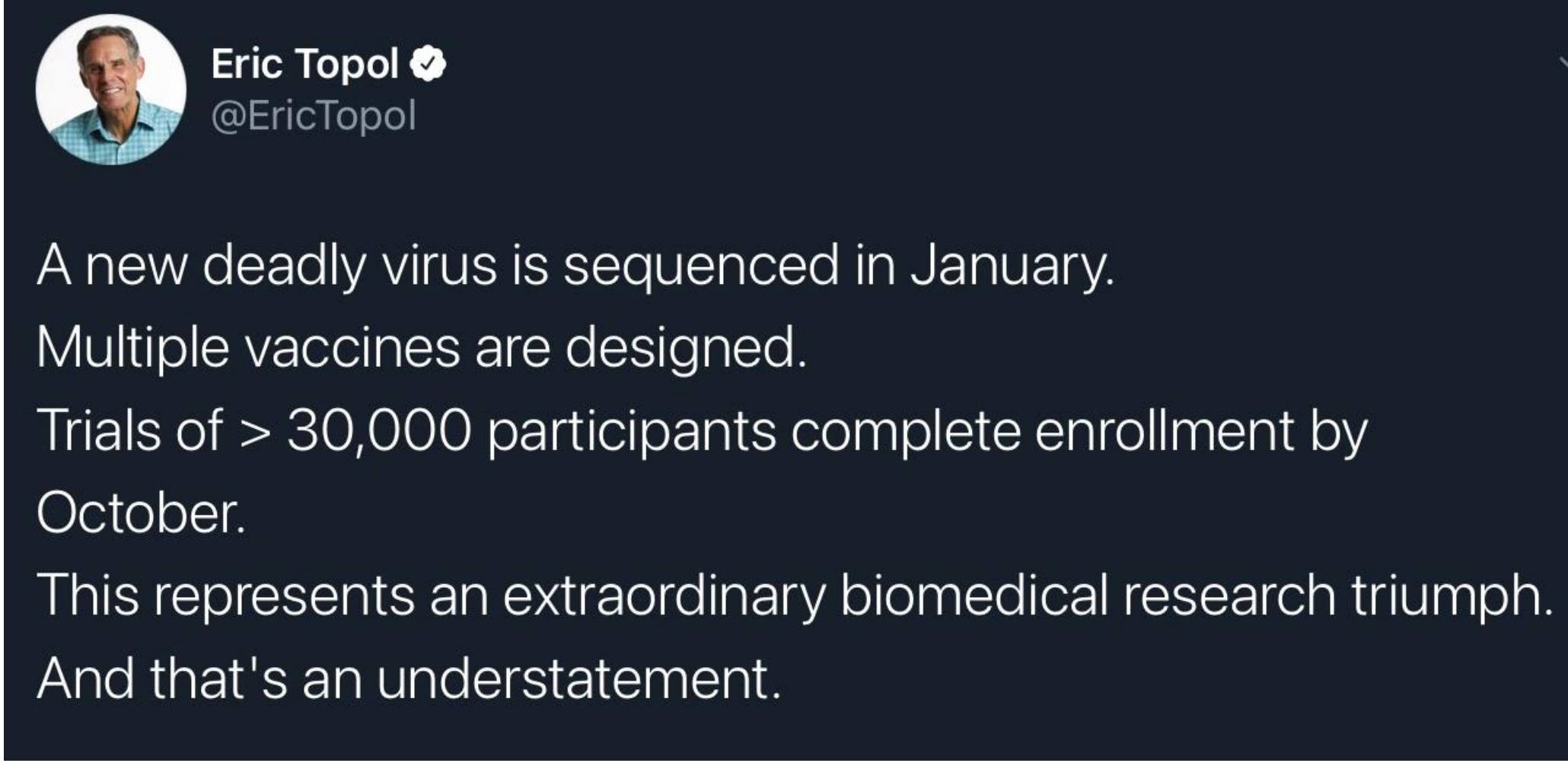
The European pharmaceutical system: strengths and weaknesses

