Developing an “affordability” agenda under the pharmaceutical strategy for EU to keep the sustainability of Health Systems

3A Conference Availability, Accessibility, Affordability

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Sylvain Giraud, Head of SANTE B4
European Commission

Affordability in the Pharmaceutical Strategy

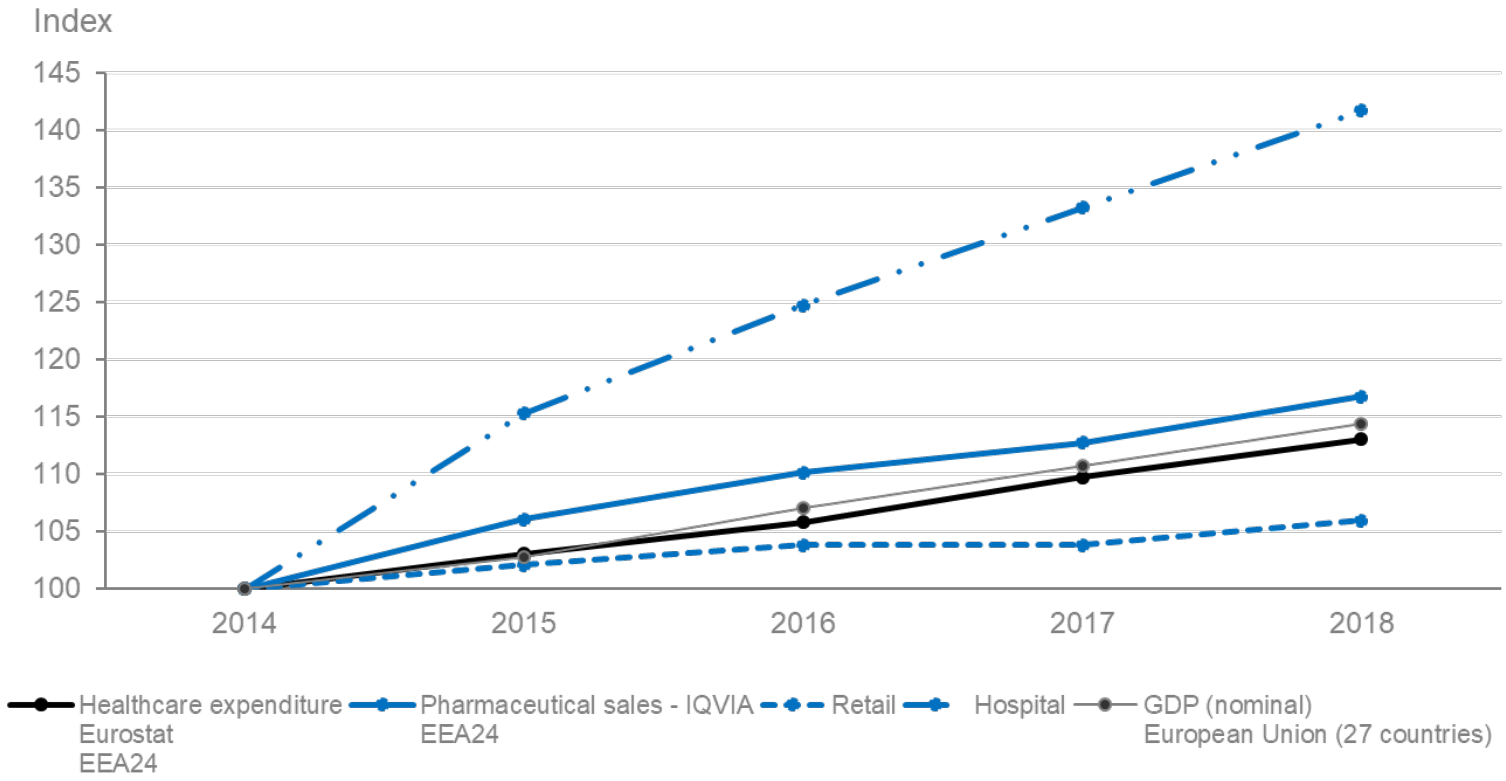
Affordability

Source: The Truman Library

- Implications for both public and household finances
- The **business model** has moved from selling blockbusters to marketing ‘niche-busters’.
- 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.

Sustainability of health systems – understand the drivers

- Pharmaceutical expenditure outpaces GDP and healthcare expenditure again as of 2014.
- This is primarily driven by growth in hospital settings.
- Market analysis reveals barriers to the entry of competing generics, biosimilars and ‘older’ products.



