



AIM

Healthcare and
social benefits
for all

FAIR PRICES FOR
PHARMACEUTICALS

WHY AND HOW ?

4 December
9.00 – 11.00

European Parliament,
Room ASP 5G305

Hosted by MEP Ismail Ertug (S&D, DE)



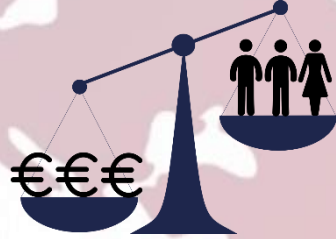
EUROPEAN FAIR PRICES

AIM's model

Anne Hendrickx
Socialist mutual fund (*Belgium*)



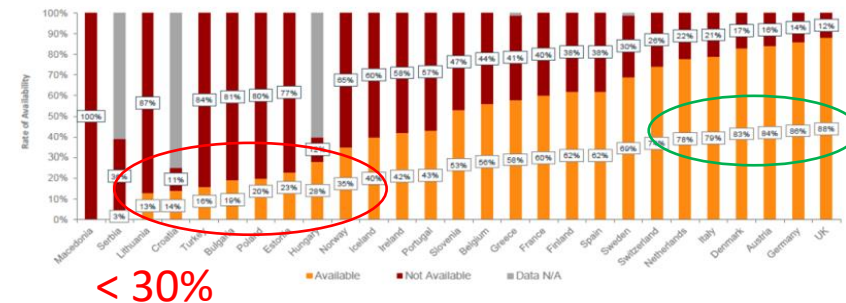
Why do we need fair prices?



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

Rate of Availability (%)

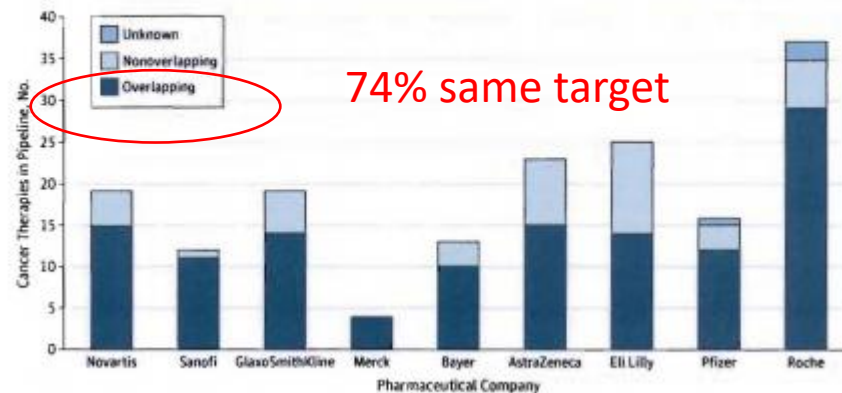
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2018: for most countries this is the point at which the product gains access to the reimbursement list.



Data N/A- data is not provided by associations (companies have not sent data or are not members of the association)

IQVIA

Figure 2. Comparison of Cancer Therapies in the Pipelines of Pharmaceutical Companies According to Their Putative Mechanisms of Action



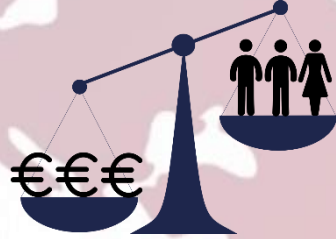
Unintended consequences of expensive cancer therapeutics. Fojo et al, JAMA 2014

Pharma giant Pfizer pulls out of research into Alzheimer's

10 January 2018



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

Health Dec 1, 2015 11:30 AM EST
10 largest companies (2014)
▪ \$66 bio R&D
▪ \$98 bio marketing
▪ \$90 bio profit
DiMasi et al. 2016

Cystic Fibrosis scandal: MP demands deal for drug is struck now

Health Secretary Matt Hancock has been urged to try to strike an immediate interim deal for lifesaving cystic fibrosis drugs. MP Sarah Wollaston has asked Mr Hancock to get US pharmaceutical giant Vertex, the NHS and the National Institute for Health and Care Excellence to "urgently explore" ways of making drugs more readily accessible.