Company perspective

Ansgar Hebborn, F. Hoffmann-La Roche AG

XIII Foresight Training Course, 23 October 2020

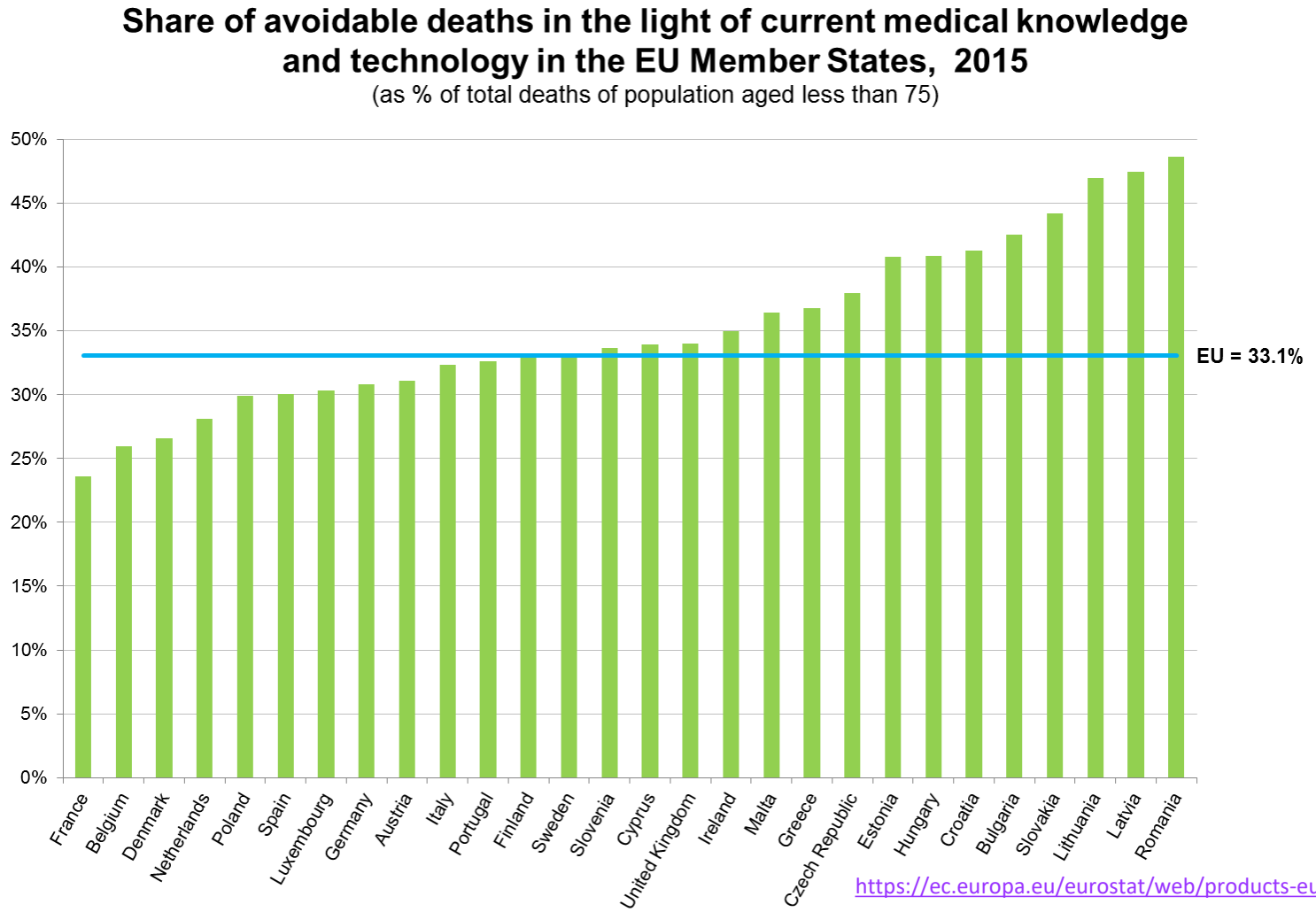


@EricTopol – 22.10.20 – 16:16

UNEQUAL ACCESS ACROSS THE EU – THE MAJOR WEAKNESS OF THE EU PHARMACEUTICAL SYSTEM

