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European Medicines Agency

Highlights – 4th EMA- EUCOPE bilateral meeting

Chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement

1. Welcome and introductions

The Chair and the EMA Executive Director welcomed the EUCOPE delegation emphasising the importance of maintaining an open dialogue and ensuring that the voice of small and mid-sized enterprises is heard particularly in preparation for anticipated legislative changes with a focus on the revision of the general pharmaceutical legislation (GLP) and the upcoming biotech act.

2. Presentation of EUCOPE commissioned study

EUCOPE shared results from a study assessing the impact of current and future legislations on the competitiveness of the EU life science sector, including the GPL, clinical trials, medical devices and *in vitro* diagnostic (MDR/IVDR), and health technology assessment (HTA) regulation.

In addition, EUCOPE noted that the number and speed of regulatory changes are especially challenging for small and mid-sized companies.

EMA remains firmly committed to supporting innovation. We will continue to closely engage with stakeholders and partners to shape future actions that support Small and Medium-sized Enterprise (SMEs), foster innovation and competitiveness and accelerate patient access to new therapies. These efforts will also explore how to best assist Small Mid Cap (SMCs), taking into account the upcoming pharmaceutical legislation reform and other EU initiatives, including the Biotech Act, the Critical Medicines Act, the Biotechnology and Biomanufacturing and the Life Sciences strategies.

3. Revision of the General Pharmaceutical Legislation (GPL)

EUCOPE emphasized the need for guidance to navigate upcoming changes and identified key areas for development, such as unmet medical need and environmental risk assessments. It also outlined its priority actions, including proposed changes in the committee structures and on paediatric provisions. EUCOPE stressed the importance of being involved in the process, and highlighted the unique perspective it can offer through its membership.

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EMA confirmed plans to engage industry stakeholders through the Industry Standing Group and provide regular updates, ensuring transparency, and opportunities for input throughout the implementation phase.

4. Shaping the future of the regular network: opportunities from the Biotech Act

EUCOPE outlined strategic priorities for the Biotech Act, aimed at strengthening Europe's biotech ecosystem. It proposed establishing a coordinated innovation and access helpdesk for SMEs and SMCs covering multiple regulatory frameworks, to facilitate the development and approval journey of biotech products.

EUCOPE also recommended several measures aimed to harmonise and simplify clinical trial processes including shorter assessment timelines and greater empowerment of the reporting member state.

EMA noted EUCOPE's proposals and reiterated its support for streamline clinical trial approvals, referencing ongoing work under ACT-EU and the new FAST-EU initiative led by Heads of Medicines Agencies aimed to accelerate the authorisation of multinational trials.

5. HTA Regulation: First experiences from Joint Clinical Assessment

EUCOPE shared feedback on the initial phase of the joint scientific consultations, highlighting the challenges faced by small and mid-sized companies. EMA confirmed its commitment to working with members states and the European Commission, key drivers of HTA legislation, to identify ways to support these companies.

6. Conclusions and next steps

EMA values the constructive dialogue with EUCOPE, which represents the voice of small and mid-sized enterprises, and acknowledges its crucial role in the implementation of the revised pharmaceutical legislation and the upcoming Biotech Act. The Agency will continue to engage with stakeholders to promote innovation while safeguarding public health.