28 June 2023
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Highlights of EMA-AESGP Bilateral meeting of 18th April 2023 meeting

18th April 2023 – chaired by Marie-Helene Pinheiro

1. Welcome and introduction

The chair welcomed attendees highlighting the importance of collaboration and strategic discussion in order to have a mutual understanding of the key priorities and challenges on our respective organisations.

2. Electronic Product Information (ePI) and PI content

Product information (PI) is considered fundamental as it is the source of information for patients using self-medication and in this context AESGP provided a number of recommendations on how to ensure an appropriate transition to the electronic PI (ePI). EMA provided a status update on the ePI development and the foreseen pilot phase as outlined in the March quarterly system demo.

AESGP highlighted the need to improve content of the leaflet (independently of its format, paper or electronic). The expectation to have an EU implementing roadmap and to have guidance on language and symbols/pictograms to use was flagged.

3. Labelling of medical devices co-packed with medicinal products

AESGP provided proposals to identify an acceptable way and harmonised approach of providing the applicable labelling particulars for medical devices co-packed with medicinal products taking into account the applicable legal framework consisting of different legislations (Directive 2001/83/EC, Regulation (EC) 726/2004, Medical device Regulation (EU) 2017/745).

EMA confirmed that the proposals received were discussed with labelling specialist of the national medicines regulatory agencies in Europe. However, the Notified Bodies were ultimate, responsible for the assessment of the devices and for ensuring compliance with the labelling requirements detailed in Annex I of the MDR. The expectation was to reach a suitable compromise that works for all parties involved. And later if possible, to reflect it as part of the planned update the EMA/CMDh Q&A on MDR/IVDR implementation.

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4. EMA experience with borderline products and interplay between EMA and Medical Device Coordination Group (MDCG) Borderline Working Group

Although the remit of providing an opinion of borderline products is at Member State level, EMA provided overview of platforms supporting discussions on these products which include two platforms enabling formal discussion: advance therapy classification, and requests under article 4 of regulation EU 2017/745 and article 3 of regulation (EU) 2017/746), and two new platforms for informal and early dialogue (Innovation Task Force, HMA-EU Innovation Network Borderline Classification Group). It was stressed the fact that, although EMA can provide advice, the final decision is always made by the relevant member state.

Input upon EC request is also provided to the Medical Devices Coordination Group Borderline Working Group.

AESGP highlighted the importance of relevant transparency of these platforms for industry stakeholders to better understand what their scope and remit are and make best use of them at early stage in the context of national decision processes.

5. EMA implementation actions under the MDR

The medical device regulation EU 2017/745 foresees the consultation of EMA or relevant authorities by the notified bodies for medical devices composed of substances systemically absorbed. For organisation purposes, EMA consulted the pharmaceutical industry in September-October 2022 in order to gain insights on expected product pipeline which could be subject of consultation. AESGP was asked to keep the Agency updated as new information on expected submissions is identified within its members.

6. Well established use legal basis

Clarifications were provided on the nature of the fees allocated to article 10a of directive 2001/83/EC for well-established use i.e. proportionate with the assessors' workload activity. This principal was applied for all EU MAAs' legal basis proposal.ma

EMA also stressed how the use of this legal basis is considered valuable especially for orphan products and repurposed medicines. AESGP was invited to provide any additional feedback on the use of this legal basis.

7. Conclusions and next steps

The continuation of the dialogue between EMA and AESGP is considered valuable and both parties committed to further engage as required