

Medicines Reimbursement Policies in Europe

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Introduction – Presenter

WHO Collaborating
Centre since 2010



Network of public authorities for
pharmac. pricing & reimbursement:
≈ 90 institutions, 46 (mainly
European) countries, WHO, OECD,
EC, World Bank

WHO
CC



GÖG (Gesundheit Österreich GmbH)
Austrian Public Health Institute

Pharmaco-
economics
Department

PPRI

PPI

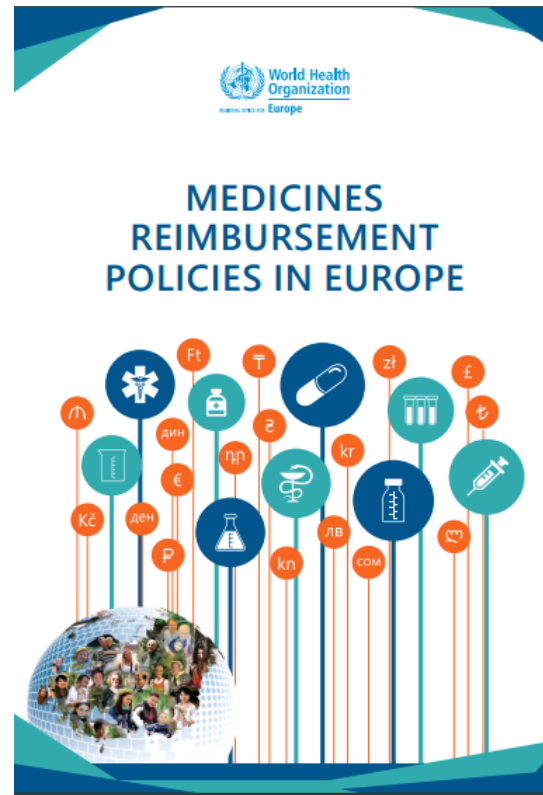
Medicine price data of
30 European countries

Introduction – Today's talk

» Objectives

- » To provide a comparative review and analysis of different medicine reimbursement (R) policies applied by the countries in the WHO European region
- » To identify practices that best protect vulnerable groups from excessive OOP payments on medicines

Mixed methods



» Contents

- » Descriptive overview of R systems/policies in 45 countries
- » Assessment of identified R models in 9 case study countries **interviews**
- » Findings from literature review
- » Analysis of the financial burden of co-payments for funded medicines groups in 9 countries



Study of the WHO Regional Office for Europe

http://www.euro.who.int/__data/assets/pdf_file/0011/376625/pharmaceutical-reimbursement-eng.pdf?ua=1

Disclaimer and acknowledgements

The information and data provided in this presentation was collected and analyzed by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies located at the Pharmacoeconomics Department of Gesundheit Österreich GmbH (GÖG).

The data do not have any legally binding value. This is not a presentation of WHO. The presenter is responsible for the views expressed in this presentation, and they do not necessarily represent the decisions and policies of the World Health Organization.

Credits go to:

- PPRI team members & WHO Collaborating Centre staff at GÖG
- The members of the PPRI network (= competent authorities for pharmaceutical pricing and reimbursement)

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Outline

Rationale: Need for R policies

Elements of R systems in European countries

Co-payments

Impact of R policies and conclusions

Rationale: SDGs

3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

Sustainable Development Goals



1. Rational selection

Reimbursement lists elaborated using transparent and accountable procedures, up-to-date treatment guidelines elaborated using the best evidence, etc.

2. Affordable prices

Price negotiation, sound generic policies, etc.

4. Reliable health and supply systems

Development of pharmaceutical national policies, quality assurance reinforcement, etc.

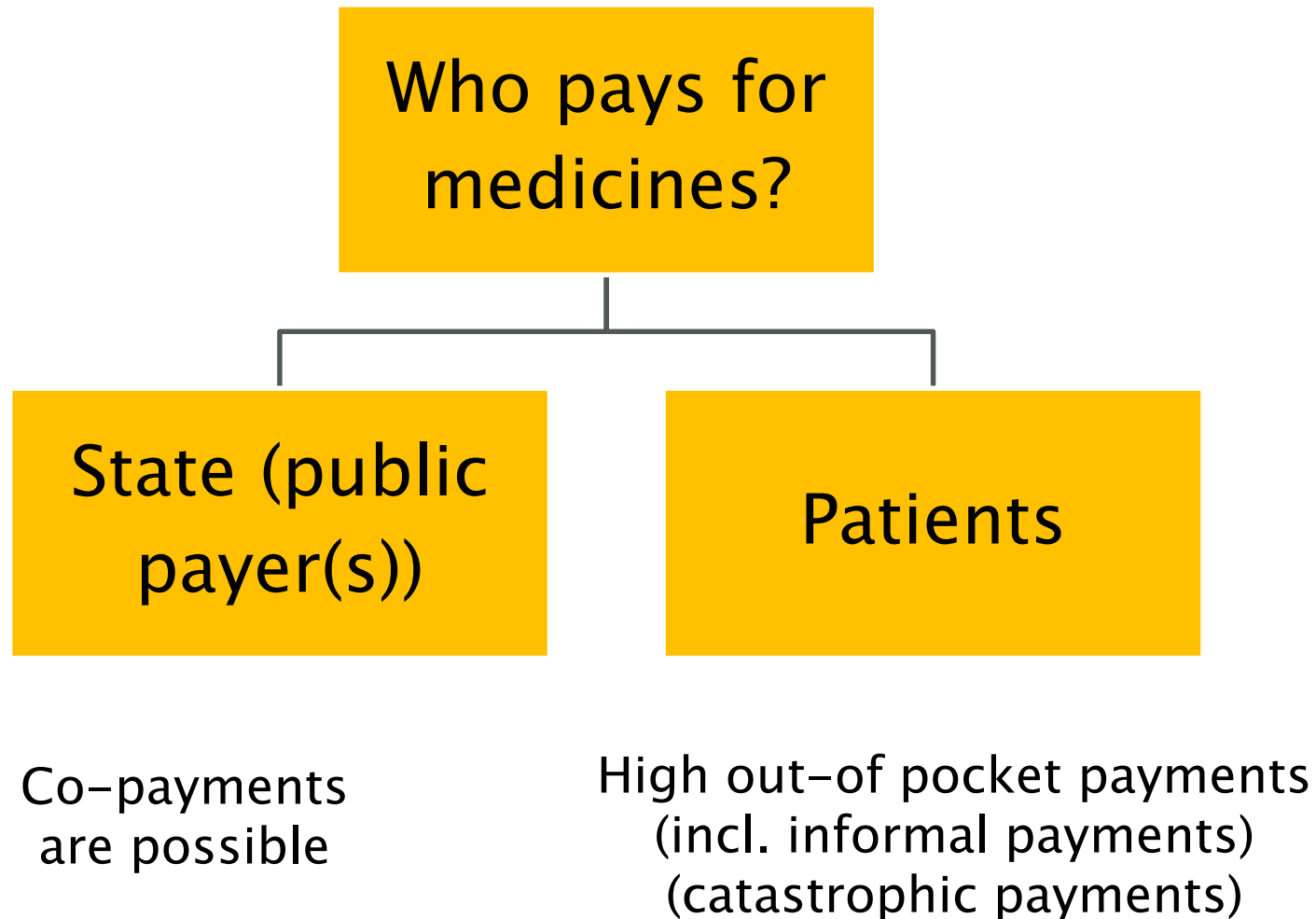
3. Sustainable financing

Increase and prioritization of public funding for medicines, identification of efficiency gains, etc.

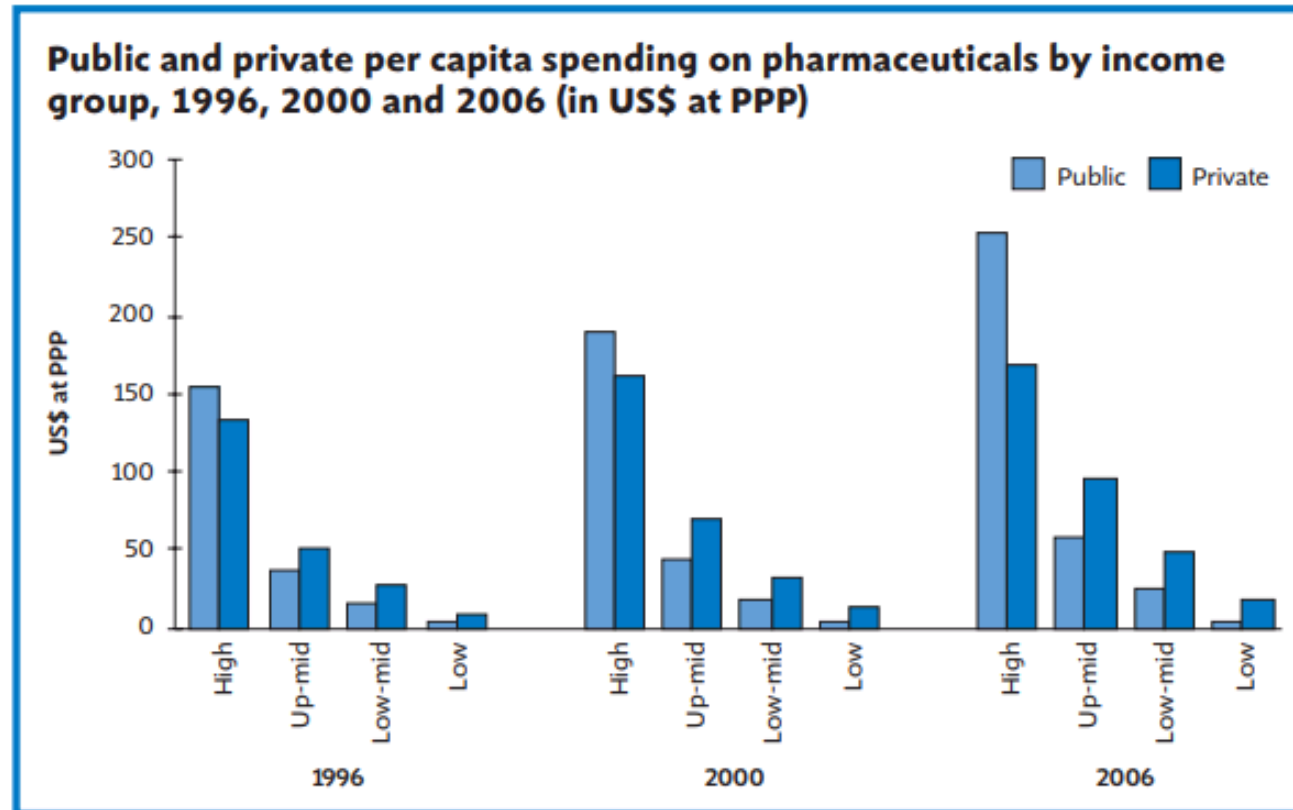


WHO: Equitable access to essential medicines: a framework for collective action. 2004

