23 January 2025
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European Medicines Agency

Highlights – 6th EMA-AESGP (Association of the European Self-Care Industry) bilateral meeting

23 January 2026 – Chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The Chair and Executive Director welcomed the AESGP delegation and the opportunity for an open dialogue on sector-specific views and proposals for the implementation of the revised general pharmaceutical legislation and beyond. The importance of clear and timely communication in ensuring industry preparedness was acknowledged.

2. AESGP priorities on the implementation of the revised pharmaceutical legislation

The AESGP expressed its views on elements to be prioritised when implementing the revised general pharmaceutical legislation stressing the need to have science based and proportionate implementation decisions. The need of ensuring transparency, timely guidance and on retaining scientific expertise was stressed.

The publication of a dedicated webpage for updates on the implementation of the revised pharmaceutical legislation as well the governance structure to guide and oversee EMA's implementation of the pharmaceutical legislation were welcomed.

The Agency acknowledged the importance of transparency regarding the revised legislation implementation activities and confirmed that additional details and engagement activities will follow once of the final legislative text is available.

3. AESGP feedback on communication campaigns

The AESGP emphasised the importance of clear and timely communication when addressing public concerns about medicine safety.

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The Agency shared this view, confirming the importance of aligning with the principles set out in the Framework for interaction between the European Medicines Agency and industry stakeholders. The need for science-based communication, free from any perceived conflicts of interest, was emphasised. However, collaboration with stakeholders to raise awareness of communication campaigns was encouraged.

4. Medical devices and drug-device combinations

The AESGP presented its position on the revision of the medical device regulation highlighting elements of interest to the self-care industry and stressing the importance of avoiding any duplication, ensuring presence of relevant expertise and involving stakeholders.

It was clarified that the EMA is not an official party to the legislative process, and therefore it was not possible to comment on some of the proposals made. Nevertheless, the Agency welcomed the publication of the European Commission's proposal to amend the Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation. The EMA confirmed its general support for provisions that make a meaningful contribution to the device sector and for ensuring that they are practical and implementable and ensure the effective use of resources.

The role of the recently established Combination Products Operational Groups (COMBO) was clarified. COMBO aim to bring together all relevant stakeholders and regulators to discuss operational challenges, without duplicating the work of the Medical Device Coordination Group. The Agency also confirmed its intention to engage with industry stakeholders via dedicated meetings with interested parties and to provide regular updates to the Industry Stading Group (ISG).

5. Centralised switching

The AESGP presented industry experience with the centralised switching procedures and discussed proposals on how to promote its use.

The Agency emphasised the importance of industry to submit applications in order to identify and provide relevant guidance needs and support. EMA also welcomed proposals on therapeutic areas where the centralised switching could be considered beneficial for European healthcare systems. The AESGP was also advised to engage in a dialogue with healthcare professionals and pharmacists and also with the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

6. Environmental Challenges for Medicines

The AESGP presented initiatives such as substance-specific consortia and matchmaking, which were established to ensure the availability of environmental risk assessment data. The EMA welcomed these efforts and the insight provided, and emphasised the importance of companies making use of supporting mechanisms such as the scientific advice, or the support of the SME Office in case of small and medium-sized enterprises (SMEs).

7. Pharmacovigilance non-prescription medicines

The AESGP presented its members' experience with the European Union Reference Dates (EURD) list and Periodic Safety Update Reports (PSURs).

The Agency acknowledged the queries and proposals that were shared. The importance of clarifying changes for companies and international partners was also recognised.

8. Conclusions and next steps

The meeting provided an opportunity to focus the dialogue on the value of non-prescription medicines for healthcare systems and European patients.