efpia
European Federation of Pharmaceutical Industries and Associations

Academie Nieuwezorg

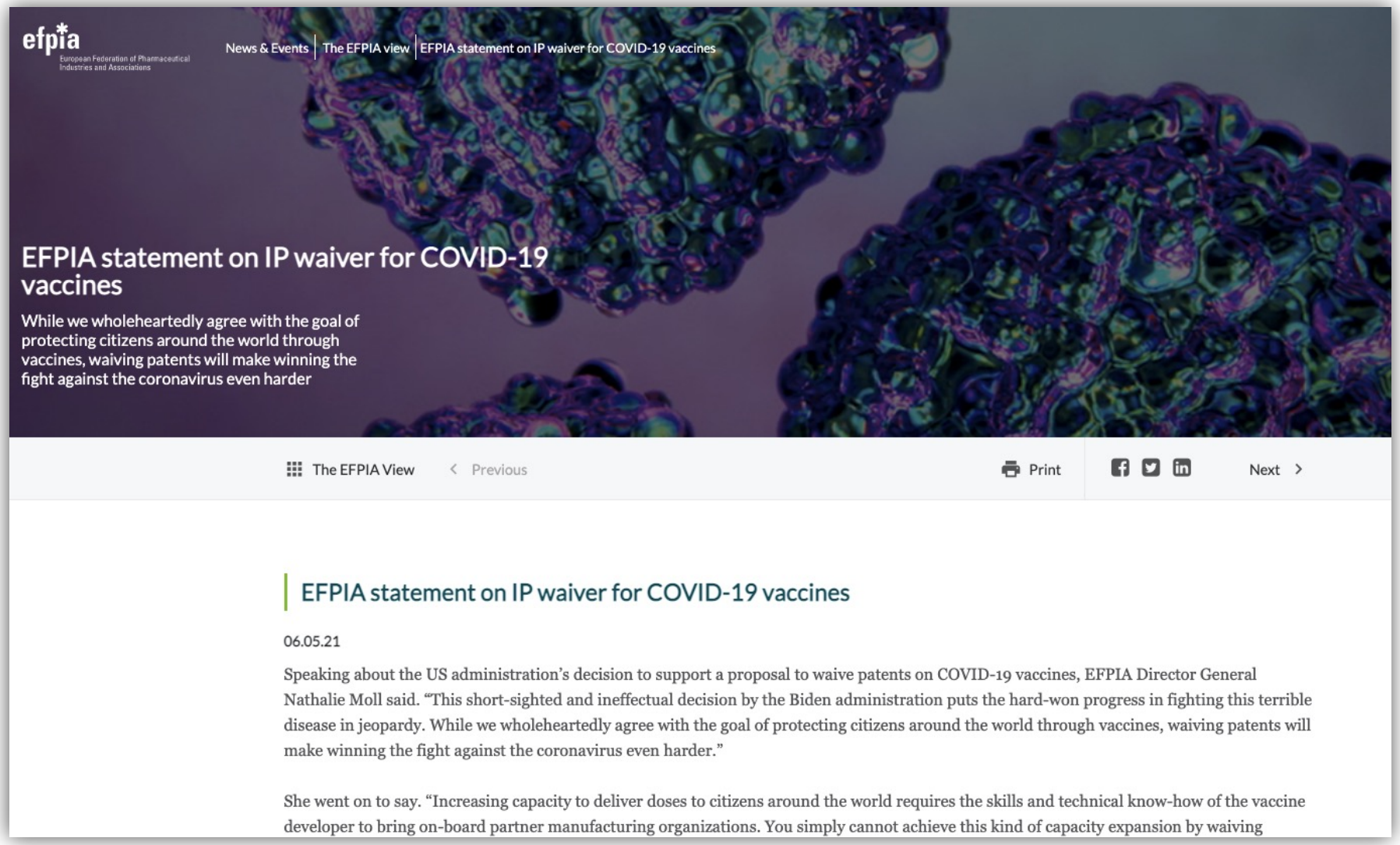
Pharmaceutical Strategy for Europe






Presentation Elizabeth Kuiper, *Executive Director Public Affairs Efpia*

EFPIA statement on IP waiver for COVID-19 vaccines



Key messages

- **We share the goal of getting as many vaccines to as many people as possible, as quickly and as safely as possible**
- In just a year since who declared a pandemic, we have achieved the impossible: We have 4 approved, safe and effective vaccines being given to millions of Europeans, and people around the world.
- All our focus should be on removing barriers to collaboration,
    - ensuring the free flow of materials around the world to support supply chains
    - Sharing doses where there is excess capacity
    - Supporting COVAX
- **Waiving patents on COVID-19 vaccines will make winning the fight against the coronavirus even harder.**
    - it would fail to increase the global capacity to manufacture COVID-19 vaccines
    - It would divert resources away from highly efficient manufacturers
    - It opens the door to counterfeit vaccines entering the supply chain around the world.
    - The waiver would remove incentives for companies to continue research
- **As a global hub for vaccine manufacture, our focus should remain on creating the partnerships and investing in facilities to increase capacity to meet the needs to citizens across Europe around the world.**
- EFPIA statements on IP/COVID: 1, 2, 3

Pharmaceutical Strategy for Europe adopted on 25 November – 4 objectives

”**Access** to medicines is a **huge issue**... there can be **no first and second-class citizens** in the EU... **inequalities** are simply **unacceptable**"

Stella Kyriakides, Commissioner For Health

"We want to **prioritise research and development** and **incentivise innovation** including on neurodegenerative and rare diseases and cancers"

"Access to medicines will be improved through **supporting generic and biosimilar medicines**, which are cheaper"

"Ensuring affordability of medicines will be guaranteed through bolstering **transparency on R&D costs and expenditure on medicines in healthcare systems**"

"We will be announcing the **overhaul of the legislative framework around medicines**, pharmaceuticals and their placing in the market and safety"

Margaritis Schinas, Vice President EU Commission

"This will be a **long process**, today it is only the beginning of a **vast *chantier***"

Indicative 2021 timeline

Q2
Study launched to accompany the **evaluation of basic legislation on medicines for human use**, Directive 2001/83/EC and Regulation (EU) No 726/2004

