



European Federation of Pharmaceutical
Industries and Associations

A New Era for Health Care in Cyprus:

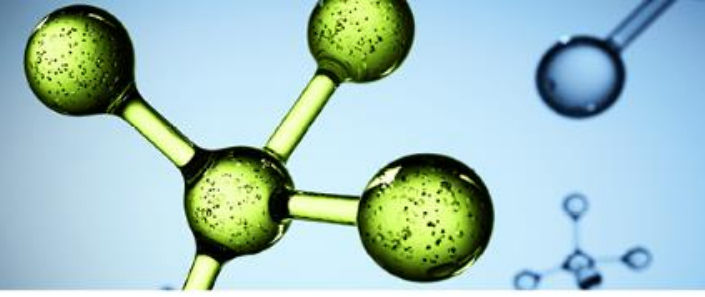
Embrace | Evaluate | Evolve

**Invigoration of Slovenian health care system
through innovation**

Dorjan Marušič, Slovenia

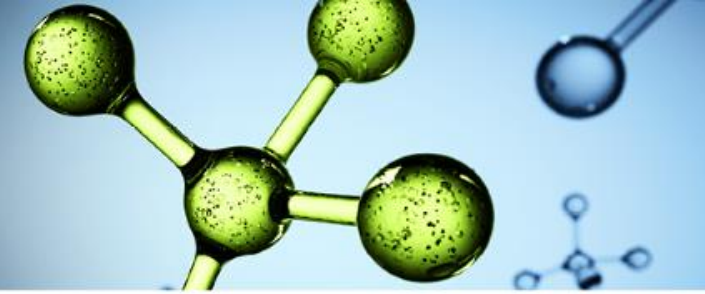
11th November 2022





Let us start from the end

- Use of health data promotes data-driven decision making for more sustainable HC system.
- Innovations bring value for money, savings to health systems, economic growth and are key driver of improved health and longer lives.
- Patients centered systems promote value-based health care.
- National and international strategies should capitalize efforts to improve quality of patient care.



Slovenia – reimbursement process for innovation

 Medicines - NHI



HTA-like assessment



NHI negotiation



Reimbursement

 Procedures - MoH



Medical association
/(PAG) submission



Healthcare council
assessment/approval



One payer - NHI

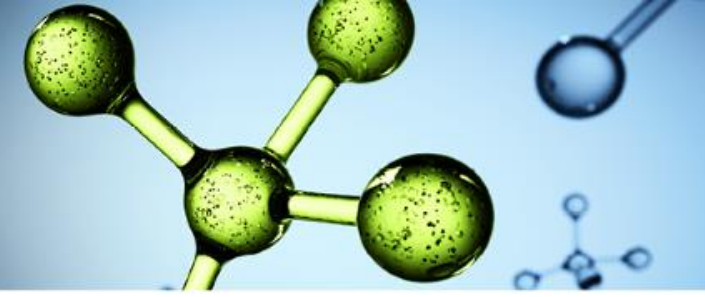




Slovenia – key facts

- **Population:** 2.106.215¹, population over 65: 21,1%¹
- **Area:** 20,273 km²
- **2021: GDP** 52.2 b €³, **GDP growth:** 8,2%³, **GDP per capita:** 24.770 €³
 - **88%** of the EU-28 average², **37th** in world ranking²
- **HC Expenditures (2020):** 4.424 m €¹ (+3,6% vs 2019), 9,5 % GDP, **per capita:** 3.498 USD⁴
 - NHII exp. 2021: 3.518 mEUR; 531 mEUR⁵ (15,1% for medicinal products) and 55 mEUR⁵ (1,7% for pharmacies);
 - 3120 of product available; 846 active substances; 8,4 prescriptions per capita
- **Positive:** lowest infant mortality, cardiovascular diseases
- **Concerned about:** ageing population, insufficient staffing





