



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 January 2024  
EMA/513750/2023

## Highlights – Second EMA – EUCOPE bilateral meeting

29 November 2023 - Chaired by Marie-Hélène Pinheiro

### 1. Welcome and introductions

The Chair and the Executive Director welcomed EUCOPE delegates to this second bilateral meeting acknowledging the importance of the engagement with Industry stakeholders representing small and medium sizes enterprises, which are a major source of innovation in Europe.

EUCOPE Director General highlighted a steady growth in its members affiliation in scope and numbers.

### 2. EUCOPE regulatory (policy) priorities 2023- 2025

EUCOPE's priorities for the next years were presented and including the new EU pharmaceutical legislation review, Health Technology Assessment (HTA) and Substance of Human Origin Regulations implementation, European Health Data Space.

EUCOPE flagged the importance of a flexible and robust regulatory environment enabling adequate support to Small-and Medium sized Enterprises (SMEs) and in this regard early engagement in multi-stakeholders platforms, e.g. EMA-HTA and EMA-FDA parallel scientific advice were highlighted as key to foster innovation in Europe. EUCOPE suggested to consider providing training to SMEs on the upcoming regulatory/HTA interactions under the HTA regulation, which EMA will follow up through SME office's training activities.

EMA also encouraged EUCOPE to continue to engage in relevant discussions in the context of relevant [Industry platforms meetings](#), where and as appropriate.

### 3. Reform of EU pharmaceutical legislation – EUCOPE position

EUCOPE shared their views, positions and priorities. The importance of ensuring availability of the adequate expertise from EU Network of Regulatory Agencies to contribute to drug development advice and evaluation both at national and central level was highlighted.

The EMA welcome the publication of the European Commission's legal proposal for the revision of the EU pharmaceutical legislation and EMA Executive director stated that this revision is a unique opportunity to reshape medicines regulation in the EU and make the EU regulatory framework fit for

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purpose for the next 20 years taking account of medicines and technologies' advances, to promote greater access to medicines for patients and to address the major public health challenges of the future. It was also clarified that EMA, not being an official party to the legislative process, will therefore not comment on any of the proposals made but referred them to the European Commission and thanked EUCOPE for sharing their positions.

EMA has not yet started any formal activities related to the implementation of future changes linked to the revision of the pharmaceutical legislation and has not yet started engaging directly with stakeholders. Once preparations for the implementation begin, EMA will involve relevant stakeholders as needed.

#### **4. Utilisation of different data sources such as RWD/E across life cycle medicines development for Regulatory decision making in particular for ATMPs/Oncology medicines**

EUCOPE highlighted the need for specific guidance on when to use Real World Data and Evidence. The Chair flagged that as part of the [draft workplan of the Methodology Working Party](#), currently under consultation until 30<sup>th</sup> November 2023, a "Reflection Paper on the use of Real-World Data to generate Real-World Evidence in non interventional studies" and a "Roadmap for the development of RWE guidance" are foreseen, pending future CHMP adoption.

It was also highlighted the need to have more clarity on how the project [Data Analysis and Real World Interrogation Network \(DARWIN EU®\)](#), which includes off-the-shelf studies, is expected to fit into the regulatory evaluation process. Clarifications were given on the involvement of Industry stakeholders in DARWIN EU.

In this respect the upcoming [Multistakeholder workshop on Patient Registries on 12-13 February 2024](#) was mentioned as important for EUCOPE Members.

#### **5. AOB**

EUCOPE was invited to follow [Clinical Trials Information System \(CTIS\) bitesize talk: Training materials, CTIS pre-requisites, and updates on transparency rules](#) for additional guidance on CTIS and the updated transparency rules.

#### **6. Summary of follow up items, Close of meeting**

Both parties welcomed the discussions and acknowledged the shared goals to ensure optimal use of the relevant industry stakeholders fora in place and appreciated the support of EUCOPE in coordinating and voicing SMEs specificities and needs.