Q4
Public consultation for the evaluation and the inception impact assessment of the **general pharmaceutical legislation**

Launched in H1 2021 (for 12 weeks)
Public consultation **OMP/Paediatrics Regs**

Until Q2 2022
Impact assessment **OMP/Paediatrics Regs**

Q1-Q4
"**Structured dialogue**" with interested parties to identify vulnerabilities in the global supply chain of critical medicines to contribute to reflexions on possible action aimed at strengthening the continuity and security of supply in the EU

Q1-Q4
AMR: non-legislative measures + optimize use of existing regulatory tools + pilot innovative approaches to EU R&D and public procurement

Q2
5-year work plan for collaboration with transatlantic Taskforce on **AMR** 2021-2026

Run until Q4 2021
Impact assessment **HERA**

Q4
Legislative proposal on **HERA**

Q1-Q3
Legislative negotiations on **Health Union Package** (EMA and ECDC mandate extensions, cross-border health threats Regulations)

Q4 (TBC)
Health Union Package adoption

Q2-Q4 (TBC)
Trilogues on the **HTA Regulation** and adoption of Regulation

Additional initiatives mentioned by the European Commission 2021 management plan, with no associated 2021 timeline:

- Developing the **affordability agenda** with competent authorities on costing, pricing, payment and procurement methods
- Publication and discussions of the Commission study to map the **root causes of shortages** and assess the way the legal framework could be strengthened to avoid shortages
- Starting two pilot projects on **market launch and repurposing of medicines**

Q2
External study supporting IA for the legislative proposal on the **EHDS**

Q4
Legislative proposal on **EHDS**

Q4
Publication of the proposal to revise **blood, tissues and cells legislation**

Q2
Event on lessons learned from **Joint Procurements**

Q4
Launch of the pilot project on the **secondary use of data**

Q4
Proposal on **EMA fees**

Q4 (TBC)
Review of SPCs system and "Bolar" exemption

Q2-Q4
Legislative proposal on **Public Private Partnerships** under Horizon Europe

Q2
Adoption of **Zero Pollution Action Plan**

In conclusion…

- More than 50 different legislative and non-legislative actions are proposed, which will be implemented during the coming 4-5 years

- Will include a review of:
  - The pharmaceutical directive from 2001
  - The ‘EMA Regulation” from 2004
  - The Orphan Drugs Regulation from 2000
  - The Paediatric Regulation from 2006

Basic pharmaceutical legislation

Will the EU pharmaceutical strategy help Europe come back as a world-leader for medical innovation?

