

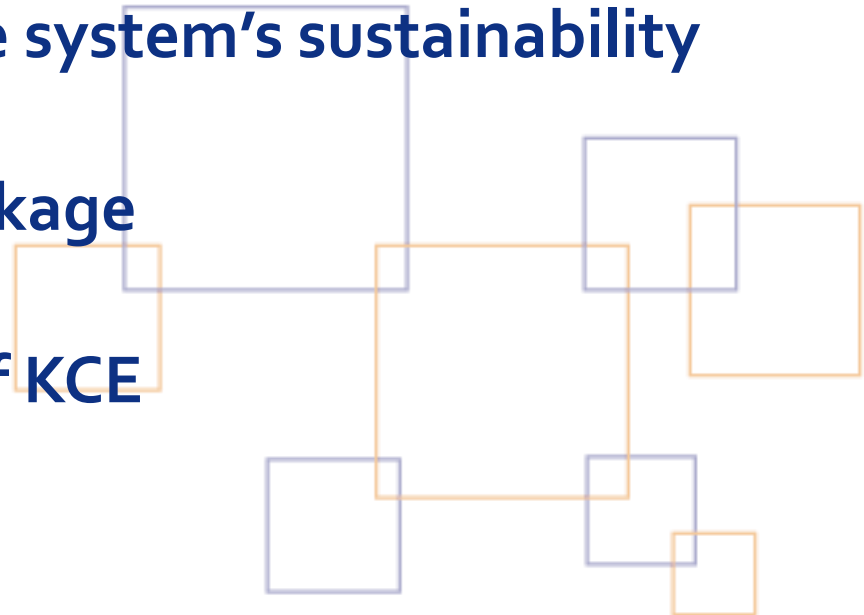
The EU pharmaceutical revision and HTA: A revolution or much of the same?

**Yannis Natsis, Director
European Social Insurance Platform (ESIP)**

Symposium '20 years KCE', Brussels, 30 November 2023

Symposium '20 years KCE'
*The EU pharma revision & HTA:
A revolution or much of the same?*

- **The legacy of the covid19 pandemic**
- **The financialization of pharma**
- **Evidence gaps & the system's sustainability**
- **The EU pharma package**
- **The next 20 years of KCE**





ESIP's Mission:

- Health systems=pillar of the welfare state
- Solidarity at the core



Before covid19



- I want you to look at ways to help ensure Europe has the **supply of affordable medicines** to meet its needs. In doing so, you should support the European pharmaceutical industry to ensure that it remains an innovator and world leader.

Stella Kyriakides

Commissioner for Health and Food Safety

The legacy of the pandemic



EU executive rebuked for not disclosing Von der Leyen-Pfizer texts

Regulator heavily critical of aides to European Commission president in relation to Covid vaccine messages



FROM POLITICO PRO

MEPs want to grill von der Leyen over Pfizer vaccine contract

The European Parliament's COVID-19 committee will ask the European Commission president to appear before the panel.



**European Commission sued
over von der Leyen's secret
Pfizer texts**

The legacy of the pandemic

‘Who needs HTA, when everything can be arranged at procurement?’



01 October 2021 - Assessment of COVID-19 monoclonal antibodies is needed

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The Beneluxa Initiative considers value assessments of medicines prior to reimbursement in their respective countries, to be essential in quantifying the potential added benefit of treatments relative to the price requested. This concept was reaffirmed in a recent joint statement with the Nordic Pharmaceutical Forum.¹

The urgency of the pandemic had required some changes to normal medicine regulatory processes to tackle the global pressure on health systems; for the EMA this has resulted in the introduction of rolling reviews. Rolling reviews involve a real time examination of evidence to establish if sufficient information is available to support a marketing authorization. This allowed countries to prepare early on for joint procurement of e.g. vaccines at an exceptional time.

More recently the EMA has begun rolling reviews on monoclonal antibodies to treat some patients with COVID-19 (September 2021)². However the Beneluxa considers it appropriate at this stage of the pandemic that these therapies³ are assessed for value within established national processes, before decisions on reimbursement or procurement are made. Informed decision making in this matter includes exchange of available HTA information within Beneluxa.

¹ <https://amgros.dk/4889/>

² <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-covid-19/covid-19-treatments-under-evaluation>

³ <https://www.bmj.com/content/374/bmj.n2231>

EU in times of permacrisis

**Cut
dependencies**

**Supply
resilience**

**Strategic
autonomy**



Financialization of pharma

? Where is public investment in pharmaceutical R&D most needed to address **unmet societal needs**?

