Opinion on Innovative payment models for high-cost innovative medicines.

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. 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 2014\(^1\)). 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 Commission is committed to use existing tools to create the necessary conditions at EU level to ensure accessibility of patients to innovative medicinal products and explore possible synergies between various bodies in the EU. To that end, the Expert Panel on effective ways of investing in Health has been requested to work on an Opinion on Innovative payment models for high-cost innovative medicines. This Opinion will:

1. analyse the current role of the national pricing and reimbursement authorities to improve access on innovative medicines, focusing in particular on whether there is 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

2. to answer the question of how health outcomes can be reflected on price setting, looking in particular to the role of RWD for innovative payment models

3. Elaborate on a theoretical framework of health system performance assessment in the area of pharmaceuticals

This 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.

The opinion of the Panel is expected to be finalised by November 2017.

The Expert Panel

The Expert Panel on effective ways of investing in health is an interdisciplinary and independent group established by the European Commission to provide non-binding advice. The Expert Panel aims to provide the necessary evidence that will support the EU countries in delivering high quality care and making their health systems more resilient and efficient whilst improving accessibility to all.

They currently work on questions related to:

- Innovation in pricing models for innovative medicines
- Access to healthcare in the EU
- Assessing the performance of health systems