Rationale: Burden for payers and patients



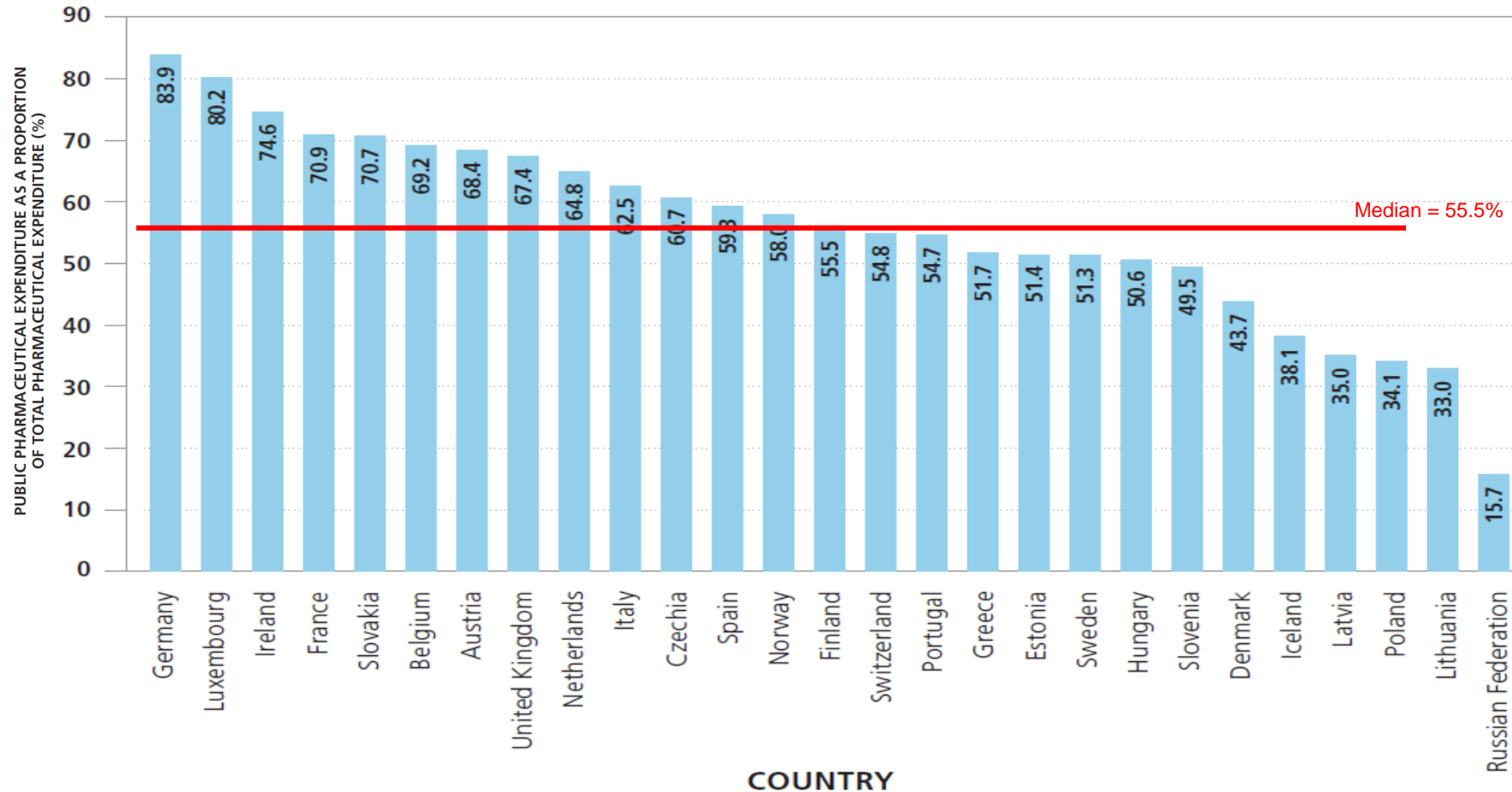
Rationale: Funding globally



Source: WHO NHA database

WHO. The World Medicines Situation 2011, chapter on Medicines Expenditure.
<http://apps.who.int/medicinedocs/documents/s18767en/s18767en.pdf>

Rationale: Public pharmaceutical expenditure as a proportion of total pharmaceutical expenditure in countries in the WHO European Region, 2015



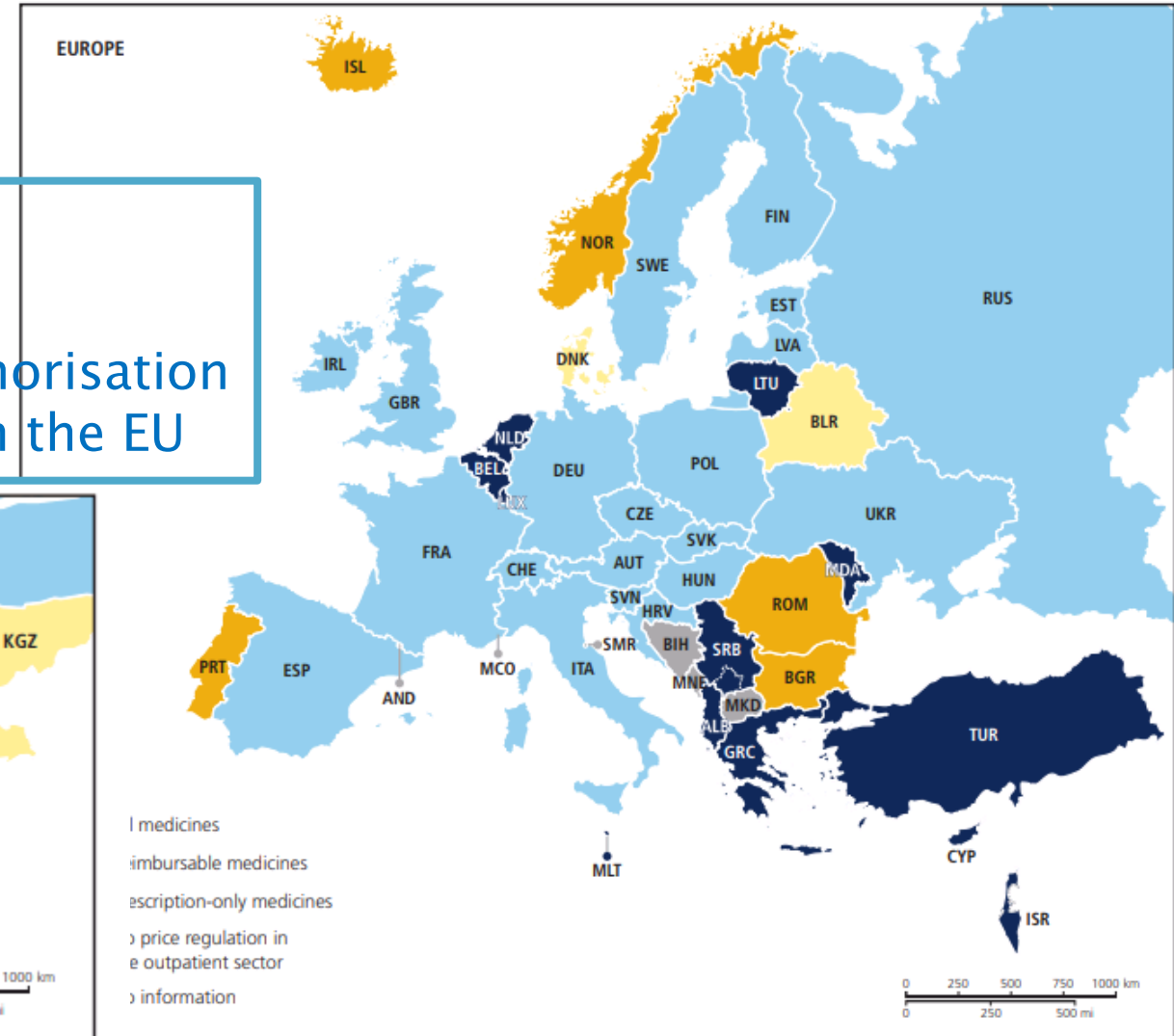
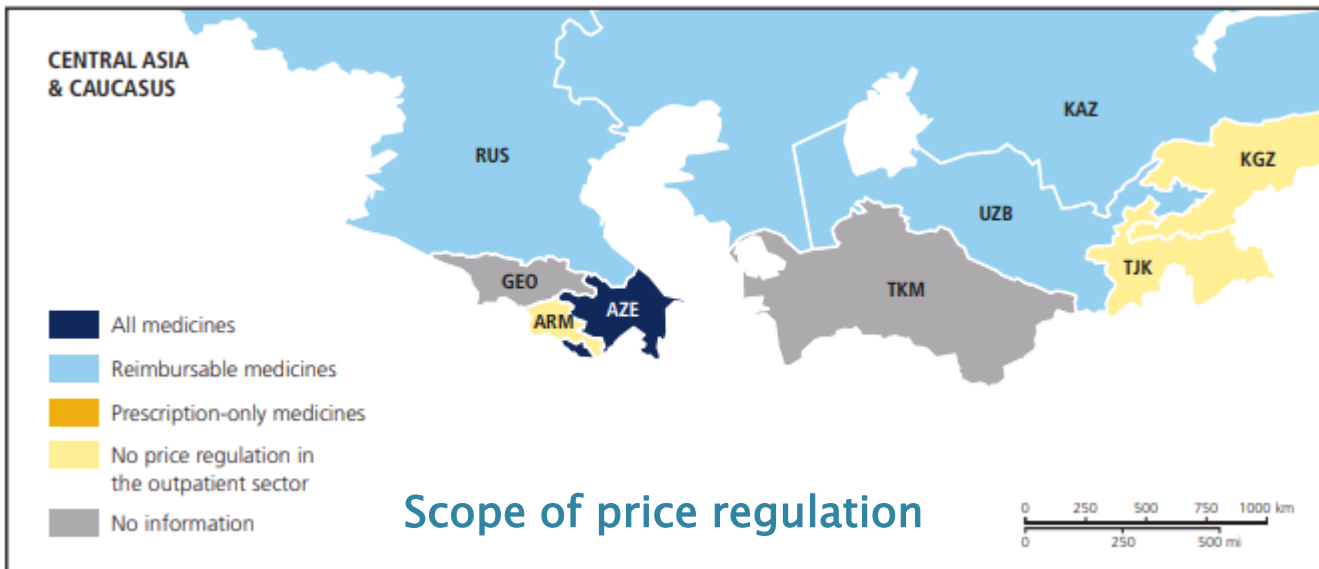
R in Europe: Intro – WHO European region