By CHRIS RICHES

PUBLISHED: 13:22, Thu, Mar 14, 2019 | UPDATED: 13:30, Thu, Mar 14, 2019

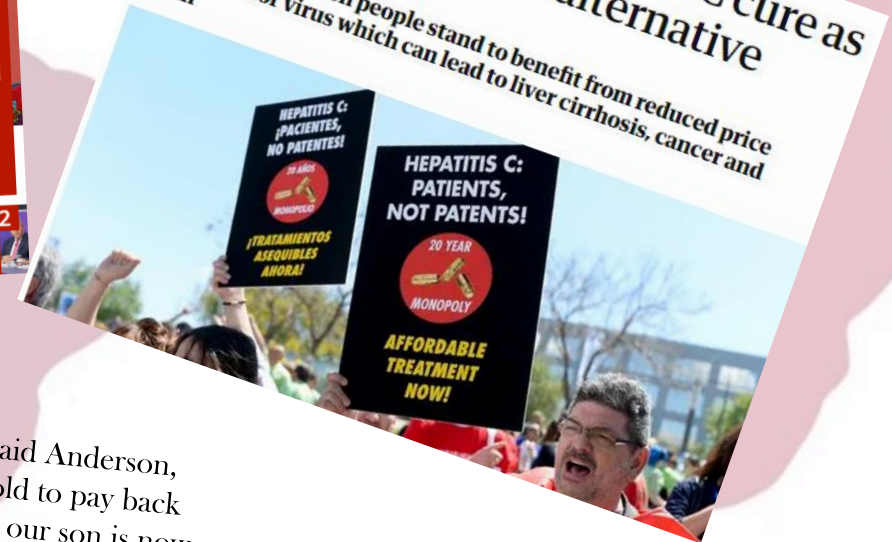
SHARE f TWEET in p



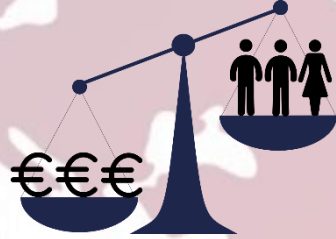
"To me, you cannot put a price on your child's life," said Anderson, who lives in Mansfield, Ohio. "If tomorrow we were told to pay back everything, we would. We would figure it out. Because our son is now alive and well."

Non-profit's \$300 hepatitis C cure as effective as \$84,000 alternative

Exclusive: 71 million people stand to benefit from reduced price treatment for virus which can lead to liver cirrhosis, cancer and death



Tricky concepts : Value based pricing

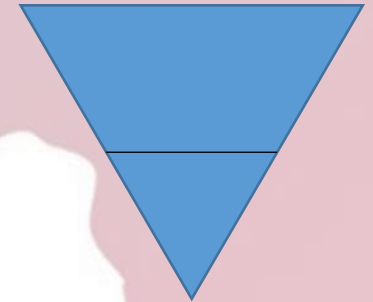


Nice concept supposed to allow comparison
(international and amongst treatments) on objective criteria but ...



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 ?



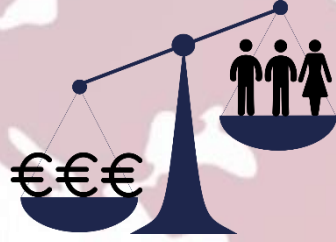
"Over the past few months, Novartis CEO Dr. Vasant Narasimhan tossed out a bunch of price anchors for Zolgensma that ranged from \$1.5 million to \$5 million. Just before the big reveal, he told reporters the price would be well shy of \$5 million, and it was. MEA everywhere for everything

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 ?

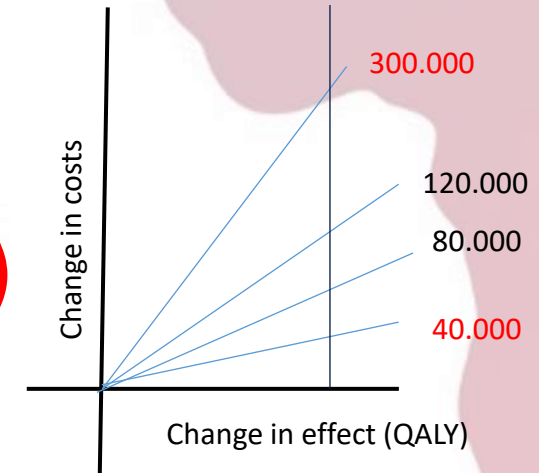
= ensure the **maximum health gain** for the budget ?

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

Negotiation starting point totally disconnected from costs

= profit

or **profiteering** ?



