AIM Healthcare and social benefits for all

AIM's EUROPEAN FAIR PRICE CALCULATOR FOR MEDICINES

Based on AIM's FAIR PRICING model

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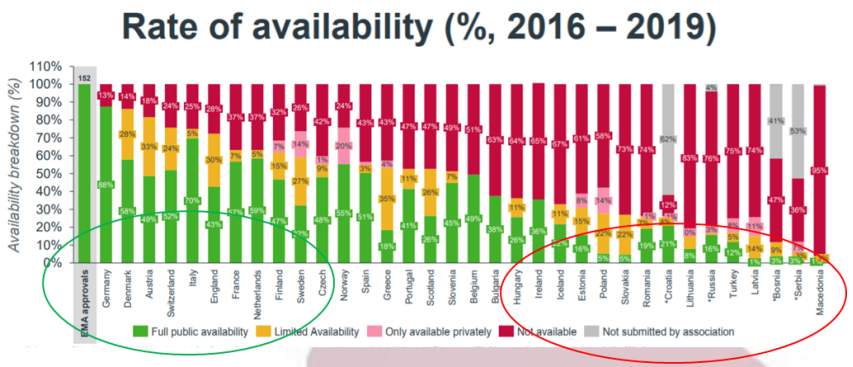
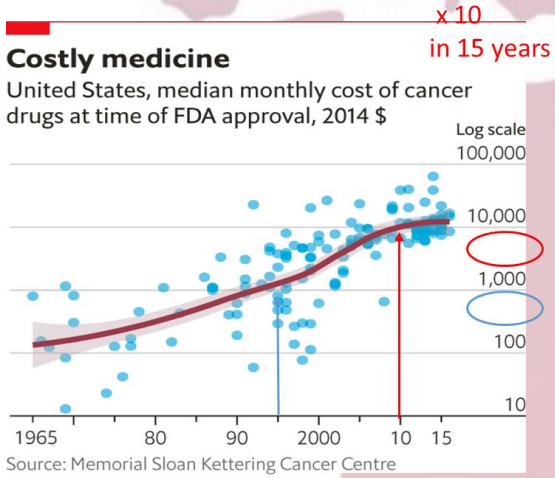
Why do we need fair prices ?

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



EFPIA Patients W.A.I.T. Indicator 2020 Survey



Company		Total revenue ($)	R&D costs ($)	Sales and Marketing costs ($)	Other activities' costs* ($)	Profit ($)	Profit Margin (%)
1.	Johnson & Johnson	71.3	8.2	17.5	31.8	13.8	19
2.	Novartis	58.8	9.9	14.6	25.1	9.2	16
3.	Pfizer	51.6	6.6	11.4	11.6	22.0	43
4.	Hoffmann-La Roche	50.3	9.3	9.0	20.0	12.0	24
5.	Sanofi	44.4	6.3	9.1	20,5	8.5	11
6.	Merck	44.0	7.5	9.5	22.6	4.4	10
7.	GSK	41.4	5.3	9.9	17.7	8.5	21
8.	AstraZeneca	25.7	4.3	7.3	11.5	2.6	10
9.	Eli Lilly	23.1	5.5	5.7	7.2	4.7	20
10.	AbbVie	18.8	2.9	4.3	7.5	4.1	22
Total Top 10 global companies Percentage of total revenue – profit		429.4	65.8 (19%)	98.3 (29%)	175.5 (52%)	89.8	20.9%

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

https://www.youtube.com/watch?v=aabrV1OmLU0

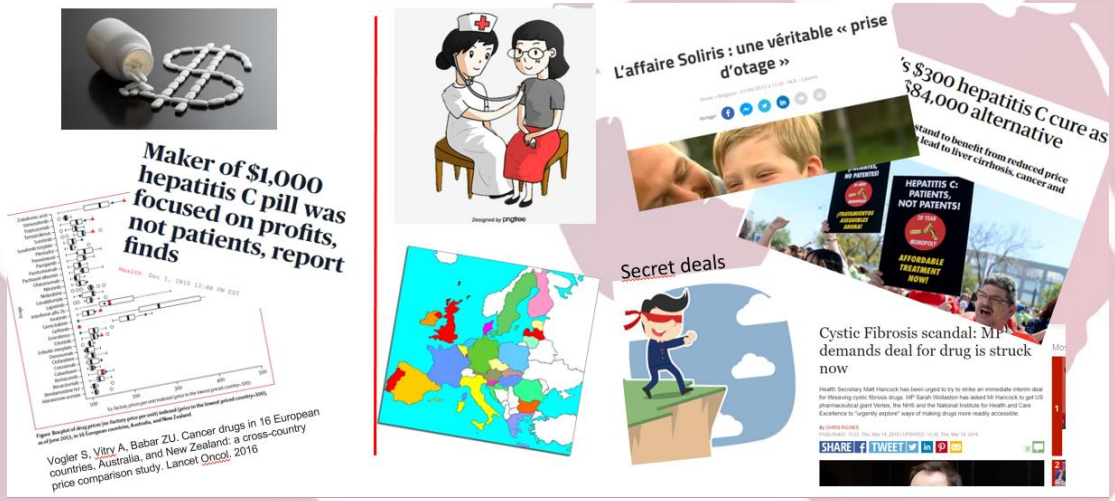
What’s wrong with the price setting?