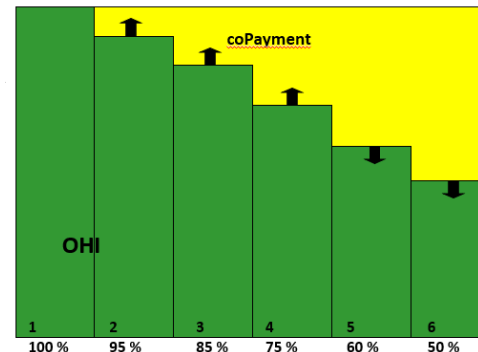
Slovenia – Healthcare in Brief

- **Healthcare model and insurance:** whole population have equal access to the reimbursed procedures and medicines, covered by compulsory (universality, solidarity, equity) and top-on co-insurance as an option (co-payment, voluntary insurance)
- **NHII** - single provider of CHI of three large fields of benefits: health services, sick leave (> 30 days) and medicines
- **There is no HTA agency**

Compulsory insurance (99,8%)

Voluntary insurance (95%)

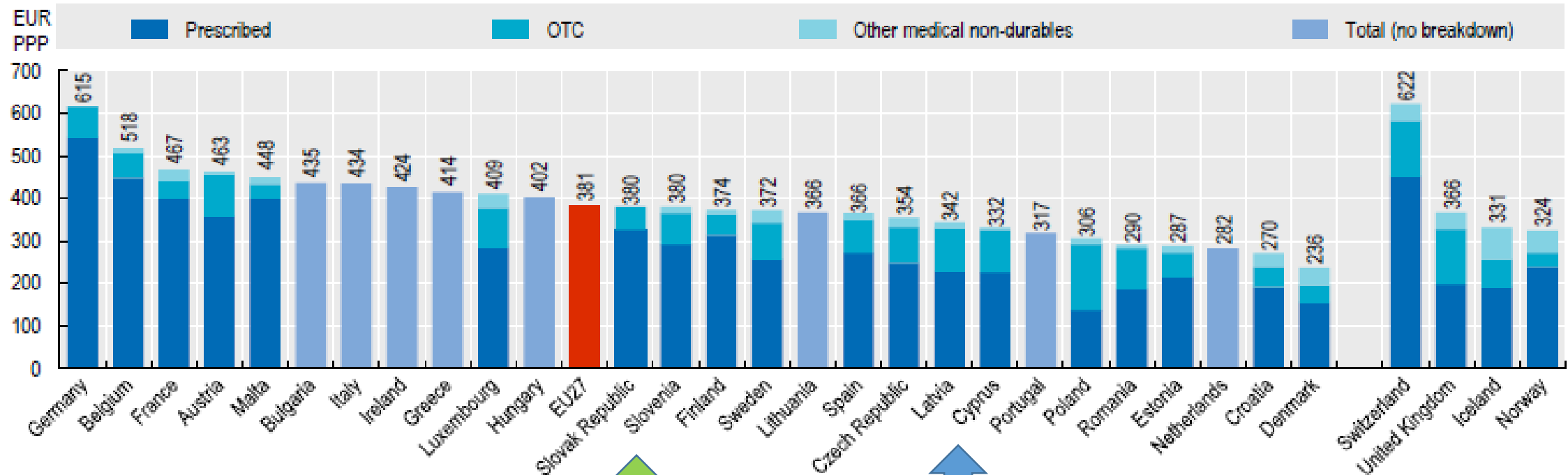
Supplementary insurance (4%)



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Expenditure on retail pharmaceuticals per capita, 2018



Note: The EU average is unweighted.

