EUROPEAN FAIR PRICES

AIM’s model

Anne Hendrickx
Socialist mutual fund (Belgium)
Why do we need fair prices?

• Unequal and delayed access (EU28 and ww)
• Bankrupt of health systems?
• Lack of R&D where needed

Pharma giant Pfizer pulls out of research into Alzheimer’s

74% same target

Unintended consequences of expensive cancer therapeutics. Fojo et al, JAMA 2014
Why do we need fair prices?

• Opposed goals and unbalanced price negotiations!

Maker of $1,000 hepatitis C pill was focused on profits, not patients, report finds

10 largest companies (2014)
- $66 bio R&D
- $98 bio marketing
- $90 bio profit

“...To me, you cannot put a price on your child’s life,” said Anderson, who lives in Mansfield, Ohio. “If tomorrow we were told to pay back everything, we would. We would figure it out. Because our son is now...”
Tricky concepts: Value based pricing

Nice concept supposed to allowing comparison (international and amongst treatments) on objective criteria but ...

Long-term value? ”The first two years of treatment with Spinraza cost around 50% of one Zolgensma infusion, but Spinraza treatments must continue for life at a cost of $375,000 each year.”

So much cheaper than a (way too expensive !!!!) drug ?

“Over the past few months, Novartis CEO Dr. Vasant Narasimhan tossed out a bunch of price anchors for Zolgensma that ranged from $1.5 million to $5 million. Just before the big reveal, he told reporters the price would be well shy of $5 million, and it was. MEA everywhere for everything. We all got anchored, then we got a discount, and now there actually is a gene therapy on the market with a multimillion-dollar price tag.”

PETER B. BACH - JUNE 4, 2019

or emotion based pricing?
Tricky concepts: Willingness to pay

ICER/QALY thresholds (€40.000, £100.000, £300.000/1 year in perfect (quality) health)

= what we want to pay (societal reference point)?

or what we have to pay?

= ensure the maximum health gain for the budget?

or maximum profit (“What the market can bear”)

Negotiation starting point totally disconnected from costs

= profit

or profiteering?
Tools are being developed

- International cooperation (Beneluxa, Valletta, Sofia,...)
- Horizon scanning
- EU collaboration on HTA (?)
- MEA everywhere (for everything)
- WHO Transparency Resolution
- Academics: Pricing models 😊

but too little too slow!
Because every stakeholder has new tools...

Industry

- Adaptive pathways
- Creative outcome based agreements (ICER/QALY on 80 years horizon)
- Innovative payment schemes (annuity based, ...)

And patients!

- A belgian family got a (€1,9 million) drug paid by a crowdfunding campaign!
And it won’t stop!

(excessive) Global revenues

- Cost of goods
- R&D
  - Real costs
  - Potentially cheap new drugs
- Sales and marketing

M&A
- Buyouts
  - Stock buyback
  - Shareholders

Huge costs!

- Expensive new drugs!

novation gap?

- Gilead’s purchase of Kite Pharma: $11 billions
- Celgen’s purchase of Juno Therapeutics: $9 billions
- GSK’s purchase of Tesaro: $5 billions
- Eli Lilly’s purchase of Loxo Oncology: $8 billions
- Novartis’s purchase of AveXis: $8.7 billions
How do we get fair prices ?????
How can we get fair prices?

- Defining **our rules** and **our limits** (willingness to pay)
- Restauring **balance in negotiation** (EU28 = 1 market)
- Link to the **wealth** of each MS
- Restauring link with **reality** (costs)
- **Predictability** and **transparency** (at least on the method)

➢ 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)*
How to set a fair price?

A new model = AIM’s algorithm:

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

= European average fair price

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

- **Transparency** → real amount R&D (global)
- **But maximum**: €2.5 billions at the start
- **No transparency**: €250 million lump sum

Including cost of failure (but only once – audit needed)

Clear rules about:

- publicly funded R&D (40% public sector and others – 60% industry*)
- tax refunds
- opportunity costs
- buyouts, M&A
- ...

