



The International Association of Mutual Benefit Societies (AIM)

**AIM** Healthcare and  
social benefits  
for all

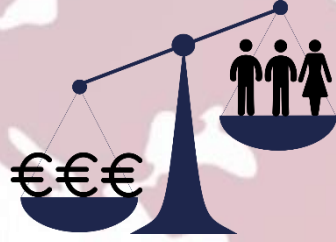
# Transparency of (real) pharmaceutical costs : Would transparency make a difference for payers ?

Anne Hendrickx



Transparency of (real) pharmaceutical costs - Januari 18, 2022

# 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



“Gilead’s marketing, pricing, and contracting strategies were focused on **maximizing revenue**—even as the company’s analysis showed a lower price would allow more people to be treated—not only for Sovaldi, but more importantly for its follow-on sofosbuvir-based product pipeline. Significantly, when confronted with the widespread initiation of access restrictions, Gilead refused to offer substantial discounts and did not significantly modify its contracting strategy to improve patient access.”



## ➤ Payers :

- Evaluate the (theoretical) therapeutic value (QALY)
- Limit to ability and willingness to pay (money threshold / budget) ?  
or **reluctancy to refuse?**

What the market can bear !

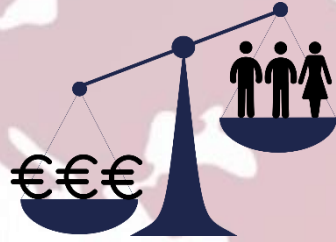
# How does it work today ?

➤ **Results** : unjustified high prices

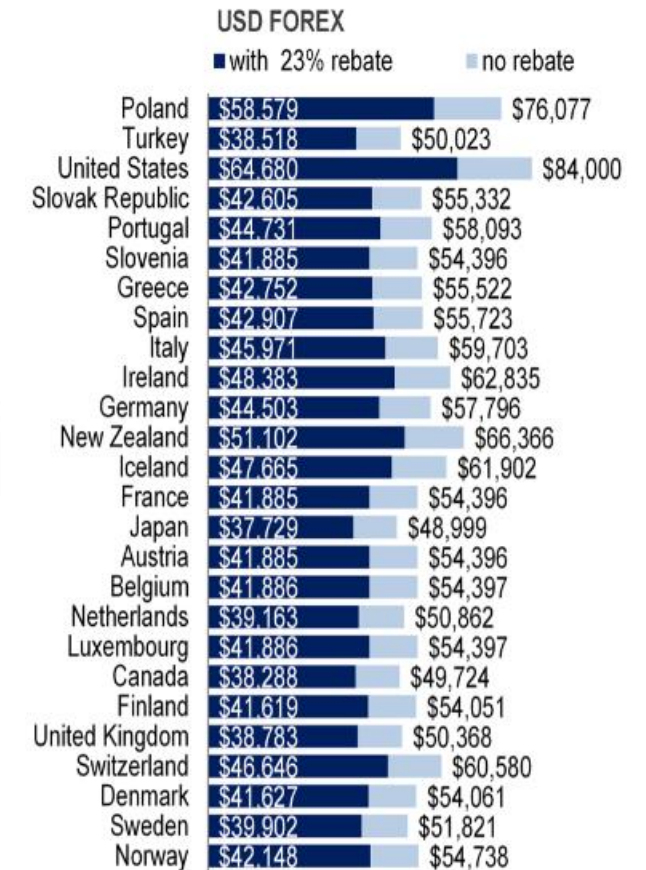
Example : Sovaldi  
(1st hepatitis C direct acting antiviral)

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 !