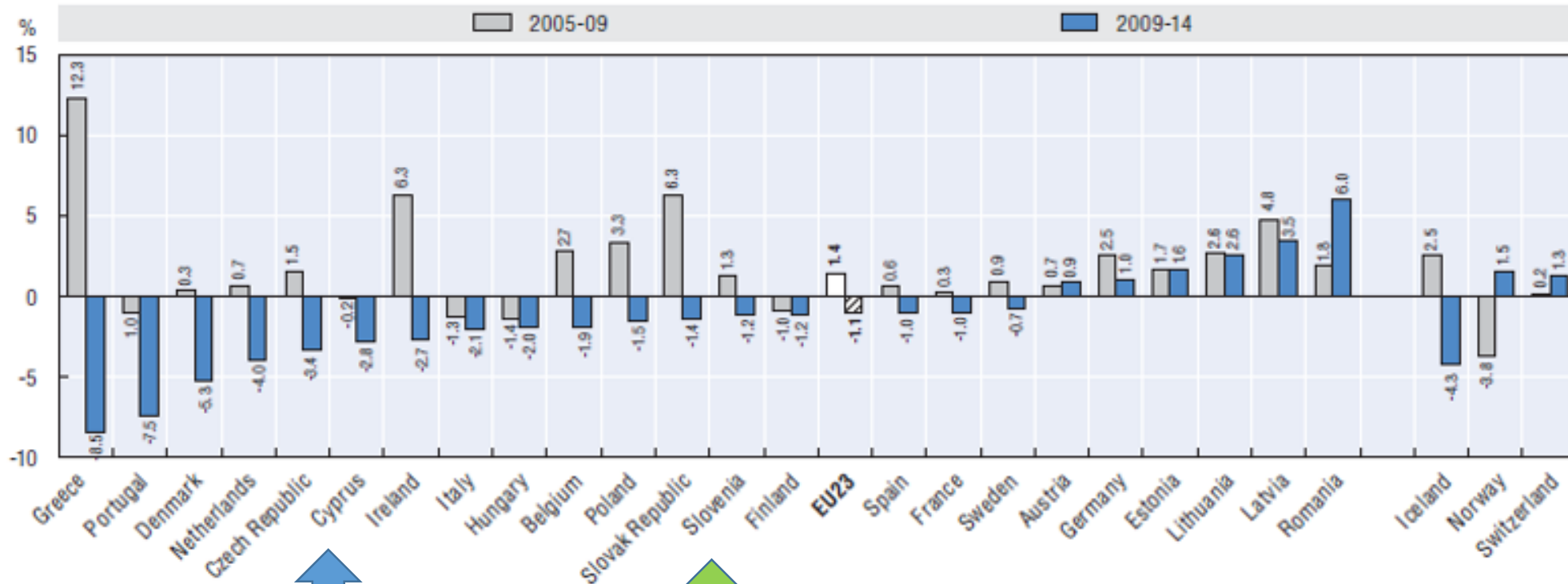
Source: OECD Health Statistics 2020; Eurostat Database.

51% CHI
26% VHI
23% OOP

StatLink <https://stat.link/84ynae>

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Average annual growth rates in pharmaceutical expenditures in EUR PPP



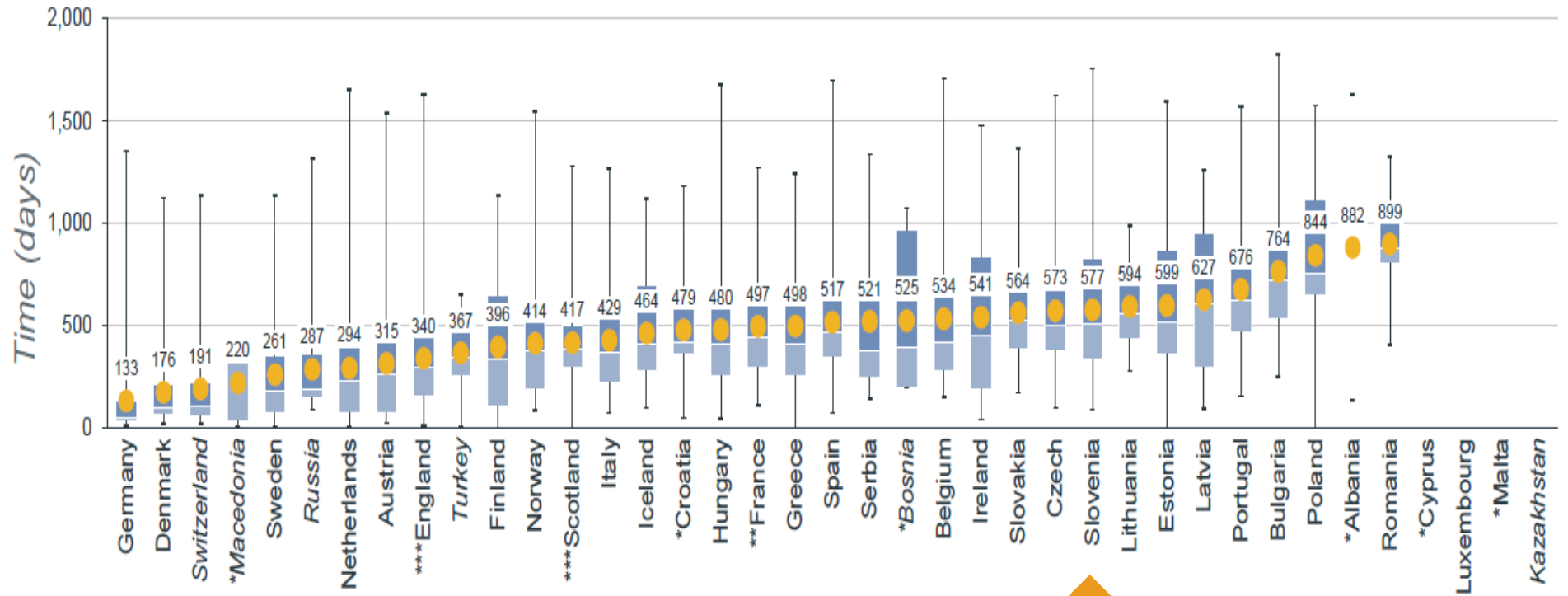
1. Includes medical non-durable
Source: OECD Health Statistics 2016

