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

AIM event on fair pricing and medicines affordability

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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?

- A growing challenge for most Member States. The **budgetary sustainability** of health systems is at risk, and reduces the possibilities for patients to have **access** to these medicines.
- Pharmaceutical budgets account for 20-30% of **hospital expenditures** and are growing faster than retail spending. Expenditure on medicines in hospital settings is incompletely reported at EU level.
- **Lack of competition** / market barriers to competing generics, biosimilars and ‘older’ products (hard to enter or stay in the market. This thus inhibits price savings.

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

Developing an “affordability” agenda
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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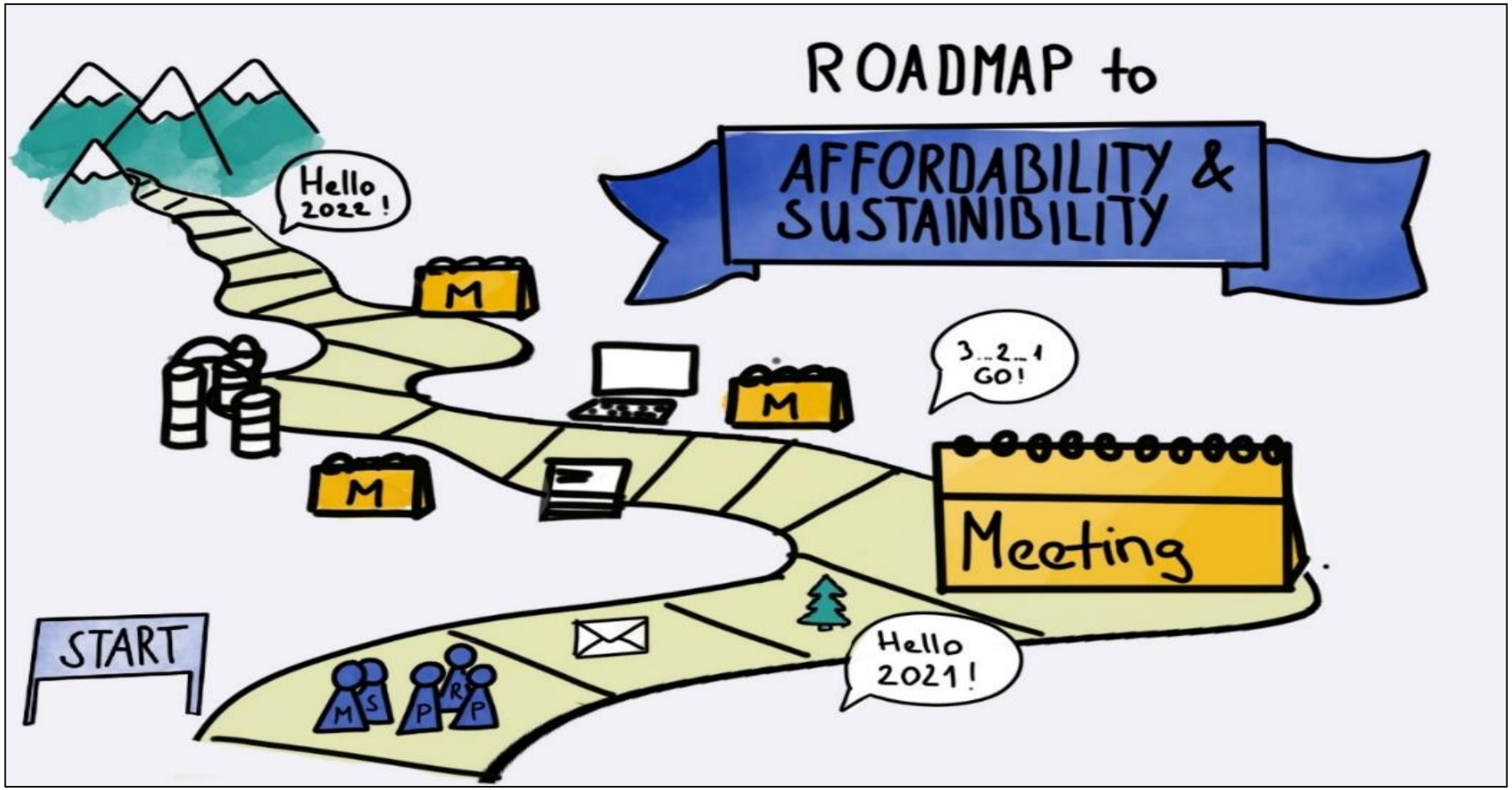
Developing an “affordability” agenda – role for a PRP Community



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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