The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Editor:	**Team-NB**	Adoption date 07/10/2026	Version 1

Team-NB proposal for involving notified body experts in EMA expert panels

Executive summary

- Team-NB supports the involvement of qualified notified body experts in EMA expert panels to make better use of validated scientific, technical and regulatory expertise.
- NB experts should participate as individual professionals, not as representatives of their employing notified body. Participation must be double voluntary, employing NB and expert must consent.
- Their participation should be subject to clear procedural and legal safeguards for independence, impartiality and confidentiality.
- Case-specific inclusion should prevent conflicts of interest, while avoiding institutional disadvantage for notified bodies that allow their experts to contribute is important.
- Making NB expertise available to expert panels would broaden the scope and practical value of advice to manufacturers and contribute to safer and better-performing medical devices for patients.

Rationale

Currently, the EMA coordinates and hosts expert panels that provide mainly clinical opinions on medical devices. Here, competent authorities share their experience with industry in scientific advice procedures. In this context, medical device manufacturers have long asked for greater regulatory clarity during device development, and for good reasons. Several current proposals on the revision of the MDR and IVDR reflect that the absence of notified bodies in the expert panel procedure is perceived as a weakness of the system, and there is a desire amongst different stakeholders to benefit from the long-standing experience of these organizations in the technical documentation assessment and certification of medical devices. However, the current legislative framework does not allow notified bodies to share the full regulatory and technical expertise of their authorised personnel, even though that expertise has been validated by national designating authorities. By the relevant guidance documents and communication, it is evident that this restriction has been imposed on the basis that employment by a notified body has been considered equivalent to employment by a medical device company and therefore viewed as giving rise to an unacceptable conflict of interest[1]. However, Team-NB considers this position overly conservative and not sufficiently reflective of the legally defined role of notified bodies as independent conformity assessment bodies. This position paper therefore

[1] Expamed document D 4.3 April 2023, https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/medical-device-expert-panels, section “Who can join an expert panel”;

assesses alleged and actual conflict-of-interest risks against the benefits of allowing these resources to be put to full use for expert panel advice. This aligns with the intent to allow the scope of advice to be widened to all scientific, technical, medical and regulatory topics relevant for medical device development, many of which substantially overlap with the core competencies of the notified bodies. This would increase regulatory clarity for medical device developers and support better performing and safer medical devices for patients.

In the proposal for revision of the MDR and IVDR, the Commission has included a legal provision allowing the participation of notified body experts in expert panels for all procedures, except for clinical evaluation consultation procedures according to Art. 54(1) MDR (clinical evaluation consultation procedure), or Article 48(6) IVDR (performance evaluation consultation procedure) through their proposed amendment of MDR Article 106[2]. This is an important first step. However, to make the participation of notified body experts workable in practice, the Team-NB amendments in Annex I of the position paper should be inserted into the Commission proposal for the revision of MDR, which is currently under discussion in the European Parliament and in the Council. This paper therefore proposes additional legal and procedural safeguards to ensure the independence and impartiality of notified bodies when their experts are involved in expert panel advice.

Procedural considerations

While further legal clarification in the MDR is proposed in Annex I of this document, most considerations for involving notified body experts in expert panels are procedural in nature and are best addressed at guidance level. The following principles would safeguard the impartiality and independence of notified bodies when their experts are involved in expert panels:

- **Notified body experts apply and are appointed to expert panels as individual professionals**, *not* as representative of their employing notified body.
- **The employing notified body must consent** to authorised personnel joining an expert panel to avoid resource bottlenecks as for any other secondary activity. Notified Bodies should not be mandated to send experts to expert panels, as smaller notified bodies may not be able to let experts participate without limiting their own ability to perform conformity assessments. At the same time, the nomination process should ensure a balanced representation of experts across all interested notified bodies.
- **NBCG-Med may provide a shortlist** and propose notified body personnel for expert panels based on expertise and under consideration of their affiliation to avoid any undue advantage for individual notified bodies. For the purpose of setting up and maintaining this shortlist, NBCG-Med coordinates with all notified bodies and implements a structured management for expert proposal.
- **EMA appoints notified body experts from the pool in a rotational principle, applying the same criteria as for other expert panel members**, including transparency requirements.