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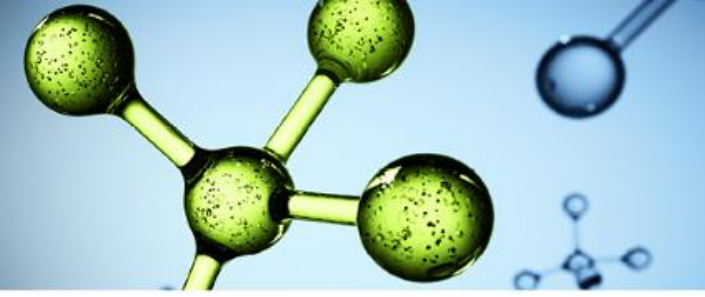


An average reimbursement time from EMA to the reimbursement in Slovenia is **577 days**¹;

Time to Availability in Slovenia



¹EFPIA patient WAIT indicator 2022



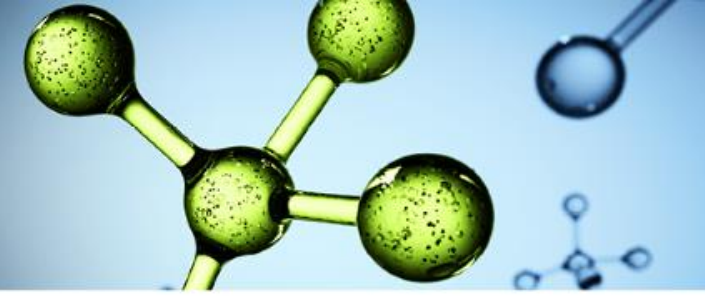
Pricing and reimbursement process of prescription medicines, funded by public means, are strictly regulated

JAZMP (Public agency for medicines and medicinal devices) domain

- Medicinal Products Act (Zakon o zdravilih)
- Rules on determining the Prices of Medicinal Products for human use (Pravilnik o določanju cen zdravil za uporabo v humani medicini)

NHII domain

- Public funding of medicines is defined in the Healthcare and Health Insurance Act (Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju)
- Rules of Reimbursement (Pravilnik o razvrščanju zdravil na listo)



Pharmaceutical policy

- **Pricing:**

- Max. prices for originators and generics (ref.: France, Germany, Austria) – JAZM
- Negotiations and agreements (all types incl. pay-back, managed-entry agreement) – NHII
- Discounts on companies' portfolio

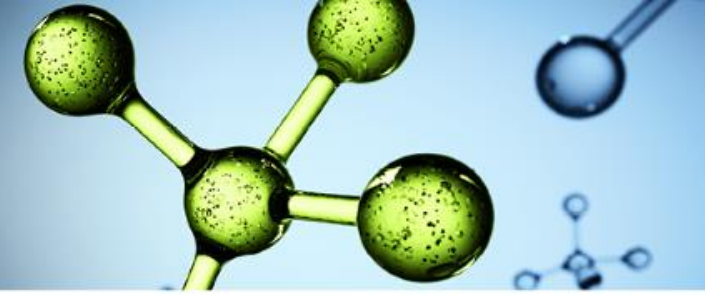
- **Reimbursement:**

- Prescribing restrictions
- 2003: reference pricing system for exchangeable drugs (ATC 5)
- 2013: reference pricing system for therapeutic drug groups (clusters, ATC 4 or 3)

- **Financing of injectable drugs to providers:**

- Expensive hospital drugs
- Injectable pharmaceuticals for outpatients (preferred way of treatment)

