up

Statutorily regressive mark-ups for all pharmaceuticals changing from 9% to 2%.

+Pharmacy Mark-Up

Statutorily regressive mark-ups for all pharmaceuticals changing from 25% to 12%.

+VAT

Standard rate is 18%, but VAT is 8% for all pharmaceuticals.

=Retail Price

In order to calculate reimbursement prices, mandatory discount rates varying from 0% to 41% are applied depending on the state and ex-factory prices of the pharmaceuticals. The discount rate for generics is max 28%.

-Statutorily Discounts

Internal RPS: There are equivalent groups based on the active substance and reimbursement is capped at 10% above the base price in each group. SGK only pays up to 10% over the base price and the remaining is financed out-of-pocket.

=Reimbursement Price

Using managed-entry agreements, discount rates and reimbursement prices may be kept confidential.

IN-PATIENT

Pricing in the in-patient/hospital sector

Pricing policies for medicines
Pricing procedures are same as in out-patient sector. In public hospitals, pharmaceuticals are usually procured and distributed by centrally. In addition, hospitals can make individual purchases according to needs. University hospitals and private hospitals make individual purchases.

Four ways of purchasing:
Open tendering, tendering among predetermined competitors, bargaining, negotiations and direct purchase.

Wholesale remuneration
Same as out-patient sector.

Pharmacy remuneration
No pharmacy remuneration.

VAT: VAT is 8% for all pharmaceuticals.

Reforms
Exchange rate: Fixed to 60% of previous year’s average exchange rate since Feb 2019.
Reassessment of price increases: Price Evaluation Commission reassess all the price increases annually.

REIMBURSEMENT

The universal health insurance system operates on the basis of a list of pharmaceutical products for which costs are covered by the SGK. SGK collects contributions from citizens. Also the State pays a subsidy amounting to the one fourth of actually collected contributions of Universal Health Insurance.

OUT-PATIENT

Coverage / reimbursement in the out-patient sector

Reimbursement Procedures

- Reimbursement Commission
- Alternative Reimbursement Commission
- Named Patient Supply Programme
- Weekly Assessment

Positive List
Positive list dated 26 Sept 2019 includes 8450 pharmaceuticals. Addition to positive list, Named Patient Supply Programme List dated 19 Sept 2019 includes 383 pharmaceuticals.

Internal RPS of cluster of substitutable medicines
Internal Reference Pricing System is used at ATC-5 (active substance) level since 2005. The products of the same active substance in the same pharmaceutical form and dosage have to be in the same equivalent group.

Co-Payments
Percentage co-payment: 10% of the medication cost for pensioners and their dependents
20% of the medication cost for other insured persons and their dependents.
Prescription fee: 3 TL up to 3 packages prescribed and plus 1 TL for each of the additional packages.

Mechanisms for vulnerable groups
Medications for chronic diseases (e.g. cancer, hypertension, diabetes) are exempt from co-payment. Lower co-payment for pensioners and their dependents (10%).

IN-PATIENT

Coverage / reimbursement in the in-patient sector

Reimbursement
In-patient medicines are financed by hospitals under the annual global budget agreements between MoH/universities and SGK. Private hospitals provide in-patient medicines individually and SSI finances them over the cost of prescription..

Hospital formularies
The positive list of SGK includes in-patient medicines. Hospitals form their own formularies in accordance with positive list.

Co-payment in hospitals
In-patient medications are exempt from co-payment.

Mechanisms for vulnerable groups
No specific mechanisms.

Reforms
Alternative Reimbursement Process: Controlled inclusion of innovative, personalized and expensive pharmaceuticals in the reimbursement list by managed-entry agreements since 2016.
MEDULA (Medical Communicator) System: The transactions between SGK and health care providers run via MEDULA system since 2007. This system makes easier the provision process and plays very important role for controlling health care expenses.
E-Prescription Application: Prescriptions have been preparing online since 2012 to prevent misuse and abuse in the medication system.

