



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Highlights from the 2<sup>nd</sup> Expert Panels and Notified Bodies workshop

23 May 2025 - Chaired by Alberto Gañan Jimenez; Moderated by Silvy da Rocha Dias

### 1. Welcome and introduction

The Chair and Moderator welcomed delegates from Notified Bodies (NBs), the European Commission (EC), and the Coordination Committee (CC). The agenda focused on three topics: the Clinical Evaluation Consultation Procedure (CECP), advice to manufacturers under MDR Art. 61(2), and implementation of MDCG 2024-10 guidance on orphan medical devices.

### 2. Clinical Evaluation Consultation Procedure

Four notified bodies voluntarily shared their experiences with the CECP. They highlighted the fruitful collaboration with the Expert Panel secretariat and emphasized the benefits of clear and accurate communication throughout the procedure. Following feedback from the 2024 NBs workshop, the systematic implementation of meetings between experts and NBs—as mentioned in point 5.1(b) of Annex IX of the MDR—has proven a significant process improvement.

The NBs highlighted the need for a revision of the CEAR template (MDCG 2020-13) and also noted that a clinical evaluation report (CER) template would help standardise and structure the presentation of clinical data and clinical evaluation.

A discussion explored enhancements to the CECP, including a more iterative approach with opportunities for clarifications after the initial opinion. Participants noted that Expert Panel opinions reflect the NB's assessment at the conformity assessment stage, but NBs act on panel recommendations, thereafter, potentially altering the final clinical evaluation. An additional clarification round before opinion finalisation would benefit all parties, though the current 60-day legal timeframe lacks provision for extension; the ongoing MDR/IVDR evaluation may offer a chance for revision.

NBs stressed the importance of including clear, actionable recommendations in final opinions to minimise interpretive differences. They confirmed that commercially confidential information can be identified at the opinion is provided (not just at publication stage), though its classification may evolve over time.



### **3. Advice to manufacturers under Art. 61(2)**

The secretariat presented an overview of the interim pilot report on clinical advice from expert panels. NBs reported limited experience with files that had received such advice but underscored its value in enhancing market predictability, particularly regarding required clinical data levels. It was clarified that scientific advice remains available only for Class III devices and Class IIb devices intended to administer/remove medicinal products, consistent with the pilot and legislation.

Expert panel chairs shared positive experiences from the pilot, noting productive discussions with manufacturers that advanced device development. Manufacturers frequently requested integrated regulatory and clinical advice, alongside greater NB involvement to align stakeholders. It was reiterated that manufacturers must duly consider panel advice in their CERs, and that the CECP remains a distinct process.

### **4. Implementation of guidance MDCG 2024-10**

Experts reported on initial requests for confirmation that devices meet the orphan definition, highlighting associated methodological challenges that require consistent handling. NBs shared their application experiences, affirming the guidance's importance for industry and ensuring market access for small-population devices.

The NBs also shared their experience in applying the guidance, recognising its importance for industry and for ensuring that devices intended for small populations can stay on the market. How the orphan status is provided by the Expert Panels vs the NBs and how to centralise this information once the procedure is established were points of discussion. It was clarified that NBs can consult with the Expert Panels on the orphan status during the conformity assessment and reach out to the EMA secretariat for support.

All parties endorsed the planned establishment of a dedicated orphan devices panel as a key long-term measure to safeguard access for underserved patients.

### **5. A.O.B.**

Participants recommended regular interactions between NBs and Expert Panels, including a follow-up workshop to further discuss processes—particularly the CECP.