EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 765

PHARMACEUTICAL COMMITTEE
1 April 2019

Subject: **Innovation and access from the regulatory and competition enforcement perspectives**

Agenda item 4

1. BACKGROUND

Innovation has been a buzzword in many recent political discussions about the pharmaceutical system. For example, the June 2016 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States[1] mentioned the various angles to innovation (e.g. recital 8, 9, 26).

However, it is not always obvious to define what exactly constitutes innovation in the pharmaceutical sector. Different concepts are currently used to describe and frame novelty and innovation. In the regulatory field they reach from 'significant benefit' to 'clinical superiority' and are often summarised under the concept of 'unmet needs'.

Competition and industrial policy try to define and measure innovation, too. In this field, some argue that innovation in the pharmaceutical sector is rather commercial, as opposed to truly need driven innovation.

Some recent studies[2] suggest that in the past decade the pharmaceutical industry relied heavily on incremental innovations (e.g. "me too" drugs). While this may change with the acceleration of the pace of innovation in recent years (important discoveries and technical advances like digitalisation, artificial intelligence or genome sequencing may lead to transformational changes in the sector), it is claimed that small innovations achieve a proportionally larger reward.

Lastly, it is important to remember that research is also an important element to foster innovation and it has been noted that both public and private investments are essential for the research and development of innovative medicinal products.[3]

[1] https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balancepharmaceutical-system/.

[2] See for example: Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe (Copenhagen Economics); 2016: https://publications.europa.eu/en/publication-detail/-/publication/8ffeb206-b65c-11e8-99ee-01aa75ed71a1/language-en/format-PDF

[3] For example in Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (June 2016); recital 20.

2. WHAT IS INNOVATION AND HOW TO MEASURE IT?

In the 1 April meeting of the Pharmaceutical Committee the aim is to consider some element of the innovation principle.

DG COMP will present its recent report on competition enforcement in the pharmaceutical sector and its experience with innovation and access from the broader competition policy perspective[4].

What is innovation and whether it has catered sufficiently for unmet medical needs of patients with rare diseases and the paediatric population is also considered in the context of the evaluation of the orphan, paediatric legislation.

It is expected that innovation in the pharmaceutical sector would require a far longer discussion than the time foreseen in the Pharmaceutical Committee of 1 April. Therefore, we see it as a first reflection to be continued later this year.

3. NEXT STEPS

To support the discussion we invite the Committee members to consider their replies to the following questions:

Q.1 What defines innovation in the pharmaceutical sector?

Q.2 Does the regulatory framework enable 'need driven innovation'?

Q.3 What has been the role of the pharmaceutical incentives in driving innovation? To what extent has there been any unintended consequences?

Q.4 Have you experienced anti-competitive behaviour in your country, where companies exploit the regulatory framework to limit competition or hamper innovation?

[4] http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html