Academie Nieuwezorg

Several welcome improvements…

- New incentives ("pull-incentives") to combat antimicrobial resistance
- Setting up a European Health Data Space & creating an interoperable data access infrastructure for R&D
- Modernised regulatory framework
  - Dynamic regulatory assessment
  - Drug-device combinations
  - Real World Data
  - Innovative trial designs

- Support public-private and public-public partnership through the Innovation Health Initiative
- Strengthening Europe's bio-preparedness with a flexible, collaborative and agile Health Emergency and Response Authority

…but some areas to watch

- Linking EU-level incentives for R&D investments to access in national markets
- The review of Orphans and Paediatric Regulations risks reducing incentives for R&D leading to less innovation for patients without solving issues around access
- Pricing based on R&D costs instead of value

A comprehensive access discussion is needed in Europe

EU Health Coalition

EU HEALTH COALITION

A SHARED VISION FOR HEALTH

RECOMMENDS

Forum for Better Access to Health Innovation

Stakeholders

+ Industry
+ Healthcare professional
+ Patients
+ Civil society
+ Regional authorities

European Commission

Member States

AUSTRIA, BELGIUM, BULGARIA, CYPRUS, CZECH REPUBLIC, DENMARK, ESTONIA, FINLAND, FRANCE, GERMANY, GREECE, HUNGARY, IRELAND, ITALY, LATVIA, LITHUANIA, LUXEMBOURG, MALTA, NETHERLANDS, POLAND, PORTUGAL, ROMANIA, SLOVAKIA, SLOVENIA, SPAIN, SWEDEN, UNITED KINGDOM

EFPIA commitment: shared, evidence-based understanding of the root causes of shortages, barriers and delays in access to treatments with a view to co-creating solutions

Academie Nieuwezorg

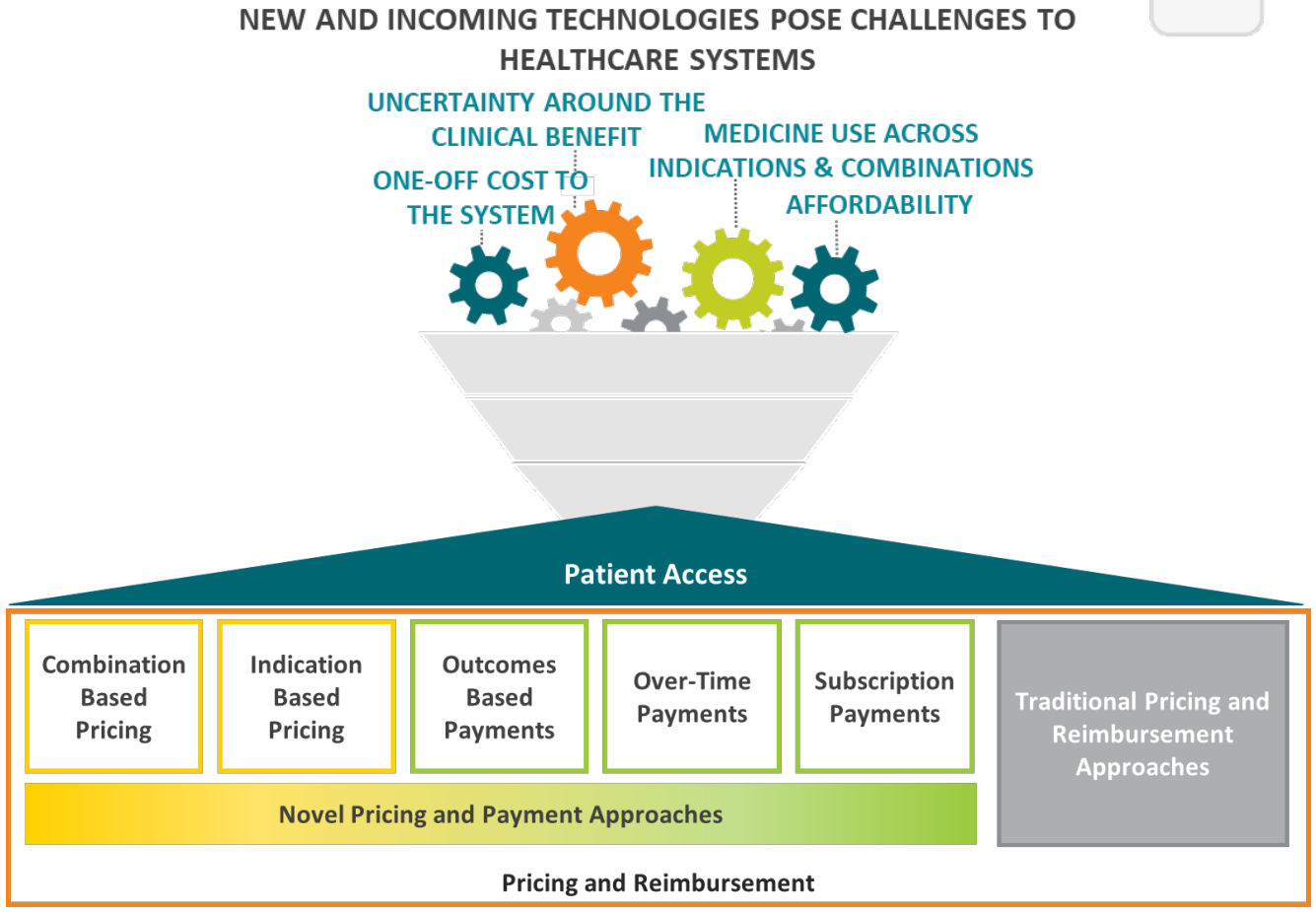
- Identification of 10 root causes for lack of access and availability
- Forum for Better Access to Health Innovation with Member States and health stakeholders to discuss solutions