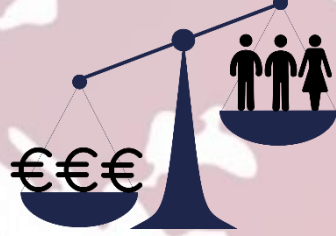


a) sofosbuvir price



Source : PLOS Medicine May 31, 2016

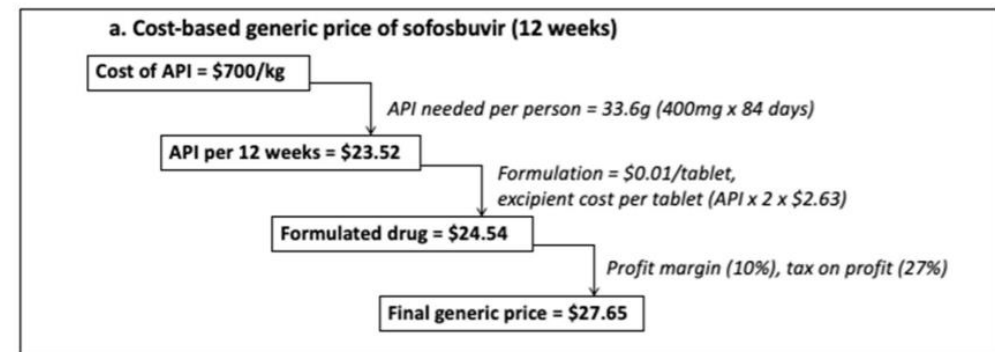
# Would transparency on costs make a difference ?



## 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) !!!**
- And very low **production costs** :

BMJ 2016;354:i3718 doi: 10.1136/bmj.i3718

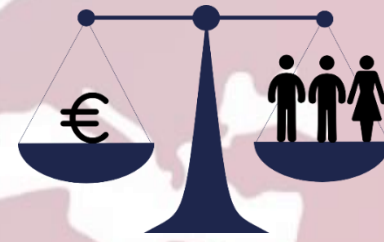


<https://doi.org/10.1016/j.jve.2020.06.001>

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

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

# No, but setting transparent and fair rules would !



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

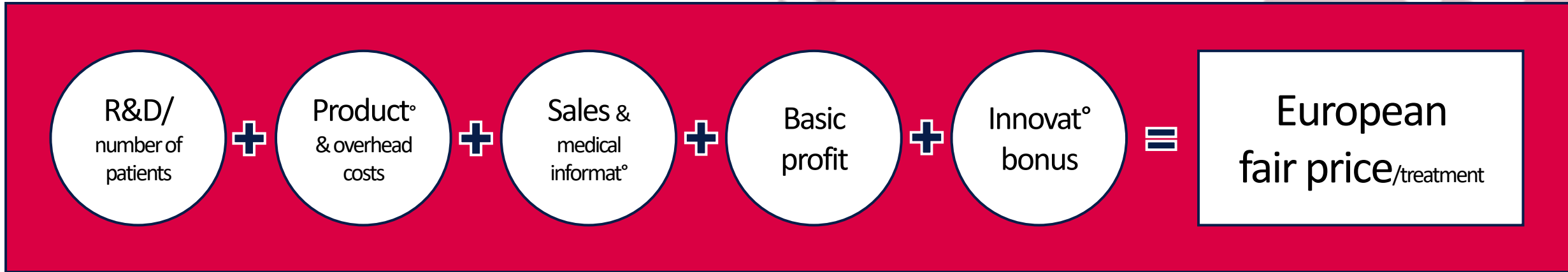
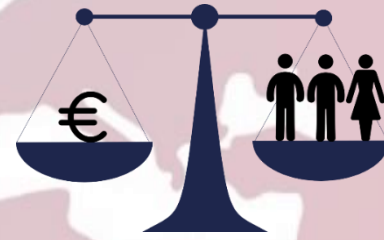
Fair price = “one that is affordable for health **systems and patients** and that at the same time provides sufficient **market incentive for industry** to **invest in innovation** and the production of medicines”.  
(WHO)

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

- 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

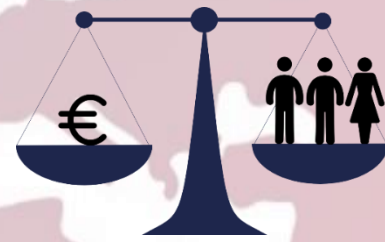
A mechanism can be added to make a link with the wealth of each MS (compensation fund)

Principles :

- Based on cost and value elements
- Not captive of full transparency
- Objective criteria



# Current parameters of AIM's model



## R&D

- 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, ...

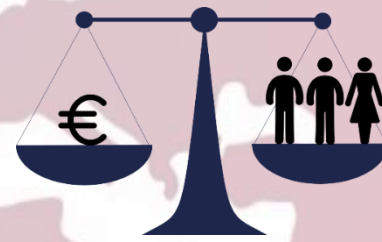
**Methodology : R&D by Pharmasset : 11 billion USD or 271 million USD???**

X 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)**

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not captive of full  
transparency

