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European Medicines Agency

Guide to manufacturers and notified bodies on the procedure for requesting advice from expert panels for orphan medical devices

Advice on orphan status and clinical advice (advice on the clinical development strategy or clinical data required for the clinical evaluation)

1. Background information

1.1. Basis

The advice from expert panels for (claimed) orphan medical devices is provided pursuant to the MDCG guidance document 2024-10. Formal legislative provisions for orphan devices are expected to be included in the next revision of the Medical Device Regulation (MDR).

1.2. Pilot phase

A pilot programme opened on 2 August 2024. Following successful completion of the pilot, EMA is now fully implementing the orphan device programme, and extending its scope to all device classes as envisaged in the MDCG guidance.

1.3. Scope

Applications can be submitted by the manufacturer or by the notified body depending on the stage of development of the medical device. For manufacturers not established in a country of the European Union (EU), European Economic Area (EEA) or Turkey, an EU authorised representative is required for the application.

All device classes are now in scope of the programme.

In the frame of this programme, clinical advice (advice on the clinical development strategy for 'early stage' devices, or on the clinical data required for the clinical evaluation for 'late stage' devices) is provided only for devices already designated as orphan devices by the expert panels. Should a device not be designated as orphan, and if it 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 manufacturer can request clinical advice from the expert panels through the dedicated advice to manufacturers procedure pursuant to Article 61(2) of the MDR.

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1.4. Fees

Fees are currently not levied for this programme.

2. Procedure and instructions for application

The steps below apply to both types of advice requests: orphan status and clinical advice. Please refer to the notes below the table for additional information.

Step	Instructions for applicant	Additional comments
1. Letter of interest	The form to be completed is at the following link: ServiceNow Please select the option "**Advice in scope of MDCG guidance 2024-10**". 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 briefly present their device and the stage of development.	EMA will briefly present the procedure and answer procedural questions.
3. Draft briefing document submission*	The briefing document template is published on the dedicated EMA webpage: https://www.ema.europa.eu/en/expert-panel-support-orphan-medical-devices 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). Alternatively, 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 questions and answers outlined in their draft briefing document. The applicant is also requested to take notes during the meeting.	The pre-submission meeting will focus on discussing the questions from the applicant and feedback on 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 dedicated EMA webpage: https://www.ema.europa.eu/en/expert-panel-support-orphan-medical-devices	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

Step	Instructions for applicant	Additional comments
	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 dedicated EMA webpage: https://www.ema.europa.eu/en/expert-panel-support-orphan-medical-devices The final briefing document (clean version showing changes compared to the initial draft version*) should be uploaded using the original ServiceNow ticket.	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 dedicated EMA webpage: https://www.ema.europa.eu/en/expert-panel-support-orphan-medical-devices	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 using the original ServiceNow ticket.	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.
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 dedicated EMA webpage: https://www.ema.europa.eu/en/expert-panel-support-orphan-medical-devices	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.

**List of questions and discussion meeting are less common for the orphan status stage.

3. Steps after the procedure

3.1. Publication of the advice

Aggregated information on advice provided by the expert panels (procedural and operational information) may be published 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 (in case the manufacturer is the applicant)

The expert panels' advice is provided upon a voluntary request from the applicant. MDCG 2024-10 provides that the manufacturer shall give due consideration to the expert panel's views. 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). In addition, the expert panel advice should be made available to the notified body, for example as an annex to the clinical evaluation report.

3.3. Considerations for the notified body (in case the notified body is the applicant)

The expert panels' advice is provided upon a voluntary request from the notified body. MDCG 2024-10 provides that the notified body should include the expert panel's considerations in its clinical evaluation and, if the notified body has a different view than the expert panel, should give reasons for such divergent views in its clinical evaluation assessment report.