The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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The Role and Experience of Expert Panels under Article 54 MDR: Reflections on the Clinical Evaluation Consultation Procedure (CECP) and Opportunities for Improvement

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Executive Summary

The Clinical Evaluation Consultation Procedure (CECP), established under Article 54 of Regulation (EU) 2017/745 (MDR), represents a unique mechanism within the European medical device regulatory framework. Through the involvement of independent Expert Panels, the procedure aims to provide an additional level of scrutiny for certain high-risk devices before they are placed on the market. The underlying objective is to strengthen patient safety, improve confidence in regulatory decision-making, and promote consistency in the evaluation of clinical evidence across Europe.

Several years into implementation, Notified Bodies (NBs) have accumulated substantial experience with the CECP process. That experience demonstrates clear strengths. Expert Panels have generally respected statutory timelines, engagement between Notified Bodies and Panels has improved significantly, and the procedure has contributed to increased attention on the quality and robustness of clinical evidence.

At the same time, challenges remain. The current process can create significant administrative burden, uncertainty regarding evidentiary expectations, prolonged certification timelines, and concerns regarding the practical impact of public negative opinions. Experience has also highlighted opportunities to improve predictability, transparency, and regulatory effectiveness while maintaining a high level of patient protection.

This paper presents a balanced assessment of the CECP and proposes targeted improvements for consideration during future MDR revision discussions.

Introduction

Article 54 MDR introduced an additional consultation mechanism whereby certain devices are subject to review by European Expert Panels prior to certification. The process was designed to provide an independent scientific perspective on the clinical evaluation conducted by manufacturers and assessed by Notified Bodies.

TEAM-NB supports the principle of independent scientific scrutiny for the highest-risk medical devices. Effective challenge and oversight are essential elements of a mature regulatory framework. However, for any regulatory mechanism to achieve its intended objectives, it must be predictable, proportionate, transparent, and capable of providing meaningful value to all stakeholders, including patients, manufacturers, regulators, and Notified Bodies.

The experience gained since implementation provides an opportunity to evaluate whether the CECP is achieving these aims and to identify areas where the system can evolve.

As of 1st November 2026, there have been 23 expert panel opinions published by the EU Commission with many more opinions awaiting publication once certification is completed.

Positive Experiences and Achievements of the CECP

Timelines Have Generally Been Respected

One of the notable successes of the CECP has been compliance with the statutory timelines established in the MDR.

Expert Panels have generally adhered to:

- The 21-day screening period.
- The additional 39-day period when a scientific opinion is required.

This adherence has provided a degree of procedural predictability and demonstrates that the Expert Panel system is capable of operating within the regulatory framework established by the MDR.

Increased Scientific Scrutiny

The CECP has undoubtedly increased the level of scrutiny applied to certain high-risk devices. Expert Panels provide an additional scientific perspective and challenge the adequacy of clinical evidence presented in support of certification.

This additional review mechanism can strengthen confidence in regulatory decisions and contribute to maintaining a high level of patient safety.

Improved Dialogue Between Expert Panels and Notified Bodies

One of the most significant improvements introduced over recent years has been the increased opportunity for dialogue between Notified Bodies and Expert Panels.

Historically, Notified Bodies would submit their assessment and receive the Expert Panel opinion at the end of the process, often with limited opportunity for discussion or clarification.

The introduction of meetings between Expert Panels and Notified Bodies, particularly when concerns are identified and a scientific opinion is anticipated, has substantially improved transparency and mutual understanding. These interactions provide opportunities to discuss clinical evidence, understand concerns, and clarify scientific positions before the final opinion is issued.

TEAM-NB welcomes this development and considers continued engagement essential to the success of the process.

Challenges and Areas of Concern

Inclusion of Class IIb Active Devices Administering or Removing Medicinal Products

The inclusion of Class IIb active devices intended to administer and/or remove medicinal products has created a disproportionate burden for both manufacturers and Notified Bodies.

Unlike Class III implantable devices, these products are often certified through quality management system certification rather than individual product certificates. Consequently, Notified Bodies are required to complete clinical evaluations for multiple devices on the certificate, before a CECP submission can be made. Where as other Class IIa and IIb non-implantable devices (including WET) would be sampled through the certificate cycle

This creates additional complexity, resource demands, and delays by not following the conventional process of QMS certification procedures.

