

22 May 2025  
EMA/101579/2025

## Highlights – EMA/ ESC bilateral meeting

22 May 2025, 15h00-17h00 CET

### 1. Introduction and tour de table

The EMA Chief Medical Officer welcomed the ESC delegation in the spirit of continuous open and direct dialogue.

### 2. Current EMA-ESC collaboration and further opportunities

ESC shared their outlook on continued and future collaboration with EMA, highlighting the importance of EMA's Healthcare Professionals Working Party (HCPWP) in bridging regulatory science and clinical practice. It was underlined that medicines bring different fields together and the HCPWP – which is composed of organisations representing different healthcare professional groups and areas of clinical expertise - works as a pivotal platform to initiate discussions on further collaboration around cross-cutting topics of interest. A possible area could be obesity and its impact on the cardiovascular-renal-metabolic system.

ESC offers a wide range of expertise through its 7 Associations, 15 Working Groups, and 7 Councils, totaling 29 subspecialty communities. These entities encompass the full spectrum of cardiology. This wide network can be leveraged to support regulatory decision-making. Further collaboration could be explored to ensure the best expertise and advice are provided in a timely manner.

The ESC Clinical practice Guidelines were also identified as an opportunity to bridge the gap between regulation and practice. The ESC proposal for further collaboration with the Cardiovascular Working Party on the revision of some EMA scientific guidelines was well noted and ESC was encouraged to identify what in the guidelines should be updated to ensure alignment with the state of the art of clinical practice.

### 3. Looking into 2025 and beyond

ESC presented the rationale behind their key asks towards the establishment of the EU Cardiovascular Health Plan. An open exchange followed around the key areas identified by ESC which included strengthening data collection and use for better patient outcomes, exploring the power of AI; restoring the EU as the world leader in cardiovascular research; and improving population health for

more resilient societies. In this context, EMA also shared a high-level overview of ongoing activities related to the European Platform for Regulatory Science Research, digital technologies and real-world evidence.

Whilst more in depth follow up discussions could be organised around digital technologies and RWE in cardiology, ESC was also encouraged to consider bringing the CVS plan and related points to the HCPWP.

#### **4. Expert panel activities in medical devices used for the circulatory system**

The role of expert panels for medical devices was presented and discussed, with a particular focus on the circulatory system sub-group on structural interventions. ESC made some suggestions on the possible contribution of learned societies. EMA noted ESC considerations on further engagement with notified bodies and to get more feedback to the panels.

#### **5. Summary of discussion/next steps and closure**

The meeting concluded with a shared sense of having had a constructive discussion, focusing on current and future opportunities for collaboration.

Future bilateral and more specific and targeted discussions on specific topics may be organised on an ad hoc basis.