? What constitutes socially acceptable **pharmaceutical prices**?

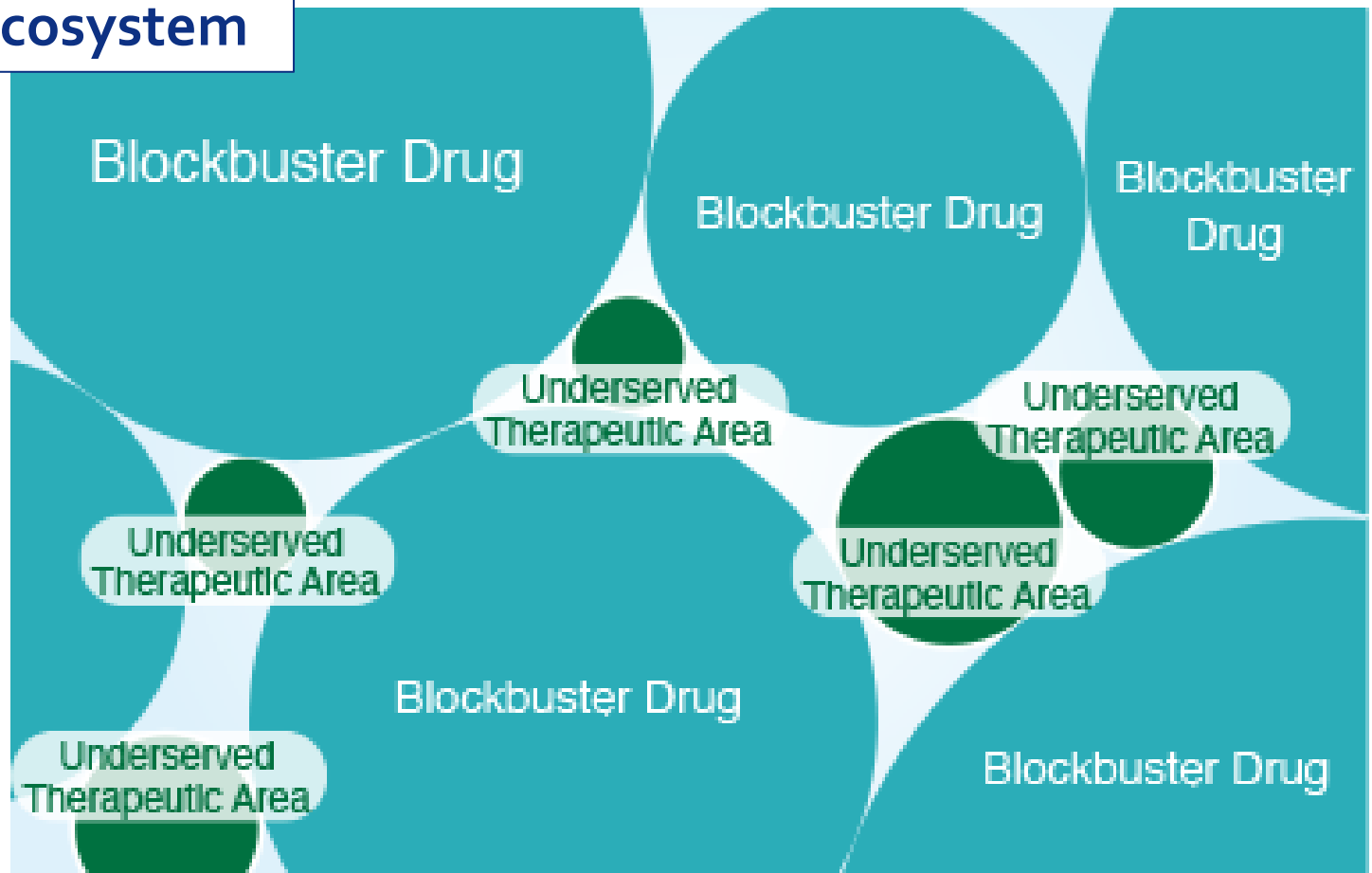


> The financial ecosystem of pharmaceutical R&D