-
- The diagram illustrates various international groupings and their member countries, categorized into several groups:
- BeNeLuxA**: Belgium, Netherlands, Luxembourg, Austria.
 - Spanish-Portuguese Initiative**: Spain, Portugal.
 - The Valletta Declaration**: Greece, Ireland, Italy, Cyprus.
 - Romanian & Bulgarian Initiative**: Romania, Bulgaria.
 - Sofia Declaration**: Hungary, Slovakia, Czech Republic, Poland, Estonia, Latvia, Lithuania.
 - Visegrad+2 Group**: Poland, Czech Republic.
 - Baltic Partnership**: Estonia, Latvia, Lithuania.
 - Nordic Council**: Finland, Denmark, Norway, Sweden, Iceland.
 - NLF**: Netherlands, Luxembourg, Finland.

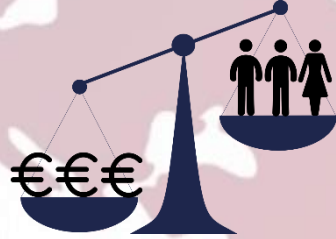


Comment | Published: 25 November 2019

Alain Fischer , Mathias Dewatripont & Michel Goldman

6

Because every stakeholder has new tools...



Industry

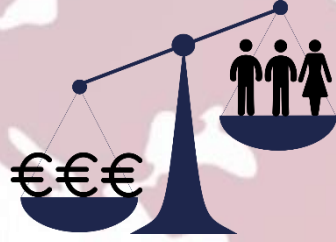
- Adaptive pathways
- Creative outcome based agreements (ICER/QALY on 80 years horizon)
- Innovative payment schemes (annuity based, ...)

And patients !

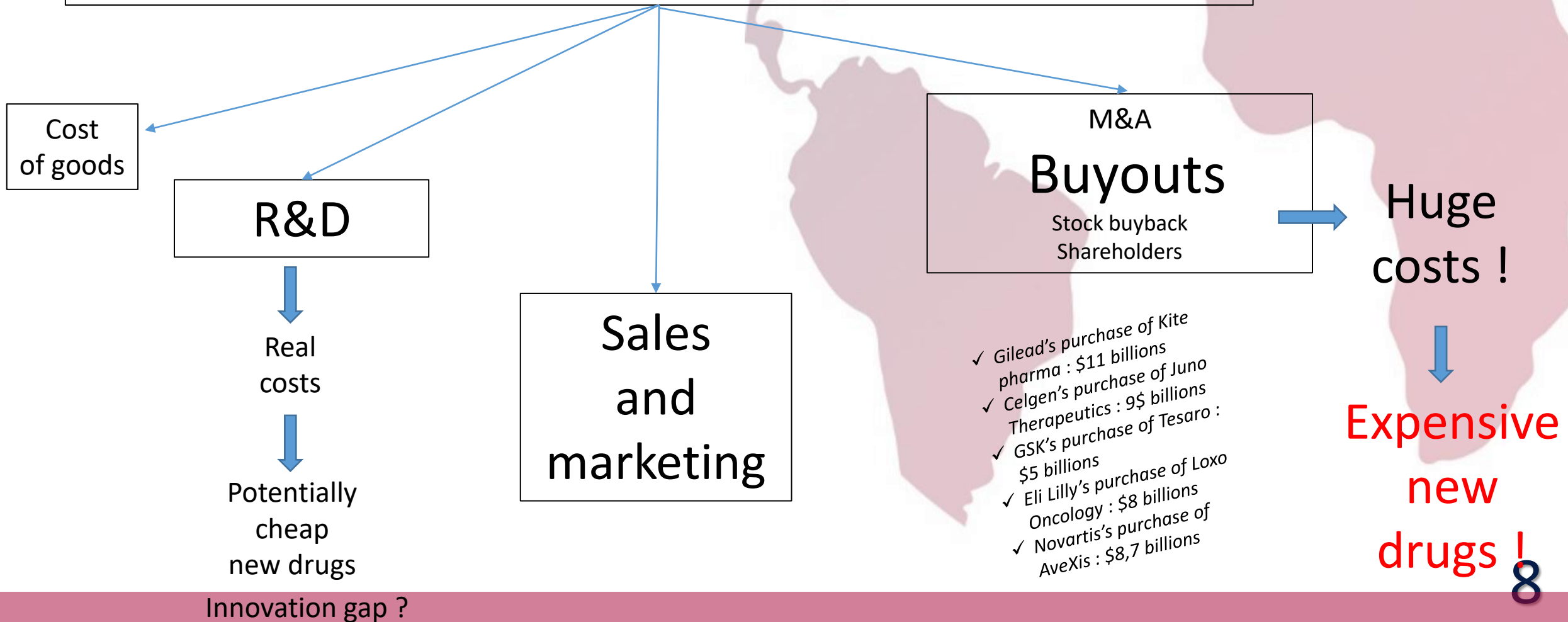
- A belgian family got a (€1,9 million) drug paid by a crowdfunding campaign !