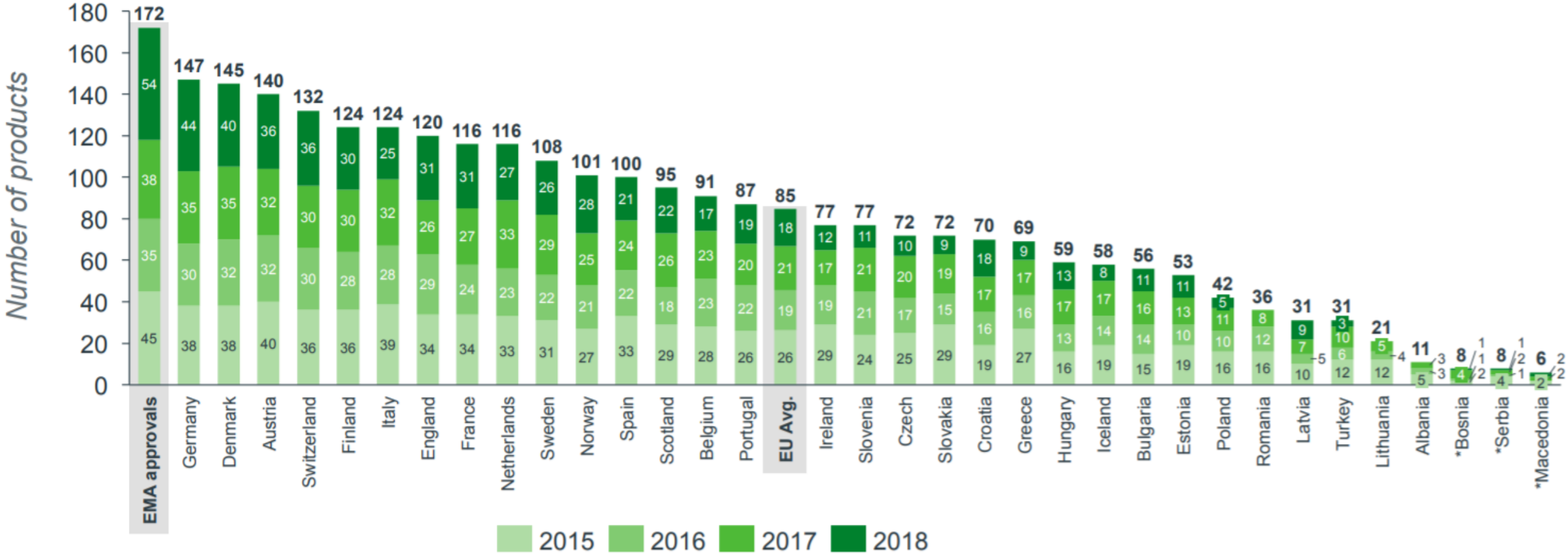
Are 1.000.000 deaths per year in the EU avoidable?

Largest shares of avoidable deaths in Romania, Latvia and Lithuania, lowest in France



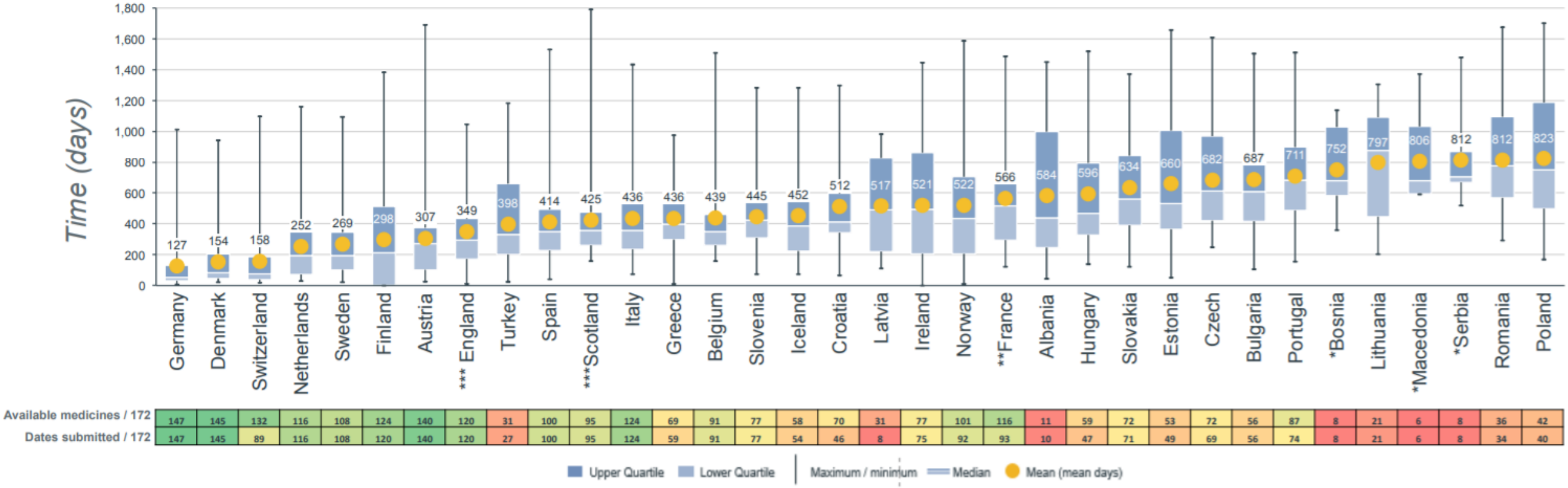
https://ec.europa.eu/eurostat/web/products-eurostat-news/-/DDN-20180629-1

