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European Medicines Agency

Highlights – 3rd EMA-EUCOPE bilateral meeting

07 November 2024 – Chaired by Marie-Hélène Pinheiro, EMA Industry Corporate Liaison

1. Welcome and introductions

The chair welcomed the EUCOPE and highlighted the crucial role of Small and Medium-Sized Enterprises (SMEs) in the development of innovative medicines and technologies as SMEs are a key sector in the industry, driving progress and improving patient access to innovative treatments across Europe

2. Key priorities for the next 3-5 years and pipeline trends

EUCOPE presented the results of its members' pipeline survey, which confirmed that SMEs are driving innovation and product development, with a strong presence in preclinical research and all stages of clinical trials, with a particular focus on oncology, immunology, genetic disorders and rare diseases. The challenges faced specifically by small and medium sized companies and the need for regulatory support were also outlined.

Discussion took place around the current EU definition of an SMEs (Article 2 (1) of Recommendation 2003/361/EC: ”enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million”) and the gap for companies - neither small nor large enough to benefit from either incentives and support from EMA and having similar constraints as SMEs (e.g. staff and financial capacity etc.) constraints. The potential need for change of the definition was highlighted to foster EU industry competitiveness.

The importance of having the opportunity to actively engage with the Agency in the context of established industry stakeholders platforms and relevant activities was stressed, especially for highly specialised companies being SMEs or mid-size.

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3. EUCOPE position on Joint Scientific Consultation – Health Technology Assessment implementation within EMA's remit

EUCOPE's position and challenges from developers' perspective with the new Joint Scientific Consultation (JSC) framework were presented. EMA clarified their specific role in the context of parallel JSC and referred to the close cooperation with the Commission and HTA Coordination group and its subgroups. The discussions at the recent SME Info Day and at the Industry Standing Group (ISG) were highlighted. The importance of ensuring medicines accessibility (identified in one of the pillars of the European medicines agencies network strategy 2028) and data confidentiality was specifically mentioned by the EMA.

4. Clinical Trial experience of Small and Mid-Sized Companies

EUCOPE presented the SME perspective and challenges to implement the EU Clinical Trial Regulation and related processes/systems. While EMA support was acknowledged, some EUCOPE members pointed out some difficulties in processing and navigating the amount of information available. The EMA acknowledged the points raised, complementing some made during the ACT EU Multi-stakeholder Platform Advisory Group (MSP AG) and during the recent MSP annual meeting. In this context, EUCOPE was informed about the imminent start of activities to simplify the available CTIS training materials, and the future development of sign-posting for clinical trials guidance documents. EUCOPE was encouraged to continue to bring the voice of its members to the ACT EU Multi-stakeholder Platform Advisory Group (MSP AG) and other relevant activities. The availability of the pilot on consolidated advice for all SMES was highlighted.

5. Feedback on EMA "Agile" Digital Systems from SMEs perspective

The feedback from EUCOPE's members on the activities related to the EMA Agile transformation was discussed highlighting the need to factor into the activities the time required for industry stakeholders to be ready and compliant with the requirements. The need to ensure better communication and collaboration between product owners, national competent authority and industry Subject Matter Expert was flagged. The feedback reported was welcomed by the EMA. The activities initiated to address the challenges raised were outlined (e.g. re-activation of the Regulatory Optimisation Group) acknowledging the need to increase presence of smaller companies. EUCOPE was also invited to continue to attend ISG meetings and relevant training initiatives, specifically in preparation to the upcoming launch of the European Shortages Monitoring Platform (ESMP).

6. EMA SME office support activities

The EMA provided an overview of the specific incentives and support for SMEs including a dedicated contact point, regulatory assistance and SME briefing meetings, and encouraged EUCOPE to promote such activities to their SMEs members. In particular, the EMA encouraged EUCOPE to raise awareness of its members on a feedback survey on early development support, including SME briefing meetings. As presented during the July meeting of the R&D platform, the survey is targeting early engagement support platforms and aims at monitoring the implementation of the framework for interaction between EMA and industry stakeholders. The survey is targeting all pharmaceutical irrespective of size, which benefitted from such support between 1 January - 15 December 2024.

EUCOPE support and participation to the EMA SME info day (18 October) was acknowledged and welcomed by EMA. Contributions to the ongoing EMA SME survey 2024 and the SME roundtable to be organised in late 2025 in the context of the 20-year anniversary of the SME regulation were also highlighted. EUCOPE will be invited to the roundtable and EMA invited EUCOPE to collect information from their members on experience with the SME regulation.

7. Conclusions and next steps

The continued dialogue on the perspective of SMEs and small- to mid-sized companies was welcomed and considered important and relevant in identifying areas where more support is needed to promote access to innovative therapies and technologies for EU patients.