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European Medicines Agency

Highlights fifth EMA- Association of the European Self-Care Industry (AESGP)

29 April 2024 - Chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The chair and EMA's Executive Director welcomed AESGP representatives and congratulating them this year 60th anniversary of activities in health and self-care and confirming EMA Executive Direct to the upcoming anniversary conference.

2. AESGP positions on One Substance One Assessment (OSOA)

AESGP shared their views on the impact of cross-sectorial EU legislation proposals and policies on medicinal products innovation and availability. The need for more clarity and early cross-sectorial interaction and discussion amongst relevant concerned authorities and expert(s), yet respecting each other's remit, was flagged.

EMA acknowledged the points made and flagged the importance for Industry stakeholders to support concerns expressed with relevant and robust scientific data evidence generation submissions to relevant authorities.

The importance of the one health EU agenda was also highlighted and reference to the recently published Cross-agency knowledge for One Health action made as a key tool to address complex and frequent threats to health which interconnect human health with the health of animals, plants, and ecosystems. In this context different examples were presented by AESGP.

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3. MP-MD combination: Update on EMA implementation actions under MDR i.e. labelling co-packed medical devices and MDs under Rule 21 first indent

AESGP discussed the technical challenges experienced for ensuring the respect of the device labelling legislative requirement for medical device co-packed with a medicinal product and asked for more guidance on a suitable approach.

The EMA updated AESGP on the current revision of the recently which was published Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 017/745 and (EU) 2017/746), which was published on 3rd May 2024. This will provide guidance for co-packaged medical devices (Class I and Class IIa) to address technical challenges highlighted by the industry specific to these devices. This guidance takes into consideration some alternative solutions proposed by Industry and AESGP, with certain considerations in order to ensure compliance with both regulatory frameworks (Medicines regulation and MDR).". As needed any further guidance might be considered.

Finally EMA and AESGP discussed briefly the substance based medical devices which are systemically absorbed and fall under Rule 21 whether any case identified by AESGP since their previous feedback to the EMA survey. AESGP confirmed that they are not aware of any submissions.

4. AESGP work on transitioning to ePL

The results from the Perception study on non-prescription medicines and digital product information conducted by Ipsos on behalf of AESGP were presented noting that it is fundamental to ensure that medicinal products are used correctly and that the key information is displayed in an accessible and easy to understand manner.

The Agency welcomed the discussion and updated on the upcoming opportunities for stakeholders to further explore requirements and optimal solutions such as the Quality Review of Document (QRD) Interested Party meeting scheduled for June 2024. AESGP was encouraged to provide workable proposals to support the use of ePI data also in non-prescription medicines.

5. AESGP position on new Variation Regulation revision

The revision of the New Variation Regulation was welcomed by AESGP who shared their views and proposals on promoting automation by leveraging the benefits of SPOR, use a risk-based approach to downgrade variations and consider more equality between herbal and chemically defined active substances and medicinal products.

AESGP was invited to participate to the upcoming stakeholder consultation on the draft revised variation guideline planned for June 2024.

Post-meeting note: Stakeholders consultation on Variations guidelines: Proposed amendments to the European Commission guidelines on variations categories and procedures.

6. Referral for well-established substances – reflection on recent and past experiences

AESGP shared their reflections on Industry experience with well-established substances referral process. Amongst other, the importance of risk contextualisation, the need for criteria to justify the trigger of a referral procedure, more dialogue between the regulators and industry stakeholders and the need to have more transparency on the nominated assessors were flagged.

The EMA welcomed the feedback and provided clarifications on the points made on the current process, including triggering criteria and timelines which are in line with the current regulation.

7. Conclusions

The meeting was an opportunity to gain more insights on current challenges, constraints and opportunities for improvement of non-prescription medicines sector. Future dialogue and collaboration was welcomed.