



The Pharmaceutical Strategy for Europe: transparency and affordability

EPHA Webinar “Transparency of (real) pharmaceutical costs”

18/1/2022

Harald Mische, Deputy Head of Unit
SANTE B4, European Commission





“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.”

President von der Leyen's mission letter to Stella Kyriakides

The Pharmaceutical Strategy for Europe



The strategy covers the full lifecycle of a medicine



Affordability

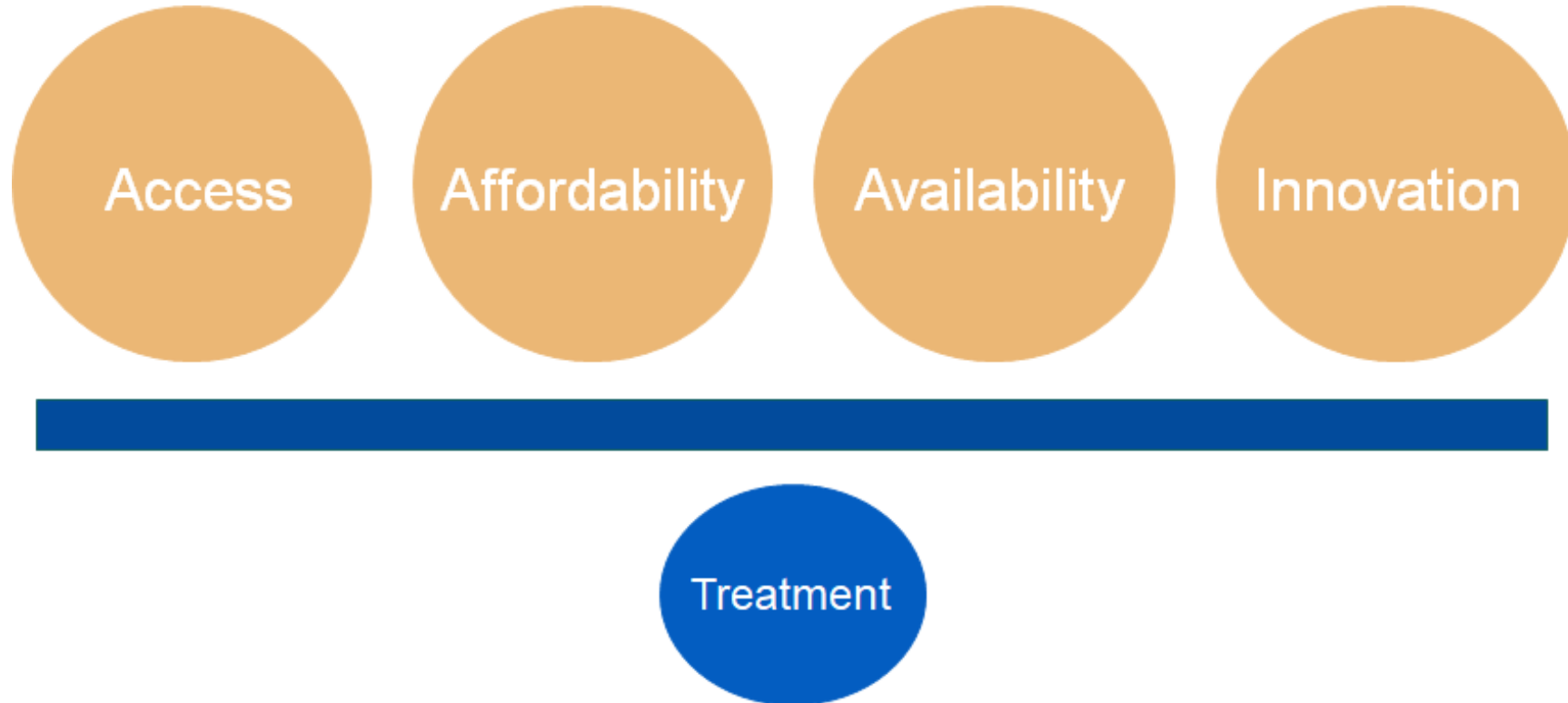


Source: The Truman Library

2.3 Ensuring affordability of medicines for patients and health systems' financial and fiscal Sustainability

- Implications for both public and household finances
- **Business models:** blockbusters & 'niche-busters'; high value acquisitions of promising pipeline products. – Products may have benefitted from public funding.
- New products are often priced even higher, with growing **uncertainty** as to their real-life effectiveness and related overall costs.
- “There is a **lack of transparency** (in particular in R&D costs) and consensus on costing principles.”

It's all about finding the right balance



What does the Strategy propose?

Further increase EU level cooperation

- Develop **cooperation in a group of national competent authorities for pricing and reimbursement and public health care payers (NCAPR)**,
- Engage with Member States in implementing **non-legislative measures** to improve transparency, such as guidelines on principles and costing methods for establishing the R&D costs of medicines.

-> (One of three) NCAPR work streams 2021- 2023:

✓ **Transparency, costing and pricing principles**

EU4Health Programme support affordability objectives 1

OECD grant (2021- 2023), different work packages:

- **Increase transparency of resource allocation in the global R&D-based pharmaceutical industry** regarding **public pharmaceutical research funding** (such as subsidies) flowing to the R&D-based pharmaceutical industry.

Objectives

- To improve MS **negotiation and monitoring capacities**, including for performance-based agreements.
- To provide MS with new information on the feasibility and potential of using **financing tools** and to help them allocate resources to the right innovation.

EU4Health Programme support affordability objectives 2

Package adopted 14.1.2022: to help implementing Pharmaceutical Strategy initiatives of ensuring affordability of medicines for financial sustainability; and promote cooperation between authorities.

...

- b. to **improve transparency on costs** of medicines by filling knowledge gaps on principles and costing methods for verifying cost claims of medicines (Strategy's flagship initiative);
- c. to identify **evidence generation needs** for NCAPR from the lifecycle of medicines and improving **transparency of data**.

The expected **results** are: **analysis on ways to make costing methods and principles more transparent** and explore the feasibility for future guidance.

Revision of the EU general pharmaceuticals legislation

... to ensure patient access: review of system of incentives, which may include greater 'conditionality' of incentives.

✓ Open Public Consultation (closed 21 December 2021)

Q4 What do you think of the following measures to support innovation, including for 'unmet medical needs'? : 7. Require transparent reporting from companies about their research and development costs and public funding as a condition to obtain certain incentives.

Very important
Important
Fairly important
Slightly important
Not important
Don't know
No Answer

... results will be published soon

International work regarding costs & transparency

- WHO Euro / OSLO Medicines Initiative (OMI)
 - 72nd WHO World Assembly, **Transparency Resolution** of 28 May 2019: calls for increasing **transparency across the value chain on pharmaceutical prices**, marketing **costs** and strategies, access decisions, subsidies and incentives. -> Fair Pricing Forum
 - **OMI**: Consultations, papers, webinars and high-level meeting June 2022:
 - Societal responsibility to secure access to these products for all patients, given the public investment that has gone into research and support for innovation?
 - Improve access to effective, novel, high-priced medicines, ensuring sustainable health systems

Thank you



European Commission
Public Health information:
http://ec.europa.eu/health/index_en.htm



@EU_Health #EUPharmaStrategy

https://ec.europa.eu/health/human-use/strategy/affordable_medicines_en