Dramatic differences in the number of innovative medicines accessible to patients in EU Member States



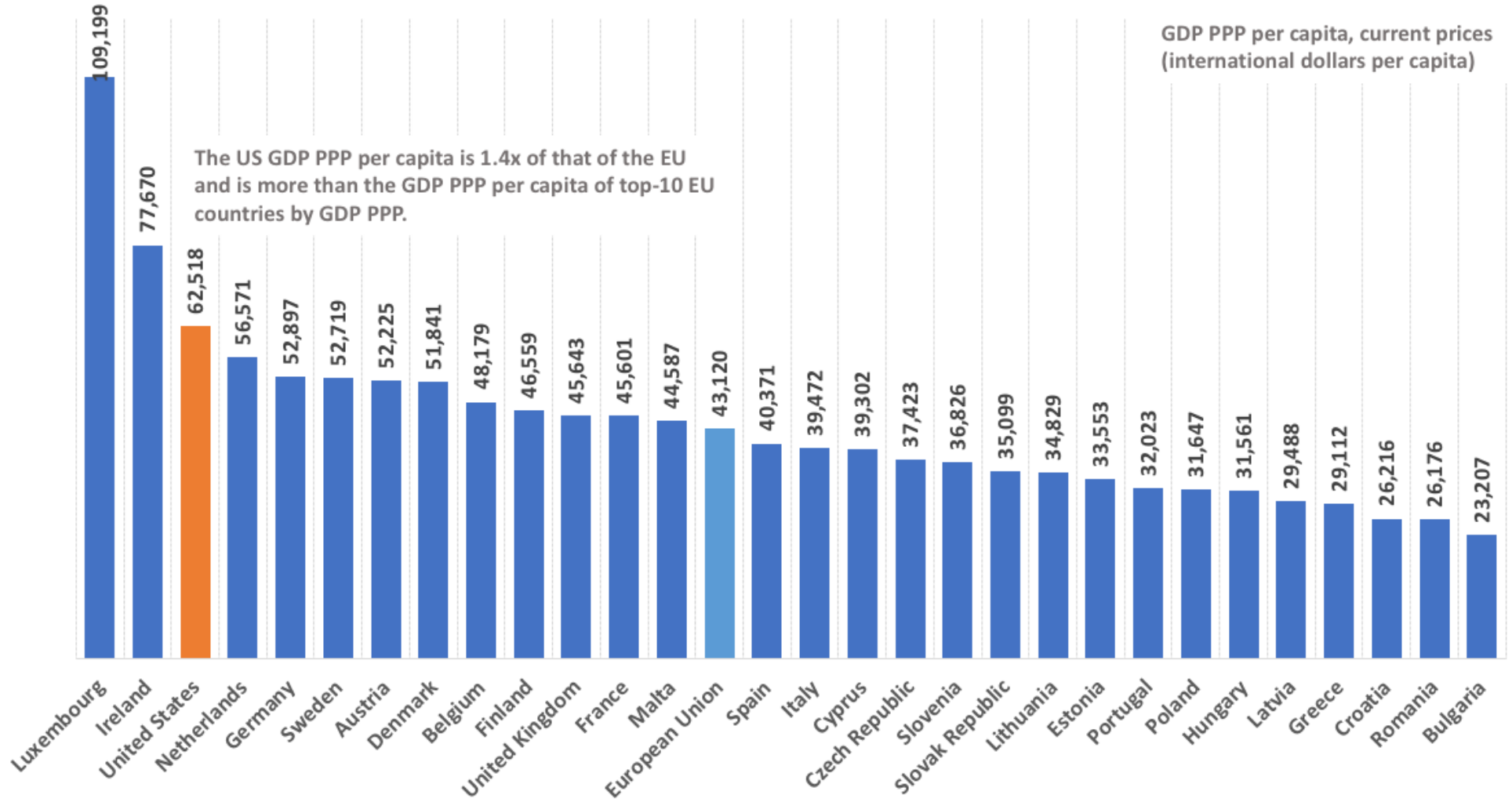
EFPIA Patients WAIT Survey 2020 (efpia.eu)

