EUROPEAN HEALTH FORUM GASTEIN 2015
Securing health in Europe. Balancing priorities, sharing responsibilities

Creating a better future for health in Europe

SAVE THE DATE - EHFG 2016 - 28-30 September 2016
Cancer medicines as a challenge for public pricing and reimbursement

Sabine Vogler

Gesundheit Österreich (GÖG / Austrian Public Health Institute)

Program Coordinator of Pharmacoeconomics and Pharmaceutical Policy Analysis
PPRI Project Manager
Head of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

European Health Forum Gastein, 1 October 2015
Outline

» Oncology medicines – example of high priced medicines

» Policy options in pharmaceutical pricing and reimbursement for high-priced (oncology) medicines (results from a survey done for the WHO report)

» Pre-launch activities – horizon scanning on oncology medicines

» ‘Treatment packages’

» Conclusions
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. This is not a publication 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:
- The members of the PPRI networks
- Nina Zimmermann (GÖG, Vienna WHO CC) for performing the survey about policy options with the PPRI network
- My colleagues working on the Pharma Price Information (PPI) service

Information used from this presentation has to be correctly quoted. Commercial exploitation is forbidden.
## Oncology medicines – high-cost medicines

<table>
<thead>
<tr>
<th>Ex-fact pr./unit (Q2/’13)</th>
<th>Medicines (selected presentations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; € 1.-</td>
<td>–</td>
</tr>
<tr>
<td>€ 1.01 – € 10.-</td>
<td>–</td>
</tr>
<tr>
<td>€ 10.01 – € 50.-</td>
<td>7 medicines: abiraterone acetate, imatinib, lapatinib, nilotinib, pazopanib, sorafenib tosylate</td>
</tr>
<tr>
<td>€ 50.01 – € 100.-</td>
<td>2 medicines: erlotinib, gefitinib</td>
</tr>
<tr>
<td>€ 100.01 – € 250.-</td>
<td>6 presentations: cetuximab, denosumab, everolimus, gemcitabine (originator/generic version), sunitinib</td>
</tr>
<tr>
<td>€ 250.01 – € 500.-</td>
<td>8 medicines: bendamustine hcl, eribulin mesylate, interferon alfa 2b, lenalidomide, nelarabine, ofatumumab, paclitaxel albumin, zoledronic acid</td>
</tr>
<tr>
<td>€ 500.01 – € 1,000.-</td>
<td>2 medicines: temsirolimus, trastuzumab</td>
</tr>
<tr>
<td>€ 1,000.01 – € 5,000.-</td>
<td>6 medicines: bevacizumab, bortezomib, cabazitaxel, clofarabine, panitumumab, pemetrexed</td>
</tr>
<tr>
<td>€ 5,000.01 – € 10,000.-</td>
<td>1 medicine: plerixafor</td>
</tr>
</tbody>
</table>
Survey – Methods

» PPRI network query:
  - Aim to collect information on policies, particularly P+R policies, of new premium-priced medicines
  - Done in the context of the WHO report, in February/March ‘14
  - PPRI: network of P+R competent authorities in 45 countries
  - Responses from 27 European countries

» Updates from PPRI
  - Country posters on pre-launch policies (Prague PPRI Network Meeting, March 2015) (same URL)
# PPRI query results – Country-specific definition

<table>
<thead>
<tr>
<th>Definition?</th>
<th>21 countries: BE, DK, CA, CH, ES, EE, EL, FI, HR, HU, LV, LU, MT, NL, NO, PL, RS, SI, SE, SK, UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development (1)</td>
<td>AT: a definition on high-cost and specialized medicines was developed at time of the survey</td>
</tr>
<tr>
<td></td>
<td>AL: ‘the expensive drugs’ in reimbursement list</td>
</tr>
<tr>
<td></td>
<td>CZ: A highly innovative product is defined as a medicine containing an active substance which can be used to treat diseases that, to date, have not responded to another medicines or which represents a promising substantial improvement in treatment but has insufficient amount of data on cost-effectiveness or on results of treatment when used in clinical practice.</td>
</tr>
<tr>
<td>Country-specific definition (5)</td>
<td>FR: There is no real definition of high-priced medicines or premium priced medicines. However, medicines with a ‘Service Médical Rendu’ (Health Benefit), i.e. ranked major, important or sometimes even moderate, and with an improvement in actual benefit moderate or above, can be classified as innovative. Moreover, a decree published on October 2 2012 specifies that a Health Technology Assessment should be conducted when the two following conditions are met: * improvement in actual benefit, ASMR (Amélioration du Service Médical Rendu) of III (moderate) up to I (major). * significant impact on health insurance expenditure, given the price of the product, its impact on the market structure, etc. Although there is no specific rule, the revenue of the product is often taken into account, especially if it is expected to exceed € 20 million by the second year of commercialization.</td>
</tr>
<tr>
<td></td>
<td>IS: ‘Specialty care high cost medicines’ are defined as medicines that need special care and clinical guidelines and are costly.</td>
</tr>
<tr>
<td></td>
<td>IT: no specific definition, but new algorithm was under development (at the time of the survey) that will provide an assessment of the degree of innovation of new medicines</td>
</tr>
</tbody>
</table>
PPRI query results – P + R in the out-patient sector