**No transparency**  $\Rightarrow$  €250 million **lump sum** (no justification required)

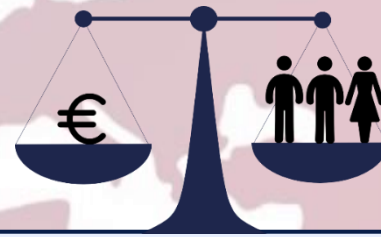
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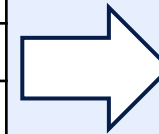
# Current parameters of AIM's model



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°

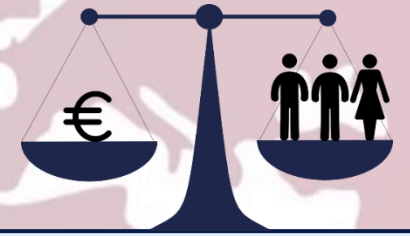
- 20% of R&D

Basic  
profit

- 8% of total costs

} Fixed %

# Current parameters of AIM's model



Innovation  
bonus

= incentive for innovation that matters, addressing therapeutic needs

cost and value  
elements

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

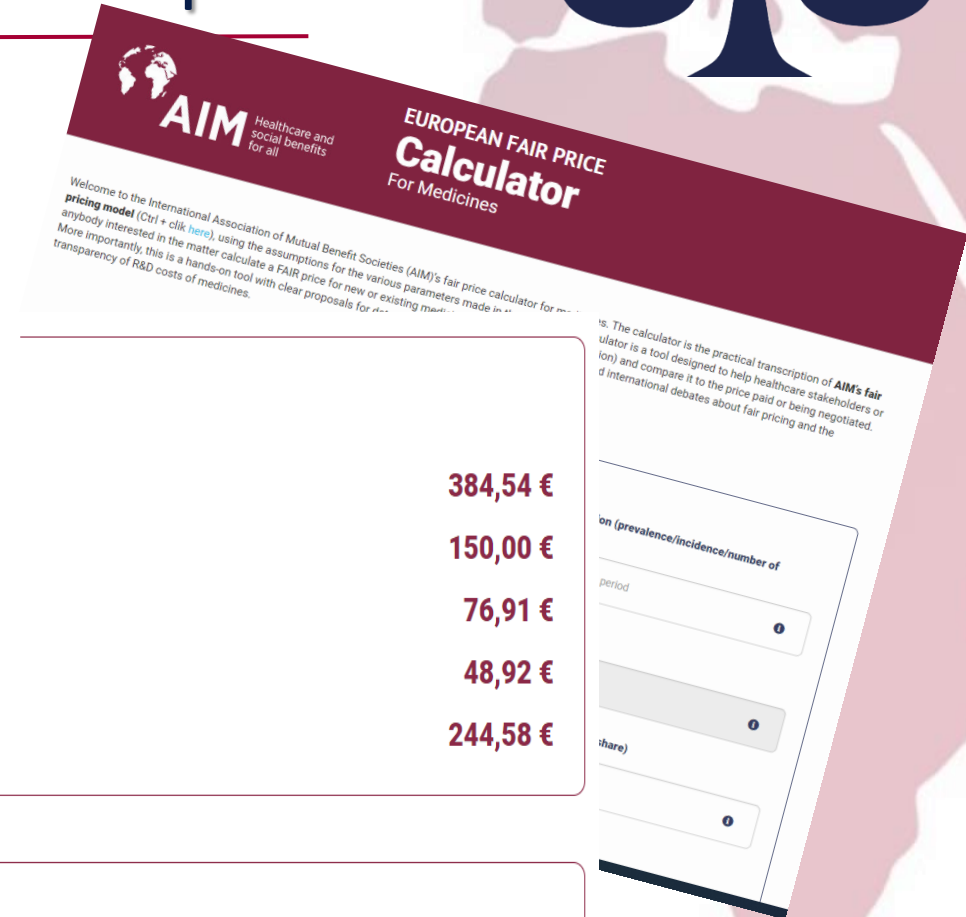
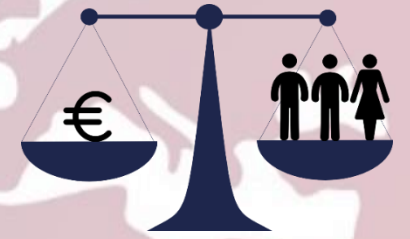
Select one or more items : ⓘ

- ☐ 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)

+ 5 to 40%  
of total  
costs

Link profit to therapeutic value =  
incentive for usefull innovation

# Example : hepatitis C drug - AIM price



## FAIR PRICE COMPONENTS (per treatment per patient)

➔ R&D cost	-> 800 million €	384,54 €
➔ Production cost	-> 3 x lumpsum 50€	150,00 €
➔ Sales and medical information	-> 20% R&D	76,91 €
➔ Basic profit	-> 8% costs	48,92 €
➔ Innovation bonus	-> 40% costs	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 !