53 countries

- » incl. all 28 EU Member States
- » incl. Central Asian countries (NIS)

Pricing and reimbursement

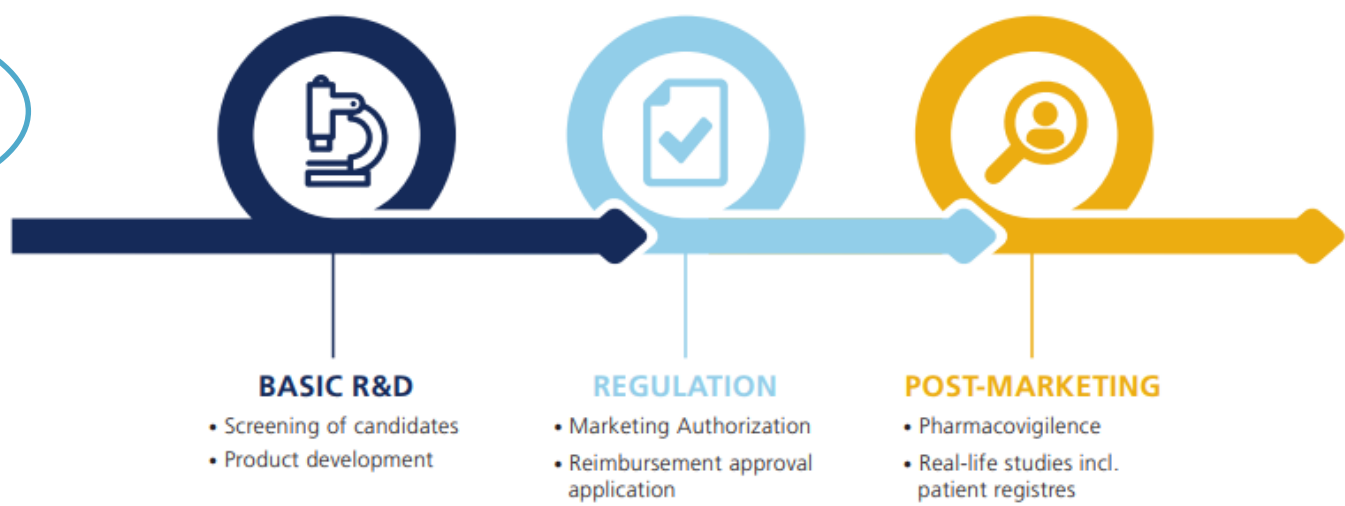
- » is a national competence
- » centralised marketing authorisation for some new medicines in the EU



R in Europe: Reimbursement framework

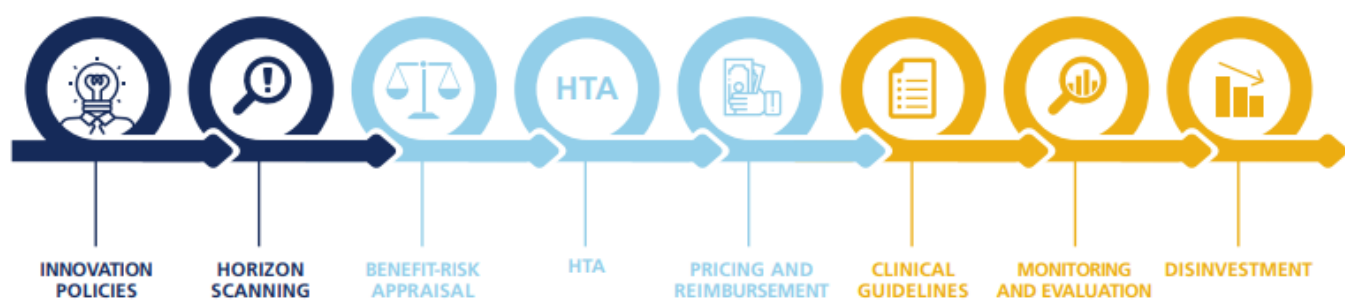
Criteria
for selection

Actors



Processes

Policies



R in Europe: Reimbursement framework

Key criteria for reimbursement	Countries
Therapeutic benefit of a medicine and/ or relative therapeutic benefit (added value compared to existing alternatives)	Armenia, Austria, Belgium, Bulgaria, Czechia, Croatia, Denmark, Estonia, Finland, Kazakhstan, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Republic of Moldova, Serbia, Slovenia, Spain, Ukraine
Medical necessity/priority	Armenia, Estonia, Finland, Kazakhstan, Netherlands, Norway, Poland, Republic of Moldova, Turkey, Ukraine
Safety	Armenia, Bulgaria, Denmark, Estonia, Iceland, Malta, Netherlands, Poland, Republic of Moldova, Russian Federation
Cost-effectiveness	Belarus, Czechia, Estonia, Finland, Kazakhstan, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Turkey, United Kingdom
Budget impact	Belgium, Bulgaria, Czechia, Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Poland, Republic of Moldova, Slovenia, Turkey

R in Europe: Health Technology Assessment (HTA)

- » Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology, in a **systematic, transparent, unbiased, robust** manner.
- » Its aim is to inform the formulation of **safe, effective** health policies that are patient focused and seek to achieve **best value**.
- » Despite its policy goals, HTA must always be firmly rooted in research and the **scientific method**.