Proposed parameters of the model

R&D

• Share of Europe: 42% (EU28 / current population of innovative drugs)

• Divided by target population for that indication
  (prevalence or 10 years incidence)

considering

  ▪ 50% treatment rate (global for EU 28)
  ▪ and maximum 3 competitors for each drug
    (to be confirmed by horizon scanning)

= R&D per patient

↓

R&D per year
Proposed parameters of the model

- Real production costs if transparency
- Otherwise costs limited to a lump sum:

<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>
</tbody>
</table>

- 20% of R&D

- 8% of total costs

X the duration of average treatment (10 years for chronic diseases)
Proposed parameters of the model

= incentive for innovation that matters, answering therapeutic needs

Example:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>life-threatening or chronically debilitating or rare disease</td>
<td>5%</td>
</tr>
<tr>
<td>+ no alternative</td>
<td>5%</td>
</tr>
<tr>
<td>+ curative</td>
<td>30%</td>
</tr>
<tr>
<td>Or if NOT curative:</td>
<td></td>
</tr>
<tr>
<td>progression free survival (PFS) vs comparator of &gt; 6 months or &gt; 50%</td>
<td>5%</td>
</tr>
<tr>
<td>overall survival (OS) 1 to 6 months</td>
<td>5%</td>
</tr>
<tr>
<td>overall survival (OS &gt; 6 months)</td>
<td>10%</td>
</tr>
<tr>
<td>major quality of life (QOL) improvement</td>
<td>10%</td>
</tr>
</tbody>
</table>

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,...)
- ...
Additional steps

Step 1: **Average** fair price

Step 2: differential price system based on GDP
-> fair price in each MS
= maximum fair price in each MS

Step 3: negociation in each country
= **real fair price in each country**

+ safety net: not higher than existing price in comparable system (New Zealand, Canada,...)
Which medicines?

- All new entities registered at EMA level
- Price set for the first indication
- New price calculation (+10% R&D if no transparency) for the second and third indications (> salami slicing)
- Me too/competitors: same price? Only if same costs and same innovation level/innovation bonus (→ pushing different indications)
Example: hepatitis C drug

European average fair price

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

392,60 €
100 €
78,52 €
45,69 €
228,45 €

= 845,26 €
Example: hepatitis C drug

Differential price

From €196 in Bulgaria to €1,733 in Ireland (and €2,496 in Luxemburg).

Based on a 2.5 billion R&D cost, the prices would have been around €2,300 (average price) which is still very far from the 40,000€ and more that are paid today to have access to this medicine.

Lowest EU price: 38.783 $
No comment

GILEAD’S TREATMENT CAS(H)CADE

≈ 67 million of people with HCV waiting for a treatment they can’t afford yet

≈ 1.79-2 million of people with HCV who received generic treatment

≈ 1.85 million of people with HCV who received Gilead’s treatment at extortionate prices

$58.6 billion HCV sales in 5 years

$25.8 billion HCV profit in 5 years

With 15.4% of this amount, Gilead could have provided life-saving treatment to an estimated 67 million people in need...

www.hepcoalition.org
# Does it make a big difference?