Source: IQVIA MIDAS LCE_MNF_QTR

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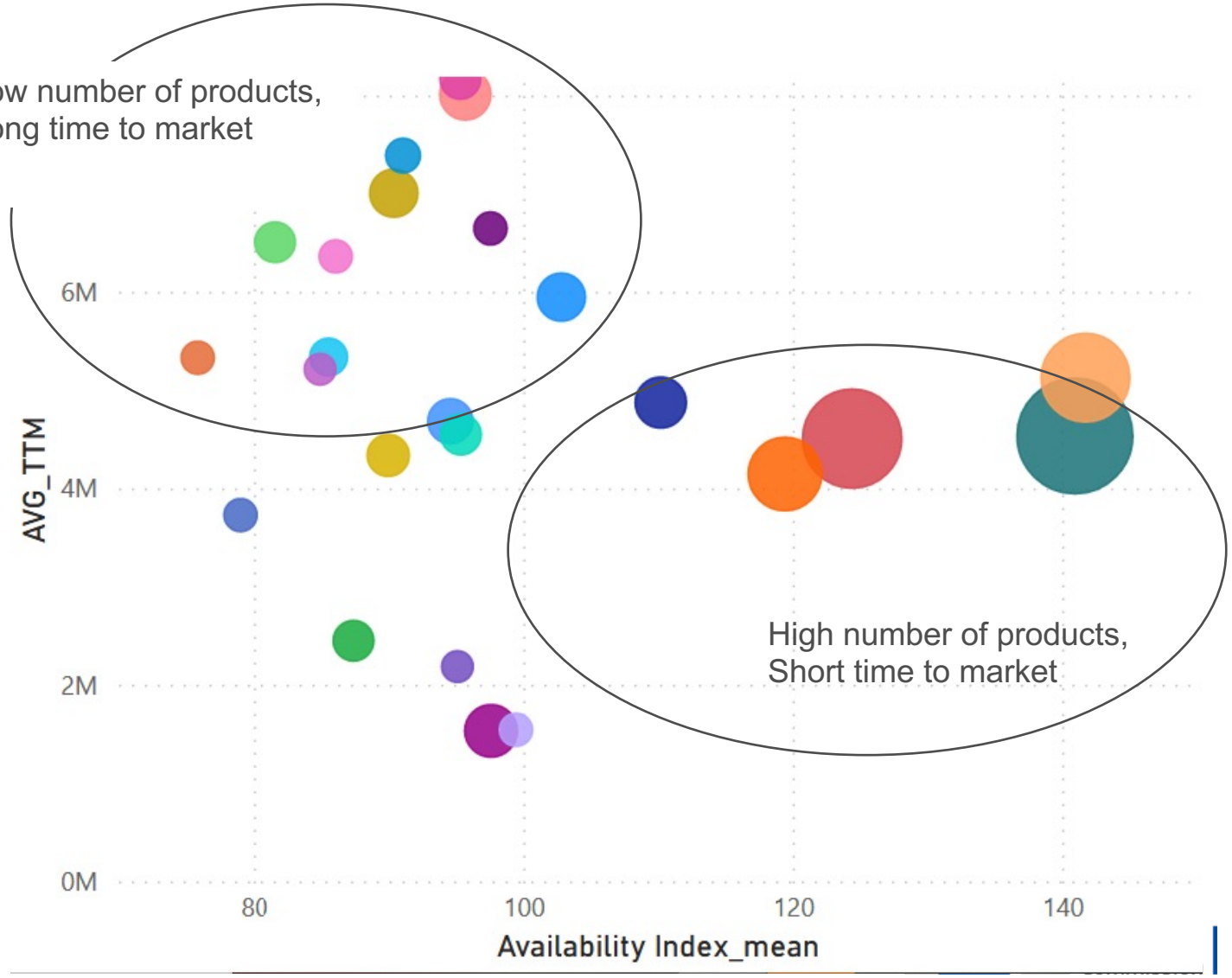
Interplay of affordability and availability

Countries with the longest time to market often see a lower number of products and molecules (top left).

The GDP of the country plays also a role : the bigger bubbles represent higher GDP (and larger population). These countries see higher number of available products and shorter time to market (bottom right)



Source: IQVIA MIDAS LCE_MNF_QTR

What does the Strategy proposes ?
Revise the legislation to address affordability challenges - 2022

- addressing aspects that impede the competitive functioning of the markets and to take account of market effects impacting on **affordability** .
- taking into account the relationship with intellectual property rights, the system of incentives and obligations, to support innovation, access and the **affordability** of medicines.
- addressing **market competition** considerations and thus improve access to generic and biosimilar medicines.