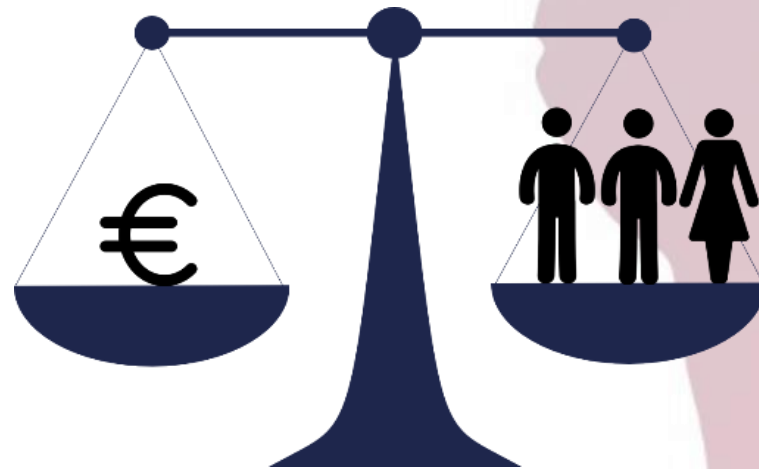
And it won't stop !



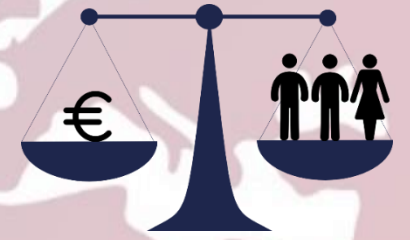
(excessive) Global revenues



How do we get fair prices ?????

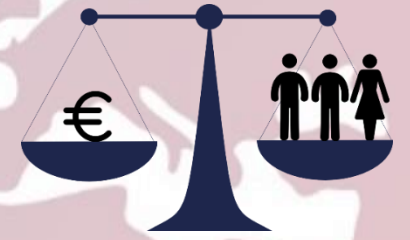


How can we get fair prices ?

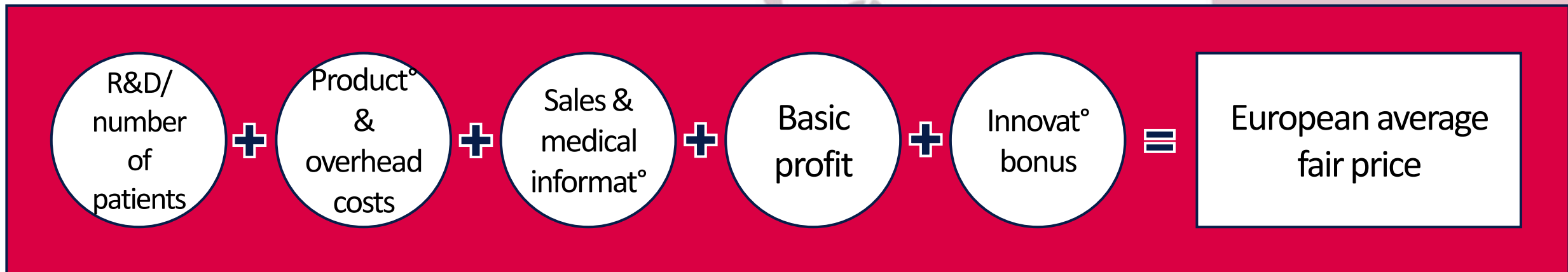


- Defining **our rules**
and **our limits** (willingness to pay)
 - Restoring **balance in negotiation** (EU28 = 1 market)
 - Link to the **wealth** of each MS
 - Restoring link with **reality** (costs)
- + **predictability**
and **transparency** (at least on the method)
- Fair price = “one that is **affordable** 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 ?

