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Question and Answer on the submission of applications for the expert panels' advice to manufacturers

Pilot on advice from the expert panels

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1. Background information

This Q&A document was prepared following the webinar held on 25 January 2023 to inform manufacturers and the wider public on the EMA pilot advice from the expert panels on certain high-risk medical devices. It provides answers to the most frequently asked questions received during the webinar.

2. Question and Answer

2.1. What is the scope of the pilot advice to be provided by the expert panels to manufacturers?

According to Article 61(2) of the Regulation (EC) 2017/745 on medical devices (MDR), the devices in scope of the expert panels' advice are class III devices and class IIb active devices intended to administer and/or remove a medicinal product from the human body (Section 6.4 of Annex VIII (Rule 12) for the latter). This scope applies to the pilot as well.

It is for the applicant to determine the type and risk class their device belongs to before submitting the request to the expert panels. Questions regarding the qualification of a product as a medical device or its risk classification are outside the scope of the meeting and of the advice procedure itself.

2.2. What type of advice is provided by the expert panels?

According to Article 61(2) of the MDR, the expert panels may provide advice on the manufacturer's intended clinical development strategy and proposals for clinical investigation.

The advice is not on the preclinical development strategy. However, preclinical information might be relevant for the experts when developing their advice. This will be discussed with the applicant on a case-by-case basis.

The advice of the expert panels is prospective by nature. The advice of the experts is not an assessment of already generated data. However, experts may have to consider the data already available when developing their advice, in particular for the review of the clinical development strategy. The relevance of such data will be assessed by the experts on a case-by-case basis, considering the specificities of the device under development.

2.3. How will the expert panels decide on the applications that will be selected to receive advice?

The number of advice procedures delivered will be limited during the pilot. Therefore, the expert panels might need to select applications. To ensure the relevance of the pilot, applications should cover a spectrum of situations in terms of:

- types of devices
- medical areas
- applicants, with a special attention given to SMEs. Applicants will have to indicate whether they qualify as SMEs based on the definition provided on the Commission website.

Concerning the types of devices, the following prioritisation criteria will be applied by the experts (in no particular order):

- **Devices intended to benefit a relatively small group of patients** in the treatment or diagnosis of a disease or condition (for example "orphan devices" and devices for paediatric use)

- **Devices for unmet medical needs, i.e.,** 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 definition of "breakthrough devices" in MEDDEV 2.7/1 rev.4, Appendix 8)
- **Novel devices that have a possible major clinical or health impact.**

The applicant will have to provide a justification as to how the device meets any of these criteria when submitting the letter of interest.

- For devices intended to be used in a small group of patients, the justification should be based on a description of the target population of patients. The applicant should provide a quantitative estimate of this population in the EU indicating the sources on which this estimation is based as well as the uncertainty around this estimate.
- As regard to devices for unmet medical needs, the applicant should provide a description of the disease(s)/condition(s) and the current available treatments indicating the sources of information used.
- Regarding novel devices, the justification should be based on the Commission guidance on the interpretation of the CECP decision criteria that includes the criterion on novelty and related clinical or health impact.

There will be two phases of selection, first in April 2023 and second in September 2023. Manufacturers can submit letters of interest from 27 February 2023 until the end of August 2023. Letters of interests that have not been selected in the first phase of the pilot will be considered in the second phase of the pilot unless the applicant withdraws the application.

2.4. Will my company be able to engage with the expert panels during the pilot procedure for advice?

During the pilot, each selected applicant will have the opportunity to interact with the experts in charge of the advice in two moments of the procedure.

The first interaction will be a pre-submission meeting that will take place before the submission of the final advice request. The selected applicant is required to provide a draft submission prior to the meeting. It is highly recommended that this draft submission is as detailed as possible so that practical suggestions can be made regarding the adequacy and comprehensiveness of the content.

Before the advice of the expert panels is finalised, another meeting with the applicant will take place to clarify any remaining doubts from the experts. The applicant will be informed in advance of the remaining issues in order to adequately prepare for the discussion. Although there is no further opportunity for the applicant to submit additional documentation after the final advice request, very specific information may be presented at this meeting if considered to be key for the experts' advice.

Both meetings will be held remotely. The applicant is expected to share in advance the participants' names and affiliation list for each meeting.

2.5. Can I choose which panel to provide the advice?

The applicant needs to indicate the clinical area(s) the device will be intended to be used in. The group of experts that will provide the advice will be constituted of experts from all relevant fields.