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Journal homepage: [www.elsevier.com/locate/jval](http://www.elsevier.com/locate/jval)

## Cost-Based Price Calculation of Mexiletine for Nondystrophic Myotonia

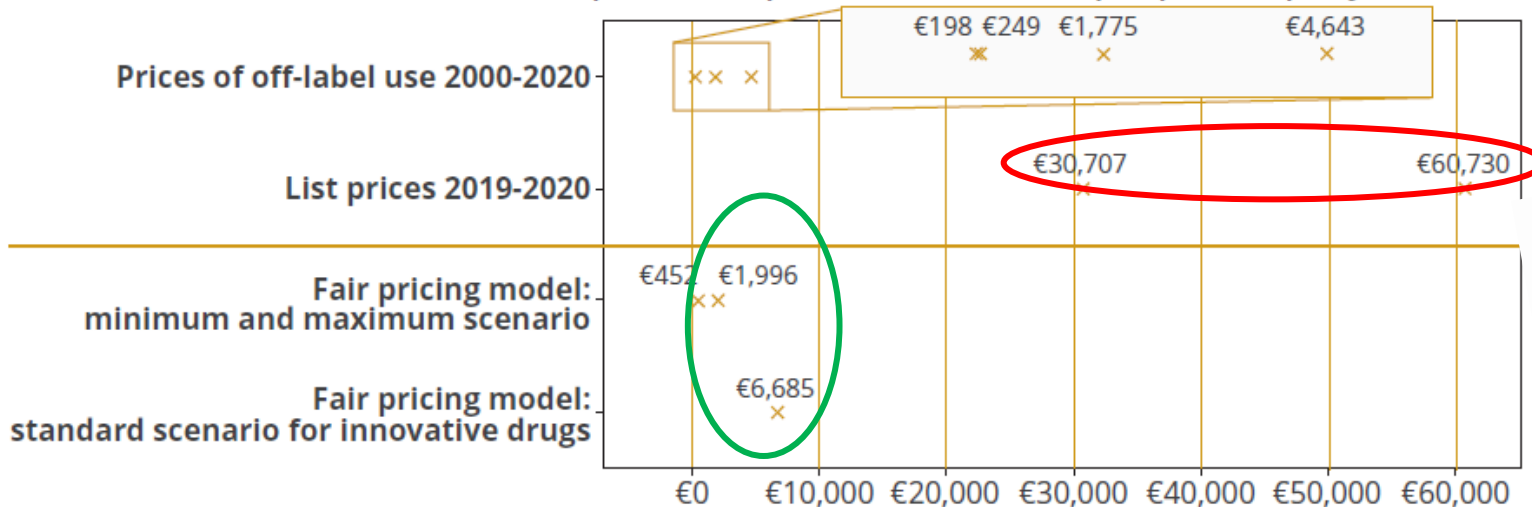
Sibren van den Berg, MSc, Vincent van der Wel, MSc, Saco J. de Visser, PhD, Bas C. Stunnenberg, MD, MSc, Lonneke Timmers, PharmD, PhD, Martijn H. van der Ree, MD, Pieter G. Postema, MD, PhD, Carla E.M. Hollak, MD, PhD

### ABSTRACT

**Objectives:** Mexiletine is a long-known drug used for the treatment of arrhythmias and repurposed in the 1980s for patients with nondystrophic myotonia (NDM). Recently, the price of mexiletine in Europe increased significantly after registration as an orphan drug for NDM. This led to international discussions on affordability and willingness to reimburse mexiletine in the absence of background information that would justify such a price. Our objective was to calculate a cost-based price for mexiletine for adult patients with NDM based on detailed information on development costs.