Patients wait more than 6 times longer for access to new medicines in neighboring countries



EFPIA Patients WAIT Survey 2020 (efpia.eu)

Large economic differences between Member States with major implictions for health and health systems



Data Source: IMF World Economic Outlook, October 2018

Data Analysis by: MGM Research

10 interrelated factors of why access for European patients may be delayed

Category	Potential root causes
The time prior to market authorisation	1. The speed of the regulatory process 2. Accessibility of medicines prior to marketing authorisation
The price and reimbursement process	3. Initiation of the process 4. The speed of the national timelines and adherence
The value assessment process	5. Misalignment on evidence requirement 6. Misalignment on value and price 7. The value assigned to product differentiation and choice
Health system readiness	8. Insufficient budget to implement decisions 9. Diagnosis, supporting infrastructure and relevance to patients
Delay from national to regional approval	10. Multiple layers of decision-making processes

CRA/EFPIA 2020

- Rooted in the access systems and processes of EU Member States and the corresponding impact on commercial decision making
- Many interrelated factors could explain unavailability and it is not possible to untangle their impact with perfect precision

SO WHAT CAN WE DO?

The time is now!

Major EU initiatives with opportunities for improved patient access and outcomes across the EU

EU4Health

Emerged as a result to COVID-19 crisis and pushes for a stronger EU role on health issues. EU will invest financial resources to EU Member States, health organisations and NGOs with impact on healthcare staff, patients and health systems in Europe. Focus on creating reserves of medical supplies and staff and boost the cross-border health crisis response, but also on issues such as combatting the antimicrobial resistance.

Europe's Beating Cancer Plan

The current Commission's flagship initiative in health aims to improve the way we prevent, diagnose and treat cancer, in addition to the follow-up care. Special groupings across the EU institutions are evaluating opportunities for the EU to take concrete action, identifying legislation and other measures that can help prevent and fight cancer, and looking into the best ways to support research.

Pharmaceuticals Strategy

Aims to ensure equal access to safe, state-of-the-art and affordable therapies for all Europeans while taking advantage of digitalization and reducing environmental burden. The strategy will also tackle the issue of the EU's reliance on importing active pharmaceutical ingredients from third countries by incentivizing production to return to the EU, while pushing for third countries to adopt harmonized international standards on quality and safety. Linkage with Horizon Europe is anticipated.

Health Technology Assessment legislation

Assessment of the added value of new or existing health technologies – medicines, medical devices and diagnostic tools, surgical procedures, as well as measures for disease prevention, diagnosis or treatment – compared with other health technologies. Renewed interest in passing legislation post-COVID-19 by several EU Member States to gain a powerful tool in dealing with access to medicines.

