11 October 2022
EMA/775191/2021
Stakeholders and Communication Division

EMA – EUCOPE bilateral meeting highlights

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Chair: Juan Garcia Burgos (EMA), via WebEx

1. Welcome and introduction

Tony Humpheys (EMA) opened the meeting and welcomed all participants, Axel Korth (EUCOPE) also made some introductory remarks. The meeting was chaired by Juan Garcia Burgos (EMA).

2. EUCOPE Regulatory vision and priorities up to 2025.

EUCOPE was recognised as a relevant stakeholder by the EMA and the EU Regulatory Network. Its work is mainly focused on three areas: EU Advocacy, P&R/Market Access at national level and regulatory activities. EUCOPE's work is carried out in close cooperation with its members and different topics are discussed in its working group, steering group and task forces.

An overview of the Regulatory Working Group was given. The priorities are divided into 4 pillars: Implementation of the EU pharmaceutical strategy and the EMA/HMA strategy until 2025, Clinical Trials, Data and continuous generation of evidence, and MDR/IVDR implementation. EUCOPE's Regulatory Working Group is further divided into several focus groups which cover, among others, topics such as the orphan and paediatric regulatory framework, PRIME, centralised procedure, e-PI, MDR/IVDR implementation with a focus on innovative drug-device combination products and companion diagnostics, CTR/CTIS implementation, ACT EU, RWE and patient-centred medicines development.

Other priorities are, among others, the use of raw data in submissions, the qualification framework, regulatory confidence and predictability of marketing authorisation submissions.

EUCOPE underlined its commitment to continue discussing and working on mutual priorities to foster a European regulatory framework that supports innovative approaches to regulatory science. They also highlighted their efforts to foster collaboration between trade associations.

EUCOPE highlighted recent examples of collaborations with the EMA, such as the participation in the EMA-Industry Focus Group on the Practical Implementation of Integrated Development Support or the collaboration in the PRIME initiative, which for EUCOPE remains a key initiative on EU innovation.

EUCOPE underlined the importance of further improving the EU paediatric framework and confirmed that they will continue to collaborate through the EMA-Industry Focus Group on the practical implementation of the principles relevant to the PIP framework, including opportunities for simplification and improvement of regulatory processes.

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EUCOPE expressed support for an integrated dialogue during drug development and referred to an opportunity to improve linkages and integrate more R&D activities within regulatory activities.

EUCOPE referred to its position paper "The Modernisation of the Centralised Procedure – A Proposal for Reform" issued on 19 April 2022 (https://www.eucope.org/wp-content/uploads/2022/04/cp-regulatory-position-paper-framework-final-2022.pdf) to modernise the centralised procedure, and highlighted how the review of European pharmaceutical legislation offers opportunities to modernise the procedure and ensure it is fit for purpose and fit for the future as new and increasingly innovative therapies are developed.

Proposals covering the different phases (pre-submission, evaluation and EC decision-making) were mentioned. Among them, the training of evaluators was mentioned as a way to increase capacity and expertise within the EU network.

EMA acknowledged the proposals and recalled the need to operate within the existing legislative framework. Although the EMA is not responsible for the development of new legislation, it is committed to working on its implementation, in collaboration with all stakeholders.

3. Innovative medicines: combination medicinal products, SME development pipeline, requirements and needs

Facilitating the integrated pathway for medicinal products to use in combination with medical devices remains a priority for EUCOPE in the context of a possible pilot on scientific advice on drug-device combinations.

While the EMA recognises the need in this area, EMA highlights that this is a comprehensive ambition with some challenges to bring a number of players together taking into account remits and responsibilities of each other. Hence for this mid/long-term perspective, a stepwise approach needs to be considered.

In that regard in follow-up to the discussion at the 8th R&D stakeholder platform meeting, EMA asked Industry (incl. MedTech industry) to provide an in-depth analysis of scope/remit for SA involving expert panels as well as typical types of questions that would be subject to such advice . An initial submission from a cross-association group was acknowledged however more granular analysis is needed to allow shaping a successful pilot in this space.

The EMA will analyse the detailed Industry contribution (expected by end of October). The EMA assured that upon receipt of a comprehensive cross-association analysis, feedback on the EMA review of the Industry input will be provided soon, also in preparation of a discussion at the next R&D platform meeting, scheduled for 5 December 2022.

Many challenges were recognised, and all agreed on the need to collaborate and work together to overcome them. It was also mentioned that the pharmaceutical legislation revision can offer opportunities to make further progress in this area.

4. CTIS implementation: challenges and recommendations from SME perspective

EUCOPE acknowledged that the Clinical Trials Regulation improves the environment for conducting large-scale clinical research and the safety of clinical trial participants in the EU.

EUCOPE provided an update on its response to the EMA survey on the use of CTIS and highlighted that most SMEs have not use it yet. They presented some of the issues faced by SME sponsors, including issues related to CCI and PD, and EMA clarified and responded to some of them.

Regarding CCI, EUCOPE referred to the comments they have provided to the EMA's draft guideline on the protection of CCI/PD, which the EMA will study carefully.

The EMA mentioned the work being undertaken to address the issues that have been identified based on experience so far, with a view to February 2023, when the use of CTIS will be mandatory.

EUCOPE also commented on some divergences in the implementation of the Clinical Trials Regulation in the Member States. In this regard, the EMA mentioned the ACT EU initiative, which will develop a platform to discuss the streamlining of governance and is expected to improve the situation in this regard. The EMA also ensured continued collaboration with sponsors and Member States to facilitate implementation and progress and to overcome any difficulties that may arise. The possibility of creating a more detailed roadmap was mentioned and the EMA will continue to explore this idea.

5. Conclusions and next steps

Tony Humphreys closed the meeting by thanking all the participants for their time and for the open and constructive discussion.

Follow up action

A short summary report will be prepared and circulated to all participants.