Health Action International

EU medicines policy & access to medicines

Workshop, Bucharest, Romania

30 September 2015

Aliénor Devalière
Health Action International

• A non-for-profit global network, established in 1981

• Comprising public health NGOs, healthcare professionals, academics and consumers

• Based in Amsterdam & Brussels

• Regional offices in Africa, Latin America and Asia

• Working to increase access to essential medicines and improve their rational use through research and evidence-based advocacy

• HAI Europe funding sources: Executive Agency for Health and Consumers (CHAFEA); Open Society Foundations (OSF); Camino Foundation
HAI and equitable access to medicines in Europe

Comprehensive approach to the question of access to needed medicines

- Access to essential medicines
  - Essential innovation
  - EU trade and access
  - IP policy
  - EU related pharmaceutical legislation

- Rational use of medicines
  - Independent medicines information
  - Public access to medicines safety and efficacy data

- Democratisation medicines policy
  - Transparency, independence, regulatory, & policy process
  - Civil society participation
Access to medicines in the EU

Key concepts

- Access
- High price
- Needed medicines
- On-patent medicine
- Generic medicine
Access to medicines in the EU

Context

• Pharmaceutical costs are the third most important component in EU Member States’ health care budgets

• Rising of pharmaceutical expenditure as part of health budgets

  2000-2009: public pharmaceutical expenditure has increased by approx. 76% across the EU

• Costs of patent medicines outpace savings of generics

• The demand for medicine is constantly growing (aging population, chronic diseases, new developments)
Health expenditure in Romania

5.34 % of GDP in 2013, according to the World Bank
(sum of public and private health expenditure)

### Table 1 – Evolution of total (public and private) outpatient pharmaceutical expenditure (1970 – 2010)

<table>
<thead>
<tr>
<th>Country</th>
<th>1970</th>
<th>1980</th>
<th>1990</th>
<th>2000</th>
<th>2010*</th>
<th>Total expenditure on pharmaceuticals (% GDP)</th>
<th>Total expenditure on pharmaceuticals (as % total current health expenditure)</th>
<th>Total per capita expenditure on pharmaceuticals (in purchasing power standards)</th>
<th>Total expenditure on pharmaceuticals (in million Euro)</th>
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<tr>
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<td>0.9 1</td>
<td>1.3 1</td>
<td>192,108</td>
</tr>
</tbody>
</table>

Source: Eurostat, OECD Health Data 2012, Commission services (DG ECFIN)
Cancer drug price increases (1980-2013)

Rapid Rise

Median Monthly Price between 1985-2010: +1330%

Source: Memorial Sloan-Kettering Cancer Center; 2013.
Sofosbuvir case

• Up to 170 million people across the world are infected with HCV / 3-4 million newly infected each year

• Sovaldi received marketing approval 6 December 2013
  Marketed by Gilead

• Officially between €25,000 - €56,000 for 12 week course in EU

• Manufacturing costs between $68 - $136 per treatment

• Ex: Sovaldi unit price in Latvia: 733.02 euros / Unit price in France: 488.11 euros

• Romania told to have obtained the lowest price!
Issue of high price of medicines

• Often set/negotiated in opacity
• Not based on real cost of R&D, which remains unknown
• Prices of cancer medicines described as: “astronomical, unsustainable and even immoral”
• Lack of competition (monopoly)
• Practices to delay entry of generics into the market

High prices put at risk universal access to healthcare and health protection system
Issue of high price of medicines

Little therapeutic advance

Out of 97 new medicines evaluated in 2010, only 4 provided a therapeutic advantage.
Access situation in lower income country (Latvia)
HAI study - Measuring variations in retail selling price (2014)
(comparative study in 8 Member States)

In Latvia, where the GDP per capita is lowest among the country sample, prices are amongst the highest

The table below shows the unit retail selling price of the originator brand and lowest-priced generic of budesonide 200μg dry powder. The unit price refers to the price of one dose.
Access situation in lower income country (Latvia)
HAI study - Measuring variations in retail selling price (2014)

In Latvia, treatment is the least affordable with both, originator brand and lowest-priced generic.

In Latvia, the percentage of a family’s monthly income allocated to pay for the standard treatment of asthma with the originator brand is **ten times higher** than the amount that families in the Czech Republic and France must pay.
Context

The economic crisis has exacerbated the situation

Changes in pharmaceutical policies reported in 23 Member States

**Most frequent measures implemented:**

- Price freezes and cuts
- Change in co-payments, margins and value added-tax (VAT) rates on medicines
- Promotion of generic medicine use
- Enforcement of policies for more rational use of medicine

**In Romania:**

→ Collection of the information on unpaid bills and reduction of payment delays
→ Implementation of a payback system (taxes)
→ Implementation of a negative list of health services and pharmaceuticals
→ New legal framework for carrying out health technology assessment
Rise of pharmaceutical expenditure

• **Cost for patients**

→ HAI is primarily concerned about the availability and affordability of medicines for patients

• **Cost for the government**
Factors influencing the price of medicines

- Taxes
- Mark up
- National policies
- Price regulation policy
- Distribution costs
- Level of competition
- National patent law
- Procurement strategies
What role for the European Union & Member States?

