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

A European Health Union: A Pharmaceutical Strategy for Europe
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The strategy covers the full lifecycle of a medicine

1. Research and innovation
2. Authorisation, Health Technology Assessment and placing on the market
3. Securing supplies of medicines
4. Delivery to patients
Affordability

- 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.

Source: The Truman Library
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 use 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
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