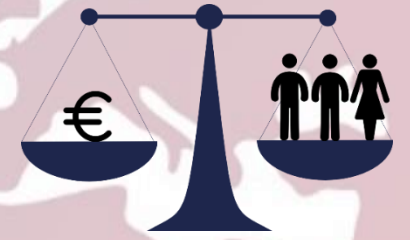


A new model = AIM's algorithm :



Model developed by AIM's Working group on Pharmaceuticals and Medical devices

Proposed parameters of the model



R&D

- **Transparency** → real amount R&D (global)
- But maximum : €2,5 billions at the start
- **No transparency** : €250 million lump sum

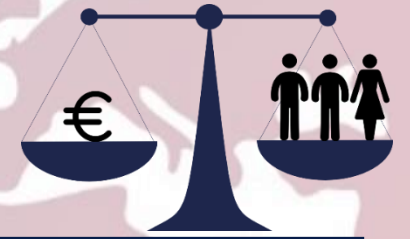
Including cost of failure (but only once – audit needed)

Clear rules about :

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

*Røttingen J, Regmi S, Eide M et al. The Lancet 2013

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

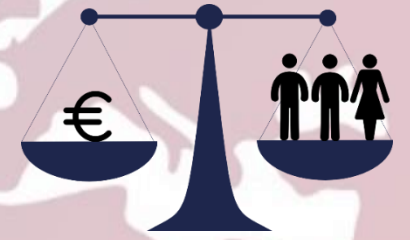
- 50% treatment rate (global for EU 28)
- and maximum 3 competitors for each drug
(to be confirmed by horizon scanning)

= R&D per patient



R&D per year

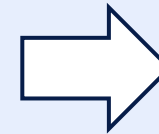
Proposed parameters of the model



Product°&
overhead
costs

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

Composition of the drug	Cost per month of treatment
Chemical	50€
Chemical orphan	250€
Biological	150€
Biological orphan	750€



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

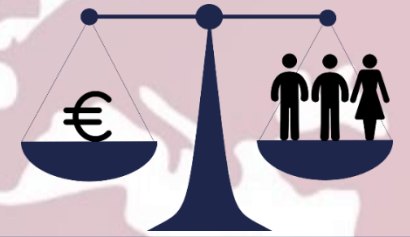
Sales &
medical
informat°

- 20% of R&D

Basic
profit

- 8% of total costs

Proposed parameters of the model



Innovation
bonus

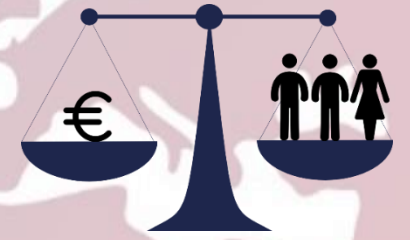
= incentive for innovation that matters, answering therapeutic needs

Example :	life-threatening or chronically debilitating or rare disease	5%
	+ no alternative	5%
	+ curative	30%
	Or if NOT curative:	
	progression free survival (PFS) vs comparator of > 6 months or > 50%	5%
	overall survival (OS) 1 to 6 months	5%
	overall survival (OS > 6 months	10%
	major quality of life (QOL) improvement	10%