Lisbon Treaty - Treaty on the Functioning of the European Union (TFEU)

Article 168 (7)

Member States are responsible for the definition of their health policies as well as for the organisation and delivery of health services and medical care. This includes measures regulating the prices of medicinal products and their inclusion in national health insurance systems.
The European Commission’s competence is restricted to:

- initiate, amend and monitor the implementation of legislation

- organisational support and/or funding of initiatives, research, information tools, studies etc.

- support cooperation and exchange of information between Member States on prices and pricing policies
The EU can facilitate best practices/set example

- **Network of Competent Authorities on Pricing and Reimbursement (CAPR):** Informal platform offering the opportunity to identify, share and discuss information, expertise and best practices/best policies with other Member States on issues of pricing and reimbursement.

- **Discussions take place in different political and technical fora:** Working Party on Public Health at Senior Level, HTA, EUnetHTA, STAMP.

- **EU price database (EURIPID):** Projet initiated by the European Commission in 2010. But not publicly accessible, no investment => failed.
What can be done at country level?

Use effective price control mechanisms & reimbursement policies

- Key information for informed and effective price negotiations missing

- Full transparency of medicines prices, R&D costs and medicines safety and efficacy data needed

- Need to deal with ‘retaliation’ companies and parallel trade when lowering prices
HAI recommendations on key conditions for effective pricing & reimbursement policies

- No COIs & transparency of decision making processes and outcomes
- Added-therapeutic value compared to existing products on the market should be key criteria
- Not shift the burden of high medicines prices onto patients through delisting or increased cost-sharing
- Need to deal with the problem of price cuts/lower prices to ‘retaliation’/parallel trade
Mechanisms currently used by Member State to lower the price of medicines

- External Reference Pricing
- Health Technology Assessment
- Joint Procurement
External Reference Pricing

• Practice widely employed in the EU

• Price based on a comparison with prices in a ‘basket’ of other Member States

• Pros and Cons?
# External Reference Pricing

<table>
<thead>
<tr>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accepted and widely used policy for cost-containment</td>
<td>Price are relatively higher in countries with lower income levels</td>
</tr>
<tr>
<td>Lower the price when decisions are based on countries with similar GDPs</td>
<td>Company initially market new medicines in countries where high prices are common so that it keep the reference price (artificially) high and delay the availability of new medicines in other Member States</td>
</tr>
<tr>
<td>Affordable administrative tool for setting prices, without recurrence to more resource intensive strategies (HTA)</td>
<td>Transparency concerns - No access to the real discounted price</td>
</tr>
<tr>
<td></td>
<td>Company launch the product where the list price is high (disclose bonus, rebates)</td>
</tr>
<tr>
<td></td>
<td>Difficult for national purchasers to make well-informed decisions about procurement prices</td>
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</table>
Health Technology Assessment

- HTA used by each Member State

- Provide recommendations on the medicines that can be paid for or reimbursed by the healthcare system (cost-effectiveness, added-therapeutic value)

- Pros and Cons?
## Health Technology Assessment

<table>
<thead>
<tr>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic added value (TAV) compared to current practice (if used this way)</td>
<td>Resource intensive: cost and expertise</td>
</tr>
<tr>
<td>Value for money is addressed</td>
<td>Difficult to conduct appraisals with sufficient quality (complex methodology/unavailable CTD)</td>
</tr>
<tr>
<td>Cost-effectiveness for particular indications, subgroups</td>
<td>Risk of situations of COI/ non-transparency of HTA processes and links between HTA findings and decision-making</td>
</tr>
<tr>
<td>Flexible: considerations revised as more evidence is available</td>
<td>(?) Generalisability of results difficult</td>
</tr>
<tr>
<td>HTA could steer innovation if TAV is considered</td>
<td>HTA as advisory mechanism instead of binding</td>
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Joint Procurement

- Combining purchasing activities
- Scope limited to serious cross-border threats to health – but recently enlarged by the EC
- Pros and Cons?
# Joint Procurement

<table>
<thead>
<tr>
<th>PROS</th>
<th>CONS</th>
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</thead>
<tbody>
<tr>
<td>Strengthen Member States’ purchasing power</td>
<td>Voluntary mechanism, never used by Member States</td>
</tr>
<tr>
<td>All Member States are treated equally</td>
<td>Does not take into account specificity of the country (GDP)</td>
</tr>
<tr>
<td>Bilateral agreements allowed (?)</td>
<td>Several Member States to active the procedure + European Commission’s competence</td>
</tr>
<tr>
<td>Contractual conditions on price, liability, confidentiality and flexibility officially published</td>
<td>(?) Sufficient safeguards for transparency and accountability</td>
</tr>
<tr>
<td>Agreement adjusted to the needs</td>
<td>(?) Serve pharma’s interest</td>
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</table>
Example of good practices