- **Prescribing on Rx for home treatment (immunoglobulins, Fabry's disease, etc.)**



Reimbursement in Slovenia

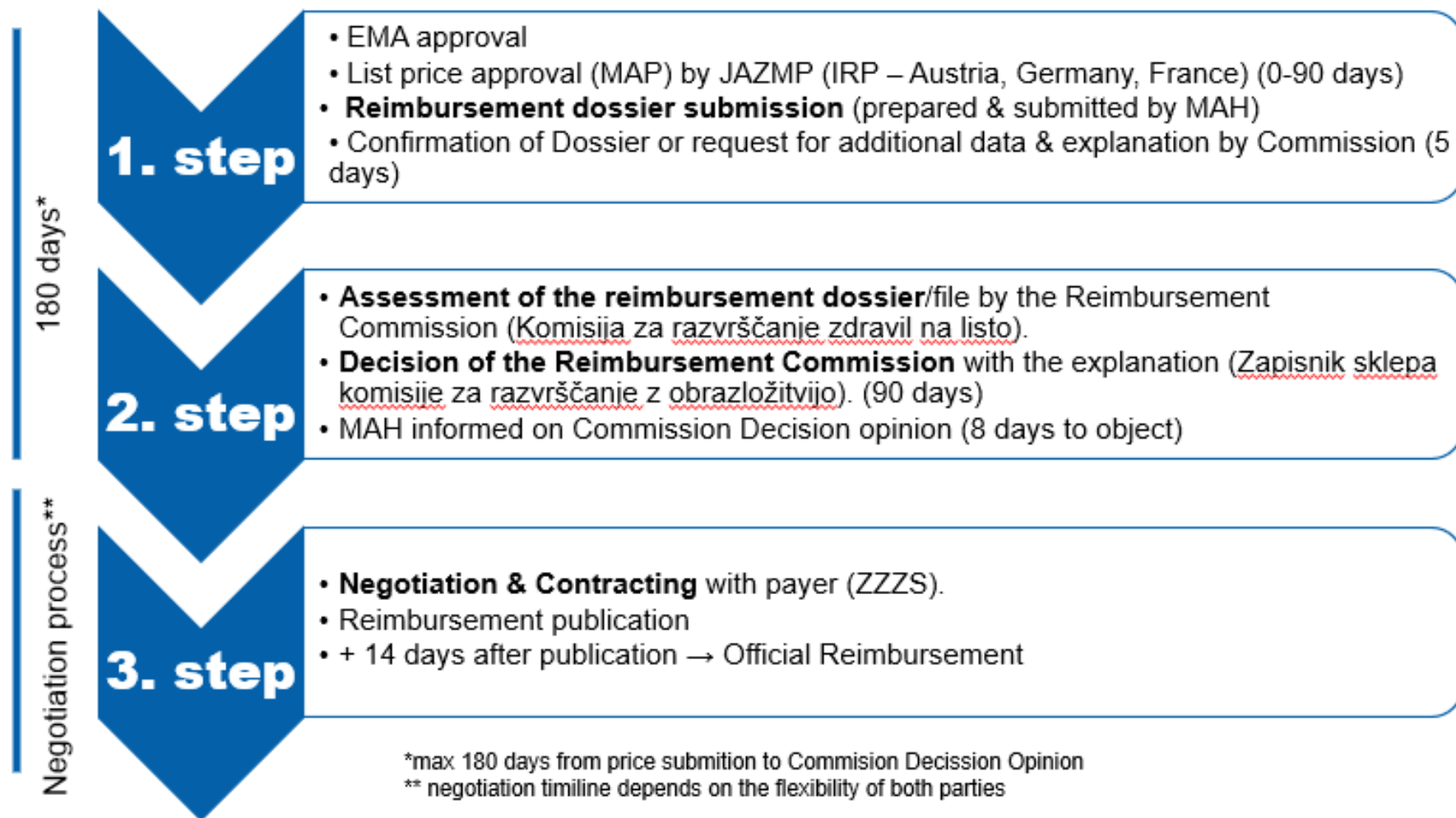
- **Long and tough** reimbursement process **but prone to the innovation**
- **Few mechanisms and cost containment measures** introduced from the NHII which **allows entrance for the innovative medicines**:
 - **General agreement**: -9% portfolio discount
 - **Managed Entry Agreements (MEA) and individual agreements** with pharma companies
 - **Highest Recognised Value (NPV)**: reference pricing system for exchangeable drugs (ATC 5)
 - **„Jumbo groups“**: reference pricing system for therapeutic drug groups (clusters, ATC 4 or 3)
- **Some therapeutic areas defined by law as priority** (oncology, muscle and nervous system diseases, epilepsy, haemophilia, mental illness, developed forms of diabetes, multiple sclerosis and psoriasis)²