@VNemecEU, 15.09.2020

EU Pharmaceutical Strategy and unequal access

Tangible progress requires a dedicated forum

- More equal access to innovative medicines across the EU is a declared key priority for the EU Pharmaceutical Strategy.
- Tangible progress requires that root causes of unequal access are identified and addressed.
- Key barriers can only be removed in multilateral engagement involving all Member States and stakeholders

ESTABLISH A FORUM FOR BETTER ACCESS TO HEALTH INNOVATION

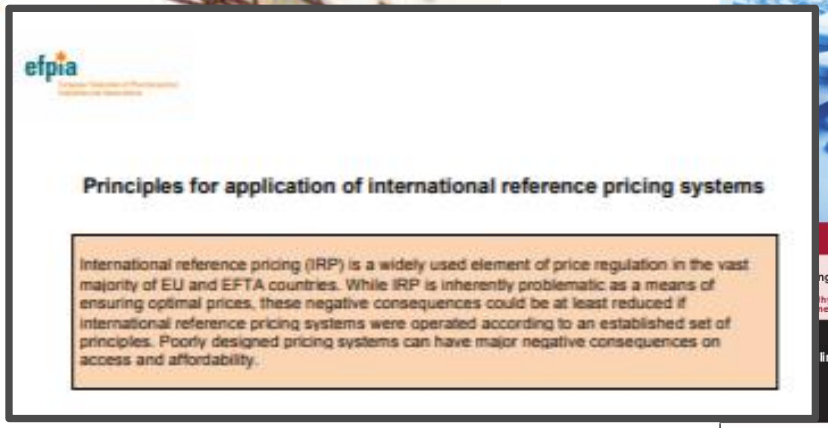
A multi-stakeholder Forum for Better Access to Health Innovation, covering all aspects of innovation, from disease prevention, therapies, technologies, and supply chains, to improvements in care pathways and healthcare services, should be established to enhance progress towards equal access across the EU. The Forum should discuss all drivers and barriers to access innovation, including economic, budgetary, organisational, and regulatory.

The European Commission should facilitate a multi-stakeholder Forum for Better Access to Health Innovation, involving all stakeholders – from Member States and regional authorities to patients and civil society, from healthcare professionals to industry.

https://www.euhealthcoalition.eu/recommendations/

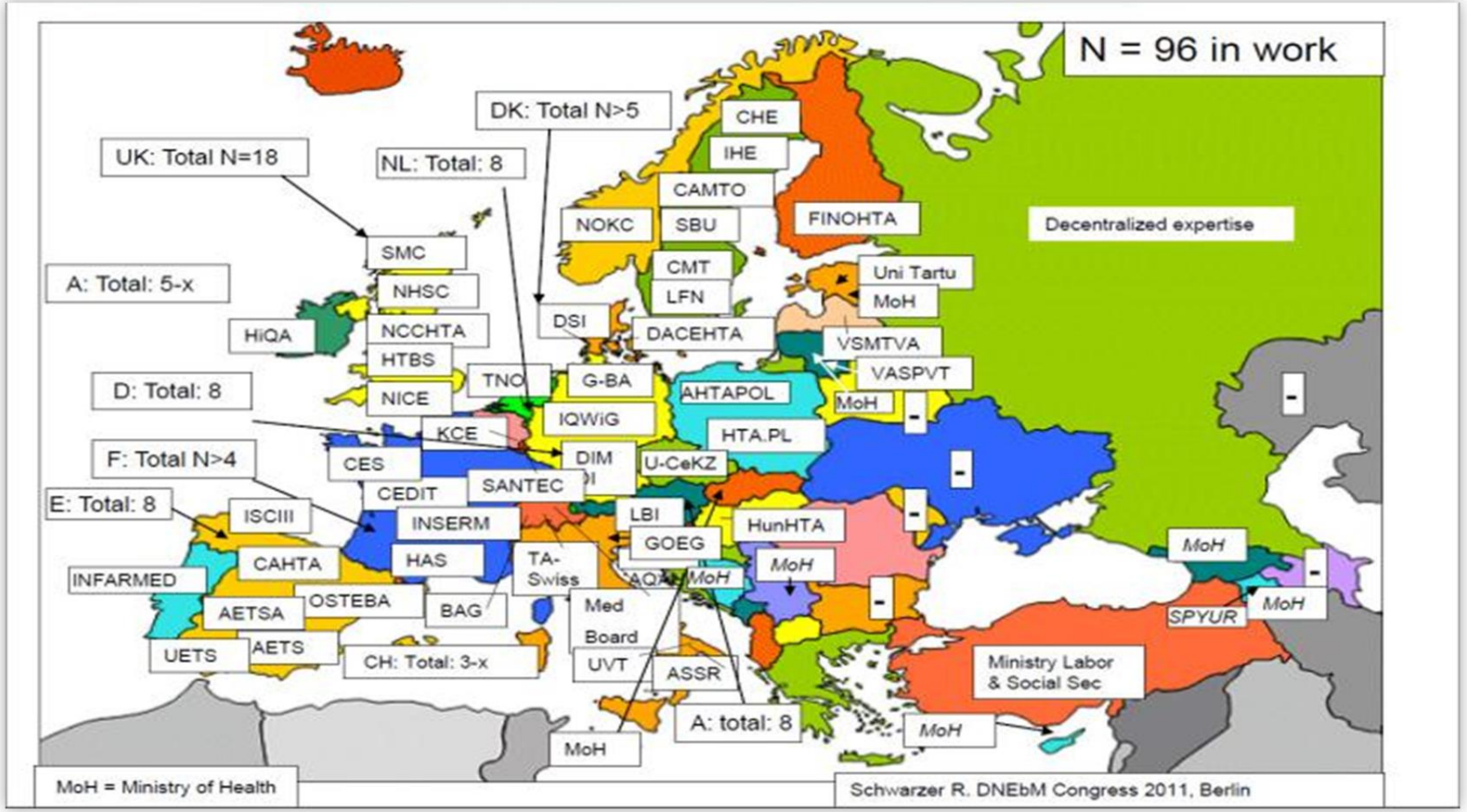
European solidarity between Member States beyond COVID-19

