Transparency of (real) pharmaceutical costs:

Would transparency make a difference for payers?
How does it work today?

• Today: very complex models ("value-based pricing") – no link with the costs

➢ Starting point: (anchor) price announced by the pharmaceutical company

➢ Payers:
   • Evaluate the (theoretical) therapeutic value (QALY)
   • Limit to ability and willingness to pay (money threshold / budget) or reluctance to refuse?
   • What the market can bear!
How does it work today?

➢ Results: unjustified high prices

Example: Sovaldi
(1st hepatitis C direct acting antiviral)

Launch net prices range 34 - 58.000 €
after confidential rebate
for a 12 weeks treatment

71 million people infected (1% of global population)
= above 200 billion € for EU 27!

Source: PLOS Medicine May 31, 2016
Documented real costs - Sovaldi:

- **R&D**: Gilead purchased Pharmasset for 11 billion USD in 2011, but Pharmasset only spent **271 million USD in R&D (2003-2011)** !!!

* Share of R&D linked to the buyout of Pharmasset. Gilead’s R&D costs to further develop Sovaldi not included.

- And very low **production costs**:

How do we deal with that information ????????

BMJ 2016;354:i3718 doi: 10.1136/bmj.i3718
No, but setting transparent and fair rules would!

- **Goal**: set objective, transparent and **FAIR** starting point for price negotiations

  Fair price = “one that is affordable for health **systems and patients** and that at the same time provides sufficient **market incentive for industry** to **invest in innovation** and the production of medicines”. (WHO)

<table>
<thead>
<tr>
<th>Fairness to seller</th>
<th>Fairness to buyer (and patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Covering R&amp;D costs</td>
<td>1. Affordability (necessary quantity)</td>
</tr>
<tr>
<td>2. Covering costs of manufacturing/distribution and registration/postapproval/admin</td>
<td>2. Link to value to the individual and society (to incentivize better products)</td>
</tr>
<tr>
<td>3. Fair profit (RoI)</td>
<td>3. Supply security</td>
</tr>
</tbody>
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Defining the concept of fair pricing for medicines. BMJ 2020;368:14726

- **Means**: Restoring balance in negotiation (EU27 = 1 market)
  Restoring link with reality (costs)
Concrete tool: AIM’s model

-> one EU price for every new drug
A mechanism can be added to make a link with the wealth of each MS (compensation fund)

Principles:
• Based on cost and value elements
• Not captive of full transparency
• Objective criteria
Current parameters of AIM’s model

- **R&D (global)**: Transparency $\rightarrow$ **real amount** (maximum €2.5 billion)
  
  Including cost of failure (but only once – audit needed). Clear rules about publicly funded R&D, tax refunds, opportunity costs, buyouts, ...

Methodology: **R&D by Pharmasset**: 11 billion USD or 271 million USD??

- $X \times$ share of Europe: 35.85% (EU27 / current population of innovative drugs)
- / target population for that indication (prevalence or 10 years incidence, considering 50% treatment rate (global for EU 27) and up to 3 competitors for each drug)

  $= \text{R&D per patient (per treatment)}$
Current parameters of AIM’s model

R&D

• **R&D (global)**: Transparency ➞ **real amount** (maximum €2,5 billion)
  Including cost of failure (but only once – audit needed). Clear rules about publicly funded R&D, tax refunds, opportunity costs, buyouts, ...

**Methodology**: **R&D by Pharmasset**: 11 billion USD or 271 million USD???

- **No transparency** ➞ €250 million **lump sum** (no justification required)

\[
X \text{ share of Europe} : 35,85\% \quad \text{(EU27 / current population of innovative drugs)}
\]

\[
/ \text{ target population for that indication} \quad \text{(prevalence or 10 years incidence, considering 50% treatment rate (global for EU 27) and up to 3 competitors for each drug)}
\]

\[
= \text{R&D per patient (per treatment)}
\]
Current parameters of AIM’s model

- **Real production costs** if transparency
- **Otherwise** costs limited to a lump sum (no justification required) according to composition/population

<table>
<thead>
<tr>
<th>Composition of the drug</th>
<th>Cost per month of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical</td>
<td>50€</td>
</tr>
<tr>
<td>Chemical orphan</td>
<td>250€</td>
</tr>
<tr>
<td>Biological</td>
<td>150€</td>
</tr>
<tr>
<td>Biological orphan</td>
<td>750€</td>
</tr>
<tr>
<td>Gene or cell therapy</td>
<td>60,000€ (one shot)</td>
</tr>
</tbody>
</table>

\[ \times \text{the duration of average treatment} \]
\[ (10 \text{ years for chronic diseases}) \]

- **20% of R&D**

**Basic profit**
- **8% of total costs**

**Sales medical informat**

**Product** & overhead costs

**Fixed %**
Current parameters of AIM’s model

= incentive for innovation that matters, addressing therapeutic needs

Innovation bonus

cost and value elements

Link profit to therapeutic value = incentive for usefull innovation

+ 5 to 40% of total costs
### FAIR PRICE COMPONENTS (per treatment per patient)

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D cost</td>
<td>800 million €</td>
</tr>
<tr>
<td>Production cost</td>
<td>3 x lumpsum 50€</td>
</tr>
<tr>
<td>Sales and medical information</td>
<td>20% R&amp;D</td>
</tr>
<tr>
<td>Basic profit</td>
<td>8% costs</td>
</tr>
<tr>
<td>Innovation bonus</td>
<td>40% costs</td>
</tr>
</tbody>
</table>

**Summary:**
- **R&D cost:** 384,56 €
- **Production cost:** 150,00 €
- **Sales and medical information:** 76,91 €
- **Basic profit:** 48,92 €
- **Innovation bonus:** 244,58 €

### FAIR PRICE CALCULATION

- **Fair price per treatment per patient:** 904,94 €
- **Fair price per month of treatment per patient:** 301,65 €
Utopia?

1st practical application!
Way forward on transparency of costs

- discussion on methodology
- experience real costs based models for new starting point in price negotiation (oncology, rare diseases, Covid)

www.fairpricingcalculator.eu

Defining the concept of fair pricing for medicines. BMJ 2020;368:14726
Thank you!

AIM Healthcare and social benefits for all

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