Additionally, for many of these devices, the primary clinical benefit is derived from the medicinal substance component rather than the device itself. In such circumstances, it may be appropriate to apply Article 61(10) of the MDR, whereby clinical data are not relied upon, provided that the safety and performance of the device can be adequately demonstrated through pre-clinical evidence. For example, performance characteristics such as the accurate delivery of the intended dose can often be verified through bench testing and other pre-clinical evaluations without compromising patient safety. Consequently, where no clinical data are required or generated to support conformity assessment, it would not be meaningful for an Expert Panel to assess the clinical evaluation, as there would be no clinical evidence upon which such a review could be based.

TEAM-NB therefore welcomes the MDR revision proposal that would remove this category from the scope of Article 54.

Limited Predictability Regarding Clinical Evidence Expectations

A recurring theme identified by Notified Bodies concerns the nature of Expert Panel opinions.

Many opinions conclude that the clinical evidence is insufficient. However, the opinions frequently do not clearly define:

- The level of evidence considered acceptable.
- The specific evidence gaps preventing acceptability.
- The scientific rationale supporting alternative evidentiary expectations.
- Reference clinical evidence or scientific benchmarks against which future applications may be assessed.

This creates uncertainty for both manufacturers and Notified Bodies.

Predictability is a fundamental requirement of an effective regulatory system. If stakeholders cannot understand what constitutes sufficient evidence, it becomes difficult to design clinical development strategies, harmonise assessment approaches, or ensure consistent decision-making across Europe.

Expert Panel opinions should provide detailed scientific reasoning and clearly describe the evidentiary expectations necessary to address identified concerns.

Public Negative Opinions and Their Consequences

Publicly available unfavourable opinions can have unintended consequences.

Manufacturers frequently express concern when informed that their device falls within the scope of CECP. The prospect of a negative public opinion can create commercial uncertainty and may discourage investment and innovation.

This concern does not diminish the importance of publishing scientific opinions.

Furthermore, an unfavourable opinion often leaves important scientific questions unresolved in the public domain. In many cases, Notified Bodies have developed extensive clinical justifications, benefit-risk analyses, and evidence assessments that support certification decisions. However, the current process provides limited visibility of these considerations once a negative opinion is published.

A system that publishes an unfavourable opinion without providing visibility of the rationale for the final certification decision may not fully support transparency or public understanding.

A recurring concern reported by Notified Bodies relates to the ability to provide transparency where a certification decision is made that does not fully align with an Expert Panel opinion. In a number of cases, Notified Bodies have sought to upload detailed scientific and regulatory justifications explaining the rationale for certification, including the clinical evidence considered, benefit-risk conclusions reached, and the reasons why the concerns raised by the Expert Panel were not considered sufficient to preclude certification.

However, several Notified Bodies have reported difficulties in being able to submit or publishing such justifications. Where such difficulties prevent publication, an unfavourable Expert Panel opinion may become publicly available, but the scientific rationale underpinning the ultimate certification decision remains absent from the public domain.

As a result, stakeholders, including manufacturers, healthcare professionals and patients, may be presented with only one perspective of a complex scientific discussion. TEAM-NB believes that a mature and transparent regulatory system should allow both the Expert Panel's opinion and the Notified Body's scientific justification to be available, thereby providing a complete picture of the evidence assessment and supporting informed understanding of regulatory decisions.

Administrative Burden Associated with Multiple Platforms

Following the introduction of the certification module in EUDAMED, Notified Bodies are increasingly expected to submit information through both EUDAMED and CIRCABC.

Maintaining duplicate submissions across multiple IT systems creates unnecessary administrative burden without adding scientific value.

Greater system integration should be a priority to reduce inefficiencies and allow resources to remain focused on scientific assessment activities.

Compressed Response Timelines

Where Expert Panels raise questions following submissions through the process, Notified Bodies may have only two to three days to prepare comprehensive responses while remaining within the overall regulatory timelines.

This creates practical difficulties, particularly when additional information must be obtained from manufacturers before a scientifically robust response can be provided.

The process would benefit from greater flexibility where substantive scientific questions require detailed responses.