Assessment

Appraisal

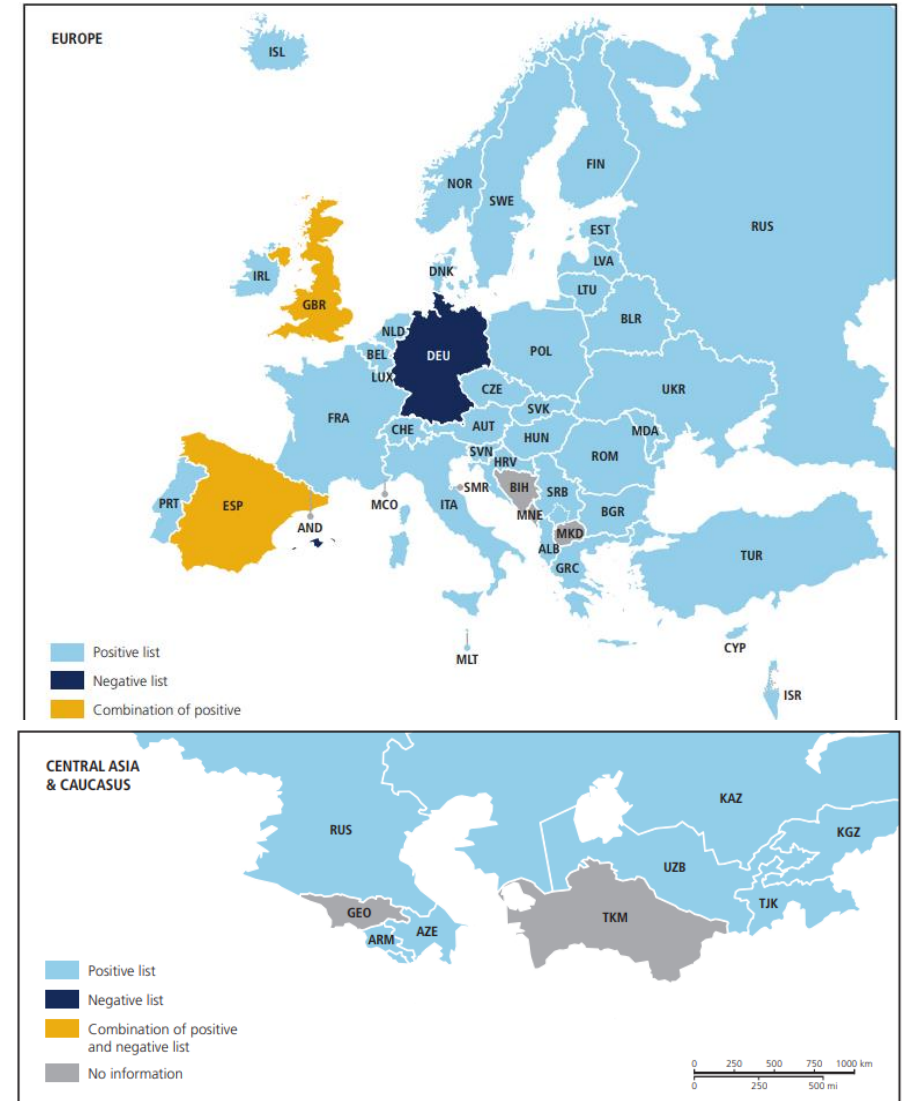
EC legislative proposal on HTA

The screenshot shows a webpage from the European Commission. The breadcrumb trail is: European Commission > Live, work, travel in the EU > Public Health > Health technology assessment >. The page title is 'Health technology assessment'. There are navigation tabs for 'All topics', 'Overview', 'HTA Network', 'EUNetHTA Joint Actions', and 'EU cooperation'. The main content area features a section titled 'Strengthening EU cooperation beyond 2020' with a sub-section for a 'Legislative proposal' dated 31 January 2018. It includes links for 'Legislative proposal', 'Press release', 'Q&A', and 'Factsheet'. There is also an 'Impact assessment' section. On the right side, there are promotional banners for 'State of Health in the EU' and 'AMR Antimicrobial Resistance', an 'e-newsletter' sign-up, and a 'Latest updates' section with social media links.

https://ec.europa.eu/health/technology_assessment/eu_cooperation_en

R in Europe: R lists

- » R lists in all countries
 - Positive lists more commonly used (44/45)
 - Negative list (DEU)
 - Combination (ESP, GBR)
- » **Scope:** larger than WHO model EML
- » Medicines included (**reimbursable medicines**) are not always 100% reimbursed

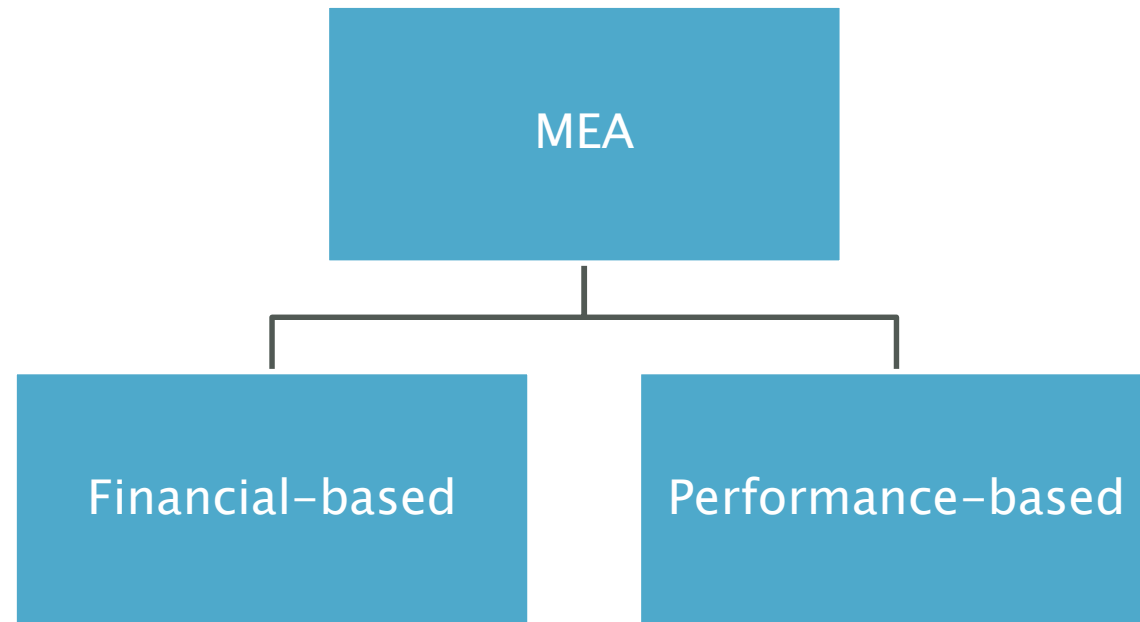


R in Europe: Managed entry agreements (MEA) for high-priced medicines

Contractual arrangement between a manufacturer and health care payer/provider that enables access to (or reimbursement of) a health technology subject to specified conditions

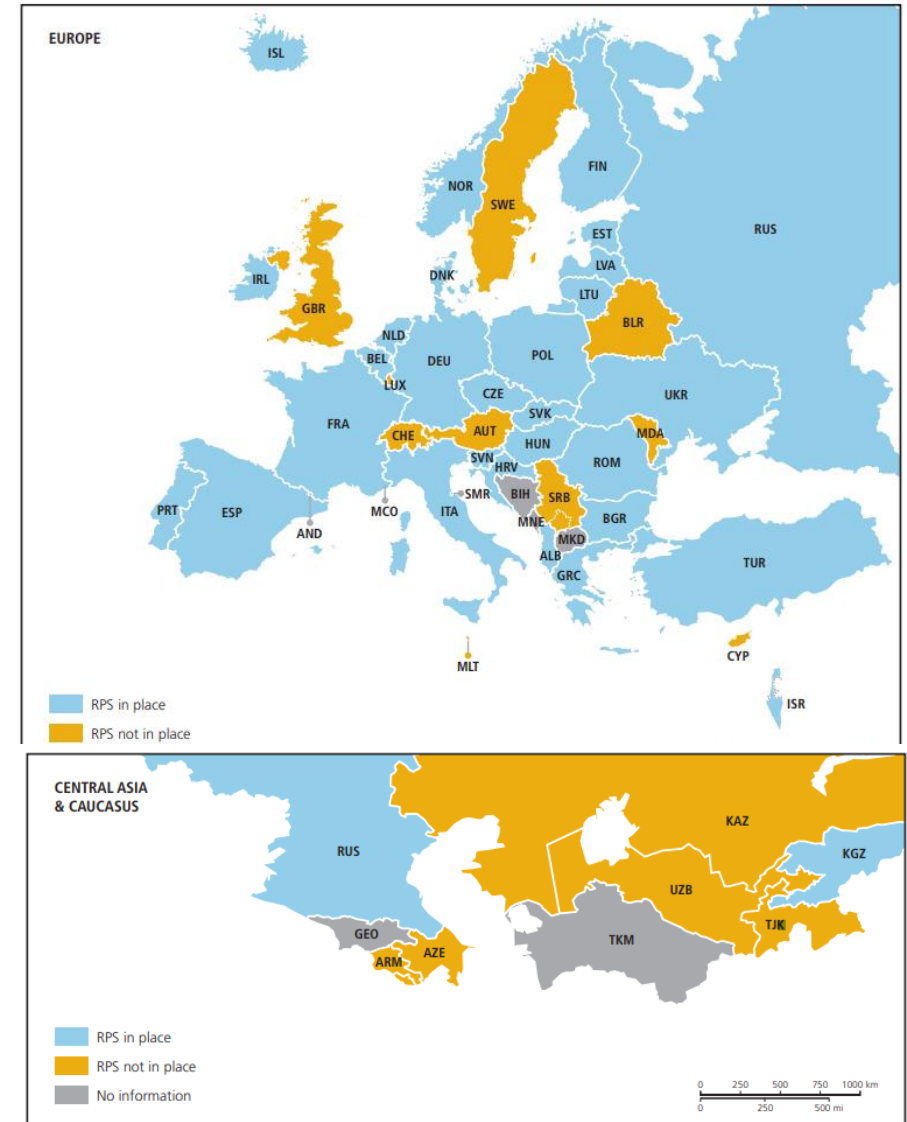
Usually confidential
(at least price)

MEAs in place in the outpatient sector	MEAs in the inpatient sector
Austria, Belgium, Bulgaria, Croatia, Czechia, Estonia, Finland, Hungary, Israel, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	Austria, Belgium, Bulgaria, Croatia, Finland, Lithuania, Malta, Netherlands, Poland, Portugal, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom



