3 October 2022
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Stakeholders and Communication Division

Fifth EMA – Medicines for Europe bilateral meeting

15 September 2022

Chair: Juan Garcia Burgos (EMA), via WebEx

1. Welcome and introduction

The meeting was chaired by Juan Garcia Burgos (EMA) who opened the meeting. Emer Cooke (EMA) welcomed all participants and Adrian van den Hoven (Medicines for Europe) also made some introductory remarks.

2. Accelerating and tailoring centralised marketing authorisation procedures for off-patent medicines

Medicines for Europe discussed the role of the centralised procedure in obtaining marketing authorisation for off-patent medicines, noting that it could be utilised further. Some reflections on the approach for handling duplicates were also discussed and could be further considered aspart of the pharma strategy and in this context Medicines for Europe were invited to liaise further with the European Commission to discuss their proposal.

Medicines for Europe made further comments regarding the use of the centralised procedure for generic applications, including suggestions for the CHMP to cope with a potential increase in the number of applications.

EMA recognises the importance of well-functioning centralised and mutual recognition/decentralised procedures and agreed that further consideration should be given to how access for generics can be optimised. Medicines for Europe agreed to gather further feedback from its members in accessing the centralised procedure for generic medicines.

3. Improving Article 10 to support off-patent medicines

Medicines for Europe raised a number of issues relating to Article 10 in the context of the increasing complexity of off-patent medicines and their development and the need to further facilitate single global development.

EMA noted that it supports the integration of new methods and further consideration of the current paradigm of bioequivalence to establish similarity in abbreviated applications based on the long-standing experience and evolution in the field.

EMA highlighted that it supports global development and is also seeking to foster alignment in terms of

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

requirements. In this respect, EMA supports activities at ICH level and ad hoc activities such as clusters with non-EU authorities. EMA also noted that the pharma strategy is drawing on lessons learnt with biosimilars and may consider extending the approach to other complex applications.

In terms of biosimilars, Medicines for Europe shared concerns regarding different interpretations at national level of suitable development strategies during scientific advice. Medicines for Europe requested changes to Article 10 to ensure greater clarity, predictability and efficiency of the approval process.

EMA informed Medicines for Europe that a statement on the interchangeability of biosimilars has been drafted together with HMA and will be shared with industry stakeholders. EMA is working closely with Heads of Medicines Agencies to ensure dissemination of this information to NCAs and stakeholders. This move was welcomed by Medicines for Europe.

EMA acknowledged that there is an opportunity for a simplified and more proportionate approach for generic applications. Within the context of the pharma strategy, considerations are being given to the possibility of relying on ERA studies for the reference product and to request an RMP only in specific situations. In the meantime, to facilitate the operability of RMPs for generics, EMA is launching a pilot in September 2022 to publish the full RMP for new products under Article 8(3). Medicines for Europe noted that the generics industry welcomes this move.

Finally, Medicines for Europe discussed recognition of the concept of value-added medicines in the legislation. with reference to the US FDA's 505(b)2 pathway.

EMA acknowledged that there are still some challenges in the current EU framework in terms of translating research for known molecules into new authorised indications, and some of these elements will be addressed in the review of the pharma legislation.

4. Transparency and stakeholders relations

Medicines for Europe noted that they appreciate the cooperation with EMA and understand the need to move towards greater efficiency through IT lean governance. In this context, they highlighted the importance of equal stakeholder representation, noting that clear visibility of the objectives would facilitate the recruitment of subject matter experts (SME) from the generic industry for projects. To provide comprehensive feedback from the industry, Medicines for Europe asked for SMEs to be able to share some background information within the trade associations. The involvement of the trade association secretariat to ensure coordination and continuity was also raised as an important part of governance (e.g., by copying the relevant secretariat on correspondence).

EMA thanked industry associations for their willingness to commit resources to the development of the portfolio roadmap and agreed on the need for clear communication. There have been a number of successful calls for SME of special interest, which detailed the scope and deliverables. EMA will also hold a strategic portfolio review with industry stakeholders on a quarterly basis.

5. Modernise maintenance procedures to foster medicines availability

Medicines for Europe highlighted the importance of digital modernisation and interoperability of systems to foster medicines availability. Important aspects include the re-use of SPOR data, the connection of regulatory and supply chain data and the electronic product information (ePI). It is key that IT projects across the network are implemented in a harmonised manner across all EU Member States, with strong data governance. The importance of an EU roadmap to reflect digital readiness of national authorities was also emphasised. In addition, the need for rapid revision of the variations framework was also raised, in order to reduce the administrative burden and ensure efficient use of resources for both regulators and industry.

EMA explained that digitalisation and automation of operations and streamlining of processes is a key strategic goal. Further, EMA supports the use of internationally agreed standards, such as IDMP and FHIR, as key enablers for interoperability. Current projects are DADI, ePI and PMS, where the same FHIR data elements are used to describe medicinal products across all use cases.

6. Oversight of manufacturing and supply chain

Medicines for Europe emphasised the importance of EMA's role in optimising the supply chain, for example, by improving demand predictability and through the ePI. They voiced their support for the development of the European Shortage Monitoring Platform (ESMP), stating that the process should be as efficient as possible for all parties. The importance of working with the European Medicines Verification System (EMVS) was also flagged as this would provide a good overview of stocks and supply needs. To achieve this, Medicines for Europe proposed a sandbox approach.

EMA explained that they are currently working to have a minimal viable ESMP product by February 2025. Although the use of EMVS as potential source of information was examined, the ESMP feasibility study identified relevant challenges such as a lack of legal provisions under the FMD, lack of alignment on the use of EMVS for shortages by EMVS' stakeholders as well as technical issues.

7. AOB

No topics were raised.

Wrap up / end of meeting

Juan Garcia Burgos closed the meeting by thanking all the participants for their time and for the open and constructive discussion.

Follow up action

A short summary report will be prepared and circulated to all participants.