EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 837

PHARMACEUTICAL COMMITTEE
11 May 2022

DISCLAIMER

This document has not been adopted by the European Commission and, therefore, it does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.

Furthermore, the topics explored in this document are based on feedback from consultations. They represent elements tested in the impact assessment. Feedback from the discussion in the pharmaceutical committee will feed into the on-going impact assessment. The document is only for the purposes of the discussion at the pharmaceutical committee and should not be distributed further.

Revision of the general pharmaceutical legislation

1. Scope of the pharmaceutical legislation

The EU legal framework for human medicines sets standards to ensure a high level of public health protection and the quality, safety and efficacy of authorised medicines. In addition, it promotes the functioning of the internal market, with measures to encourage innovation. It is based on the principle that a medicinal product requires a marketing authorisation by the competent authorities before being placed on the market. The review of the legislation provides an opportunity to revisit the scope and definitions of the legislation as described in Articles 2 and 3 of Directive 2001/83/EC. Several reasons speak in favour of a change, not with the aim of changing/expanding the scope in terms of medicinal products that might be covered by the legislation but rather to avoid regulatory gaps in view of scientific and technological developments.

2. Scope of the centralised application procedure

The scope of the centralised procedure, laid down in Regulation (EC) No 726/2004, is a subject under consideration for revision. Two specific topics are discussed in the Committee in this session first, generic medicinal products and medicinal products containing or consisting of elements that derive from nanotechnology and its applications.

- Generic medicinal products

Under the current system, the applicant for a generic medicinal product has the choice to opt for the central authorisation procedure (CAP) or the decentralised procedure (DCP) (Article 3(3) of Regulation (EC) No 726/2004). However, discussions during the Pharmaceutical Committee regulators' workshops[1] highlighted that in practice the vast majority of generic medicinal products apply for authorisation via mutual recognition/decentralises procedures, thus creating a well-functioning system overseen by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh). The Committee will exchange views whether the scope of the CAP can be updated to optimise the system and reduce administrative burden as well as allow the CHMP to focus on more complex applications.

- Medicinal products that contain or consist of elements that derive from nanotechnology and its applications

The lack of a legal definition for so called 'nanomedicines' and their complex mechanism of action were raised in the public consultation[2]. In parallel, the EMA regulatory science to 2025[3] paper recognises the need to '*develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals*'. The Committee will exchange views on whether the revision should take into account the characteristics of medicines that contain or consist of elements that derive from nanotechnology and its applications in order to better harness the potential of these products and promote a harmonised approach across Member States.

3. Product information

The pharmaceutical strategy recognises that the rules on product information represent an important tool to deliver on access, availability and futureproofing of legislation. Thus, related measures will be part of the upcoming legal revision. Discussions with stakeholders and the public consultation supporting the revision indicate that the use of multilanguage packs and electronic product information can be efficient tools to facilitate access to medicines. They also indicate an overall support for both measures although there are strong reservations about a complete elimination of paper leaflets from medicines. The Committee will exchange views on the matter in order to better inform the review process.

4. Environmental issues

The pharmaceutical strategy includes two flagship initiatives aimed to improve the quality and environmental sustainability of human medicines: (i) improving transparency of the pharmaceutical supply chain and (ii) strengthening the environmental risk assessments (ERAs) of human medicine.

In the EU, there are no specific rules regulating the emissions from pharmaceutical production into the environment; active pharmaceutical ingredients (APIs) are not covered by the REACH regulation and the Industrial Emissions Directive (IED). Furthermore, the lack of transparency in the pharmaceutical supply chain makes the tracing of the origin of APIs discharged into the environment impossible. Therefore, the Commission considers a number of measures to improve the transparency and sustainability of the pharmaceutical supply chain.

[1] Pharmaceutical Strategy for Europe Workshops March to June 2021 (europa.eu)
[2] Publicly available results: Revision of the EU general pharmaceuticals legislation (europa.eu)
[3] EMA Regulatory Science to 2025 (europa.eu)

At present an ERA is required to be submitted as part of any marketing authorisation application, however, it is not part of the benefit/risk (B/R) balance. In addition to that, the ERA addresses only risks to the environment, there is no requirement to address risks for the development and spread of antimicrobial resistance (AMR) and other risks to humans due to exposure to pharmaceutical residues via the environment. To this end, the Commission considers different options to revise the ERA requirements in the pharmaceutical legislation.

5. Pharmacovigilance

Regulation (EC) No 726/2004 and Directive 2001/83/EC provide the EU legal framework for pharmacovigilance for medicinal products for human use. These provisions were amended in 2010 and 2012 to introduce additional monitoring requirements for certain medicines, easy to identify by the inclusion of a 'black symbol'[4]. The experience gained regarding 'additional monitoring' over the time is rather inconclusive[5], which puts in question the impact of these measures. The Committee will exchange views on whether pharmacovigilance resources might be more efficiently used in other initiatives to improve spontaneous reporting.

6. Inspections

There is a clear shortfall in good manufacturing practice (GMP) and good clinical practice (GCP) inspection capacity in the EU/EEA network and these gaps have been further exacerbated notably because of the UK leaving the EU and the COVID-19 pandemic (particularly for GMP inspections). In addition, it becomes more and more important for EU inspectors to develop and maintain different expertise to inspect novel and emerging technologies.

Solutions are necessary to promote and support the network by providing additional inspection capacity and building inspector capability and expertise to strengthen GMP and GCP compliance oversight within the EU/EEA. It is therefore proposed that changes to the legal framework are implemented to facilitate the creation of an additional EU pool of experienced inspectors conducting inspections in emergency situations (e.g. public health crisis such a pandemic) but also when there is lack of capacity or capability (specific expertise) or important backlogs.

[4] The 'black symbol' is defined by Article 23 of Regulation (EC) No 726/2004 and Article 11 of Directive 2001/83/EC.

[5] Report from the Commission to the European Parliament and the Council on the national and European Medicines Agency experience regarding the list of medicines for human use subject to additional monitoring https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0591&from=EN