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Highlights of the fifth EMA-EuropaBio Bilateral meeting

06 July 2023 – chaired by Marie-Hélène Pinheiro

1. Welcome and introductions

The EMA executive director welcomed all participants highlighting the importance of engaging in a mutual dialogue and use opportunity of the pharma legislation reform to improve and promote access to medicines.

EuropaBio acknowledged the importance of engagement given the fact that they represent small and large companies who are leading on the biological landscape.

2. EuropaBio overview vision for the future of Biotechnology pharma industry in Europe

Europabio highlighted the importance of small and fast growing companies role across all sectors and the vision for the future is to ensure medicines accessibility to European patients by promoting that the technology is developed and manufactured in Europe. In this regard, the positive aspects of the revision of pharma legislation were highlighted.

3. Outlook for the regulatory network in the next 5-10 years

According to EuropaBio buyers research's preliminary results, low investments in the EU are due to the several barriers experienced particularly by small medium enterprises (SMEs) (such as complexity of reimbursement and regulatory systems, lack of adequate support/resources and harmonisation). In this regard the revised pharma legislation, with its incentives, simplification and reduced timelines, is expected to increase Europe attractiveness. The need for early engagement and support especially to SMEs was also flagged.

The Agency recognised the challenges experienced by small entities and reminded the support to SMEs provided through various tools. In addition it was noted that, through the International Coalition of Medicines Regulatory Authorities (ICMRA) collaborative assessment pilot, and other bilateral initiatives, global harmonisation is being promoted.

EuropaBio was invited to flag these points presented also to the European Commission and to National Competent Authorities.

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4. Revision of the EU general pharmaceutical legislation

EuropaBio provided their views on the proposed reform of the EU pharma legislation. It was highlighted how the incentives and the streamline of procedures and timelines were well received and are expected to promote innovation and EU competitiveness. The following were also flagged: the need for network resources, avoiding duplications, ensuring adequate transparency levels and requirements which may hinder innovation and product approval (e.g. environmental risk assessment, PRIME reduced scope of applicability, definitions of unmet medical need, practical implications to use of real world data/real world evidence, harmonisation on paediatric investigations).

EuropaBio points were acknowledged and was encouraged to participate and engage in ongoing discussions on how to improve the current processes at the level of EMA stakeholders' platforms meetings, as appropriate.

5. ACT EU and support to innovation

EuropaBio provided their experience with activities concerning the Clinical Trial Regulation (CTR) implementation in terms of challenges experienced with national requirements, Clinical Trials Information System (CTIS) and transparency.

The improvements made were recognised by EuropaBio, with the following points highlighted: the importance of increasing harmonisation between Member States and ethics committees, the need to improve predictability on assessments timelines and clarify how protection of Commercially Confidential Information (CCI) while using CTIS is ensured.

EMA clarified that, following the ACT EU multi-stakeholders platform kick off workshop, discussions on establishing an EU platform for ethics will be pursued. It was also clarified that the general approach is to streamline and simplify processes in order to reduce hurdles. EuropaBio was encouraged to further discuss these topics at the CTIS forum and in future relevant ACT EU events.

Feedback was also provided on the upcoming revision of CTIS transparency rules, which follow the public consultation held between May and June. System functionalities will be modified in line with the results of the consultation, focusing on publication of clinical trial information of relevance for EU patients and researchers community.

6. International convergence and harmonization

EuropaBio flagged the increase in the use of Real World Evidence (RWE) and Real World Data (RWD) at international level. This increase would benefit from international collaboration in this field to help addressing common challenges and further integrate the use of RWE. The need to have global collaboration and harmonised terminology was acknowledged.

EMA acknowledged the points made and reassured that work is already ongoing through ICMRA, ICH and parallel discussions with international regulators to promote international convergence.

EuropaBio was encouraged to take part in workshops and initiatives organised by the Agency on this topic.

7. Closing

The meeting was the opportunity to have a rich discussion on various aspects of current hot topics. The importance of continuous engagement on both parties was acknowledged.