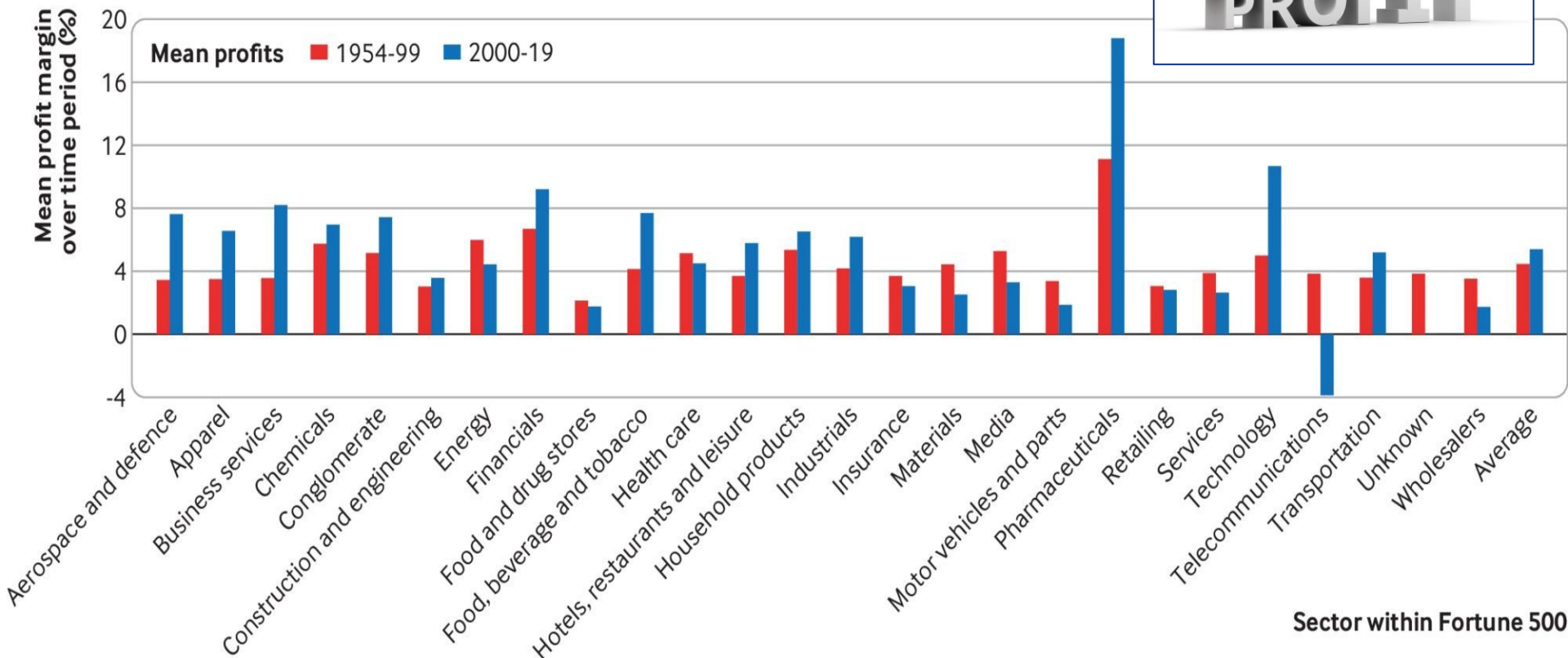
An evidence base to inform further dialogue

Neglected societal needs

Profit-centred
research ecosystem



Meanwhile....