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



European average
fair price

Step 1 : **Average** fair price



Step 2 : differential price system based on GDP

-> fair price in each MS

= **maximum fair price in each MS**

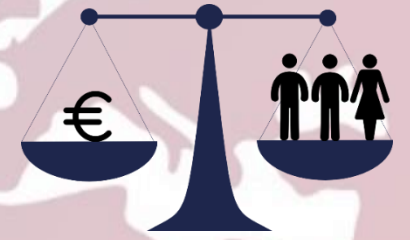


Step 3 : negotiation in each country

= **real fair price in each country**

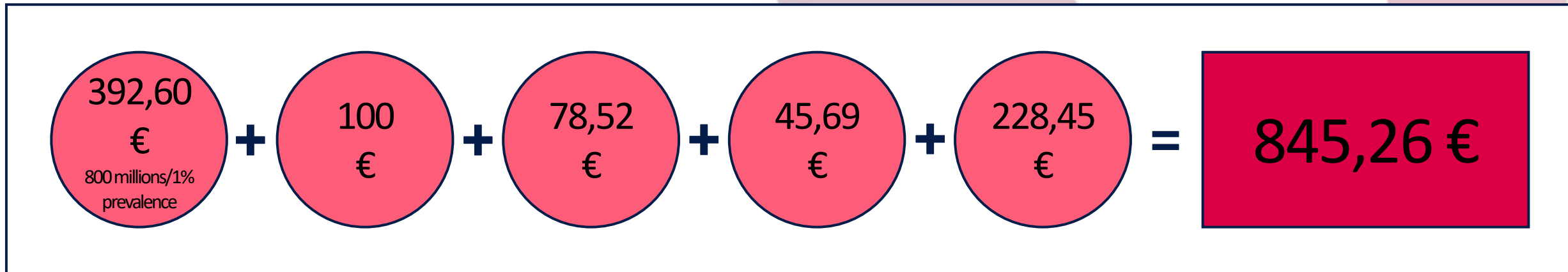
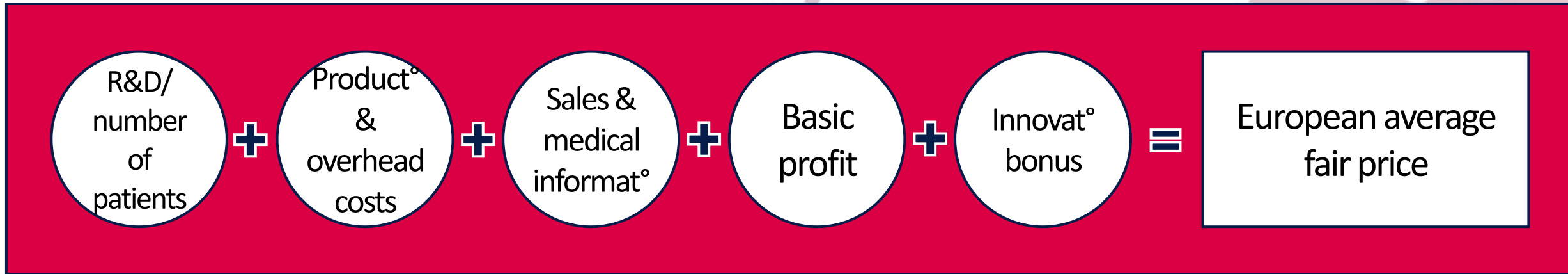
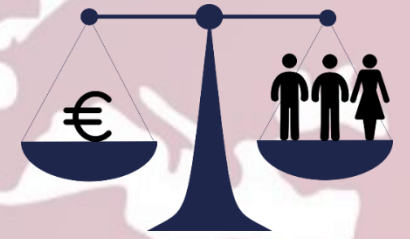
+ safety net : not higher than existing price in comparable system (New-Zealand, Canada,...)

Which medicines ?

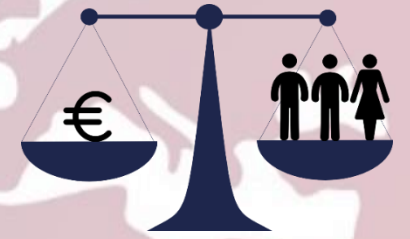


- All new entities registered at EMA level
- Price set for the first indication
- New price calculation (+ 10% R&D if no transparency) for the second and third indications (>< salami slicing)
- Me too / competitors : same price ? Only if same costs and same innovation level/innovation bonus (-> pushing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

Example : hepatitis C drug



Example : hepatitis C drug



Differential price

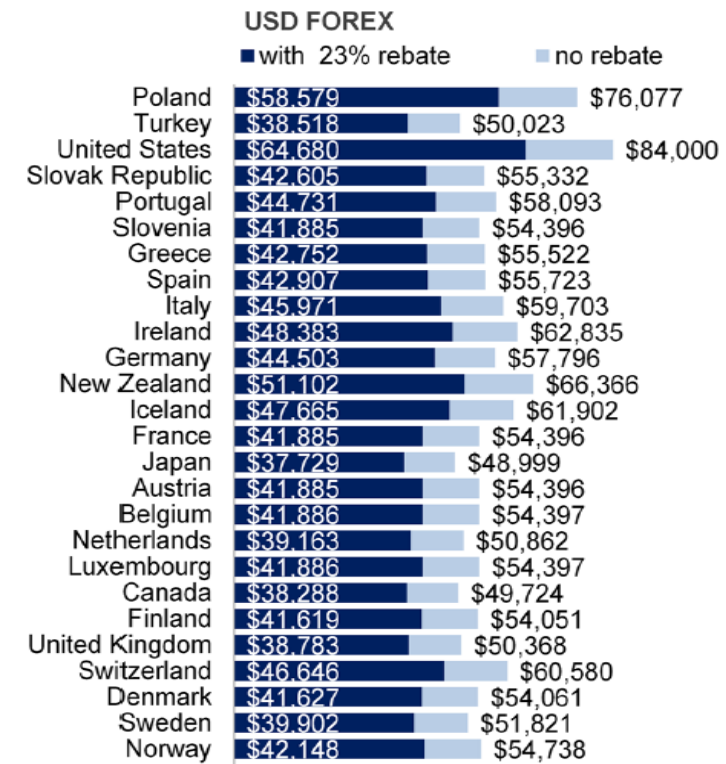
From €196 in Bulgaria

to €1.733 in Ireland (and €2.496 in Luxembourg).

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.