Source: EFPIA/CRA report "The root cause of unavailability and delay to innovative medicines" (June 2020)

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

EFPIA commitment: novel payment models can improve access to innovative medicines

- Traditional pricing and reimbursement models can become a barrier to patient access, for substances targeting rare diseases and cell and gene therapies, data available at launch is often less complete than for earlier generations of medicines
- **Novel pricing and payment models represent a key opportunity to accelerate patient access, allowing payers to manage evidential uncertainty, spread the upfront cost and thus alleviate financial pressure on healthcare budgets, whilst providing sufficient incentives for innovation**



Source: EFPIA/CRA report "Novel Pricing and Payment Models: New solutions to improve patient access" (July 2020)

New EFPIA White Paper on Principles on the Transparency of Evidence from Novel Pricing and Payment Models

Transparency principles

Rationale: The rationale for collecting outcomes data through the novel pricing and payment model, the questions that the outcomes data and evidence aim to address, and the stakeholders that would benefit from this evidence should be documented

Mutual Agreement: The type of information to be disclosed, the timeline and the stakeholders to whom it will be disclosed should be agreed between the payers and the manufacturer when negotiating the terms of the novel pricing and payment model

Data Quality: Evidence made transparent should be based on high-quality outcomes data, collected through a clear research protocol, in line with accepted scientific standards, and representative of the agreed patient population

Context of Data Collection: The context of data collection, the limitations of the outcomes data and the resulting evidence, and assumptions in the data analysis need to be disclosed

Data Interpretation and Use: Disclosed evidence should be used according to good procedural practices to ensure that it is accurately interpreted

Patient Confidentiality: Patient confidentiality must be maintained when disclosing any information about the novel pricing and payment model, in compliance with GDPR

Disclosure along the NPM timeline

Industry commitment

- Working constructively with the European Commission and other stakeholders to align on principles for the disclosure of evidence from novel pricing and payment models
- Continuing the conversation with Member States to improve the transparency of novel pricing and payment models (developing a transparency mechanism that promotes good governance and accountability, identifying the most appropriate platform for data collection, the mechanisms of evidence disclosure, and how this is going to be used)

Source: EFPIA/CRA report "Principles on the Transparency of Evidence from Novel Pricing and Payment Models" (April 2021)

efpia
European Federation of Pharmaceutical Industries and Associations

Academie Nieuwezorg

Thank You !