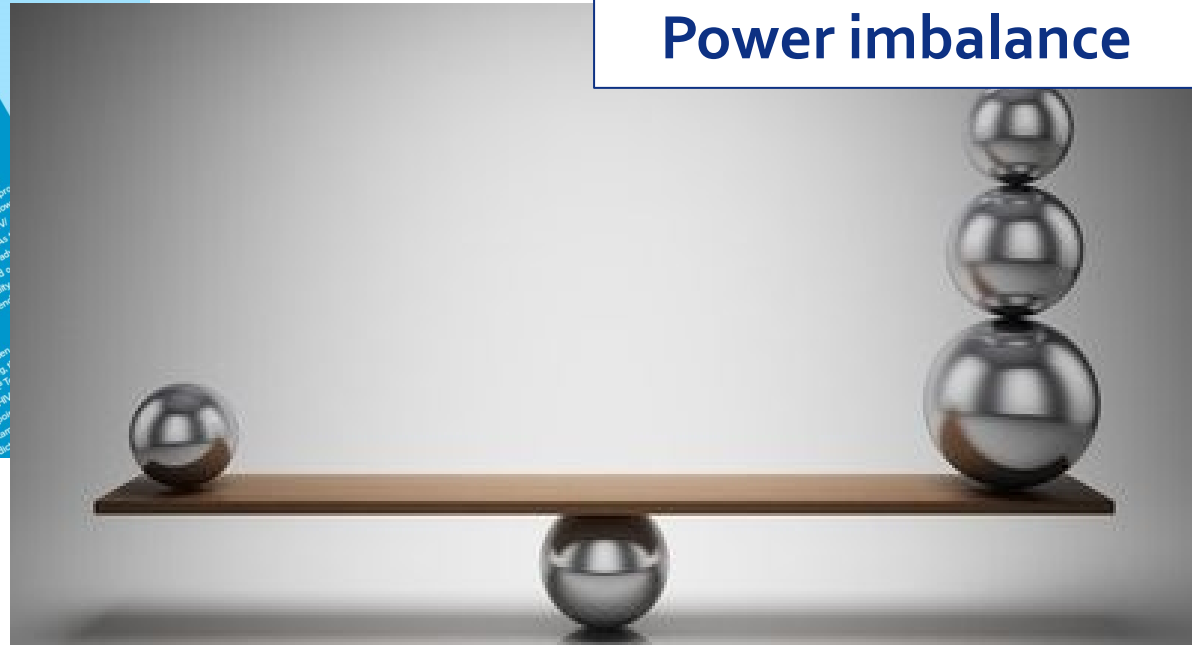
Weak evidence – High prices: Explosive mix

- Accelerated approvals
- Rolling reviews
- Unsatisfactory PLEG



Evidence gaps

**Information
asymmetry
=
Power imbalance**



Sustainable?

Profit-driven
ecosystem



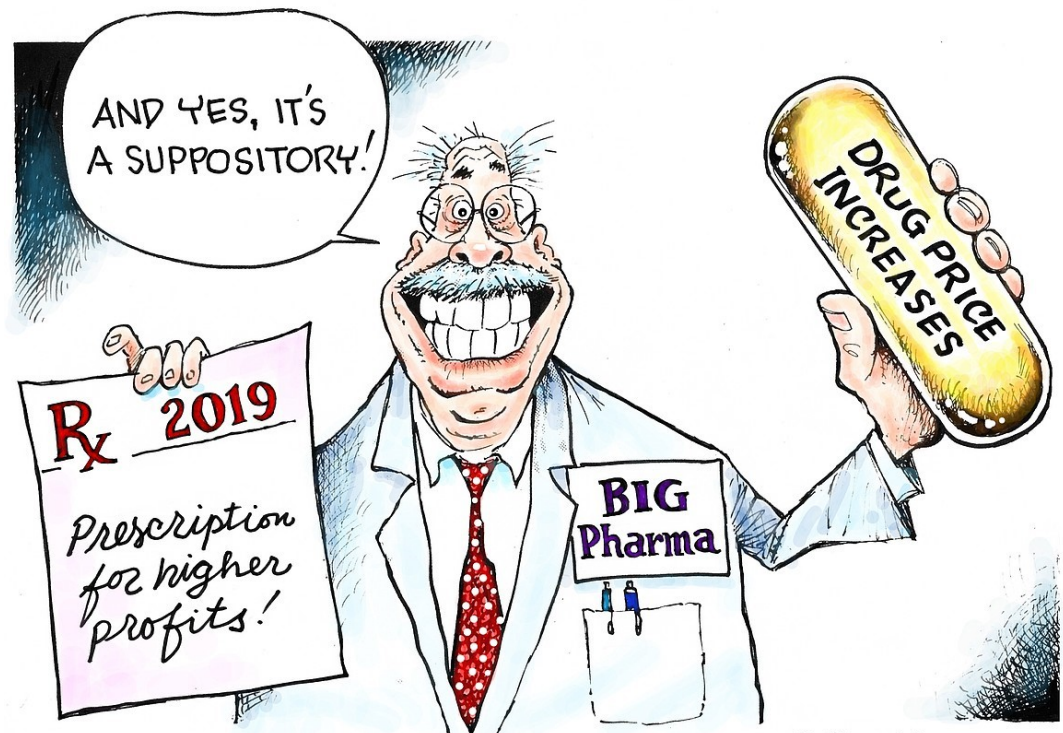
Price hikes



Budget cuts



Welfare State
sustainability





High meds prices fuel cost-containment



CBS NEWS

PRES. BIDEN SIGNS INFLATION REDUCTION ACT
ENACTMENT OF BILL MARKS MAJOR VICTORY FOR ADMIN. AHEAD OF MIDTERMS



Big Pharma is worried

**& it
threatens the EU**

**LET'S NOT SLOW DOWN MEDICAL
INNOVATION IN EUROPE**



#WeWontRest **efpia***

Payers or buyers?

