



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date>

Request for advice on the clinical development strategy and/or clinical investigations according to Article 61(2) of Regulation (EU) 2017/745 on <device name> from the medical device Expert Panels



Table of Contents

I – General Information	3
1. Applicant’s Administrative Information	3
1.1. Requester/ contact person	3
1.2. Information on the Applicant.....	3
1.3. Information on the authorised representative.....	3
2. Information on the device	3
2.1. Device name	3
2.2. Risk class	3
2.3. Risk class justification	4
2.4. Type (European Medical Device Nomenclature -EMDN* level 3).....	4
2.5. Clinical area	4
2.6. Description of the device	4
2.7. Intended purpose	4
2.7.1. Device for unmet medical needs	5
2.7.2. Device intended to benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition (e.g., orphan devices and devices for paediatric use).....	5
2.8. Development history and regulatory status.....	5
2.9. Novel device with a possible major clinical or health impact	5
II – Application – Request for scientific advice	6
3. Overview of product development	6
3.1. Current state of the art	6
3.2. Clinical background information.....	6
3.2.1. Clinical performance	7
3.2.2. Clinical safety	7
4. Questions to the expert panel and Applicant’s positions	7
4.1. Question {X}	8
{Expert panel position}.....	8
4.2. Question {Y}	8
{Expert panel position}.....	8
III - List of Abbreviations	9

Guidance text

Guidance text is in green italics. 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.

To delete guidance text: 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 XX instances”, press the “Delete” key on the keyboard.

I – General Information

1. Applicant’s Administrative Information

1.1. Requester/ contact person

Name:

Position:

Email:

Phone:

1.2. Information on the Applicant

Name of the company:

Address:

Email:

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

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

Name of the company:

Address:

Country:

2. Information on the device

2.1. Device name

Name:

2.2. Risk class

Class III	<input type="checkbox"/>
Class IIb active device intended to administer and/or remove a medicinal product (Section 6.4 of Annex VIII - Rule 12)	<input type="checkbox"/>

2.3. Risk class justification

[Please provide a justification for the risk class chosen, including the applicable classification rule.]

2.4. Type (European Medical Device Nomenclature -EMDN* level 3)

[Please indicate the EMDN type that applies to the device (multiple choices are possible).]

[*<https://webgate.ec.europa.eu/dyna2/emdn/>]

2.5. Clinical area

[Please indicate the relevant clinical area (multiple choices are possible)]

<input type="checkbox"/>	Orthopaedics, traumatology, rehabilitation, rheumatology
<input type="checkbox"/>	Circulatory system
<input type="checkbox"/>	Neurology
<input type="checkbox"/>	Respiratory system, anaesthesiology, intensive care
<input type="checkbox"/>	Endocrinology and diabetes
<input type="checkbox"/>	General and plastic surgery and dentistry
<input type="checkbox"/>	Obstetrics and gynaecology, including reproductive medicine
<input type="checkbox"/>	Gastroenterology and hepatology
<input type="checkbox"/>	Nephrology and urology
<input type="checkbox"/>	Ophthalmology
<input type="checkbox"/>	Other: []

2.6. Description of the device

[Please provide a description of the device, including the mechanism of action.]

2.7. Intended purpose

[Please provide a description of the intended purpose, including the indications and contra-indications (if applicable), patient target group or groups, and intended users.]

2.7.1. Device for unmet medical needs

Yes / No

If Yes, please provide a justification:

[Devices for unmet medical needs are defined as devices for medical conditions that are life threatening or cause permanent impairment of a body function and for which current medical alternatives are insufficient or carry significant risks (see MEDDEV 2.7/1 rev.4, Appendix 8).

Outline the main features of the disease(s)/condition(s) and the current standard medical treatments or diagnosis, referring to relevant publications or other sources.]

2.7.2. Device intended to benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition (e.g., orphan devices and devices for paediatric use)

Yes / No

If Yes, please provide a justification:

[Describe the target population of patients and provide an estimate of this population in the EU referring to relevant publications or other sources. Explicit the hypotheses made for this evaluation and provide a range of possible values reflecting the uncertainty around the estimation.]

2.8. Development history and regulatory status

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

2.9. Novel device with a possible major clinical or health impact

Yes / No

If Yes, please provide a justification:

[Provide an assessment of the novelty of the device and the expected clinical and/or health impacts resulting from that novelty. This assessment is expected to be based on the Commission guidance for the medical device expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure.]

[https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807\(01\)&rid=5](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807(01)&rid=5)

II – Application – Request for scientific advice

3. Overview of product development

[This section should give a comprehensive scientific overview of the product clinical development strategy, including its position versus the current state of the art, providing relevant systematic information in sufficient detail, together with a critical discussion. However, it should be kept in mind that any information essential for the justification of a given question should also be sufficiently discussed in the corresponding Applicant's position. The briefing document should contain all necessary information and function as a 'stand-alone' argument. 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.]

3.1. Current state of the art

[This section should give an overview of the current state of the art for the targeted intended use of the device, the levels of risk and benefit linked to these, and if applicable, how these have informed the safety and performance objectives for the device in development. It is usually based on literature search, and includes topics such as:

- Information relating to the medical condition managed with the device, and its natural course;*
- Benchmark devices;*
- Other devices and medical alternatives available to the target population;*
- Information on expected clinical benefit and potential clinical hazards;*
- Any applicable standard and guidance documents.*

Reference to applicable literature should be provided.]

3.2. Clinical background information

[A tabular overview of all relevant studies including study number (if available), main design features, patient number and characteristics, as well as current study status (completed, ongoing, planned) etc. could be informative, if not provided elsewhere. Include any additional information that might be relevant (e.g., pre-clinical information directly relevant for the clinical development strategy)

A schematic of the clinical study(ies) for which advice is requested should be included. If this(ese) study(ies) 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 current intended purpose(s), further development could be briefly summarised, where relevant.]

3.2.1. Clinical performance

[A general overview of the clinical development strategy should be based on a comprehensive discussion of, inter alia, 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. It should also demonstrate that the performance objectives were defined in the context of the state of the art, that they are clinically meaningful and measurable, allowing for comparison of the device under development with other state of the art alternatives. Information on the geographical distribution of centres participating in the clinical studies can be reflected in this section.]

3.2.2. 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 product and predecessor versions (if applicable) including the incidents observed, previous field safety corrective actions, specific safety findings, safety in special populations, etc. This section should also demonstrate that the clinical safety objectives were defined in the context of the state of the art, and that they are measurable, allowing for comparison of the device under development with other state of the art alternatives.]

4. Questions to the expert panel and Applicant's positions

[Questions should conform to the scope of this advice, i.e., on the intended clinical development strategy and proposals for clinical investigation. Questions regarding the regulatory strategy are outside the scope of this advice.]

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 to avoid too broad or too narrow questions.

The wording of the questions should be clear and concise, starting with "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. This should be repeated 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, 1 to 3 pages are recommended for each Applicant position.

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

4.1. Question {X}

Applicant's position {X}

{Expert panel position}

[The advisors of the Expert Panel address each question independently, taking into consideration the information provided in the Applicant's position.]

There is no preassessment of the data that is performed; the advice focuses on the strategy and the possibility of the proposed strategy to achieve the desired results.]

4.2. Question {Y}

Applicant's position {Y}

{Expert panel position}

III - List of Abbreviations

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