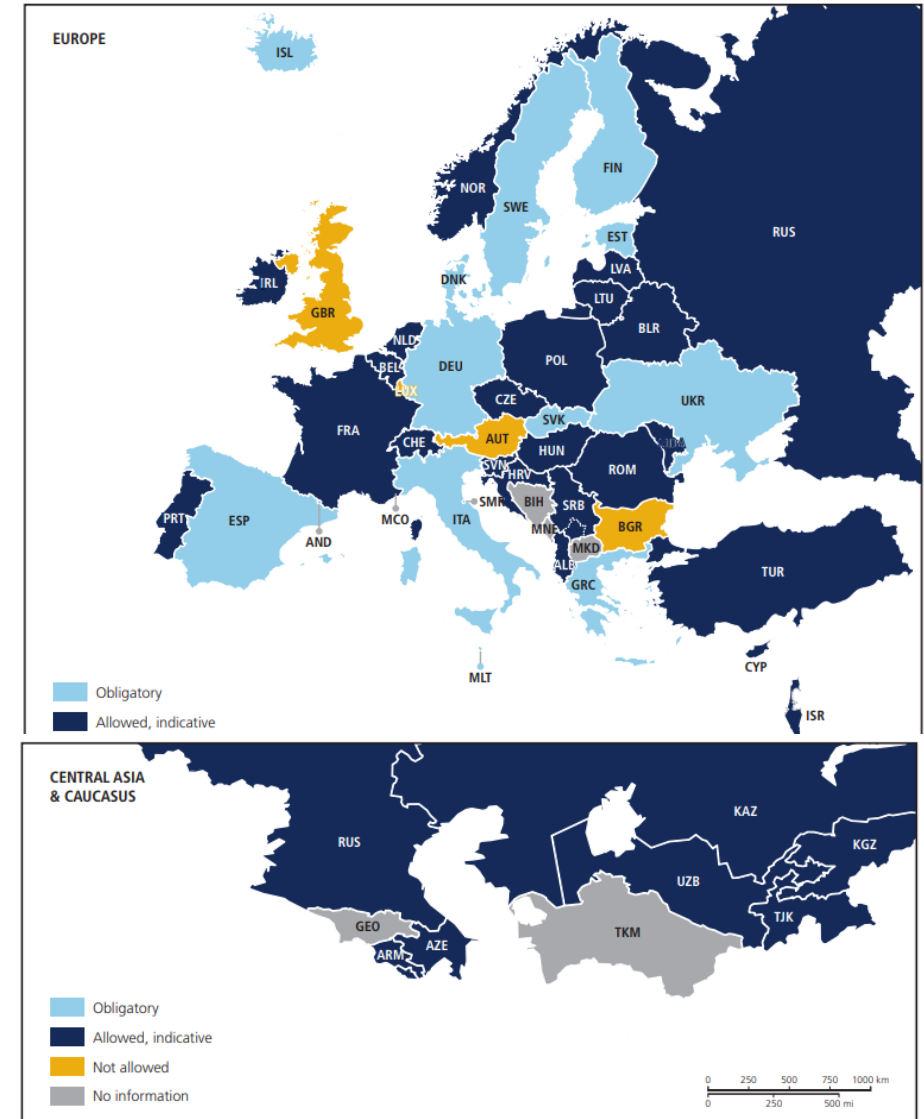
R in off-patent markets in Europe: Reference price system (internal reference pricing)

- » A **reimbursement policy** in which interchangeable medicines are clustered into a **reference group**, often by the same active substance (ATC 5) or chemically related subgroup (ATC 4). The public payer determines a price (called the “**reference price**”) to be reimbursed for all medicines included in the group. If the pharmacy retail price of the medicine exceeds its reference price, the patient must **pay the difference**, in addition to any other co-payments that may be applicable
- » 30 of the 45 countries surveyed



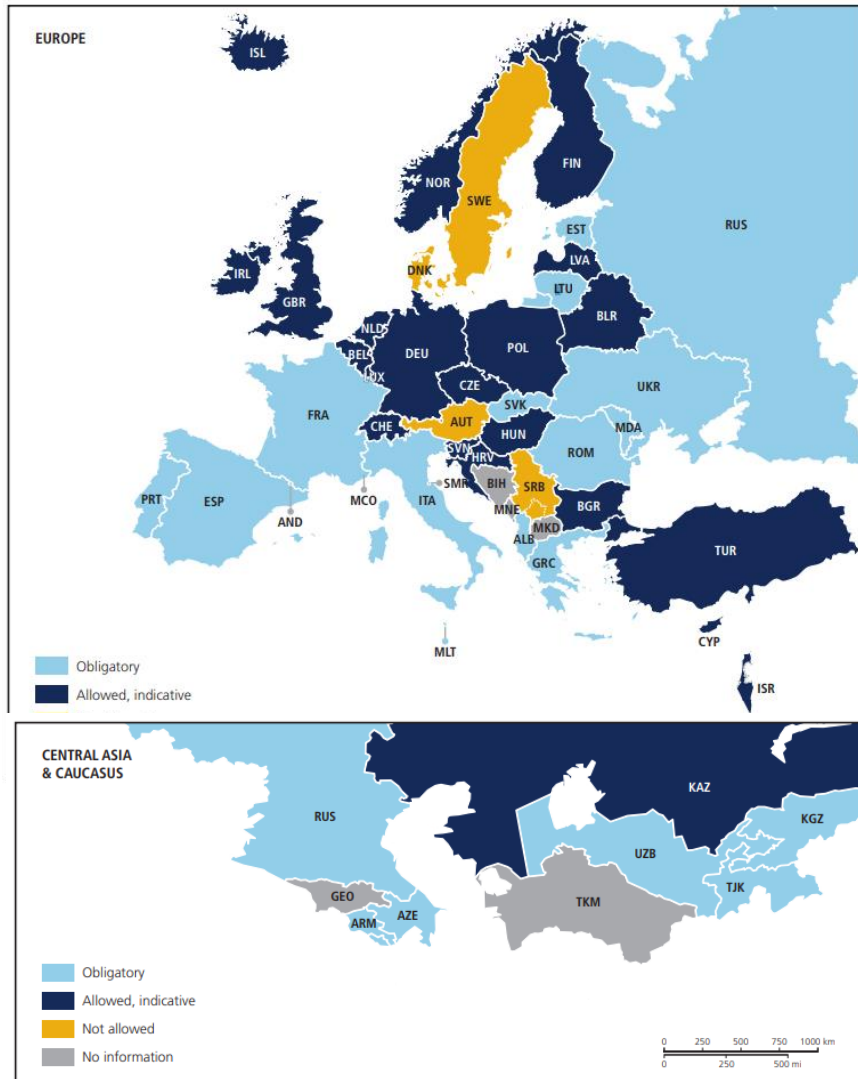
R in off-patent markets in Europe: Generic substitution

- » The practice of **substituting a medicine**, whether marketed under a trade name or generic name (branded or unbranded generic), **with a less expensive medicine** (branded or unbranded generic), often containing the same active ingredient(s) at the community pharmacy level
- » 29 countries – allowed GS
- » 12 countries – obligatory GS

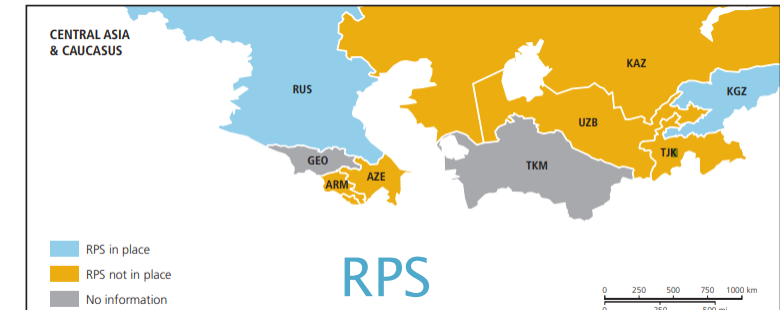
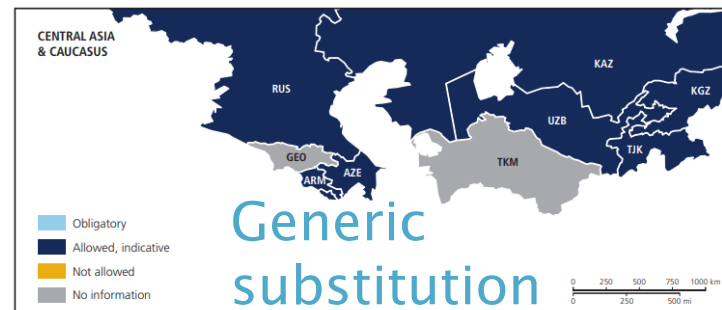
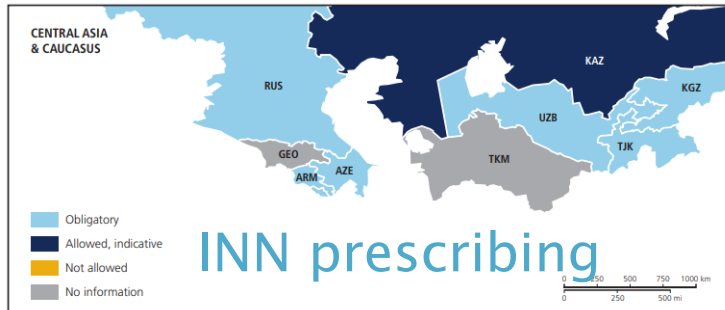
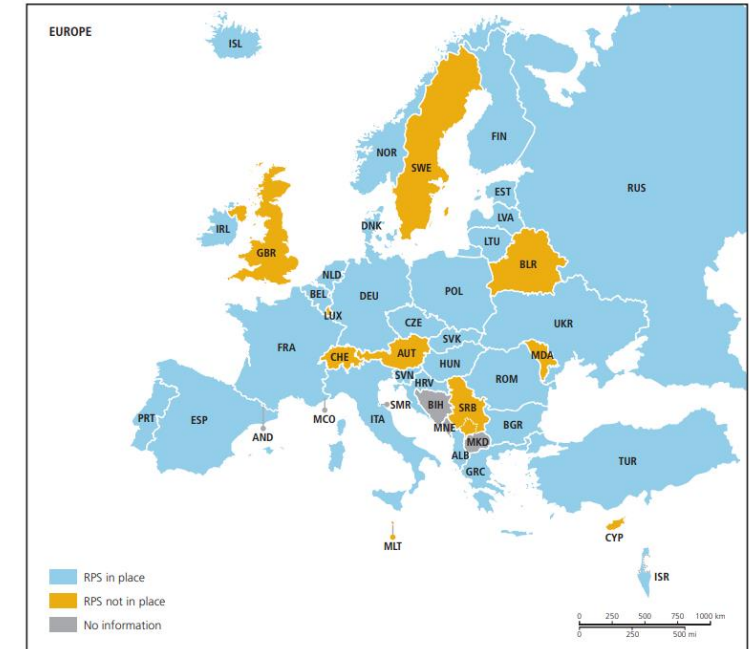
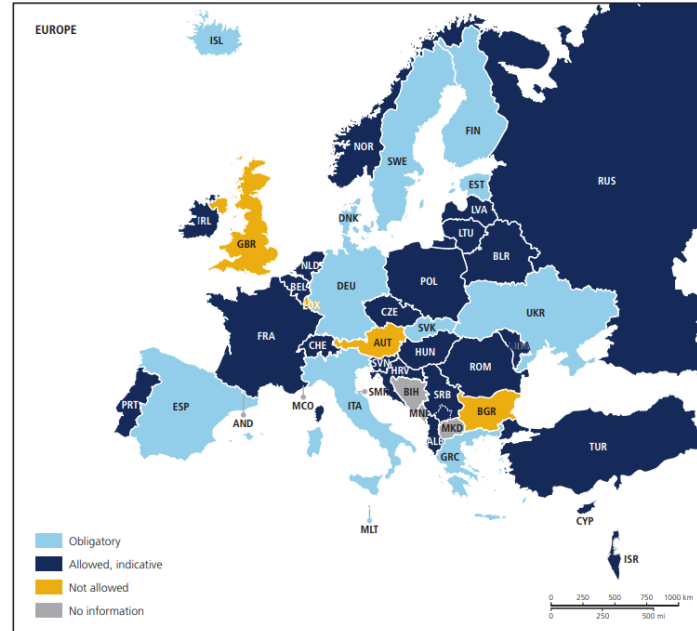
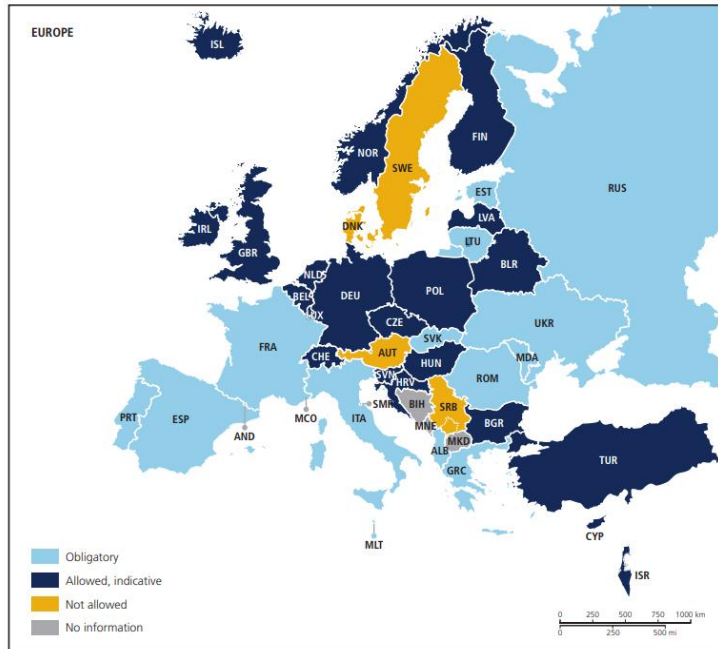