Difficult negotiations and dangerous concepts

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

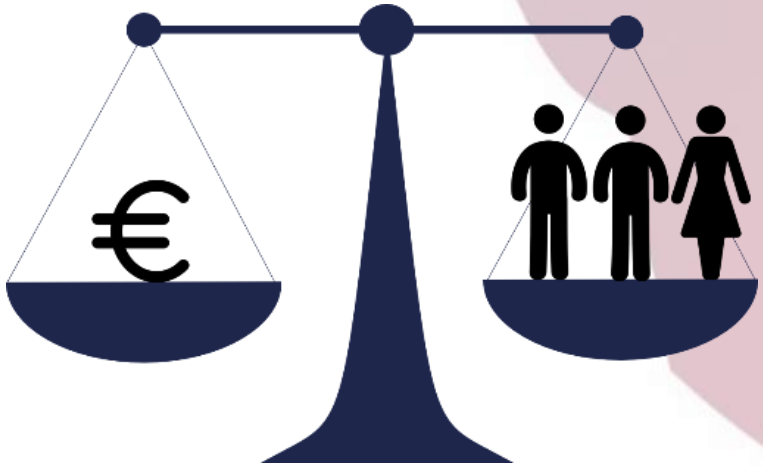
Anchoring : cognitive bias to rely too heavily on the first piece of information offered (the "anchor") when making decisions

Source : The Anchoring Effect and How it Can Impact Your Negotiation. Program on Negotiation, Harvard Law School (2019)

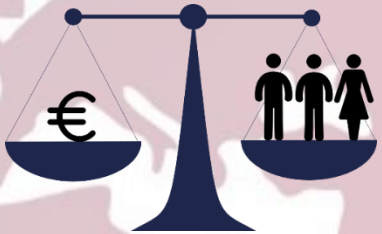


PRO(mise)S	CON(sequences)S
• highest possible health gains • in a given budget	• uncertain health gains • increased prices -> budgets ++ -> limitation in access
• Price reflecting a societal choice : "willingness (and ability) to pay" of each country	• Price = "what the market can bear" • Same (high) price everywhere (no link with GDP)
• Incentive for innovation (high value for patients)	• Incentive for me-too's (with small incremental value)
• Objective value-based	• Emotion-based

How do we reach fair prices ?



Setting new transparent rules



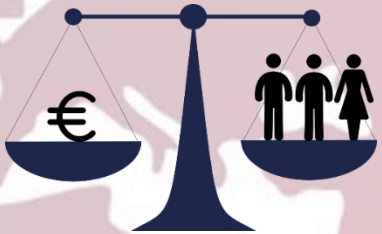
Fair price = "one that is **affordable** for **health systems and patients** and that at the same time provides sufficient **market incentive for industry** to **invest in innovation** and the production of medicines". **(WHO)**

Fairness to seller	Fairness to buyer (and patient)
1. Covering R&D costs	1. Affordability (necessary quantity)
2. Covering costs of manufacturing/distribution and registration/postapproval/admin	2. Link to value to the individual and society (to incentivize better products)
3. Fair profit (RoI)	3. Supply security

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 informat° + Basic profit + Innovat° bonus = European fair price

-> one EU price for every new drug

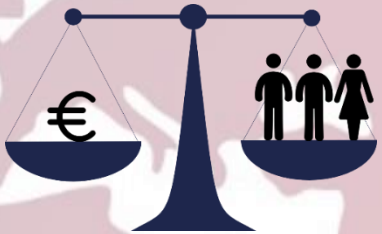
A mechanism can be added to make a link with the wealth of each MS (compensation fund)

