Medicines Reimbursement Policies in Europe

Sabine Vogler
Head of Pharmacoeconomics Department
Head of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement
Gesundheit Österreich GmbH (GÖG / Austrian Public Health Institute)

IADB Webinar
24 October 2018
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

GÖG (Gesundheit Österreich GmbH)
Austrian Public Health Institute

WHO CC

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

Contents

» Descriptive overview of R systems/policies in 45 countries

» Assessment of identified R models in 9 case study countries

» 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)

Information used from this presentation has to be correctly quoted. Commercial exploitation is forbidden.
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.

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.

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

4. Reliable health and supply systems
Development of pharmaceutical national policies, quality assurance reinforcement, etc.

WHO: Equitable access to essential medicines: a framework for collective action. 2004
Rationale: Burden for payers and patients

Who pays for medicines?

- State (public payer(s))
  - Co-payments are possible

- Patients
  - High out-of-pocket payments (incl. informal payments) (catastrophic payments)
Rationale: Funding globally

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

OECD Health Data, Eurostat
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

Scope of price regulation
R in Europe: Reimbursement framework

Criteria for selection

Actors

Processes

Policies

BASIC R&D
- Screening of candidates
- Product development

REGULATION
- Marketing Authorization
- Reimbursement approval application

POST-MARKETING
- Pharmacovigilence
- Real-life studies incl. patient registries

INNOVATION POLICIES
HORIZON SCANNING
BENEFIT-RISK APPRAISAL
HTA
PRICING AND REIMBURSEMENT
CLINICAL GUIDELINES
MONITORING AND EVALUATION
DISINVESTMENT
# R in Europe: Reimbursement framework

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

EC legislative proposal on HTA

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

<table>
<thead>
<tr>
<th>MEAs in place in the outpatient sector</th>
<th>MEAs in the inpatient sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>Austria, Belgium, Bulgaria, Croatia, Finland, Lithuania, Malta, Netherlands, Poland, Portugal, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom</td>
</tr>
</tbody>
</table>

Usually confidential (at least price)
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
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

<table>
<thead>
<tr>
<th>Country</th>
<th>Co-payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>100%, 65%, 30%, 15%</td>
</tr>
<tr>
<td>Portugal</td>
<td>100%, 90%, 69%, 37%, 15%</td>
</tr>
<tr>
<td>Spain</td>
<td>100%, 90%, 40-60% (standard rate linked to income)</td>
</tr>
<tr>
<td>Sweden</td>
<td>100%, 90%, 75%, 50%</td>
</tr>
</tbody>
</table>

**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
- Pregnant women
- Income/social disadvantage
- Exemptions & reductions
- Pensioners/retirees/war veterans
- Age
- Disability
## Co-payments for out-patient medicines – Example of financial burden

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

### Co-payments for out-patient medicines

<table>
<thead>
<tr>
<th>Country</th>
<th>Base case</th>
<th>Specific cases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pr. fee</td>
<td>%</td>
</tr>
<tr>
<td>----------------</td>
<td>----------</td>
<td>---------</td>
</tr>
<tr>
<td>Albania</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Austria</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>France</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Germany</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Greece</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hungary</td>
<td>(Y)</td>
<td>Y</td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Sweden</td>
<td>N</td>
<td>(Y)</td>
</tr>
<tr>
<td>UK (England)</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

© 2018 PPRI WHO Collaborating Centre
### Co-payments in USD PPP (and % of pharmacy retail price)

<table>
<thead>
<tr>
<th>Country</th>
<th>Medicine</th>
<th>Standard co-payment</th>
<th>Children</th>
<th>Patients on low income</th>
<th>Retired people</th>
<th>Unemployed people</th>
<th>High spenders on medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>O</td>
<td>LPG</td>
<td>O</td>
<td>LPG</td>
<td>O</td>
<td>LPG</td>
</tr>
<tr>
<td>France</td>
<td>Salbutamol</td>
<td>2.81</td>
<td>(45%)</td>
<td>2.81</td>
<td>(45%)</td>
<td>2.19</td>
<td>(35%)</td>
</tr>
<tr>
<td></td>
<td>Metformin</td>
<td>0.62</td>
<td>(7%)</td>
<td>Not applicable</td>
<td>0</td>
<td>(0%)</td>
<td>0.62</td>
</tr>
</tbody>
</table>

#### Amlodipine

- **USD PPP**

- **Standard co-payment**
- **Patients on low income**
- **Unemployed people**
- **Retired people**
- **High spenders on medicines**

© 2018 PPRI WHO Collaborating Centre
Co-payments – Financial burden as % of minimum wage

© 2018 PPRIWHO Collaborating Centre
Co-payments – Financial burden as % of minimum wage

Amoxicillin / Clavulanic acid

- Standard co-payment
- Patients on low income
- Unemployed people
- Retired people
- High spenders on medicines

© 2018 PPRI WHO Collaborating Centre
Co-payments – Financial burden as % of minimum wage

Salbutamol

- Standard co-payment
- Children
- Patients on low income
- Retired people
- Unemployed people
- High spenders on medicines

© 2018 PPRI WHO Collaborating Centre
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.

- **Co-payments**
  - Medication adherence
  - Health outcomes
  - Utilisation (no. of prescriptions)
  - Public pharmaceutical expenditure
  - Financial burden for patients

- **Generic policies** (RPS, generic substitution)
  - Public pharmaceutical expenditure
  - Medicine prices
  - Higher use of generics

- **Price regulation**
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 priorisation** 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
Contact

Sabine Vogler
Stubenring 6
1010 Vienna
T: +43 1 515 61 – 147
F: +43 1 513 84 72
Email: sabine.vogler@goeg.at
www.goeg.at
http://whocc.goeg.at