8 December 2025
EMA/115190/2026
European Medicines Agency

Highlights from the 3rd Expert Panels and Notified Bodies workshop

4 December 2025, Chaired by Silvy da Rocha Dias

1. Introduction

This workshop follows a previous session held on 23 May 2025 on the clinical evaluation consultation procedure (CECP). Feedback from Notified Bodies (NBs) and Expert Panels (ExP) prompted the organisation of this follow-up session, focused specifically on the CECP as mandatory element of ExP activities. The workshop aimed to strengthen communication with NBs, refine the CECP to ensure it meets the intended requirements, and enhance transparency in the panels' work.

2. CECP – Expert Panels' perspective

The scientific and regulatory principles underpinning the CECP was discussed. It emphasised the need to distinguish scientific interpretation, clinical performance data, and benefit–risk assessment when evaluating clinical evidence. The Medical Device Regulation (MDR) provides the overarching regulatory framework that anchors this evaluation, ensuring that both NBs and manufacturers assess clinical data according to harmonised, science-based standards.

Orthopaedic implants served as a key case study, revealing common challenges such as incomplete long-term follow-up, insufficient durability endpoints, and inconsistent clinical datasets. It was noted that these shortcomings frequently lead to divergent conclusions between NBs and panels. To address these issues, high-quality registry data were identified as crucial, offering robust long-term performance indicators such as revision rates, which better reflect clinical outcomes.

The use of surrogate endpoints, including radiological parameters or early functional results, was recognised as valuable when long-term data are pending, provided that such measures are scientifically justified. It was discussed the usefulness of conditional or staged certification as a pragmatic mechanism that balances innovation and patient safety, allowing earlier market access under controlled post-certification evidence generation.

The presentation concluded that transparent and continuous dialogue between the panels and NBs is vital in achieving coherent scientific assessments. Improved interaction would ensure that differing interpretations are resolved early and that assessments are scientifically robust and aligned with regulatory expectations.

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3. CECP – Notified bodies' experience and feedback

NB representatives provided an in-depth overview of their operational experiences with the CECP. Many reported that the process remains demanding, especially for recently designated NBs still building capacity and expertise. In some cases, clinical evidence considered adequate by NBs did not always fully meet the ExPs' scientific expectations, occasionally resulting in differing opinions and the need for further clarification or supplementary data.

It was also emphasised the need for clearer, more structured expectations from the ExP. NBs would greatly benefit from more explicit guidance on the minimum depth of clinical evidence required, the hierarchy of data sources, the relevance of endpoints chosen by manufacturers, and the expectation in relation to post-market surveillance and post-market clinical follow-up plans. Such clarity would help bring alignment between NBs' initial evaluations and the scientific considerations applied by the ExP during CECP.

The legal requirement under the MDR for NBs to justify publicly any decision not aligned with an ExP opinion was recognised as promoting accountability but also introducing procedural challenges. In cases where there are some uncertainties, NBs tend to adopt a more conservative approach, often requesting strengthened evidence packages from manufacturers to mitigate risk of disagreement.

Examples shared during the workshop illustrated that early interaction with ExPs can streamline assessments and improve predictability. However, when ExP opinions identify broad or ambiguous concerns, NBs often struggle to determine the exact corrective actions required as there is no mechanism for further feedback from ExPs possible in the current procedure, potentially delaying patient access to beneficial technologies.

Several participants proposed introducing mid-process clarification mechanisms, allowing NBs to raise targeted questions before the final opinion is issued. This iterative communication could prevent misinterpretations, reduce bottlenecks, and align expectations earlier in the process. Overall, NBs endorsed greater transparency, interactivity, and predictability within CECP to support consistent and efficient reviews.

4. Discussion and future collaboration

The open discussion highlighted ongoing distinctions in roles and responsibilities. It was reaffirmed that NBs and manufacturers retain primary accountability for determining what constitutes sufficient clinical evidence to support the benefit–risk assessment, while ExPs provide an independent scientific opinion. ExPs clarified that their assessments are based on scientific validity and real-world clinical logic rather than legal interpretation. Each opinion is developed within a specific clinical and technological context, making broad generalisations or standard benchmarks unsuitable. Nevertheless, participants agreed that clearer rationale and transparency in ExP conclusions would help NBs interpret and operationalise panel opinions with greater consistency.

Both ExP and NBs acknowledged that post-opinion communication remains a weakness. ExP receive no feedback on how their recommendations are implemented in practice, limiting insight into whether if and how their concerns are resolved. While regulatory constraints restrict direct follow-up, more visibility on the outcomes of CECP recommendations could improve mutual understanding and strengthen public confidence.

To address communication gaps, participants proposed exploring reactive channels allowing NBs to submit clarifying questions during review phases. Although constrained by resources and timelines, such dialogue could ensure more targeted and scientifically grounded assessments.

The session closed with a shared commitment to reinforcing transparency, predictability, and scientific quality within CECP. By fostering open, science-driven dialogue, the CECP can better enable timely access to innovative, safe, and effective medical technologies while supporting a consistent application of MDR requirements across the European regulatory landscape.

Action point: Working groups with experts and NBs will be organised in 2026 to progress on the topics discussed.