R in off-patent markets in Europe: Prescribing by International Non-Proprietary Name (INN)

- » Prescription of medicines by their INNs, active ingredients or generic names, instead of their brand names
- » 22 countries – indicative INN prescribing
- » 19 countries – obligatory INN prescribing



R in off-patent markets in Europe: mixture of measures



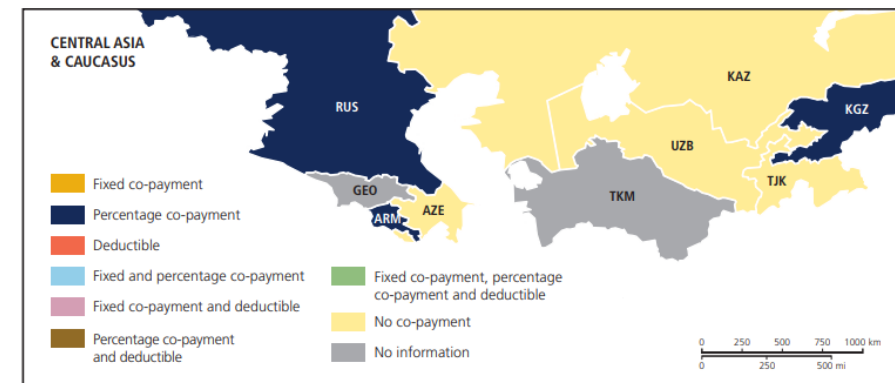
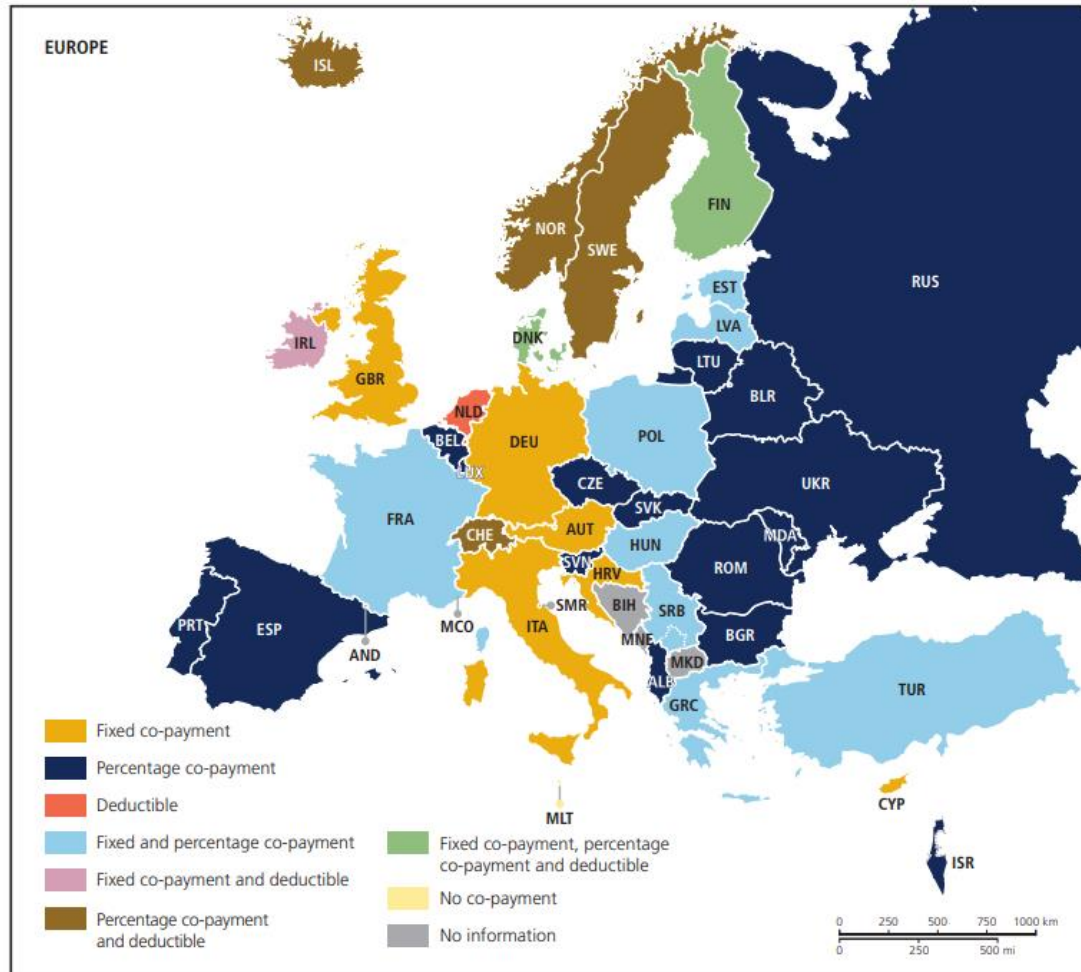
Co-payments for out-patient medicines

Prescription fee: Fixed amount per item on the prescription or per prescription

% co-payment: Fixed share of the pharmacy retail price or the reference price of a medicine

France	100%, 65%, 30%, 15% ¹
Portugal	100%, 90%, 69%, 37%, 15% ^a
Spain	100%, 90%, 40-60% (standard rate linked to income) ^a
Sweden	100%, 90%, 75%, 50% ¹

Deductible: initial expense up to a fixed amount which the patient has to pay out-of-pocket for a defined period of time before the expenses of a medicine are fully or partially covered by a public payer.