Notified Bodies are required to engage with Expert Panels as part of the consultation process; however, the notice period provided for such meetings is often very limited, creating significant operational challenges. In many cases, the short timeframe necessitates the reprioritisation of resources and the interruption of ongoing conformity assessment activities for other manufacturers in order to adequately prepare for and support these discussions. Given the complexity of the topics under review and the importance of providing informed and comprehensive responses, sufficient preparation time should be afforded to Notified Bodies.

Furthermore, the meeting dates and times proposed by Expert Panels are frequently non-negotiable, which can create additional difficulties in securing the attendance of appropriate subject matter experts. This is particularly challenging for organisations operating across multiple international time zones or where key clinical experts continue to maintain clinical responsibilities within healthcare settings. Greater flexibility in scheduling, together with adequate advance notice, would help ensure meaningful engagement and allow Notified Bodies to contribute effectively to the consultation process without adversely impacting other regulatory activities.

In situations where Notified Bodies face resource constraints and limited notice periods, a more efficient and effective approach would be to allow an initial written exchange between the Expert Panel and the Notified Body. Under this approach, the Expert Panel would provide its questions and areas requiring clarification in writing, enabling the Notified Body to prepare comprehensive responses and submit any supporting documentation as necessary. The Expert Panel could then review the information provided and determine whether any outstanding issues remain that warrant further discussion. Only where additional clarification is required should a meeting be convened. This approach would provide several benefits, including allowing Notified Bodies to allocate resources more effectively, reducing the need for urgent scheduling of meetings, and ensuring that responses are carefully considered and supported by documented evidence.

Furthermore, written submissions would create a clear and transparent audit trail, reducing the potential for misunderstandings that can arise during verbal discussions and ensuring that the rationale underpinning the Notified Body's position is accurately captured and available for future reference. Such a process would support more focused and productive interactions, enabling meetings to be reserved for the resolution of specific outstanding points rather than serving as the primary mechanism for information gathering and clarification.

Scope of Expert Panel Commentary

Expert Panels play a critical role in providing clinical and scientific expertise. However, some opinions have included commentary relating to areas beyond the clinical evaluation itself, including matters such as MRI safety, sterilisation methodologies or the use of animal-derived materials.

The Expert Panels typically review:

- The Clinical Evaluation Report (CER).
- The Clinical Evaluation Plan (CEP).
- The Post-Market Clinical Follow-up (PMCF) Plan.
- The PMCF Report (where available).
- The Notified Body Clinical Evaluation Assessment Report (CEAR).

The expert panels do not review the full technical documentation.

It is equally important that the respective roles and expertise of the different actors within the conformity assessment system are respected. Notified Bodies are subject to rigorous designation and continuous oversight by Designating Authorities and Joint Assessment Teams, which assess and verify the competence of their personnel across a wide range of technical and clinical disciplines. In many cases, Notified Bodies employ highly specialised experts, including clinicians, microbiologists, sterilisation specialists, materials scientists, software experts, engineers, imaging specialists, and other subject matter experts whose competence has been formally assessed as part of the designation process.

Whilst Expert Panels are specifically established to provide a clinical and scientific opinion on the clinical evaluation and supporting clinical evidence, there have been instances where opinions have extended into broader technical areas such as sterilisation methods, material selection, engineering design, or the use of animal-derived tissues. Such commentary may be made without access to the complete technical documentation and may require additional technical expertise. In these circumstances, there is a risk of creating uncertainty unless the relevant documentation and expertise are available and the respective responsibilities under the MDR are clear.

TEAM-NB therefore believes that Expert Panel opinions under the CECP should remain focused on the adequacy of the clinical evaluation, clinical evidence, and associated benefit-risk conclusions, while technical aspects outside the clinical evaluation should remain within the scope of the conformity assessment activities conducted by the Notified Body using suitably qualified technical specialists. This should not prevent Panels from raising technical questions relevant to clinical safety or benefit-risk.

Training and Regulatory Familiarity

The effectiveness of Expert Panels depends not only on scientific expertise but also on understanding the regulatory framework within which decisions are made.

Continued MDR-specific training and exchanges of experience would support a shared understanding of regulatory requirements among Expert Panels and Notified Bodies.

Greater investment in MDR-specific training for Expert Panel members would help ensure opinions remain aligned with regulatory requirements and practical implementation realities.