[2] COM(2025) 1023 final, Art. 1, point 86, amending MDR Art. 106

- Roles in expert panels and their employing notified body must be strictly separated for such experts:
    - **No involvement in directly related cases**: A notified body expert who has contributed to an Expert Panel opinion shall not be involved in any procedure directly relating to that specific Expert Panel opinion, including subsequent assessments for the same device.
    - **No involvement in discussions on devices previously assessed by the expert**: Notified body experts should not participate in Expert Panel discussions or opinions concerning devices that have been assessed by himself or herself in the context of conformity assessment.
- **Membership of a notified body expert in an expert panel must not preclude other experts from that notified body from working on subsequent submissions** for the device or manufacturer in question. Otherwise, an institutional disadvantage would be created for individual notified bodies, disincentivising them from allowing their experts to join expert panels.

Combined with the existing requirements for authorisation of notified bodies experts, this process would establish even stricter criteria and scrutiny for notified body personnel in expert panels than for other members. Expert panels are mainly organised by clinical area. Authorisation codes for notified body experts also cover many technical aspects that are relevant across a wide range of therapeutic areas and device types, such as biocompatibility. To bridge this apparent mismatch, a pool of notified body experts could be maintained for ad hoc appointment to procedures that would benefit from specific technical expertise.

In addition to guidance reflecting the principles above, further regulatory adjustments are needed to enable involvement of notified body experts in expert panels and to fully acknowledge the impartial and independent nature of notified bodies. Current Commission rules on expert panels still treat an interest in a notified body in the same way as an interest in the medical device industry. This does not reflect the legally defined role of notified bodies as independent conformity assessment bodies. Separate definitions of “medical device industry” and “notified body” are therefore also needed in Commission expert panel policies. The proposed appointment and shortlisting process is illustrated in Figure 1.

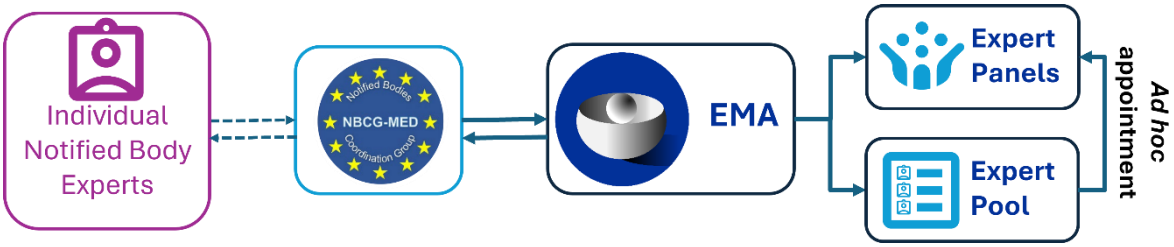

Figure 1: Proposed process – Individual notified body experts express their interest to contribute to expert panel with consent of their employing notified body. NBCG-Med shortlists applicants based on expertise and affiliation to be further selected and appointed by EMA. Technical experts (e.g. biocompatibility, metrological traceability) may be included in a pool of experts to be appointed to an expert panel for specific procedures.

Legal proposal

To establish a solid legal basis for the procedural principles outlined above, Team-NB proposes that the following amendment be inserted into the Commission proposal for the revision of the MDR and IVDR. For the MDR, the amendment should be inserted in Art. 106 “Expert panels”, as proposed to be amended by the Commission. Formal amendment wording is provided in Annex I.
The proposed amendment would allow personnel of notified bodies to contribute as individual expert panel members, while ensuring that they comply with the same independence, impartiality and confidentiality requirements as other experts. It would also clarify that the individual expert must not be involved in conformity assessment activities relating to an expert panel opinion or advice to which that expert has contributed, while the notified body itself remains eligible to perform conformity assessment through other qualified personnel. This individual-level safeguard is essential to avoid conflicts of interest without creating an institutional disincentive for notified bodies to make their expertise available.

