<Date>

Request for advice from the Expert Panels pursuant to MDCG 2025-9 guidance[1], for a device designated as breakthrough

[1] MDCG 2025-9 Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746

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Guidance text

Guidance text is in green italics. You may print a copy of this template with the drafting note, then delete them all in one go:

Click on Ctrl-Alt-Shift-S to view the "styles" window. Select "Drafting notes (Agency)" and click on the icon on the right, chose "Select all XXX instances", press the "Delete" key on the keyboard.

Do not change or delete the titles and the numbering style. (Add "Not applicable" if necessary)

Suggested font: Verdana 9.

Paragraph tab: alignment: left, outline level: body text, indentation: 0, spacing before: 0pt and after: 7pt; line spacing: at least, at: 14pt.

I – General Information

1. Administrative Information

1.1. Information on the requester

Name:

Position:

Email:

Phone:

1.2. Information on the manufacturer

Name of the company:

Address:

Country:

[For EU/EEA manufacturers]

SME status*: Yes ☐ / No ☐

*https://single-market-economy.ec.europa.eu/smes/sme-definition_en

1.3. Information on the authorised representative

[Mandatory for manufacturers outside of the EU/EEA and Turkey]

Name of the company:

Address:

Country:

1.4. Information on the notified body

[If already known]

Name of the notified body:

Address:

Country:

Notified body number:

2. Information on the device

2.1. Device name, risk class, risk class justification, EMDN level, clinical area

Reference is made to the briefing document for the breakthrough device status request.

2.2. Development history and regulatory status

[Please provide an updated brief overview of the device development. Describe the worldwide regulatory status of the device. Indicate if scientific advice has been previously requested from other regulatory authorities.]

3. Brief outcome from the breakthrough device status confirmation

[Add the conclusion and a summary of the rationale from the breakthrough device status procedure for reference, and append the breakthrough designation letter.]

4. Stage of advice request

☐ Prior to start of conformity assessment.

☐ During an ongoing conformity assessment.

[For advice during conformity assessment]

☐ The manufacturer and notified body confirm that they are in agreement for the consultation procedure.

☐ The manufacturer and notified body confirm that the expert panel consultation does not interfere with the notified body's assessment.

☐ The notified body confirms that the expert panel advice will be awaited before any Clinical Evaluation Consultation Procedure (CECP), if applicable, is submitted, and commits to reflecting in the CEAR how the advice was considered.

5. Type of support needed by applicant

☐ Non-clinical

☐ Clinical

☐ Regulatory

☐ Other, please specify:

II - Application – Request for scientific advice

1. Overview of device development

[This section should give a comprehensive scientific overview of the device clinical development strategy, providing relevant systematic information in sufficient detail, together with a critical discussion. Cross-references to annexes can be included only when additional details are needed to support the argument. The use of tabulated overviews and graphs is encouraged.

Given the potential for significant positive clinical impact of a breakthrough device, clinical evidence requirements should be balanced between pre-market and post-market to ensure patient safety and clinical benefit while fostering innovation. Provided that a well-defined plan is in place to collect confirmatory data through comprehensive PMS and PMCF/PMPF, a higher level of uncertainty may be acceptable. In order to seek advice, the applicant should describe in detail in the following sections the pre-clinical evidence, the clinical development strategy, and proposals for clinical investigation, as well as the proposed PMCF plan.]

1.1. Non-clinical and pre-clinical evidence

[Include a tabular overview of the pre-clinical studies, pursuant to Annex I of MDR and to MDCG 2025-9 (Section 6), as well as current study status (completed, ongoing, planned). The discussion should include, inter alia, evidence from pre-clinical literature, biological safety assessment, bench testing, in silico modelling and simulation, long-term pre-clinical data, usability tests, etc.]

1.2. Pre-market clinical evidence

1.2.1. Clinical background information

[A tabular overview of all relevant studies including study number (if available), main design features, patient number and characteristics, number of investigator sites by geographical region, as well as current study status (completed, ongoing, planned) etc. could be informative, if not provided elsewhere.

If advice is requested for (a) particular clinical investigation(s), a schematic of the clinical study(ies) for which advice is requested should be included.

If (a) clinical investigation is(are) ongoing, detailed information on the current status of the study(ies) should be provided, including the number of patients currently enrolled, date of first patient enrolment, anticipated date of last patient enrolment and number of investigator sites currently participating by geographical region.

Whilst the focus should be kept on the intended purpose(s), the development in future indications could be briefly summarised, where relevant.]

1.2.2. Clinical performance

[A general overview of the clinical development strategy should be based on a comprehensive discussion of e.g., the main clinical results so far, exploratory studies, special populations, supportive and pivotal clinical studies, and any analyses performed across the studies (pooled and meta-analysis). The discussion should identify the most important findings and challenges in the clinical development strategy, and

its compliance with legal requirements, relevant guidelines, previous scientific advice, etc.]

1.2.3. Clinical safety

[A general overview of the safety profile of the device should be based on a comprehensive discussion of the safety database of the device and predecessor versions (if applicable) including the incidents observed, previous field safety corrective actions, specific safety findings, safety in special populations, etc.]

1.3. Post-market Clinical Follow-up (if applicable)

[Details on the planned PMCF plan should be provided. Specific considerations for breakthrough devices can be found in Section 8 of MDCG 2025-9.]

2. Questions and applicant's positions

*[**Questions** should conform to the **scope** of this advice under the MDCG 2025-9 guidance. It is recommended that questions are phrased in a way to allow for an unambiguous understanding of the question. The scope should be carefully considered in order to avoid too broad or too narrow questions.*

The wording of the questions should be clear and concise, starting with e.g. "Does the Expert Panel agree that/with …?".

The presentation of the proposal as well as the justification for it is to be presented in the Applicant's position.

IMPORTANT INFORMATION

Each question should be followed by a corresponding, separate Applicant's position including a comprehensive justification for the chosen approach. You should repeat this for each question.

All key information about the topic should be sufficiently discussed, so that the Applicant's position can function as a 'stand-alone' argument. Issues to be covered could include the following: context and proposal, other options (potentially) considered together with a critical discussion on the relative merits and drawbacks of the various approaches, possible consequences and eventual measures to ameliorate these. In general, an extension of 1 to 3 pages for each Applicant position is recommended.

Cross-references to the relevant parts of the briefing document or annexes can be included if additional detail is needed to support the argument.

Expert Panels members address each question independently, taking into consideration the information provided in the applicant's position.

No preassessment of the data is performed; only the strategy and the possibility of it providing the results needed is advised on.]

2.1. Question {X}

Applicant's position {X}

{Expert panel position}

2.2. Question {Y}

Applicant’s position {Y}

{Expert panel position}

IIIa - List of Abbreviations

[Please provide a list of abbreviations used in this document, if applicable]

IIIb - List of Annexes

1. Breakthrough designation letter for the medical device in scope