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European Medicines Agency

Guide to manufacturers on the procedure for requesting advice from Expert Panels on clinical investigations and/or clinical development strategies for high-risk medical devices

Advice to manufacturers for high-risk medical devices

1. Background information

1.1. Legal basis

According to Article 61(2) of Regulation (EU) 2017/745 (the Medical Devices Regulation, MDR), the medical device Expert Panels may provide advice on a manufacturer's intended clinical development strategy and proposals for clinical investigation, for class III devices and class IIb active devices intended to administer and/or remove a medicinal product from the human body.

1.2. Pilot phase

A pilot programme opened on 27 February 2023 and ran for three phases, with submissions accepted until 30 June 2024. Following successfully completion of the pilot, EMA is now fully implementing the scientific advice programme.

1.3. Scope

The manufacturers of high-risk devices established in the EU or their authorised representatives can apply for advice to the expert panels. Applications will be eligible if they meet all of the following criteria:

- The device is a class III device, or a class IIb active device intended to administer and/or remove a medicinal product from the human body;
- The questions asked by the manufacturer pertain to clinical aspects only;
- Questions related to clinical investigations pertain solely to clinical investigations not yet started (pre-market or post-market).

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Of note, two of the prioritisation criteria used for the pilot (device for unmet medical needs; novel device with a possible major clinical or health impact) will only be used for prioritisation should the number of submissions for a given timeslot exceed the capacity of the expert panels.

The advice of the Expert Panels is prospective by nature and is not an assessment of the clinical data that has already been generated.

Applicants developing orphan devices are encouraged to consider the separate pilot programme published on EMA website: https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices#expert-panels-support-for-orphan-medical-devices-pilot-programme-67844. Therefore, the prioritisation criterion "device intended to benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition" used for the pilot will only be used for information purposes.

1.4. Fees

Fees are currently not levied for scientific advice submissions in 2025.

2. Procedure and instructions for application

Step	Instructions for Applicant	Additional comments
1. Letter of interest	The form to be completed to express interest is at the following link: ServiceNow The form can be accessed with an EMA account. If you have no account, register at the following link: EMA Account Management - Self-service Registration	Applicants will then be able to communicate with EMA and upload documents through the ServiceNow ticket created. EMA will confirm receipt of the application by email and offer an explanatory meeting (virtually).
2. Exploratory meeting EMA/ Applicant	The Applicant is expected to inform EMA about the regulatory status of the device and is welcome to briefly present their device and intended questions to the Expert Panel.	EMA will briefly present the procedure and answer procedural questions.
3. Draft briefing document submission*	The briefing document template is published on the EMA webpage under the following section: Medical devices | European Medicines Agency (EMA) The briefing document template includes instructions on how to complete the application. The draft briefing document should be uploaded using the original ServiceNow ticket.	EMA will confirm receipt of the draft briefing document by email and schedule the pre-submission meeting (virtually). Feedback can also be provided in writing.
4. Pre-submission meeting* EMA/Expert Panel Chair/Applicant	The Applicant is requested to prepare a brief presentation on their device and proposed	The pre-submission meeting will focus on discussing the questions from the Applicant and feedback on

Step	Instructions for Applicant	Additional comments
	questions and answers outlined in their draft briefing document. The Applicant is also requested to take notes during the meeting.	potential improvements to the briefing document. These comments will also be provided to the Applicant in writing after the meeting using the original ServiceNow ticket. The Applicant will be informed by email.
5. Final briefing document submission and start of procedure (D1)	The briefing document template is published on the EMA webpage under the following section: Medical devices | European Medicines Agency (EMA) The briefing document template includes instructions on how to complete the application. The Applicant is requested to comply with the submission timelines (column "Final Briefing Document Submission"). The timetable is published on the EMA webpage under the following section: Medical devices | European Medicines Agency (EMA) The final briefing document (clean and version showing changes compared to the initial draft version*) should be uploaded using the original ServiceNow ticket.	EMA will validate the final application received and forward it to Expert Panel advisors. EMA will inform the Applicant of the start of procedure date by email and schedule the potential discussion meeting, which will take place during the time period indicated in the timetable (column "Discussion Meeting with the Applicant"). The timetable is published on the EMA webpage under the following section: Medical devices | European Medicines Agency (EMA)
6. List of questions from Expert Panel	The list of questions will be provided to the Applicant during the time period indicated in the timetable (column "List of Questions"). The timetable is published on the EMA webpage under the following section: Medical devices | European Medicines Agency (EMA)	EMA will upload the list of questions using the original ServiceNow ticket and inform the Applicant by email. Questions include clarification requests from the Expert Panel and any major disagreement with the Applicant's proposals. If there are no questions from the expert panel, this step will be cancelled.
7. Discussion meeting EMA/Expert Panel advisors/Applicant and written answers	The Applicant is requested to prepare a presentation providing answers to the questions raised, and to send it in advance of the meeting. Within 2 working days of the meeting, the Applicant is requested to send written responses to the list of questions, taking into account the discussion during the meeting. These responses should be uploaded	The purpose of the meeting is to address the list of questions from the Expert Panel advisors. If there are no questions from the expert panel, the meeting will be cancelled.

Step	Instructions for Applicant	Additional comments
	using the original ServiceNow ticket.	
8. Delivery of advice from Expert Panel (D60)	The advice will be provided to the Applicant during the time period indicated in the timetable (column "Advice Letter"). The timetable is published on the EMA webpage under the following section: Medical devices | European Medicines Agency (EMA)	EMA will upload the advice using the original ServiceNow ticket and inform the Applicant by email.

*Applicants are encouraged to submit a draft briefing document and attend a pre-submission meeting with EMA. However, Applicants can decide to opt out of the pre-submission meeting, in which case the briefing document submitted will be the final briefing document, which will be validated by EMA between the submission date and the start of procedure.

3. Steps after the procedure

3.1. Publication of the advice

Aggregated information on advice provided by the Expert Panels (procedural and operational information) will be published on a yearly basis and may be presented at specific meetings with interested parties organised by the Agency. The advice itself will not be published.

3.2. Considerations for the manufacturer

The Expert Panels' advice is provided upon a voluntary request from the applicant. Article 61(2) of the MDR states that "the manufacturer shall give due consideration to the views expressed by the expert panel". This means that additional actions may be needed from the manufacturer after the provision of the advice. Such considerations are expected to be documented in the clinical evaluation report (CER) and taken into consideration by the notified body at the time of the conformity assessment.