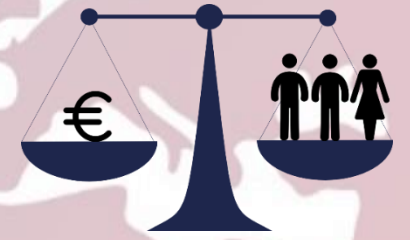
Lowest EU price : 38.783 \$

(a) sofosbuvir price



Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis - Swathi Iyengar et al.

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



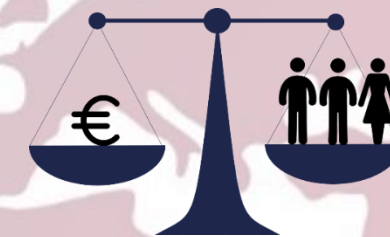
\$25.8 BILLION
HCV PROFIT
IN 5 YEARS



WITH **15.4%** OF THIS
AMOUNT, GILEAD COULD
HAVE PROVIDED
LIFE-SAVING TREATMENT
TO AN ESTIMATED
67 MILLION
PEOPLE WITH
HCV IN NEED...

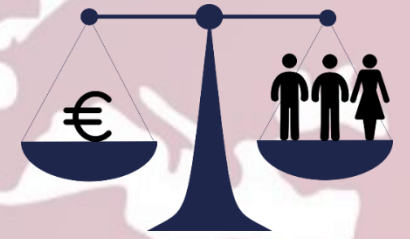


Does it make a big difference ?



	R&D per patient (global)	R&D per patient per year	Production/ year	Innovation bonus	Fair price/ year for one patient	Current price/ year for one patient
Ultra-rare disease 1/100.000 biological	122.687 € (250 millions)	12.269 €	9.000 € (750X12)	15%	29.179 € (6.760€-86.154€)	200.000€ to 500.000€
Rare disease (including cancer) 3/100.000 chemical	130.867 € (800 millions)	13.087 €	3.000 € (750X12)	20%	23.941 € (5.547€-70.688€)	200.000€ to 500.000€
Frequent cancers (per treatment) 50/100.000 incidence biological	2.454 € (2,5 billions)	2.454 €	1.800 € (150x12)	40%	7.022 € (5.547€-70.688€)	30-100.000 €

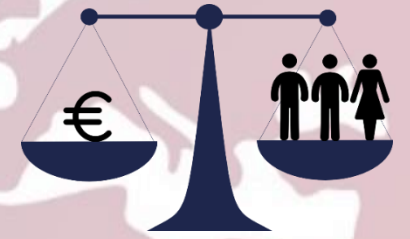
Does it make a big difference ?



	R&D per patient (global)	R&D per patient per year or * treatment	Production/ year	Innovation bonus	Fair price/y ear for one patient	Current price/year for one patient
Viral and chronic disease (hepatitis, severe asthma,...) 1% prevalence biological	€ 393 € (800 millions)	39,3 €	1800 € (150x12)	5%	2.087 €	> 10.000€
Chronic disease (diabetes, Alzheimer's,...) 5% prevalence chemical	€ 245 € (2,5 billions)	24,5 €	120 € (10*x12)	40%	221 €	500-1.000€

*for very frequent diseases, production costs will drop (/5).

Inspiring ?



	R&D per patient (global)	Production	Innovation bonus	Fair price for one patient	Current price for one patient
Ultra-rare disease 1/100.000	122.687 € (250 millions)	100.000€ ????	40% ????	365.893€	1,9 millions ?

Comment Novartis va s'enrichir grâce à l'argent du Téléthon

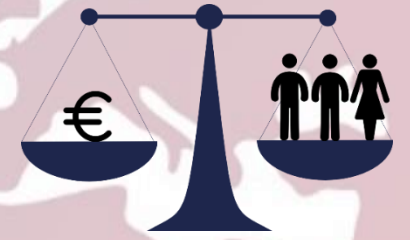
Par Stéphanie Benz,
publié le 03/06/2019 à 17:00 , mis à jour à 17:33



« 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).** »

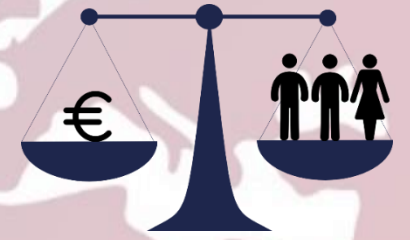
Prescrire

Who ? Where ? When can it start ?