‘Germany’s Pharmaceutical Market Restructuring Act for Statutory Health Insurance’

• Medicines should demonstrate efficacy and safety & added-therapeutic value comparing to existing drugs

Introduction of a compulsory early benefit assessment

• Requirement for higher prices of new drugs to be accompanied by evidence of an added benefit compared to alternatives

• Removed the incentive for manufacturers to launch ‘me-too drugs’ on the market at prices above those of pharmacologically and therapeutically comparable drugs
Other measures

Generic competition

Generics are on average three-to-four times cheaper than the respective off-patent originator brands

Prices tend to drop 25% a year after generic entry and 40% two years after entry

Main barriers:

• Monopoly protected by intellectual property (IP) rights

• Possibility to issue a compulsory licensing

• Strategies aiming at blocking and delaying generics entry

• EU competition law
Other measures

New innovation models

- New models could rely on other incentive mechanisms to incentivise R&D instead of patents

- Refrain from increasing monopoly protections

- Need for alternative biomedical R&D models that de-link the cost of R&D from the price of medicines
  - Various mechanisms proposed: public and indirect (tax-based) funding, inducement prizes, patent pools, …
  - Principle of open knowledge innovation: generating knowledge free of restrictions, publication of data

- Independence, transparency and accountability of decision-making processes and bodies
## RECOMMENDATIONS

### Key recommendations on pricing strategies

<table>
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<tr>
<th>Recommendation</th>
<th>Source</th>
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<tr>
<td>Share best practices in procurement price negotiations and value based assessment for reimbursement of medicines (EU)</td>
<td>EU</td>
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<tr>
<td>Assist, especially smaller Member States, in dealing with negative consequences of pricing strategies (EU)</td>
<td>EU</td>
</tr>
<tr>
<td>Verify criteria for HTA to promote value based assessment &amp; develop criteria for marketing authorisation and reimbursement that work as an incentive for needs driven innovation (MS)</td>
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### Key recommendations on Transparency

<table>
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<th>Recommendation</th>
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<tr>
<td>Encourage full transparency and public access to information about prices across EU Member States (EU)</td>
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<tr>
<td>Publish real price information (MS)</td>
</tr>
<tr>
<td>Publish secret discounts and rebates through a publicly accessible EU database, containing updated information on medicines actual prices on an annual basis (EU)</td>
</tr>
<tr>
<td>Disrupt any financial links between industry and HTA bodies (MS)</td>
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<tr>
<td>Establish full transparency of regulatory processes or decisions on marketing authorisation and reimbursement (EU+MS)</td>
</tr>
<tr>
<td>Implement robust conflict of interest policies in regulatory decision making bodies to avoid conflicting situations that could be detrimental to the public health interest (EU+MS)</td>
</tr>
<tr>
<td>Full transparency and public access to medicines safety and efficacy data to permit public health authorities, health professionals, and patients to make rational decisions about price and reimbursement (EU+MS)</td>
</tr>
<tr>
<td>Request pharma to provide full transparency and public access to R&amp;D costs if they want market access/be reimbursed (EU+MS)</td>
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RECOMMENDATIONS

<table>
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<th>Key recommendations on generic competition &amp; IP</th>
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<tr>
<td><strong>DG Competition</strong> should extend its follow up of the reported abuses of strong IP rights to delay generic competition of medicines in this Pharmaceutical Sector Inquiry of 2009 (EU)</td>
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<tr>
<td><strong>EU Member States</strong> that are in increased difficulty to provide universal access to needed medicines should consider issuing compulsory licences to guarantee affordable access to high-priced life-saving drugs with evidence of efficacy and quality</td>
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Why CSOs need to be engaged?

• Lack of information, data and transparency
• Need for more evidence-based policy/advocacy
• Gather data on micro level to assess the situation on the ground of inequality in access or lack of access to needed medicines
• Situation of access more difficult in Eastern countries: real interest in acting collectively
• Build more robust connections between information, medicines and decision-making
• Include access to medicines and their appropriate use as an explicit focus in health system strengthening
Measures implemented in Romania?

- Amendements in the list of reimbursed medicines (National Catalogue of Medicines)
  - 14 molecules added
  - Hepatitis C treatment introduced

- Introduction of cost-volume agreements

- Increase of salary of the doctors by 25% in October

- Joint Procurement Agreement signed with Bulgaria
Discussion

• What else can be done to have access to high-price medicines?

• How can the civil society be mobilised?
THANK YOU FOR YOUR ATTENTION!
ANY QUESTIONS?

alienor@haiweb.org

www.haieurope.org