¹EFPIA patient WAIT indicator 2022

²ZZVZZ, article 23



Reimbursement - step by step

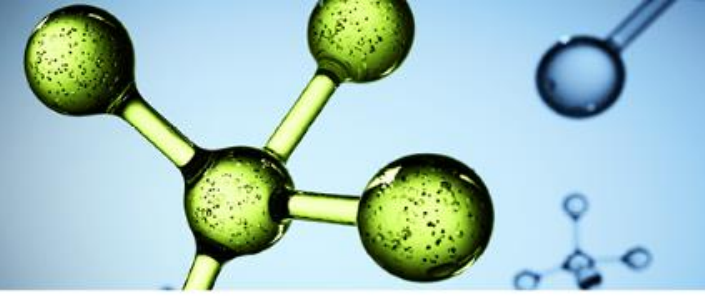




Reimbursement lists

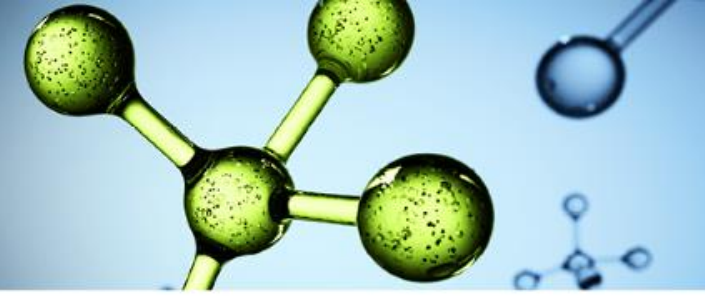
- Prescription drug list – P/V list (for pharmaceuticals and food for special medical purposes)
- Hospital drug list - B list (expensive hospital drugs)
- Ambulatory drug list – A list (injectable pharmaceuticals for outpatients: primary and secondary care)
- *Prescribing restrictions

P100	Positive list; fully covered by the compulsory health insurance
P100*	Positive list with prescription limitation; fully covered by the compulsory health insurance
P70	Positive list; covered by the compulsory health insurance in 70%, fully covered by the compulsory health insurance only in accordance with regulation.
P70*	Positive list with prescription limitation; covered by the compulsory health insurance in 70%, fully covered by the compulsory health insurance only in accordance with regulation.
PC100	Positive list of drugs with the highest recognized value; fully covered by the compulsory health insurance up to highest recognised value
PC100*	Positive list of drugs with highest recognized value with prescription limitation; covered by the compulsory health insurance up to highest recognized value
PC70	Positive list of drugs with highest recognized value; covered by the compulsory health insurance 70% to the highest recognized value, covered fully only in accordance with regulations
PC70*	Positive list of drugs with highest recognized value with prescription limitation; covered by the compulsory health insurance 70% to the highest recognized value, covered fully only in accordance with regulations
V	Intermediate list
V*	Intermediate list with prescription limitation
VC	Intermediate list for drugs with highest recognized value
VC*	Intermediate list with prescription limitation of drugs with highest recognized value
B	Drugs for hospital treatment, classified on the list of hospital drugs
B*	Drugs for hospital treatment, classified on list of hospital drugs with prescription limitation
N	Nonlisted



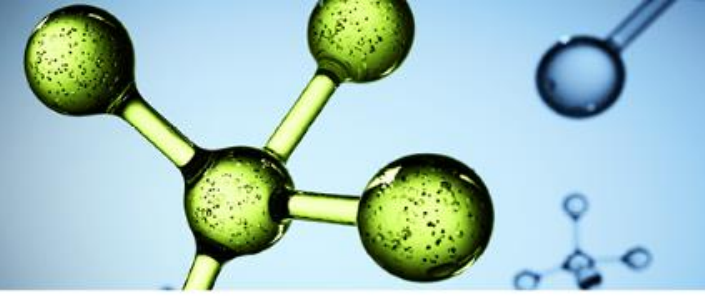
Lessons learned for potential improvement