This is particularly important in distinguishing between evidence required under the MDR and recommendations for additional evidence, with a clear explanation of their scientific and regulatory basis.

Has the CECP Achieved Its Intended Purpose?

The answer is both yes and no.

The CECP has succeeded in establishing an independent scientific oversight mechanism for certain high-risk devices. It has improved scrutiny, strengthened challenge, and introduced an additional safeguard within the European regulatory framework.

However, the system has been less successful in creating predictable and harmonised expectations regarding clinical evidence.

For manufacturers and Notified Bodies, an important additional outcome of any scientific review process should be increased clarity regarding future expectations. While Expert Panels regularly identify deficiencies in evidence, the resulting opinions do not always provide sufficient detail to help stakeholders understand how similar concerns should be addressed in future submissions.

From a system perspective, this limits opportunities for regulatory learning and harmonisation.

Recommendations for MDR Revision

TEAM-NB believes the future evolution of Article 54 should focus on predictability, transparency, proportionality, and scientific collaboration.

- **Recommendation 1: Restrict Scope to Class III Implantable Devices**

TEAM-NB supports removing Class IIb active devices intended to administer or remove medicinal products from the scope of Article 54.

The CECP should focus on the highest-risk device categories where additional scrutiny provides the greatest public health value.

- **Recommendation 2: Clarify the Scope of Expert Panel Reviews**

Expert Panel reviews under the CECP should be clearly defined as focusing on:

  - Clinical evaluation.
  - Clinical evidence.
  - Benefit-risk assessment as it relates to clinical data.
  - Post market clinical follow up (PMCF) plans

Commentary on related technical matters should be relevant to the clinical assessment and supported by appropriate expertise and access to the relevant documentation.

- **Recommendation 3: Strengthen Engagement Between Notified Bodies and Expert Panels**

Greater opportunities for structured exchange of experience should be created throughout the process, while preserving the independence of scientific opinions.

Notified Bodies possess unique insights regarding:

- Common deficiencies in manufacturer submissions.
- Emerging clinical evidence challenges.
- Practical implementation issues under the MDR.

Regular engagement between Expert Panels and Notified Bodies would improve mutual understanding and support more consistent expectations.

- **Recommendation 4: Enhance Expert Panel Training**

Expert Panel members should continue to receive MDR-specific training and updates on:

- MDR requirements.
- Clinical evaluation requirements.
- State-of-the-art principles.
- Benefit-risk determination.
- The practical realities of conformity assessment.

TEAM-NB would welcome opportunities to contribute to such initiatives.

- **Recommendation 5: Clarify the Process for Publishing Notified Body Justifications**

Notified Bodies should have a clear process for publishing their reasoned justification, including how the concerns raised have been addressed, where certification proceeds following an unfavourable Expert Panel opinion.

A transparent process allowing publication of such responses would provide stakeholders with a complete understanding of the scientific considerations underpinning certification decisions.

These decisions should remain subject to appropriate oversight by the responsible competent authorities.

- **Recommendation 6: Increase Transparency of Evidentiary Expectations**

Expert Panel opinions should clearly define:

- The specific evidence gaps identified.

- The scientific basis for their conclusions.
- The level of evidence expected.
- Where appropriate, examples of acceptable evidence approaches.

Such transparency would improve harmonisation across Europe, increase predictability for manufacturers, and facilitate more consistent assessments by Notified Bodies.

Over time, this could provide an important foundation for developing common expectations regarding clinical evidence generation under the MDR.

Conclusion

The CECP remains an important element of the European medical device regulatory framework and has delivered meaningful benefits through increased scientific scrutiny and independent expert review. The commitment of Expert Panels to statutory timelines and the improvements in dialogue with Notified Bodies demonstrate that the system is evolving positively.

Nevertheless, experience has revealed important opportunities for improvement. Greater clarity regarding evidentiary expectations, stronger regulatory training, reduced administrative burden, improved transparency, and a more narrowly focused scope would enhance the effectiveness of the process while preserving its core objective of protecting patients.

TEAM-NB supports continued use of Expert Panels under Article 54 and believes that targeted reforms as part of MDR revision can ensure the CECP becomes a more predictable, proportionate, and effective instrument for all stakeholders within the European regulatory system.