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

- **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, …

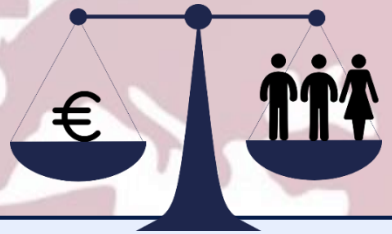
No transparency ⇨ €250 million **lump sum** (no justification required)

X 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)

= R&D per patient (per treatment)

Current parameters of the model



Product°& overhead costs

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

Composition of the drug	Cost per month of treatment
Chemical	50€
Chemical orphan	250€
Biological	150€
Biological orphan	750€
Gene or cell therapy	60.000€ (one shot)

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

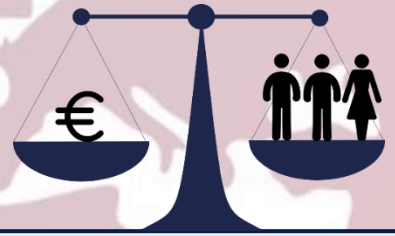
Sales medical informat°

- 20% of R&D

Basic profit

- 8% of total costs

Current parameters of the model



Innovation bonus

= incentive for innovation that matters, addressing therapeutic needs

+ 5 to 40% of total costs

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

Select one or more items :

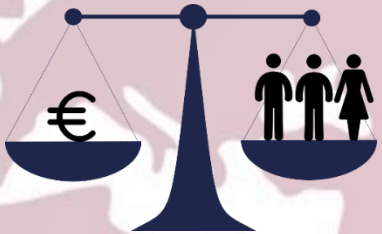
5%	The medicine is indicated for a life-threatening or chronically debilitating disease
5%	The medicine has no alternative
30%	The medicine is curative (the disease is cured) or has a major impact on the course of the disease
5%	The medicine has shown a progression-free survival (PFS) gain vs the comparator of at least 6 months or 50%
5%	The medicine has shown an overall survival (OS) gain vs the comparator of up to 6 months or has a *minor* impact on the course of the disease
10%	The medicine has shown an overall survival (OS) gain vs the comparator of more than 6 months or has a *moderate* impact on the course of the disease
10%	The medicine has shown a *major* improvement of the quality of life (QoL)

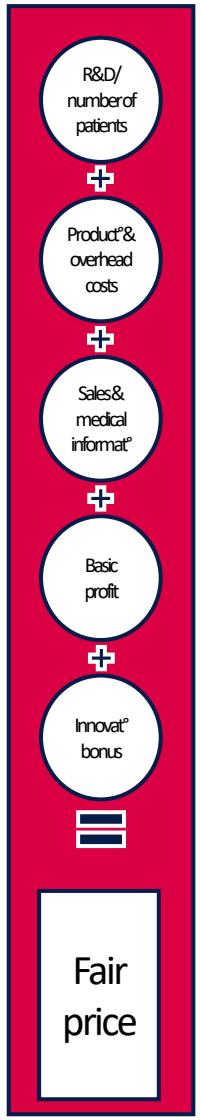
Link profit to therapeutic value

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,…)
- …

Example : hepatitis C drug - AIM price





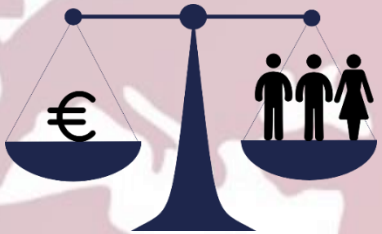
FAIR PRICE COMPONENTS (per treatment per patient)

R&D cost	384,54 €
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 €

Does the model make a big difference ?

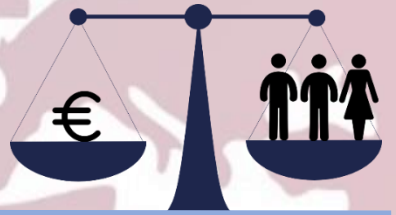


5 to 10 times lower!