- **time of the assessment - time to approval:**
 - faster approval in all steps (mostly administrative bottle necks within the system, delay due to collecting additional data during the reimbursement process)
- **flexibility in MEAs for feasible implementation**
 - with data availability on the NHII level, partnering with 3th party or unsolicited and independent partnering with Marketing Authorization Holder (registry, PSPs...)
- **indirect costs should be considered**
- **implementation of VBHC**
 - presence of the patient representative in Commission body



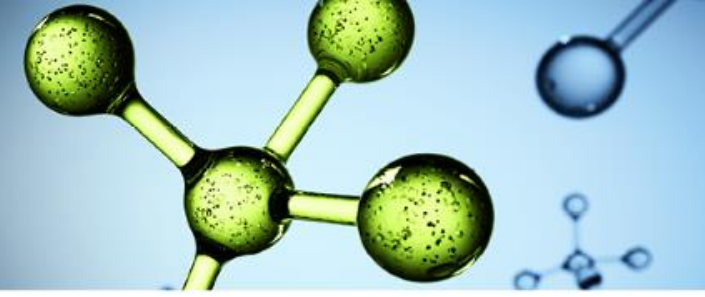
There are some other achievements, but still some problems to be tackled

- **Polarization in the market of prescription medicines**
 - 82% of medicines cheaper than 10 EUR , 97.4% cheaper than 50 EUR
 - extremely low prices for medicines with further pressure on prices could lead to disruptions in supply, and in extreme cases, even the withdrawal of the manufacturer from the Slovenian market
 - orphan drugs and extremely expensive drugs (no systematic solution for financing)
- **Slovenia is a small market**
 - potential profit is significantly lower, and the cost of entering the market for drug manufacturers is not necessarily significantly lower
- **Seamless care covered by NHII**
 - from 2023 on, hospital pharmacists will provide seamless care at the admission and discharge of the hospital patients in all hospitals
 - pharmacists will be also able to dispense medications next to the patient's bed
 - this will assure less disruption in pharmaceutical care for the hospitalized patients



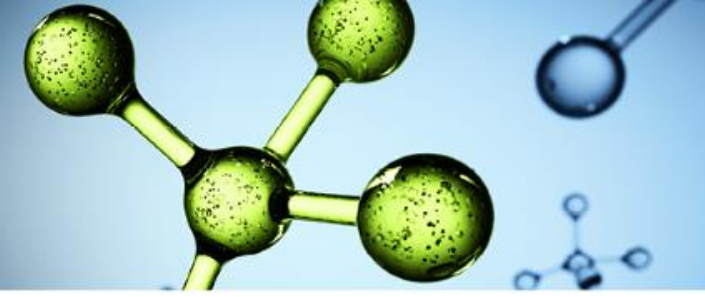
To go ...

- NHII's investments in medicines are a credit for living longer and better in Slovenia today than ever before.
- In Slovenia the consumption of prescription medicines in DDD is increasing; the growth is much slower compare to the EU average.
- The prices of medicines in Slovenia are subjected to strict regulation and negotiations between NHII and the pharmaceutical industry.
- IRP is a useful cost containment tool and contributes to rationalization of medicine costs.
- Transparency puts rapid access to the latest, effective and lifesaving medicines with potential risk of raise of prices in low-income countries.
- Overpassing administrative bottle necks, use of all available data and presence of the patient representative will improve the reimbursement process.



To go ...

- **VBHC:** medicines are and should be considered as part of integrated care with extreme influence on the result of performed care.
- **Valletta Declaration:** lobbying big pharmaceutical companies for better prices, fighting for full transparency on the prices of new medicines to be available and affordable for all citizens.
- **Pharmaceutical Strategy for Europe:** EU needs a stable but adaptable, fast, effective, and globally competitive pharmaceutical strategy in the environment that will drive research and investments into the next generation of diagnostics, treatments and vaccines for patients where their outcomes can be improved or where no treatment options exist, and an open trade environment to secure global supply chains and export medicines globally.



Let me conclude with a proposal:

**Implementation of VBHC for „green“ health care system
should become our daily obligation!**

... thank you for the invitation, your attention and potential
questions

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