Can we finally overcome the unintended consequences of international reference pricing and parallel trade?



Considerable increase of HTA activity in Europe

But does it need 30+ different clinical-scientific benefit assessments of the same medicine?



The changing face of biomedical innovation
A different approach to HTA is needed

- Smaller, focused RCTs, adaptive trial designs, expanded use of single-arm trials, surrogate- and intermediate endpoints
- Rare disease innovation with more limited information at the time of (initial) marketing authorization
- Increasing number of biomarker-specific therapies with co-depencies with diagnostic technologies (“precision medicine”)
- Lifecycle approach to medicine development, substantially increased development activity after initial launch
- Faster evolution of clinical «standards of care»
- Innovation to support personalised prescribing of medicines (“clinical decision support”)

EU HTA Regulation: 3 years in the making

Proofpoint for Member States' commitment to EU collaboration?

European Commission

More than 10 years of cooperation: projects, joint actions

ACHIEVEMENTS

- **Trust** between HTA bodies
- **Capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting **joint work** (e.g. early dialogues, joint assessments)

LIMITATIONS

- **Low uptake of joint work** ⇒ duplication of work
- Differences in the **procedural framework** and administrative capacities of Member States
- Differences in national **methodologies**
- **No sustainability** of current cooperation model

Commission legislative proposal

MEMBER STATE-DRIVEN JOINT WORK	**Member States role** • In charge of the scientific work and the decisions • Organised in a member state-led "Member State Coordination Group on HTA" (the coordination group) **Commission role** • Adoption of tertiary (implementing) legislation • Obligation to verify joint reports before their publication • Monitor implementation of common rules **and use of joint work**
JOINT WORK BASED ON 4 PILLARS	Joint clinical assessments; Joint scientific consultations; Identification of emerging health technologies *(horizon scanning)*; Voluntary coordination *(other areas of HTA)*
SCOPE: MEDICINAL PRODUCTS SUBJECT TO CENTRALISED PROCEDURE	New active substances New therapeutic indications for existing active substances Certain medical devices
TIMING	Align timing to regulatory process to ensure timely availability of the joint assessment : • at time of Commission decision for MA • but both remaining within appropriate remits