Special considerations for Breakthrough Medical Devices

It is important to note, that this proposal is not directly applicable on interactions of Notified Bodies and expert panels during procedures relating to a Breakthrough Medical Device and in vitro diagnostic devices (BtX). While independence and impartiality of notified body personnel must be maintained here as well, the BtX pathway specifically requires coordination between notified bodies and expert panels (MDCG 2025-9, 11.1, third bullet) to “ensure coherence between scientific advice and the conformity assessment process, thereby facilitating a timely and consistent evaluation”. This is a key benefit of the BtX scheme for manufacturers because it provides greater strategic clarity at an early stage and helps avoid divergent positions between the relevant notified body and expert panel.

Other than in the expert panel participation being subject of this position paper, for the purpose of expert panel advice to manufacturers of Breakthrough Medical Devices or IVDs, notified body experts should therefore have a controlled role as active observers. Active observer means that the experts will not participate in the scientific advice directly, but express opinions on the feasibility of regulatory aspects towards the members of the expert panel.

Conclusion

The expertise, experience, impartiality and independence of authorised notified body personnel meet the highest standards. Yet this expertise remains a largely unutilised resource in advising medical device and IVD manufacturers. Involving notified body experts in expert panels, subject to additional safeguards for impartiality, independence and confidentiality, would broaden the scope and practical value of expert panel advice to scientific, technical, clinical and regulatory questions. To make this possible, the Team-NB amendment should be inserted into the current EU legislative proposal for the revision of the MDR during the ongoing discussions in European Parliament and the Council. This should be complemented by updates to Commission and EMA expert panel policies and by procedural guidance. Together, these measures would close a gap in the current advice schemes for manufacturers, strengthen regulatory predictability, and support patient access to safe and effective medical devices and IVDs.

Annex I – Proposed legal amendment

Amendment

Proposal for a regulation
Article 1 – paragraph 1 – point 86
Regulation (EU) 2017/745
Article 106 – **New paragraph 2a**

Text proposed by the Commission	*Amendment*
	In Article 106, the following paragraph 2a is inserted: "2a. Personnel of notified bodies may be appointed as members of expert panels, provided that they: *(a)* possess relevant scientific, technical or regulatory expertise validated through authorization procedures according to Annex VII, Section 3.2, or through other documented evidence of relevant expertise where the scope of the panel or procedure so requires; *(b)* comply with the independence, impartiality and confidentiality requirements applicable to all expert panel members; *(c)* act in an individual capacity and not as representatives of their employing notified body; and *(d)* are not personally involved in any conformity assessment activity relating to an expert panel opinion or advice to which they have contributed. The restrictions referred to in point (d) shall not preclude the employing notified body from carrying out conformity assessment activities through other qualified personnel. With the consent of the employing notified body, candidates may be nominated by the notified body coordination group established by Article 49(1) and appointed to expert panels in accordance with the procedures applicable to expert panel members. By derogation from point (a), experts appointed to panels or procedures with a broad or cross-cutting scope, including screening, rare diseases, paediatrics, breakthrough devices or other general matters, may qualify by means other than authorisation under Annex VII, Section 3.2, including demonstrated broad experience in scientific, technical, regulatory, strategic or leadership roles across the field of medical devices."

Justification

Experienced and knowledgeable medical device professionals from notified bodies should be able to contribute to expert panels where their expertise is relevant and where appropriate safeguards are in place. Experts employed by notified bodies fulfil stringent qualification criteria and undergo rigorous training to obtain and maintain authorization in accordance with Annex VII of Regulation (EU) 2017/745 and Regulation (EU) 2017/746. Their expertise is therefore a valuable Union-level resource that should be made available to support more consistent and predictable implementation of the MDR and IVDR.

The amendment ensures that notified body personnel participate as individuals, not as representatives of their employing notified body. It also preserves impartiality by excluding the individual expert from conformity assessment activities relating to an expert panel opinion or advice to which that expert has contributed. At the same time, the notified body itself should not be excluded from carrying out conformity assessments through other qualified personnel, because such an institutional exclusion would disincentivize notified bodies from making expertise available.

For broad or cross-cutting procedures, including breakthrough devices, paediatric devices, rare diseases or screening functions, formal authorization under Annex VII, Section 3.2, may not always be the most relevant qualification criterion. In such cases, broad scientific, technical, regulatory, strategic or leadership experience in the medical device field may be more appropriate.