Type indication Prevalence *Type treatment*	Market share	R&D global	R&D per patient for full treatment	Production costs /month	Treatment duration (months)	Innovation bonus	Fair price/year for one patient	Current price/year for one patient
Rare disease 3/100 000 *chemical*	50%	€800 million	€85 843	€250	120	20%	€16 966	€200 000 to €500 000
Ultra-rare 1/100 000 *gene or cell*	100%	€250 million	€40 056 (per treatment)	€60 000 (per treatment)	/	15%	€132 923	€700 000 to €2 million
Cancers 50/100 000 *biological*	100%	€2,5 billion	€801 (per treatment)	€150	12	40%	€4 087	€30 000 to €100 000
Chronic disease (hepatitis, severe asthma,...) 1% prevalence *biological*	33%	€250 million	€120	€150	120	5%	€2 050	> €10 000

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 negociating and compare with the price requested by the seller – also outside Europe


ELSEVIER
ScienceDirect
Cost-Based Price Calculation of Mexiletine for Nondystrophic Myotonia

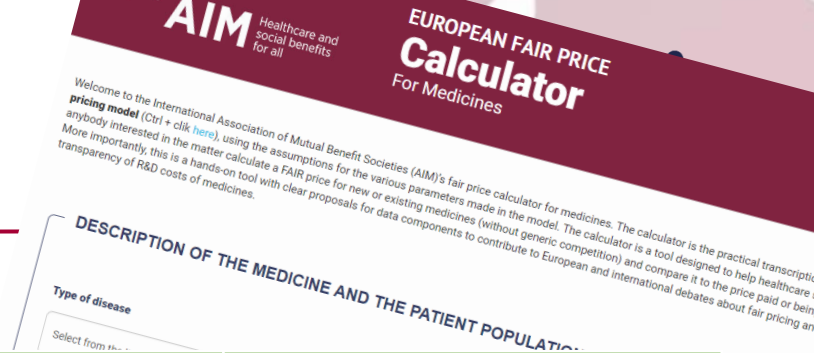
Long term : implementation at EU level

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

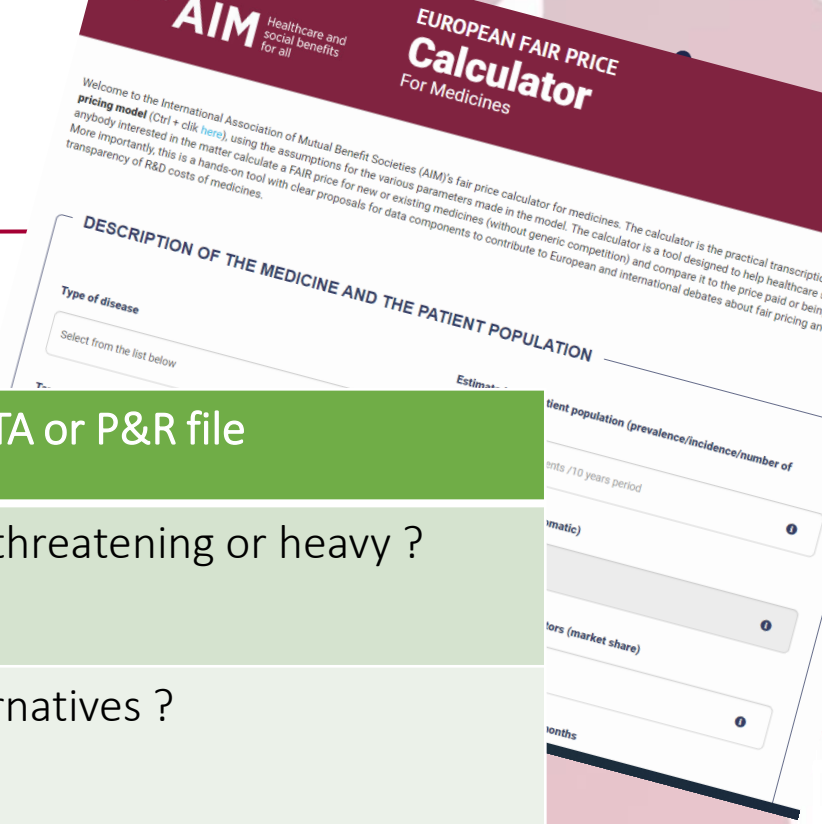
Data needed in calulator	Real/well documented	Otherwise
R&D	Real (global) including cost of failure (max €2,5 billion)	Lump sum of €250 million
Patient population	In P&R file	Prevalence/incidence of indication (websites)
Production costs	Real	Type of composition -> lump sum/month of €50/150/250/750/gene
Treatment duration	In P&R file	In SmPC

Today : AIM's calculator

- One appraisal :

value of the treatment

Appraisal in the calulator	In HTA or P&R file
Severity of disease	Life threatening or heavy ?
(Un)met need	Alternatives ?
Added therapeutic value	Curative ? Minor/moderate/major impact on disease? Major quality of life ?



Thank you!

AIM Healthcare and social benefits for all

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