AIM’s EUROPEAN FAIR PRICE CALCULATOR FOR MEDICINES

Based on AIM’s FAIR PRICING model

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Why do we need fair prices?
The pharmaceutical market today

- Huge price increase for new drugs
- Access: Europe ≠ Europe
- Not enough investment in research
- Finance-driven business model with excessive revenue fuelling expensive buyouts and high costs

Source: Van der Gronde T, Uyl-de Groot C A, Pieters T. Addressing the challenge of high-priced prescription drugs in the era of precision medicine: A systematic review of drug life cycles, therapeutic drug markets and regulatory frameworks; 2017
What’s wrong with the price setting?
Difficult negotiations and dangerous concepts

- Opposed goals and unbalanced negotiations
- Value-based pricing: a flawed mechanism
- Tricky concepts: price? discount?

*Anchoring: cognitive bias to rely too heavily on the first piece of information offered (the “anchor”) when making decisions*

How do we reach fair prices?
Setting new transparent rules

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>
</table>

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

- Restoring balance in negotiation (EU27 = 1 market)
- Restoring link with reality (costs)
- Predictability
AIM’s algorithm

- R&D/ number of patients
- Product & overhead costs
- Sales & medical information
- Basic profit
- Innovat bonus

\[ \text{European fair price} \]

-> 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:
- not captive of full transparency (lump sum)
- cost and value elements

Model developed by AIM’s Working group on Pharmaceuticals and Medical devices
Current parameters of the model

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

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

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

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

  \[ = \text{R&D per patient (per treatment)} \]
Current parameters of the 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>

$X$ the duration of average treatment
(10 years for chronic diseases)

- 20% of R&D

- 8% of total costs
Current parameters of the model

= incentive for innovation that matters, addressing therapeutic needs

Innovation bonus

+ 5 to 40% of total costs

Current parameters of the model

Link profit to therapeutic value

But can also include:
- Quality of data: double blind RCT, choice of comparator (not placebo), choice of endpoints (no surrogate)
- Choice of disease
- Specific populations (children, elderlies, ...)
- ...
### FAIR PRICE COMPONENTS (per treatment per patient)

<table>
<thead>
<tr>
<th>Component</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D cost</td>
<td>384,54 €</td>
</tr>
<tr>
<td>Production cost</td>
<td>150,00 €</td>
</tr>
<tr>
<td>Sales and medical information</td>
<td>76,91 €</td>
</tr>
<tr>
<td>Basic profit</td>
<td>48,92 €</td>
</tr>
<tr>
<td>Innovation bonus</td>
<td>244,58 €</td>
</tr>
</tbody>
</table>

### FAIR PRICE CALCULATION

| Price per Treatment per Patient          | 904,94 € |
| Price per Month of Treatment per Patient | 301,65 € |
### Does the model make a big difference?

<table>
<thead>
<tr>
<th>Type indication</th>
<th>Market share</th>
<th>R&amp;D global</th>
<th>R&amp;D per patient for full treatment</th>
<th>Production costs/month</th>
<th>Treatment duration (months)</th>
<th>Innovation bonus</th>
<th>Fair price/year for one patient</th>
<th>Current price/year for one patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare disease 3/100 000 chemical</td>
<td>50%</td>
<td>€800 million</td>
<td>€85 483</td>
<td>€250</td>
<td>120</td>
<td>20%</td>
<td>€16 966</td>
<td>€200 000 to €500 000</td>
</tr>
<tr>
<td>Ultra-rare 1/100 000 gene or cell</td>
<td>100%</td>
<td>€250 million</td>
<td>€40 056 (per treatment)</td>
<td>€60 000 (per treatment)</td>
<td>/</td>
<td>15%</td>
<td>€132 923</td>
<td>€700 000 to €2 million</td>
</tr>
<tr>
<td>Cancers 50/100 000 biological</td>
<td>100%</td>
<td>€2.5 billion</td>
<td>€801 (per treatment)</td>
<td>€150</td>
<td>12</td>
<td>40%</td>
<td>€4 087</td>
<td>€30 000 to €100 000</td>
</tr>
<tr>
<td>Chronic disease (hepatitis, severe asthma,…) 1% prevalence biological</td>
<td>33%</td>
<td>€250 million</td>
<td>€120</td>
<td>€150</td>
<td>120</td>
<td>5%</td>
<td>€2 050</td>
<td>&gt; €10 000</td>
</tr>
</tbody>
</table>

5 to 10 times lower!
Who? Where? When?
A staged implementation

Today = at (inter)national level

- **Raise awareness**, increase transparency/no more a blackbox (costs and net prices)
- **Fuel the debate** (and scientific work) on drug prices and fairness
- **Inspire payers and decision-makers** for (inter)national negotiations: **objective and transparent price** to start negotiating and compare with the price requested by the seller – also outside Europe

Long term: implementation at EU level

Fair price to be set **together with registration** (avoiding regulatory delays) **as a condition to access the EU market**

1. All data needed collected by **EMA** in market authorisation application (MAA) file
2. Appraisal of innovation bonus by (inter)national **HTA body**
3. Decision by Commission

**Not short term** because need for predictability (huge impact on industry) and new EU regulation
Today : a tool - AIM’s calculator

• Users need little data:

1. R&D spent

2. Prevalence/incidence

3. Production cost

4. Duration of treatment

<table>
<thead>
<tr>
<th>Data needed in calculator</th>
<th>Real/well documented</th>
<th>Otherwise</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>Real (global) including cost of failure (max €2,5 billion)</td>
<td>Lump sum of €250 million</td>
</tr>
<tr>
<td>Patient population</td>
<td>In P&amp;R file</td>
<td>Prevalence/incidence of indication (websites)</td>
</tr>
<tr>
<td>Production costs</td>
<td>Real</td>
<td>Type of composition -&gt; lump sum/month of €50/150/250/750/gene</td>
</tr>
<tr>
<td>Treatment duration</td>
<td>In P&amp;R file</td>
<td>In SmPC</td>
</tr>
</tbody>
</table>
Today: AIM’s calculator

• One appraisal: value of the treatment

<table>
<thead>
<tr>
<th>Appraisal in the calculator</th>
<th>In HTA or P&amp;R file</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of disease</td>
<td>Life threatening or heavy?</td>
</tr>
<tr>
<td>(Un)met need</td>
<td>Alternatives?</td>
</tr>
<tr>
<td>Added therapeutic value</td>
<td>Curative? Minor/moderate/major impact on disease? Major quality of life?</td>
</tr>
</tbody>
</table>
Thank you!

AIM Healthcare and social benefits for all

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Follow us on Twitter! @AIM_healthcare