What does the strategy proposes ?
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 Members 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.

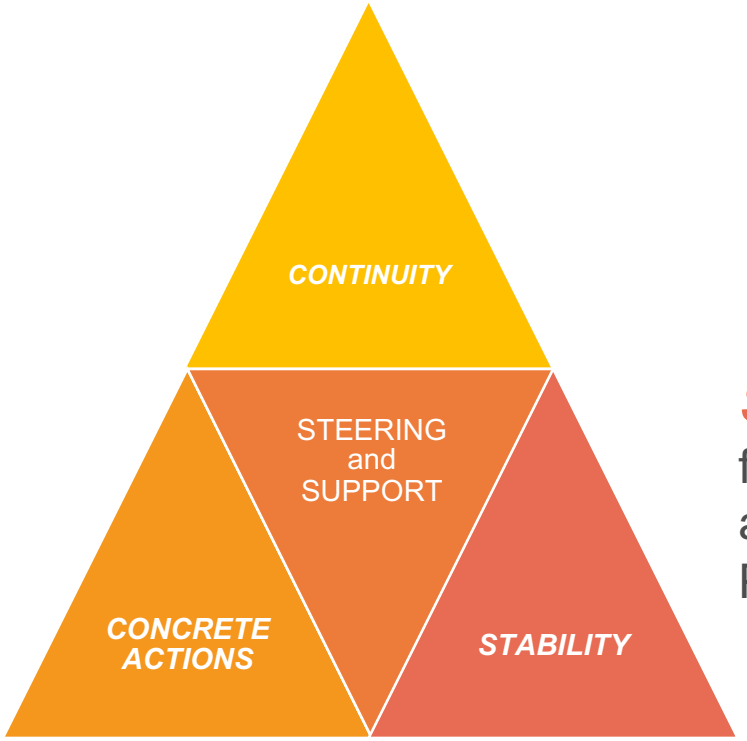
NCAPR – what's new?

- Mutual learning in an area of national competence
- Building on existing structure and past experience in NCAPR / new momentum that the Strategy brings to **stability, continuity, concrete actions** to this cooperation
- Pharma Strategy proposes to develop further
  - *cooperation between national competent authorities, based on mutual learning and best-practice exchange*
  - *on pricing, payment and procurement policies,*
  - *to improve the affordability and cost-effectiveness of medicines and health system's sustainability*
- A voice for the payers at EU level /provide an input on other aspects of the Strategy that impact affordability

NCAPR Group

CONTINUITY across presidencies through an agreed long term rolling agenda and action plan.

CONCRETE ACTIONS focus on specific actionable issues to support and help national policy making *(data and information sharing, best practices, IT tools, common methodologies, etc.)*



STABILITY in membership but flexible to allow holistic approach and dialogue and coop with others : Pharma Ctee, EMA/HMA, HTA etc

STEERING role for Presidencies and Commission;
SUPPORT by EU4health.

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Type of actions

Internal discussions (mutual learning), multi-stakeholder meetings

Feedback to policy processes and to the Pharma Strategy

Proposals for studies, data analytics, opinions, workshops, joint actions, twinning projects, trainings,

(EU4Health Programme)

Exchanges on best practices, peer reviews a and peer support, pilot projects?; support to collaboration mechanisms

Proposals for guidelines, guidance docum ent, common approaches, common principles to support pricing, reimbursement and procurement policies at national level

Sharing data. Mapping existing datasets, data needs, prototypes for analytics, interoperability, access

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Areas of action

Evidence for action

- Transparency on R&D costs and consensus on R&D costing principles
- Implications for markets of changing business models and novel payment approaches
- Improve the reporting of expenditure on medicines in hospital settings at EU level
- Optimise data publicly available on centrally authorised products in view of accountability (see also section 3.3)
- Improve the measurement of cross-country differences in patient access (beyond time-to-market)
- Assess the effectiveness of current financial protection mechanisms for patient access (such as deductibles, regulated co-payments, means testing, cost exemption groups)

Exchange on pricing, payment and procurement policies

- Optimise the of procurement as a strategic tool to achieve savings on sustainable basis
- Mitigate coordination challenges and foster information exchange in price increase decisions
- Assess and optimise the functioning of novel pricing and payment models
- Collaboration between existing committees/networks of regulators, health technology assessment (HTA) bodies and payers for a lifecycle approach starting with trial design and improved availability and affordability (see also section 2.1)
- Support regional initiatives of joint negotiation or joint tendering, as these contribute to improving the affordability and cost-effectiveness of medicines and health system’s sustainability (see also section 2.2)