2.6. What would be the content of the advice request?

The advice request is divided in two parts: 1) the letter of interest in view of the selection phase and 2) the final advice request ("full application") for the applicants whose proposal has been selected for the pilot.

The advice request has a "question-and-answer" format to help the applicant present its questions about the clinical development strategy and/or clinical investigation in a freely manner.

The applicant's contribution provided in the advice request is paramount to ensure the usefulness and adequacy of the advice to be provided. The applicant's position should be a stand-alone section, detailed enough to ensure a clear understanding of the proposed strategies envisioned, but also concise and objective to help the experts deliver their advice in a timely manner. Any additional documentation that might be helpful as scientific support can be presented as an annex document. The content of the full application will be discussed on a case-by-case basis during the pre-submission meeting.

The experts will provide their advice in the same template used for the submission of the request, addressing one question at a time.

2.7. What are the timelines for providing the advice?

Once the selection process is concluded, the applicant is informed and the date for the pre-submission meeting is agreed. The final advice request should be submitted one month later at the latest, and a start date for the advice procedure is set according to the availability of the experts. It is expected that the advice will be provided within 60 days on average. However, some procedures may require additional time depending on the complexity of the advice and/or the availability of the experts. The exact timelines will be communicated to the applicant at the start of the procedure.

2.8. Is the advice legally binding?

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 to be documented in the clinical evaluation report (CER). This will allow the notified body at the time of the conformity assessment to have an overview of the expert panels' advice and the way the manufacturer considered this advice in its clinical development strategy and/or clinical investigations.

Article 61(2) of the MDR also states that a "manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure". Scientific advice is different in nature and content from the conformity assessment. The expert panels provide their advice on the proposed clinical development strategies and clinical investigations but there is no guarantee that the evidence generated will be sufficient for the conformity assessment procedure.

2.9. Will the advice be published?

The advice delivered during the pilot will not be published.

Reflection is ongoing on the format of the future publication of the advice of the expert panels falling under Article 61(2) MDR to ensure compliance with Article 109 of the MDR once the pilot has ended.

2.10. Will the CECP panel be composed of the same experts as that who gave the advice?

The advice will be provided by experts in the clinical field(s) relevant for the device.

Both procedures will be managed to ensure independence, impartiality, objectivity and absence of conflict of interest as outlined in Article 107 of Regulation (EU) 2017/745.

2.11. Who can participate in the pilot?

The pilot is open to manufacturers based in the European Economic Area countries.

2.12. How can my company participate in this pilot?

Interested applicants are invited to submit a letter of interest that will include the main information related to the device and other elements that will help with the selection for the pilot. The template of the online application form can be found in the Documents section of the webinar (Information session on the pilot for expert panels' scientific advice to manufacturers of high-risk medical devices | European Medicines Agency (europa.eu)).

2.13. When and how can I submit my "letter of interest" for advice from the expert panels?

Letters of interest can be submitted online from 27 February 2023.

The applicant is allowed to submit more than one request, i.e., for different devices, to the expert panels advice pilot. Each of those will need to be submitted separately. In the end, only one proposal for each manufacturer can be accepted.

2.14. If someone has already an EMA IT account, can it be used, or a new account must be created?

If an applicant has already an EMA account for the IT systems, there is no need to register for a new account. All EMA accounts have access by default to the system for the submission of the letters of interest.

2.15. Is there a specific contact at EMA in case of questions concerning the scientific advice process prior to an application?

Before the submission of a letter of interest, questions concerning the expert panels advice process can be addressed to EXPAMED-SA@ema.europa.eu.

For applications selected to be part of the pilot, the applicant will be informed, and a procedure lead will be appointed. The procedure lead will serve as the main contact point for any questions related to the advice procedure throughout the process.

2.16. Are there any fees requested to the manufacturers to participate in the pilot?

There are no fees for the applicants during this pilot. The pilot is entirely funded from the EU4Health budget.

2.17. When is it expected for the pilot to finish for regular applications for advice from the expert panels?

The pilot for advice provided by the expert panels is planned to run until the end of Q1 of 2024. Based on the experience gathered during the pilot, the process may be revised for the full implementation of the *ad hoc* advice for the high-risk medical devices mentioned in Article 61(2) of the MDR. Once the definitive advice procedure is launched, fees will be levied for the submissions. The fees will be determined according to an Implementing Act to be developed by the European Commission after the

adoption by the European Parliament and the Council of a revised regulation on fees and charges payable to the EMA. Once additional information is available, it will be made public on our website, www.ema.europa.eu.