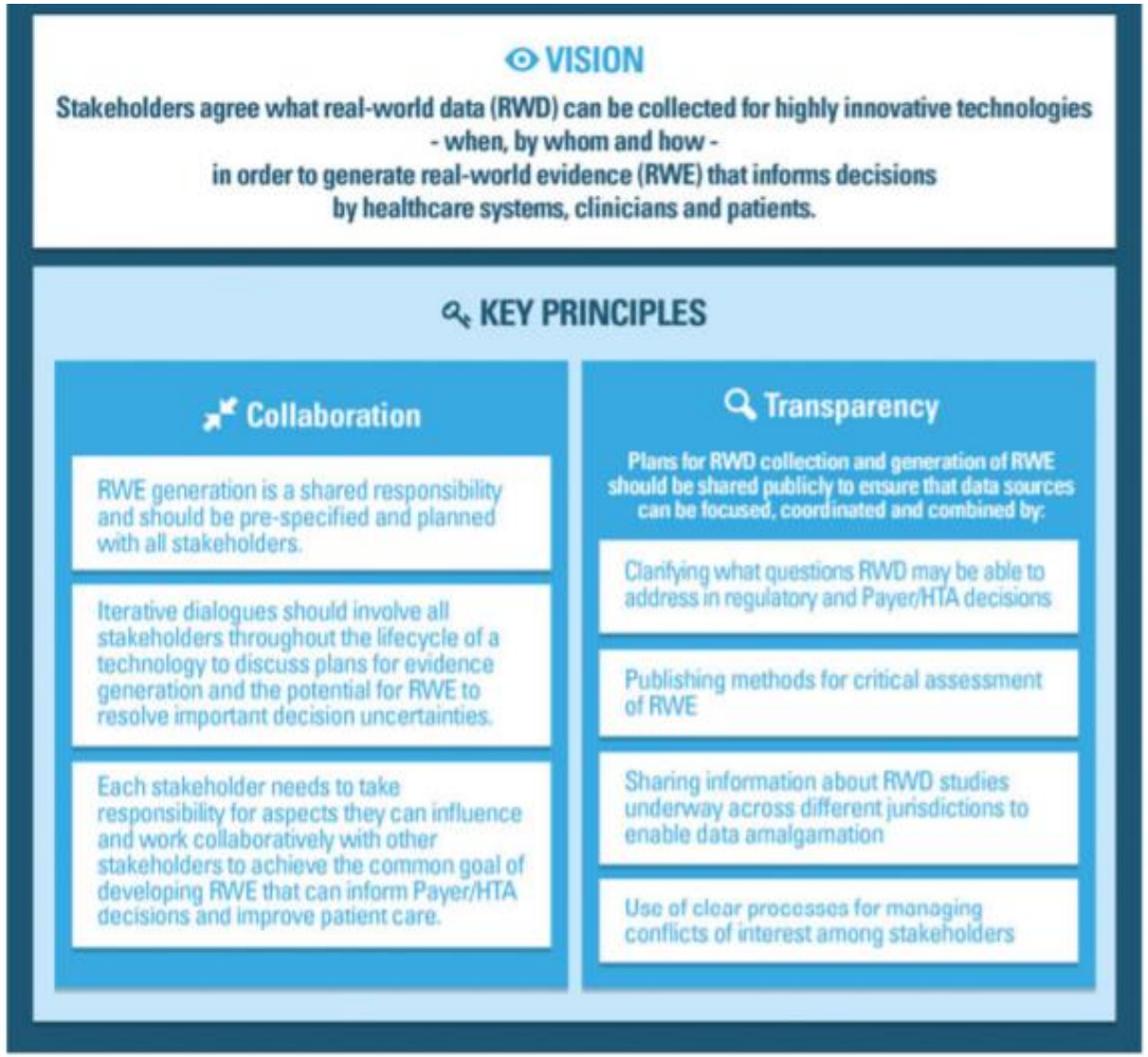
Source: Sanofi

efpia

www.efpia.eu

Risk, that poor legislative compromize will add new layer of complexity to current patient access pathways.

RWE4Decisions - Towards a multi-stakeholder EU Learning Network for the use of RWE in decision making



Facey, Rannanheimo, Batchelor, Borchardt, de Cock 2020

www.rwe4decisions.com

In summary

1. Unequal access to innovative medicines across the EU is the major weakness of the EU pharmaceutical system.

2. COVID-19 experience and already existing or soon to be released EU programmes represent a major opportunity to achieve tangible progress towars more equal access across the EU.

3. Progress cannot be achieved in a vacuum. It needs a EU-level multi-stakeholder forum where root causes of unequal patient access are identified and sustainable solutations are developed, moderated by the EC.

4. Achieving rapid and meaningful progress with a EU HTA regulation that effectively reduces complexity and duration of patient access pathways will be a proofpoint for Member States‘ commitment to EU-level collaboration.

Doing now what patients need next