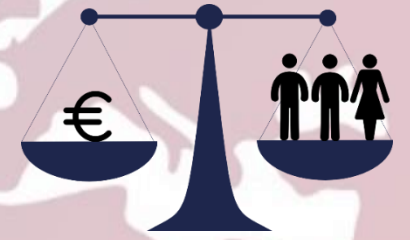
- Average price and national maximum prices to be set **at the time/just after registration** (avoiding regulatory delays)
- By existing european body (close to EMA, new european HTA body ?) – preferably **no additional body**
- Possible implementation ? Not short term ...
but payers could already be inspired by the model
for (inter)national negotiations !

What else do we need to adapt ?



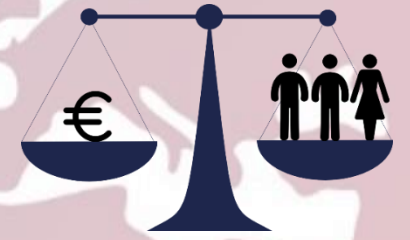
- External reference pricing : STOP
- Industry's quotas : STOP (no new shortages !!!!!)
- Parallel trade : STOP
 - legal (exception to parallel trade) ?
 - tracking system (European Medicines Verification System)?

Is it really going to help ?



- Unique (maximum) price together with registration
 - reduced **delay** in access
 - symmetry in information (not need for MEA on prices)
 - **balance in negotiation** power
 - less HR in pricing and reimbursement (and more in R&D?)
 - **SOLIDARITY**

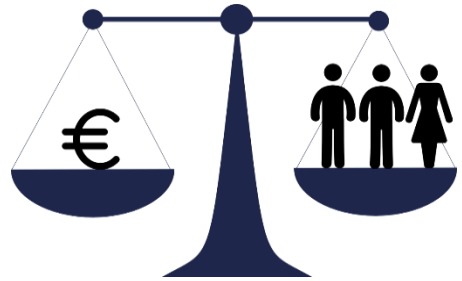
Is it really going to help ?



- 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 !



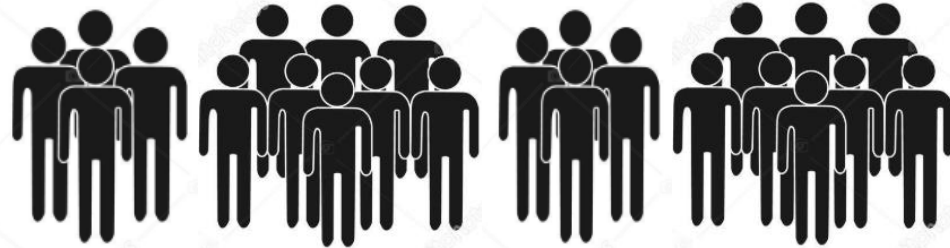
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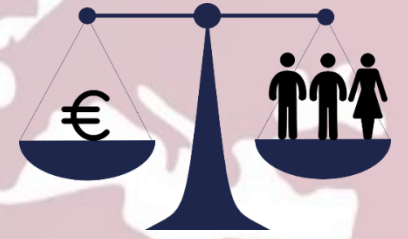
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Eradication ?

Want to know more ?



AIM

Healthcare and
social benefits
for all

AIM PROPOSES TO ESTABLISH A EUROPEAN DRUG PRICING MODEL FOR **FAIR AND TRANSPARENT PRICES** FOR 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
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www.aim-mutual.org

Follow us on Twitter!



@AIM_healthcare

FAIR PRICES FOR
PHARMACEUTICALS

WHY AND HOW ?

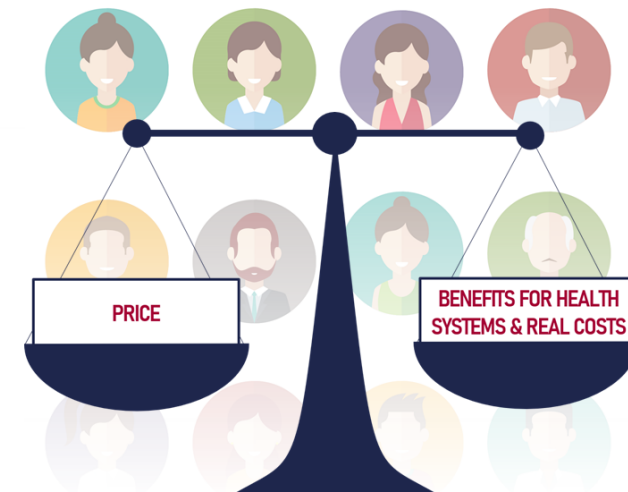
4 December
9.00 – 11.00

European Parliament,
Room ASP 56305

Hosted by MEP Ismail Ertug (S&D, DE)



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