Co-payments for out-patient medicines

Specific illness/
condition

Pregnant
women

Income/social
disadvantage

**Exemptions &
reductions**

Pensioners/
retirees/war
veterans

Age

Disability

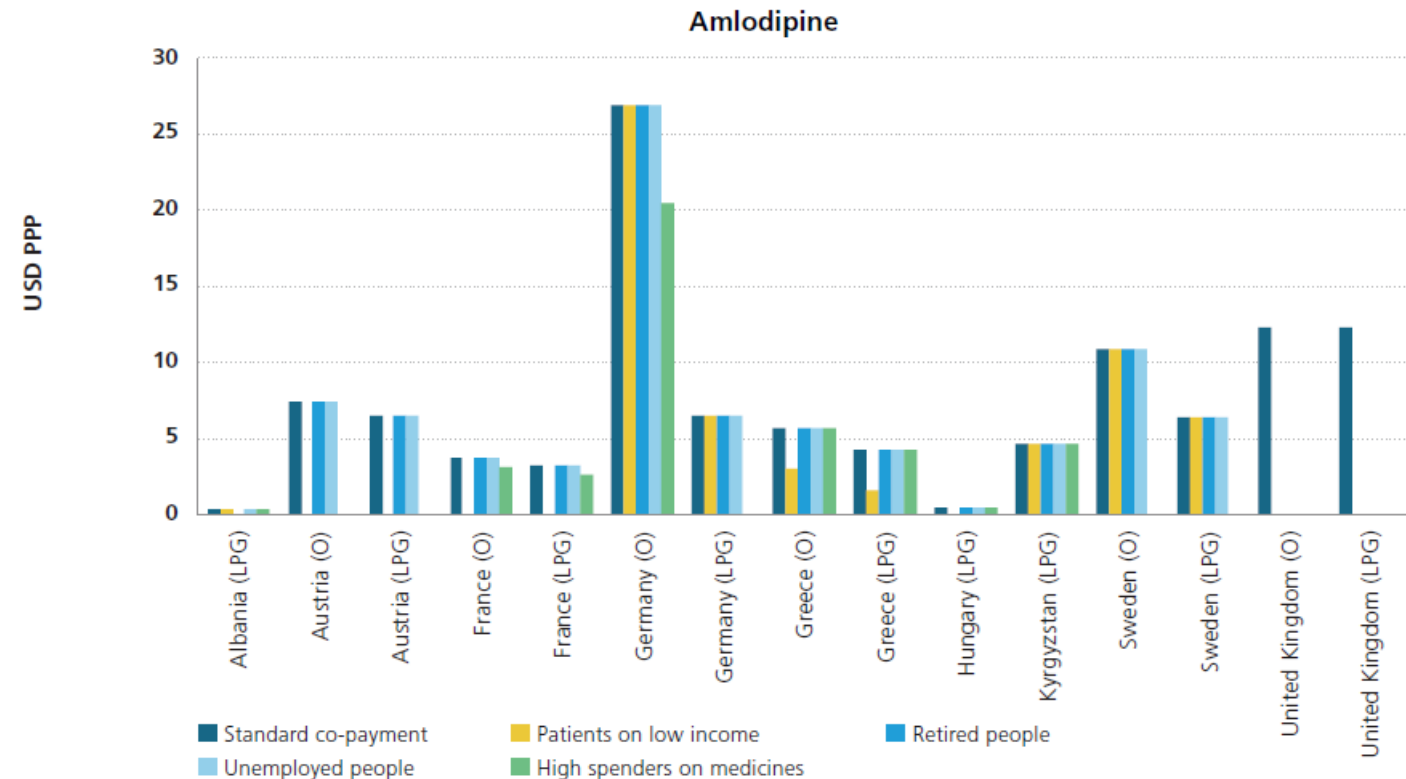
Co-payments for out-patient medicines – Example of financial burden

Molecule	Pharm. form/ dosage/ pack size	Indication
amlodipine	5 mg, 30 tablets	cardiovascular
amoxicillin/ clavulanic acid	875 mg/125 mg , 21 tablets	infectious disease
ibuprofen	600 mg, 30 tablets	pain/inflammation
salbutamol	100 µg, 200 inhalation solution/pressurized inhalation	asthma
metformin	500 mg, 100 tablets	diabetes

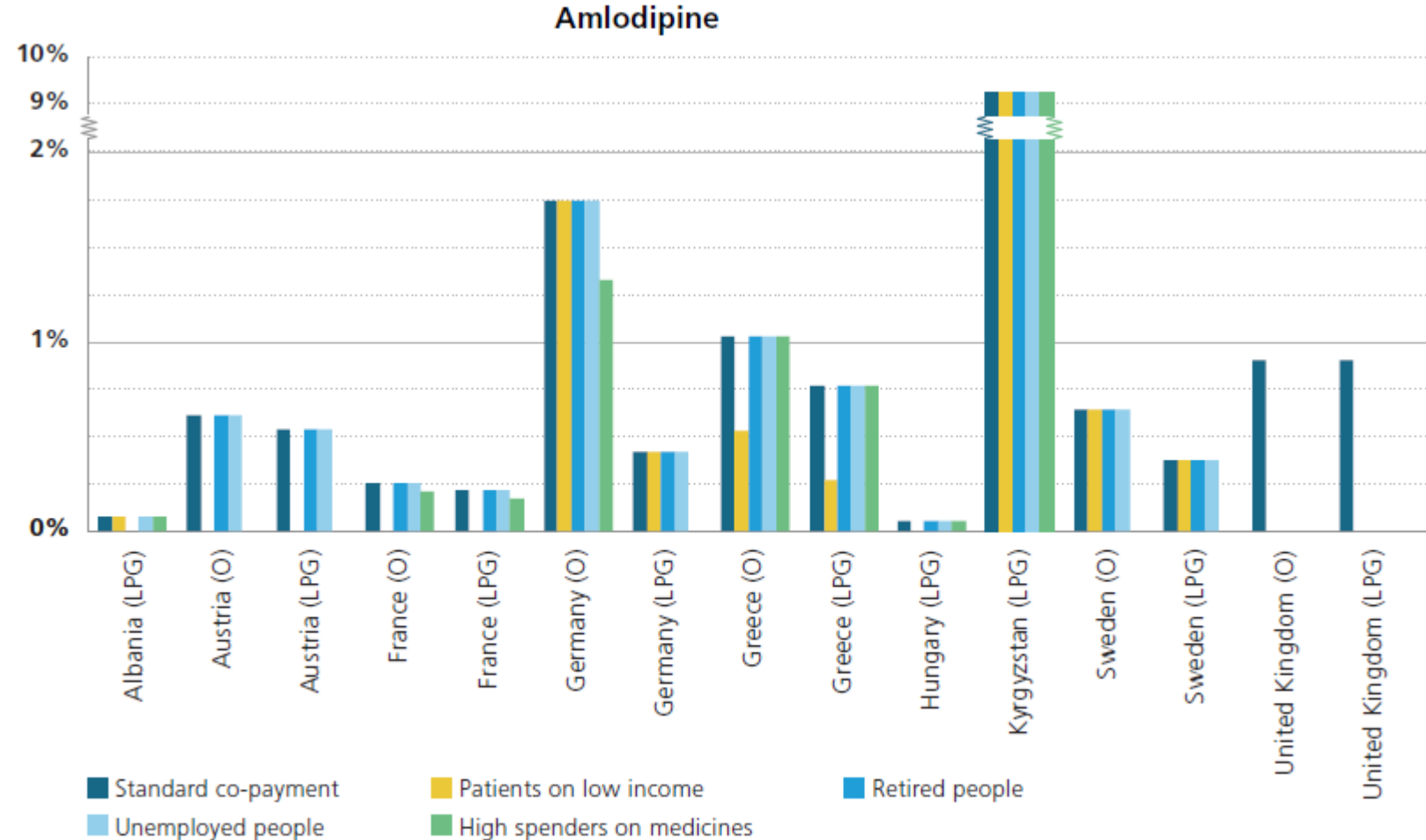
Country	Base case				Specific cases				
	Pr. fee	%	Ded.	RPS	Children	Low income	Retired	Unemployed	High spenders
Albania	N	Y	N	Y	0	=	0	=	=
Austria	Y	N	N	N	=	=	=	=	0
France	Y	Y	N	Y	0 (pr. fee)	0 (pr. fee + %)	=	=	0
Germany	Y	N	N	Y	0	=	=	=	0
Greece	Y	Y	N	Y	=	0	=	=	=
Hungary	(Y)	Y	N	Y	(0)	0 (ceiling)	0 (ceiling)	=	0 (ceiling)
Kyrgyzstan	N	Y	N	(Y)	=	=	=	=	=
Sweden	N	(Y)	Y	N	0	=	=	=	0
UK (England)	Y	N	N	N	0	0	0	0	0 (prepayment)

Co-payments in USD PPP (and % of pharmacy retail price)

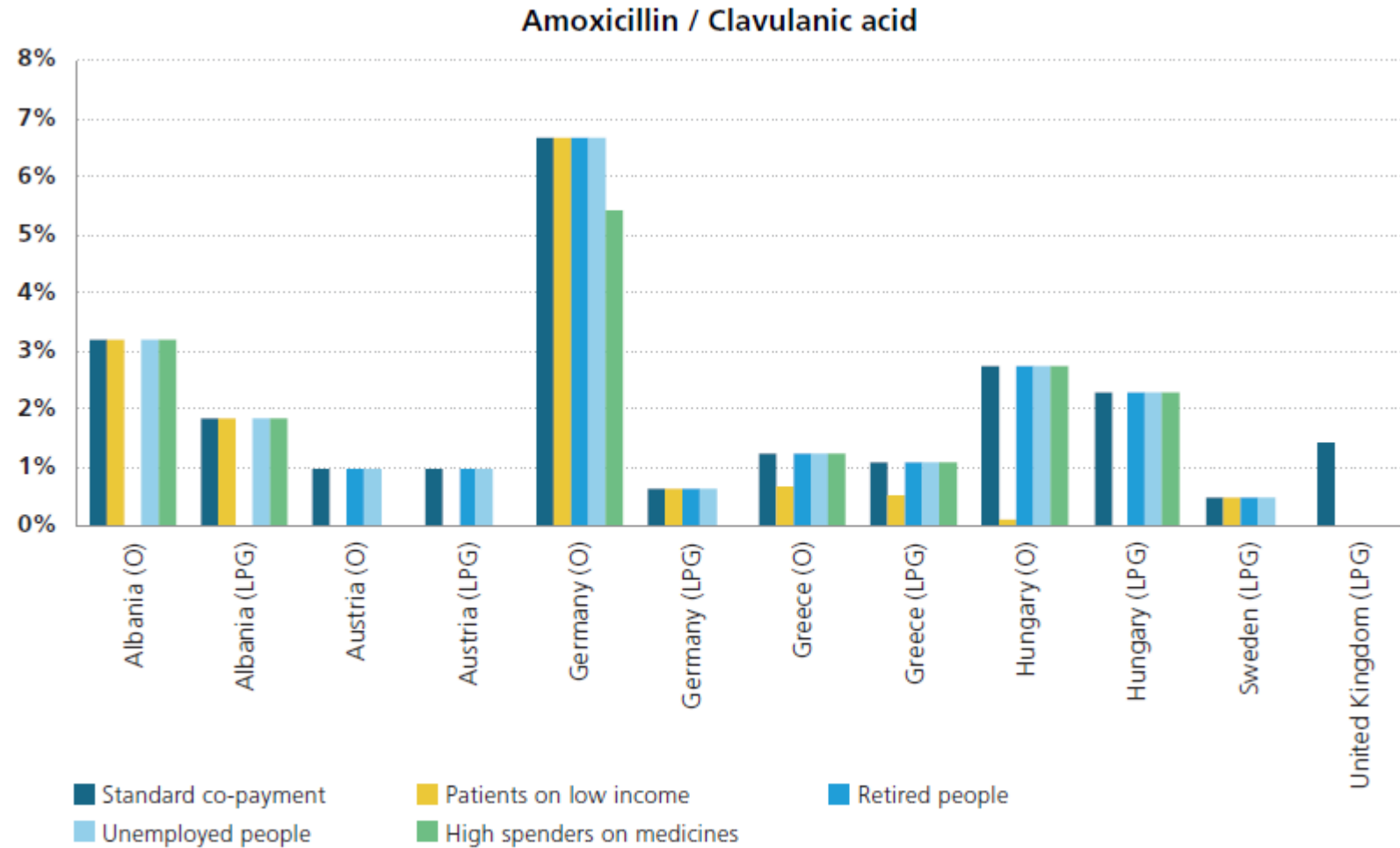
Country	Medicine	Standard co-payment		Children		Patients on low income		Retired people		Unemployed people		High spenders on medicines	
		O	LPG	O	LPG	O	LPG	O	LPG	O	LPG	O	LPG
France	Salbutamol	2.81 (45%)	2.81 (45%)	2.19 (35%)	2.19 (35%)	0 (0%)	0 (0%)	2.81 (45%)	2.81 (45%)	2.81 (45%)	2.81 (45%)	2.19 (35%)	2.19 (35%)
	Metformin	0.62 (7%)	0.62 (9%)	Not applicable		0 (0%)	0 (0%)	0.62 (7%)	0.62 (9%)	0.62 (7%)	0.62 (9%)	0 (0%)	0 (0%)