» Overall, the rules for pricing and reimbursement of new premium-priced medicines do not differ from the ones for the other medicines

» Increased use of HTA and pharmacoeconomic evaluations
  – New application and decision-making process for ‘specialty care high-cost medicines’ with clinical and economic evaluation in IS since mid-2013)

» Frequent use of price-volume agreements, managed-entry agreements, risk-sharing schemes and similar was reported from some countries (e.g. ES, FR, PL, HU; SK – ‘conditional categorization’
In principle, no specific P + R procedures for premium-based medicines in many countries, but specific funding models, processes, schemes:

- **DK**: Regions established the Coordination Council for the Application of Hospital Medicine (KRIS) to coordinate the application of cancer medicine

- **NO**: A cooperation to improve the evaluation of cost-effectiveness of new technology (incl. medicines) in hospitals was established in 2014; a selection of medicines will be evaluated by the Norwegian Medicines Agency (NoMA)
PPRI query results – P + R in the in-patient sector/2

» Special funding models:
  
  - Funding outside the DRG system: individual product reimbursement (AT, BE, EE, FI, FR)
  
  - Special agreements between hospitals and social health insurance: costs for medicines used in hospitals are (partly) funded by social health insurance (FR, EL, NL – new arrangement since 2013, SI; NO – TNF and MS medicines & (since 2014) oncology medicines are always funded by hospitals
  
  - Special programs: LV, PL
  
  - Special funds: Cancer Drug Fund (UK)
Managed-entry agreements in oncology

» MEA ensure access to medicines, part. Those with limited cost-effectiveness

» Can lead to reduced transparency (content is confidential)


http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/Experiences%20and%20impact%20of%20European%20risk-sharing%20schemes.pdf
Pre-launch activities: Horizon scanning

» Few countries do horizon scanning
  – Italy – Veneto region project
  – UK/PharmScan
  – **Sweden**: joint effort of four county councils on behalf of all the Swedish county councils, in collaboration with medical institutions, governmental agencies & SALAR (Swedish Association of Local Authorities and Regions)
  – Austria – HS project on oncology medicines

» Need for horizon scanning became very clear in 2014
  – Ad horizon scanning exercises (e.g. CZ – innovative & very expensive medicines)
  – Plans to implement: HR, PT, RU
Prices of the medicine and its accompanying diagnostics

» **Diagnostics**: Very limited price data available
  - **AT**: approx. price of € 110.– for diagnostic test
  - **EE**: price of € 418 for a FISH test and € 29 for an IHC test
Funding models for trastuzumab and its accompanying diagnostics

- **Model 1**: full hospital funding
  - State: Cyprus, Ireland, Latvia, Malta, Norway, Portugal, United Kingdom (=England & Wales)

- **Model 2**: full third party payer funding
  - Regions: Austria, Denmark, Finland, Spain, Sweden, Italy

- **Model 3**: combined hospital / third party payer funding
  - Belgium, Bulgaria, Czech Republic, Estonia, France, Germany, Greece, Hungary, Iceland, Lithuania, Netherlands, Poland, Slovenia and Slovak Republic

- **Model 4**: combined company / third party payer funding

**Assessment**

**Treatment package**

- Test & trastuzumab
Need for alternative pricing policies

« ‘Policy mix’ report:

- Competent authorities & payers ranked external price referencing (EPR) last, together with differential pricing (DP) and ‘discounts / rebates / negotiations / claw-back’

« Focus group discussion with PPRI network:
Possible reasons for low rank of EPR:
- Authorities reference to official list price instead to actual discounted prices
- EPR is well-known to them (daily practice), including its limitations
- It is not a ‘fair’ system
- Availability issues: it may contribute to medicines shortages
Focus group discussion on pricing policies/cont.

» But: Benefits of EPR
  – ‘Easy’ (however: resource-intensive) system
  – Short-term savings
  – Methodological choices can have an impact
  – Which are the alternatives?

» Conclusions of the focus groups
  – Countries will continue to use EPR due to a perceived lack of alternative pricing policies
  – Using improvements in methodology
  – Unilateral ‘GDP pricing’ was seen as only feasible differential pricing approach
Conclusions

» High priced medicines constitute a major challenge, targeting also and particularly oncology medicines

» Need for new alternative (pricing) policies

» Need for increased cooperation between countries

» Dialogue with stakeholders
Thank you for your attention!

Sabine Vogler
Stubenring 6
1010 Vienna
T: +43 1 515 61-147
F: +43 1 513 84 72
E-mail: sabine.vogler@goeg.at

www.goeg.at
http://who.cc.goeg.at
http://who.cc.goeg.at/Conference2015