<https://doi.org/10.1016/j.jval.2021.02.004>

Comparison of prices of mexiletine per patient per year



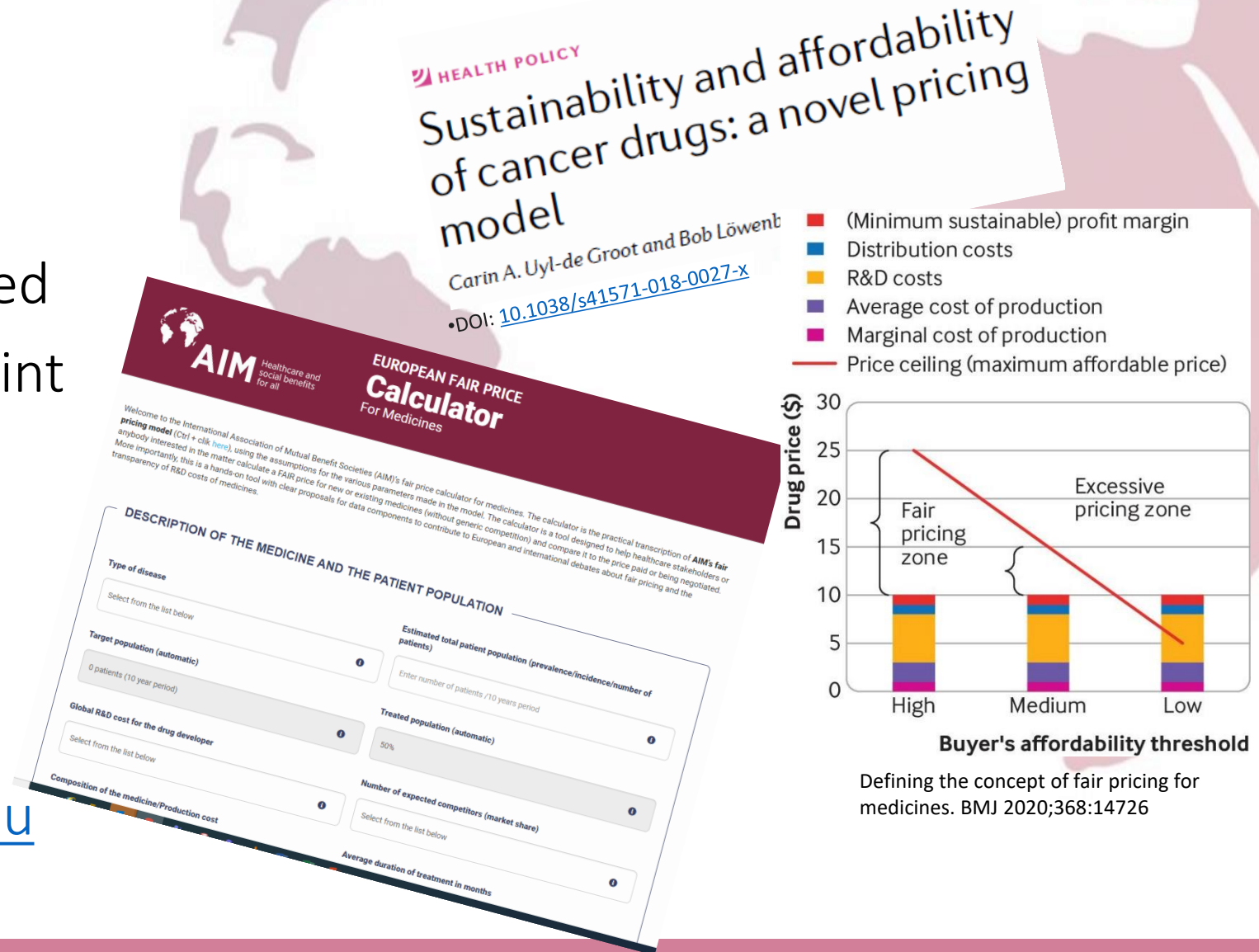
Bij de uitspraak dat de prijs van Namuscla onnodig hoog is baseert het Zorginstituut zich op een rekenmodel dat zij, samen met onderzoekers van het Amsterdam UMC, hebben ontwikkeld.<sup>4</sup> Omdat het ontwikkeltraject van Namuscla niet uitgebreid was en de kosten relatief eenvoudig te schatten waren, is het mogelijk dit model te hanteren. Ik vind **dit rekenmodel** voor dergelijke situaties een **waardevolle ondersteuning**, conform ik in mijn antwoorden op Kamervragen over dit model ook heb aangegeven.<sup>5</sup>

[www.rijksoverheid.nl/documenten/kamerstukken/2021/07/07/kamerbrief-over-geen-opname-namuscla-in-basispakket](http://www.rijksoverheid.nl/documenten/kamerstukken/2021/07/07/kamerbrief-over-geen-opname-namuscla-in-basispakket)

# 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](http://www.fairpricingcalculator.eu)



# Thank you!



## AIM

Healthcare and  
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for all

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