<table>
<thead>
<tr>
<th></th>
<th>R&amp;D per patient (global)</th>
<th>R&amp;D per patient per year</th>
<th>Production/year</th>
<th>Innovatio n bonus</th>
<th>Fair price/year for one patient</th>
<th>Current price/year for one patient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ultra-rare disease</strong> 1/100.000 biological</td>
<td>122.687 € (250 millions)</td>
<td>12.269 €</td>
<td>9.000 € (750X12)</td>
<td>15%</td>
<td>29.179 € (6.760€-86.154€)</td>
<td>200.000€ to 500.000€</td>
</tr>
<tr>
<td><strong>Rare disease (including cancer)</strong> 3/100.000 chemical</td>
<td>130.867 € (800 millions)</td>
<td>13.087 €</td>
<td>3.000 € (750X12)</td>
<td>20%</td>
<td>23.941 € (5.547€-70.688€)</td>
<td>200.000€ to 500.000€</td>
</tr>
<tr>
<td><strong>Frequent cancers (per treatment)</strong> 50/100.000 incidence biological</td>
<td>2.454 € (2.5 billions)</td>
<td>2.454 €</td>
<td>1.800 € (150x12)</td>
<td>40%</td>
<td>7.022 € (5.547€-70.688€)</td>
<td>30-100.000 €</td>
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## Does it make a big difference?

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<tr>
<td><strong>Viral and chronic disease (hepatitis, severe asthma,...)</strong>&lt;br&gt;1% prevalence biological</td>
<td>€ 393 € (800 millions)</td>
<td>39,3 €</td>
<td>1800 € (150x12)</td>
<td>5%</td>
<td>2.087 €</td>
</tr>
<tr>
<td><strong>Chronic disease (diabetes, Alzheimer's,...)</strong>&lt;br&gt;5% prevalence chemical</td>
<td>€ 245 € (2,5 billions)</td>
<td>24,5 €</td>
<td>120 € (10*12)</td>
<td>40%</td>
<td>221 €</td>
</tr>
</tbody>
</table>

*for very frequent diseases, production costs will drop (/5).
### Table: R&D and Economic Considerations for Ultra-rare Disease

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<td>40%</td>
<td>365,893€</td>
<td>1,9 millions ?</td>
</tr>
<tr>
<td>1/100,000</td>
<td></td>
<td>????</td>
<td>????</td>
<td></td>
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« Une équipe du Généthon (laboratoire français de recherche au statut associatif financé grâce à la générosité publique du Téléthon et à des subventions) met ensuite au point une thérapie génique ... AveXis, teste cette thérapie chez des enfants et signe un accord de licence avec le Généthon. Après les résultats encourageants de ces essais, Novartis rachète AveXis en 2018 pour 8,7 milliards de dollars (2). »

Prescrire
Who ? Where ? When can it start ?

• Average price and national maximum prices to be set \textit{at the time/just after registration} (avoiding regulatory delays)

• By existing european body (close to EMA, new european HTA body ?) – preferably \textbf{no additional body}

• Possible implementation ? Not short term ... but payers could already be inspired by the model for (inter)national negotiations !
What else do we need to adapt?

• External reference pricing: STOP
• Industry’s quotas: STOP (no new shortages !!!!)
• Parallel trade: STOP
  ▪ legal (exception to parallel trade)?
  ▪ tracking system (European Medicines Verification System)?
Is it really going to help?

• Unique (maximum) price together with registration
  ➢ reduced *delay* in access
  ➢ symetry in information (not need for MEA on prices)
  ➢ *balance in negotiation* power
  ➢ less HR in pricing and reimbursment (and more in R&D?)
  ➢ SOLIDARITY
Is it really going to help?

• Innovation bonus = incentive for
  ➢ what really matters
  ➢ no (less) duplication in R&D
  ➢ QOL trials (duration of treatment, patient outcomes, …)
  ➢ more money in R&D

FLEXIBILITY (for new criteria)
nobody is bankrupt!
AIM PROPOSES TO ESTABLISH AND TRANSPARENT PRICES

A EUROPEAN DRUG PRICING MODEL FOR FAIR AND ACCESSIBLE PHARMACEUTICAL INNOVATIONS

Introduction

The International Association of Mutual Benefit Societies (AIM) proposes a concrete alternative for setting the price of new medicines. In order to make innovative essential medicines accessible, AIM calls for a fair European maximum price calculation model.
Thank you!

AIM Healthcare and social benefits for all

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Follow us on Twitter! @AIM_healthcare