EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 838

PHARMACEUTICAL COMMITTEE
11 May 2022
99th meeting

SUMMARY RECORD

The meeting was organised via video conference and was attended by representatives from the Commission, 24 EU Member States, Norway, Iceland, Lichtenstein and the European Medicines Agency (EMA) and members of the Heads of Medicines Agencies Coordination Group for Mutual Recognition and decentralised procedures – human (CMDh). .

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 836) was adopted with the addition of a point under A.O.B.

2. Scope of the pharmaceutical legislation

Discussions covered the legal provision defining 'pharmaceutical product' and the scope of the legislation (inclusions / exceptions). Special consideration was given to the term 'industrial process' and whether its inclusion or not in the scope can help in regulating new technologies such as personalised medicines, decentralised manufacturing but without extending the scope of the legislation to cover non-pharmaceutical products. Member States mostly agreed that the definitions in legislation should be reviewed as they need to be future-proof. It was also pointed out that flexibility should be built-in the legislation to allow for adaptations of the definition to the rapid changes in science and technology. They also highlighted that the review should contribute to clarity and predictability and to support innovation and patient access. However, some experts highlighted the risks inherent to the qualification of borderline products and called for a procedure to solve rapidly such issues (e.g. use a committee to receive a harmonized opinion on whether the product is within the scope of medicinal regulations and if not on how to assess). As regards the exemptions foreseen in Article 3 the MS mostly called for the exemptions on magistral and officinal preparations to be kept and called for some adaptations of the hospital exemption and more harmonisation to ensure better evidence generation in this process.

3. Scope of the centralised application procedure

The first question examined was the possibility of exclusion of generic applications from the

centralised procedure to allow the EMA Committee for Medicinal Products for Human Use (CHMP) to focus on more complex and innovative applications. While some Member States maintain that applicants should have the choice between the national and centralized procedures and some other Member States agree to the transfer to national level, other Member States agreed to a more nuanced approach e.g. transferring the simple generics to the Member States (MRP/DCP procedures) and keep the complex generics with the centralized procedure.

The second question pertained to medicines containing or consisting of elements deriving from nanotechnology and its applications (popularly also known as 'nanomedicines'). These are complex to manufacture but offer numerous advantages. The Committee discussed whether such medicines should always be approved under the centralised procedure, especially since many of the early 'nanomedicines' are coming off patent and their off patent counterparts come to the market there is a call for harmonised assessment of these products by different Member States. Even though Member States thought that a definition and harmonised criteria for assessing such products can be useful (including through guidelines) there is currently no apparent need for a special pathway or to include them in the mandatory scope of the CAP. Members of the Committee maintained that the current rules sufficiently guarantee the main principles of the assessment process including for these medicinal products.

4. Product information

The Committee discussed multilingual packages and electronic product information as part of the upcoming legal revision.

The OPC indicates a general support for additional possibilities to have multilingual packages and for the provision of the product information by means other than printed form (electronic product information).

As regards *multilingual packages*, even though language exceptions are already a possibility in legislation, the categorization of labelling particulars to mandatory ones and expanded ones to make room for more languages to fit on the same package and / leaflet was not opposed by members of the Committee. However, most Member States made a scrutiny reservation regarding which details and information would be left out of the mandatory particulars list. Regional multi-language packages was mentioned as another way to increase availability of medicines and respond to shortages.

As regards *electronic product information* members of the Committee agreed that adding the possibility to provide product information by means other than the printed packages and leaflets is an important tool to deliver on access, availability and futureproofing of legislation. Members of the Committee were open to a stepwise approach to allow such possibilities in a first phase for specific categories of products (such as medicines administered by a healthcare professional, or used in hospitals) or to leave the final choice on the use of electronic product information to each Member State. Moreover, it was proposed that in principle for over the counter medicines, medicines sold in some geographical areas, patient categories and exceptional situations (blackouts, crises) paper should continue to be present to ensure the appropriate use of medicines. It was also mentioned that changes in this regard should not transfer the costs to patients and health systems.

5. Environmental issues

The first question examined transparency regarding the sustainability performance of all actors in the pharmaceutical supply chain to reduce the environmental impact of medicines and appropriate measures to achieve this objective. Members of the Committee expressed support for more transparency. However, they raised concerns about the accessibility of data by the public health and water control authorities. The second question was whether GMP is the appropriate framework to establish environmental standards for the prevention of AMR. The Member States acknowledged the difficulty of the discussion mainly because of reasons related to the lack of mandate and specialised expertise of inspectors to examine environmental matters and adding this requirement in GMP would significantly increase inspectors' workload. The possibility of a "declaration of compliance with an environmental standard" was also proposed as an alternative. The third question was about strengthening Environmental Risk Assessment (ERA) in the context of marketing authorisation of medicines. The members of the Committee that took the floor generally supported measures to strengthen ERA in the context of medicines authorisation and discussed ways to better enforce the submission of a complete ERA report in the authorisation dossier while avoiding including the ERA in the benefit / risk assessment of a medicine itself.

6. Pharmacovigilance

The point covered medicines which are subject to additional monitoring. They are identified by the inclusion of a 'black symbol' (a black inverted triangle) in the product information and an explanatory statement in the product information. The aim was to discuss with Member States whether this legal provision should be revised. Most Member States supported the elimination of the measure and its replacement with pharmacovigilance actions outside legislation stressing that the general pharmacovigilance requirements in the legislation are working well and that the black triangle has not proved its effectiveness. Some Member States suggested that the additional monitoring status should be kept but limited in scope and based on "an active substance" and not "the product" as it is now in order to avoid situation that generics do not have the black triangle.

7. Inspections

The Committee discussed providing additional inspection capacity and building inspector capability and expertise to strengthen Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) compliance oversight within the EU/EEA. The discussion covered the possible models for building common EU inspection capacity and capability building for GMP and GCP inspections. Member States argued for the need to continue to build national capacity and also stressed the essential need for training of inspectors and international aspect of inspections raising the possibility for cooperation with strategic partners, notably within Mutual Recognition Agreements and relevant third country authorities.

8. A.O.B.

Romania raised the need for solidarity from other EU Member States on immunoglobulin

shortages.

Next meeting will take place in autumn at a date to be announced.