1

Asymmetry of information



2

Willingness to pay
for real innovation



3

Most possible health for
taxpayers' money



Rebalancing the ecosystem & EU Health Policies

The EU Pharma Package:
a revolution for HTA or
much of the same?



Good afternoon, I am **proud** to present today, with Commissioner **Kyriakides**, the revision of the pharmaceutical legislation. It is the most complex, neuralgic, **epic**, big package we have prepared in the area of health throughout our mandate.

The EU Pharma Package

What works well for better evidence generation?

Article 162 Proposal for a Regulation

The Agency shall establish a consultation process with relevant national authorities or bodies for the exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency, in particular guidelines on unmet medical needs and the design of clinical trials, other studies and the generation of evidence along the life cycle of medicinal products.

The consultation process shall include bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 and national bodies responsible for pricing and reimbursement.

Article 81 Proposal for a Directive

In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004].

Rebalancing the ecosystem: The EU Pharma Package

What are the worrisome trends?



Formalisation of new accelerated & adapted approval pathways
→ rolling reviews
→ sandboxes



Incentives for randomised controlled trials



Acceptance of **unvalidated surrogate endpoints**



Missing strong requirements for post-authorization studies & penalties for non-compliance





- ✓ **Strengthen** evidence requirements early on
- ✓ **Finetune** regulatory incentives
- ✓ **Better define** unmet medical & societal needs
- ✓ **Prevent** evergreening & further orphanisation of reg. environment
- ✓ **Promote** competition within pharma

ESIP & MEDEV Recommendations

ESIP AND MEDEV POSITION PAPER

REVISION OF THE
EU PHARMACEUTICAL LEGISLATION



Looking ahead: EU 2024-2029

Beyond the EU Pharma Package

Addressing medicine shortages in the EU



Commission européenne
European Commission

Promoting our
European way of life

- EU's 'strategic autonomy' agenda **beyond supply dependencies**
- Prioritise research into **areas of real unmet needs**
- Emphasis on **affordability**



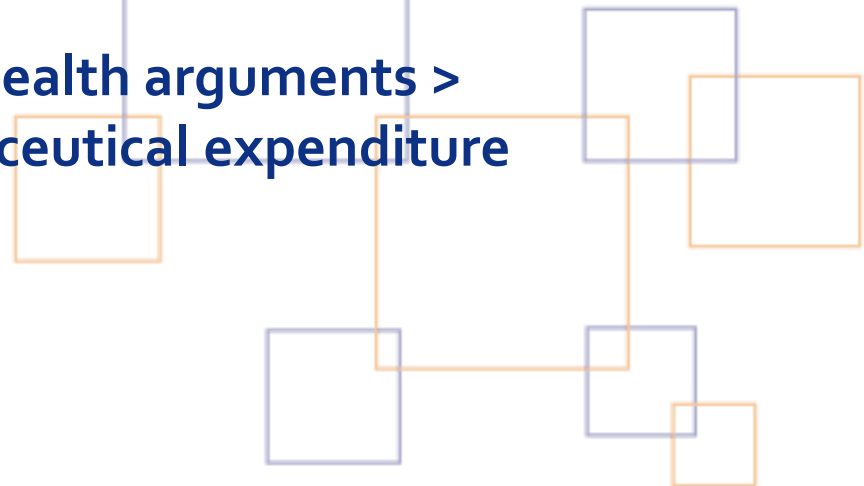


A new paradigm for thriving welfare states: Solidarity & Sustainability check



On to the next 20 years of KCE

- 1) Build up public administration capacity
- 2) Fight silos & policy fragmentation
- 3) Empower HTAs: Pool capacity, resources & expertise
- 4) Strengthen public health arguments >
Rationalise pharmaceutical expenditure



On to the next 20 years of KCE

- 5) Build bridges with Regulators > strengthen data requirements early on, demand more from companies
- 6) Drive the debate on RWD while defending RCTs
- 7) Use the HTAr to the max > Seek more & better data
- 8) Safeguard patients' access to evidence-based healthcare, a value & priority at the heart of KCE's work
- 9) Accessibility, availability, affordability > solidarity, sustainability & a new social contract=pillars of Europe's strategic autonomy

Thank you for your attention!



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