

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

Request for a scientific opinion: Innovative payment models for high-cost innovative medicines.

Background – Rationale

Medicines are an important input in the 'health system production process' and they constitute an important determinant towards effective, accessible and resilient health systems (Communication 2014¹). DG SANTE has committed to work further using existing tools to create the necessary conditions at EU level to ensure accessibility of patients to innovative medicinal products and explore possible synergies between the work of regulatory bodies, HTA bodies and payers in the EU².

The issue of access to medicines is complex and it touches upon questions of societal choices, patients' access and sustainability of health care systems, and support to innovation and to industrial policy. It is also a long term consideration: from research and development, to regulatory approval and finally effective market uptake and surveillance. In the EU, the pharmaceutical legislation lays down harmonised regulatory standards for the authorisation and supervision of medicines for human use and provides regulatory tools under certain conditions. However, efforts to invest on development and timely authorisation of innovative medicines are confronted with challenges, such as the sustainability of health systems, patient access and affordability.

Innovative medicinal products are high valued, leading to higher prices compared to the traditional ones. In OECD countries they account for 25 to 50% of overall pharmaceutical spending with an expected upward future trend. Entry price by life year gained have been seen as very high, questioning sustainability and the future of truly innovative treatments. Moreover, the targeted populations for the treatment and the real uptake and consumption by the patient are important factors of uncertainty in relation to costs and budget impact (ie towards more personalised treatments, uptake of combination of therapies etc).

Promoting access to innovative medicines should therefore be conditioned on a clear set of requirements³. Strategies to improve access to medicines include the development of new payment mechanisms for innovative medicines. As a previous EXPH opinion on Access to health care highlighted, current costing approaches are complicated and new payment mechanisms have to be further examined⁴. In addition, an EU Health programme study underlined the importance of fostering cooperation between Member States and suggested a future pilot at EU level to be considered⁵.

¹ http://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/com2014_215_final_en.pdf

² <http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>

³ http://ec.europa.eu/economy_finance/publications/eeip/pdf/ip037_vol1_en.pdf

⁴ https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/015_access_healthservices_en.pdf

⁵ http://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf

A call to move from the traditional price models towards more innovative/ dynamic ones for cycles of care that reward true innovation and/or the right behaviour is frequently debated⁶. Sophisticated payment mechanisms are increasingly proposed, usually under the headings of 'risk-sharing agreements' or 'payment for performance' or 'Outcome Based pricing' or 'Differential Pricing' or 'Pricing by indication' or combination of current pricing models. Such schemes are difficult to negotiate and administer, while the role of evidence on agreed outcomes and the Real World Data (RWD) is crucial for the monitoring and exit scenarios.

As a way to increase their resilience, health systems have to focus on strengthening capacity and evidence base for price setting mechanisms and monitoring of the costs of pharmaceuticals. The experts' opinion is expected to clarify methodologies and provide a tool for the national competent authorities. It will also identify the gaps of current models and propose areas to further develop for those authorities willing to increase their resilience.

Terms of Reference for the Expert Panel on Health

The Expert Panel on effective ways of investing in Health is requested to analyse the following:

- (a) What is the current role of the national pricing and reimbursement authorities to improve access on innovative medicines? Is there a scope to explore new ways of setting prices for specialty medicines in terms of improving access, while taking in to account the costs, the benefits, the budget impact and the future return on investment on a transparent way? How to deal with polypharmacy/ combination of treatments? What are the existing frameworks for such dynamic payment models? Any experience from other economy sectors (transport or telecommunications) that can potentially be applied to medicines?
- (b) How can the use and uptake of medicines impact the health care costs? Can this be reflected on price setting ie reward for the right behaviour? Ways to monitor the adherence to treatment? What is the importance of choosing the right outcomes to measure the performance? What is the role of RWD for innovative payment models and are there any prerequisites to develop such system? Is it possible to develop a common definition for RWD from all different perspectives (regulators, HTA bodies, payers, pharmacovigilance etc)?
- (c) Is there a theoretical framework for the interpretation of the results and outcomes? Is there a framework of health system performance assessment in the area of pharmaceuticals and possible areas for future work? Is there a scope to improve resilience and cooperation between those bodies that are involved in the decision making process? What type of synergies can be developed between the payers, HTA bodies and regulators in the EU?

Timing

Ideally the opinion of the Panel should be finalised by **June 2017**.

⁶ See indicatively statements from stakeholders: http://www.beuc.eu/publications/beuc-x-2015-104_access_to_medicines.pdf ; <http://epha.org/no-more-taboos-in-the-quest-for-affordable-medicines/>; <http://www.efpia.eu/mediaroom/352/43/EFPIA-statement-on-the-EMA-report-quot-Adaptive-pathways-key-learnings-and-next-steps-quot>; <http://aim-mutual.org/uncategorized/462/>