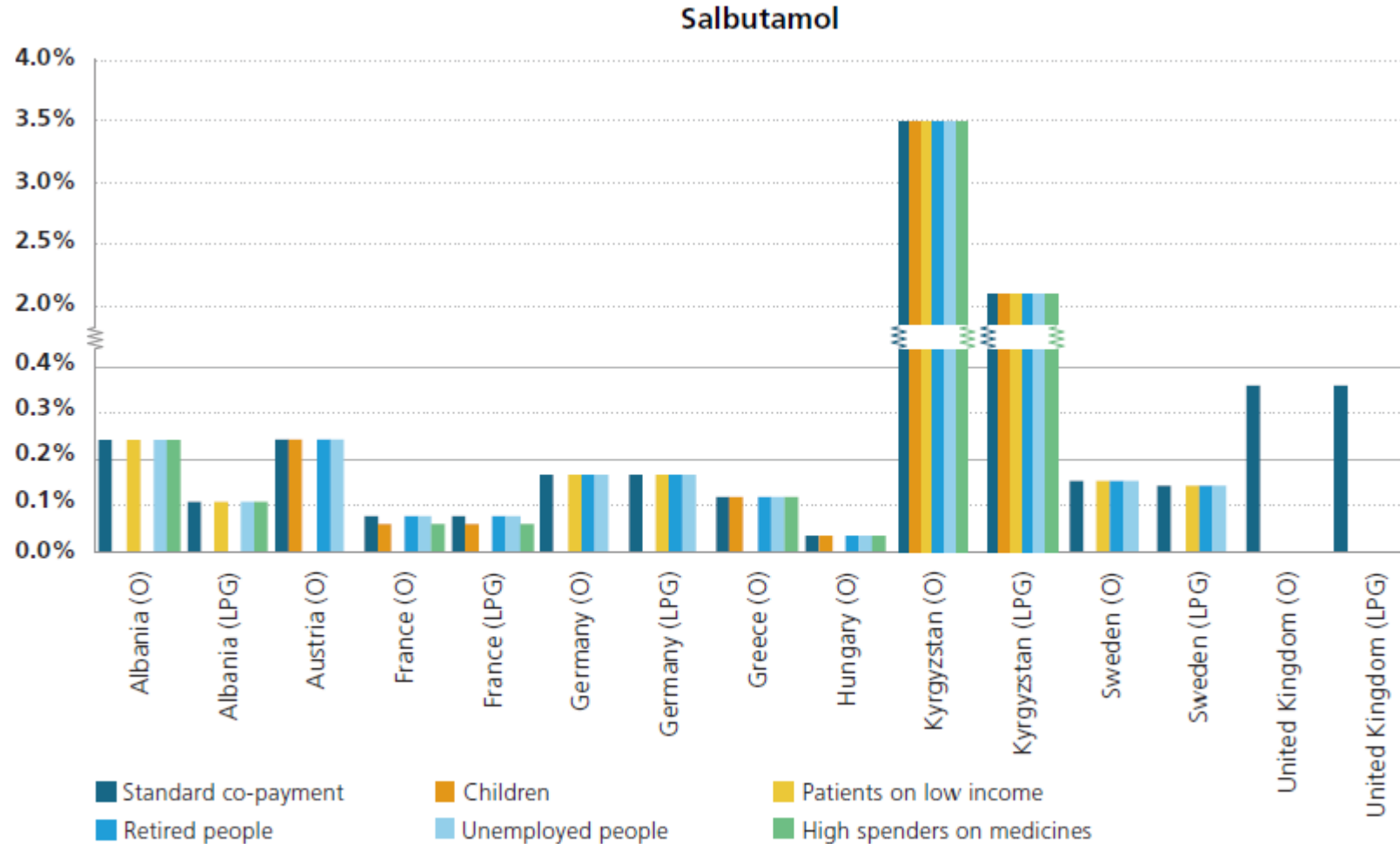
Co-payments – Financial burden as % of minimum wage



Co-payments – Financial burden as % of minimum wage

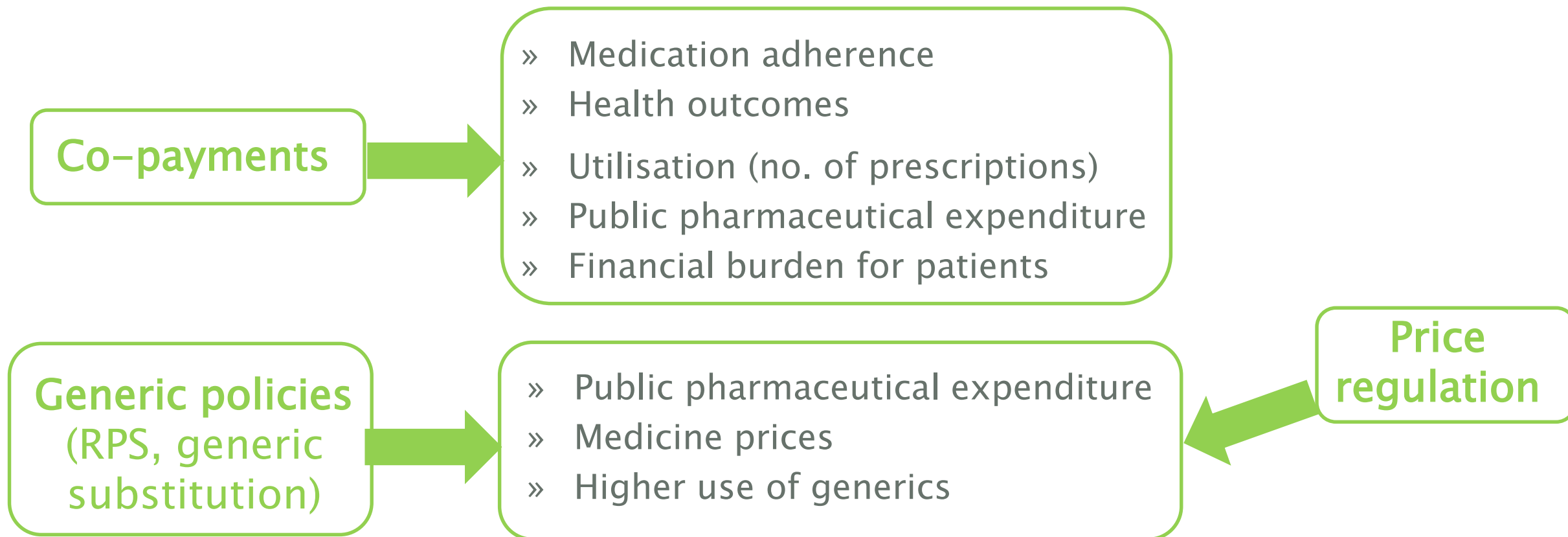


Co-payments – Financial burden as % of minimum wage



Impact of R policies – Literature review

Literature suggests that R policy measures can have an impact on **affordability, accessibility, medication adherence, health outcomes, expenditure** and **utilisation** of medicines.



Impact of R policies – Key findings

- » **Increased financial investment** is critical
- » **Disease orientation** may leave socially disadvantaged people behind
- » **Different designs of system** lead to **different outcomes**
- » **General policy options beyond R** may be supportive or hindering

Impact of R policies – Conclusions on good practice

- » **Clear prioritisation** is crucial
- » **Evidence-based decision-making** and **RWD generation** are fundamental requirements
- » **Processes** should be **transparent and smooth**
- » **Vulnerable population groups** need to be identified
- » **Price regulation** is required
- » **Use of generic, biosimilar and further lower-priced medicines** should be fostered
- » **Patent involvement** should be encouraged
- » **Evaluation, monitoring and adjustments** are needed
- » It is important to create an **appropriate strategic design of individual measures and appropriate policy mix**

**No 'size fits all'
R policy model**

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