MINISTRY OF HEALTH OF UKRAINE

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

UKRAINE

Ministry of Health of Ukraine

moz.gov.ua

Pharmaceutical pricing and reimbursement policies in Ukraine

In Ukraine, a new edition of the National Essential Medicines List (NEML) (427 INNs) has been approved, based on the WHO 20-th EML (2017)
Medicines included in the NEML are to be procured and reimbursed at the expense of the state budget

Out-patient sector

Pricing in the out-patient sector for medicines, the cost of which is reimbursed from budget funds

Medicines pricing policy:
From 2017 Ukraine introduced state regulation of the prices on medicines for the treatment of cardiovascular diseases, type II diabetes and asthma, the cost of which are reimbursed from the budget funds. The list of reimbursed medicines includes 23 INNs, that are included in the NEML

Pricing procedure:
Price regulation is carried out by comparing prices in 5 reference countries (Poland, Latvia, Slovakia, Hungary, Czech Republic). Based on data from 5 reference countries the wholesale marginal prices for 23 INNs are established and recalculated into the recommended by WHO daily dose (DDD).

Regulation of mark-ups:
Affordable medicines Program:
On the list of 23 INNs for the treatment of cardiovascular diseases, type II diabetes and asthma, which are included in the NEML, mark-ups are set:
Wholesale is 10 %
Retail is 15 %
Program to reimburse the cost of insulin:
Wholesale is 10 %
Retail is 10 %

Additionally:
- The next mark-ups on medicinal products purchased at the expense of the state budget and local budgets are set:
Wholesale is not higher than 10 %
Retail is not higher than 10 %

-For medicines that are included in the NEML, *margins* are set:
Wholesale is not higher than 10 %
Regressive retail margins in % ratio (from 10 to 25%) depending on the cost of the medicine

Reimbursement in the out-patient sector

Government Program "Affordable Medicines"
The program operates with a list of 23 INN medicines for the treatment of cardiovascular diseases, type II diabetes mellitus and bronchial asthma, that are included in the NEML and the cost of which is reimbursed at the expense of the state budget.

For today, the Register of medicines, the cost of which is fully or partially reimbursed, contains 254 brands of medicines (78 brands are dispensed for free, without co-payment):
195 (61 – for free) – cardiovascular diseases
45 (11 – for free) - type II diabetes mellitus
14 (6 – for free) – bronchial asthma
Medications are prescribed via an electronic prescription.
Program is administered by the National Health Service of Ukraine

Government program to reimburse the cost of insulin for patients with type I diabetes
- Patients who receive insulin are included in the Register of patients who need insulin therapy
- Patients receive insulin for free or with a co-payment
- The register of prices for insulin preparations, approved by order of the Ministry of Health of Ukraine, contains 77 brand insulin preparations that are dispensed to patients with a co-payment (in the form of cartridge / syringe pens) *
* and without co-payment in the form of vials
- Reimbursement of the cost of insulin is carried out at a level not higher than the approved price (reimbursement price) in the Register
- The reference price (reimbursement price) for foreign-produced insulin preparations is calculated based on prices in reference countries (Bulgaria, Moldova, Poland, Slovakia, Czech Republic, Latvia, Serbia and Hungary)

The plans for 2020:
- Prescribe insulin products via an electronic prescription
- Transfer the administration of the insulin reimbursement program to the National Health Service of Ukraine

In-patient sector

Reimbursement and pricing of medicines in the in-patient sector

Reference pricing:
From October 2019, the state regulation of prices for 23 INNs of medicines, which are purchased for budget funds and included in the National List of Essential Medicines (NEML) has been introduced. Price regulation mechanism is similar to the Affordable Medicines program mechanism where comparing prices in 5 reference countries (Poland, Latvia, Slovakia, Hungary, Czech Republic) is performed. As a result of this comparison, a marginal wholesale price for purchases is set.
Criteria by which the medicines from NEML fall under reference pricing:
- annual procurement of such medicines (by INN) is more than 5 million. UAH (USD 202,000)
- prices in Ukraine for this category of medicines are higher in comparison with reference countries (Poland, Latvia, Slovakia, Hungary, Czech Republic)

Procurement and provision of medicines to patients:
- Centralized procurement of medicines at the expense of the state budget are carried out by international organizations that procure the medicinal products under the order of the Ministry of Health of Ukraine to cover the main therapeutic areas (oncology, tuberculosis, hepatitis, autism, etc. – 40 programs/diseases in total) on the basis of tender proposals from pharmaceuticals manufacturers
- Procurement of medicines that are included in the NEML by the second health care facilities and ensuring the need of patients that undergo treatment in these facilities
- Procurement of medicines under regional programs, that operate in the regions
- From April 2020, the introduction of the packages of guaranteed medical services, the cost of which is covered from the state budget via National Health Service of Ukraine (NHSU) administration, on basis of health care facilities contracting.