Market entry and competition

- Improve the uptake of biosimilar medicines
- Assess and optimise the role of so-called "dynamic competition" ("me too" competition)
- Include competition and affordability effects when revising the pharmaceutical legislation to improve access to generic and biosimilar medicines (see also section 2.2)
- Strengthen pro-competitive elements when revising the pharmaceutical legislation to provide for simplification/streamlining of existing Marketing Authorisation rules (see also section 3.3)
- Optimize the use of transparency directive in view of market entry and affordability

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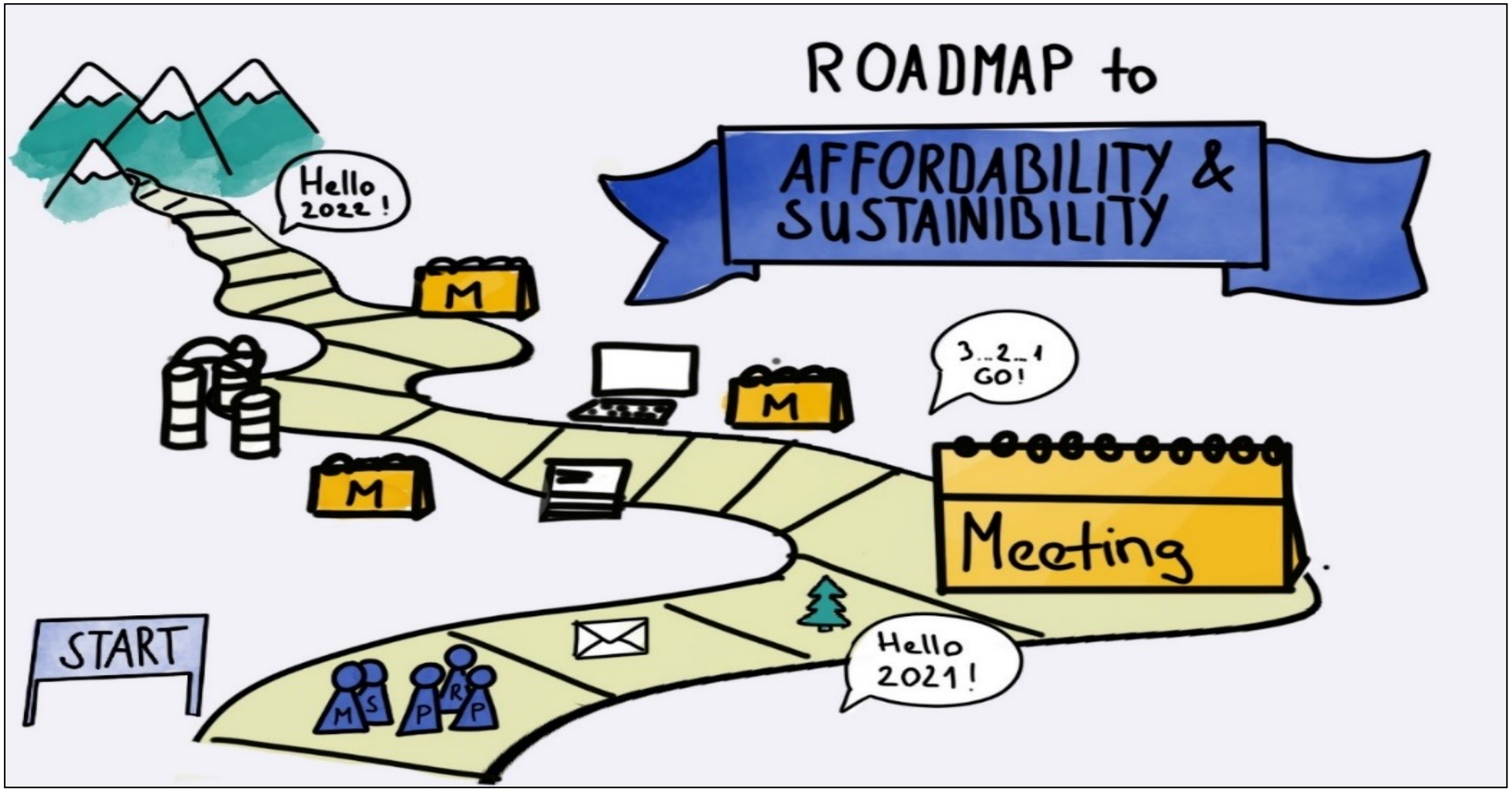

Thank you

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

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

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