EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pilot on the Advice from the Expert Panels to Manufacturers of High-Risk Medical Devices

Interim report on the experience with the pilot from February 2023 to December 2024

An agency of the European Union

Executive summary

A pilot on advice to manufacturers on their clinical development strategy and/or proposals for clinical investigation for certain high-risk medical devices, as provided for in Article 61(2)[1] of the Medical Devices Regulation, was launched by the European Medicines Agency (EMA) in February 2023 and is currently concluding.

The advice is provided by Expert Panels. This is the first time in the European Union (EU) that manufacturers have access via a dedicated regulatory procedure to experts that will advise on the best possible way to design and conduct clinical investigations and address questions concerning clinical development strategies to support the certification of the devices. This will help manufacturers have timely access to early consistent advice through a single EU regulatory pathway on the clinical development of their products, thus enhancing the predictability on clinical evidence generation and ultimately facilitating healthcare professionals and patients access to innovative, safe and effective devices without unnecessary delays.

This interim report provides an overview of the applications received during the pilot until the end of December 2024. A final report on the pilot will be published once all pilot procedures are finalised.

Based on the successful outcome of the pilot, the advice to manufacturers was fully implemented as of February 2025. Improvements to the procedure were made considering the feedback received from both experts and manufacturers during the pilot.

[1] According to the Medical Device Regulation (EU) 2017/745 Art 61(2), for **all class III devices and for the class IIb active devices intended to administer and/or remove medicinal product(s)**, the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation.

Table of contents

Introduction

Legal basis for the pilot and the role of EMA

Regulation (EU) 2017/745 on medical devices[2] (Medical Devices Regulation, MDR) Article 106 and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices[3] (*In Vitro* Diagnostic Medical Devices Regulation, IVDR) Article 48 provide the legal basis for the establishment of the Expert Panels[4] on medical devices and for *in vitro* diagnostics, respectively. The MDR has been applicable since 26 May 2021 and the IVDR has been applicable since 26 May 2022.

According to Article 61(2) of the MDR, the Expert Panels can provide advice to manufacturers on their clinical development strategy and/or proposals for clinical investigation, for certain high-risk medical devices.

Regulation (EU) 2022/123 on a reinforced role for the EMA ("the Agency") in crisis preparedness and management for medicinal products and medical devices[5] has given the Agency the responsibility to provide the Secretariat for the Expert Panels, which was handed over from the European Commission's Joint Research Centre to the Agency on 1 March 2022.

General considerations

The Agency launched a pilot in February 2023 to help set up an efficient and fit-for-purpose process to handle the request and delivery of the advice to manufacturers provided for by Article 61(2) of the MDR. A webinar[6] to stakeholders was held on 25 January 2023 and covered an introduction to the pilot and a description of the process, with timings and prioritisation criteria for participation in the pilot. This interim report provides an analysis of the key deliverables, performance indicators and feedback from manufacturers and experts on the 20 finalised advice procedures up until 31 December 2024.

Goal

Support innovation and availability of high-risk medical devices with the first EU advice pilot from the Expert Panels on the manufacturer's intended clinical development strategy and proposals for clinical investigation

The Expert Panels that provided the advice were organised into panels of 5 advisors (Chair, Rapporteur, Co-Rapporteur and 2 Reviewers) from the clinical field of the device.

The following prioritisation criteria were applied:

- **devices used in a relatively small group of patients to help diagnose or treat a disease or condition (e.g., orphan devices, paediatric-only devices);**

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN
[4] https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/medical-device-expert-panels
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02022R0123-20250101
[6] https://www.ema.europa.eu/en/events/information-session-pilot-expert-panels-scientific-advice-manufacturers-high-risk-medical-devices

- **devices that help address an unmet medical need, i.e., devices for medical conditions that are life-threatening or can cause permanent impairment, and for which the treatment currently available is insufficient or carrying significant risks for patients;**
- **novel devices that can have a major clinical or health impact.**

Additionally, the pilot prioritised proposals that covered different medical areas/types of devices and proposals presented by Small and Medium-sized Enterprise (SME) manufacturers. The applicants would also need to be established in the EU or have an authorised representative in the EU.

To take part in the selection phase, each applicant was invited to present a letter of interest. Amongst other information, a brief description of the device and its intended purpose was to be provided, as well as a brief overview on the device's development and how it would fit the selection criteria.

Overview of the process

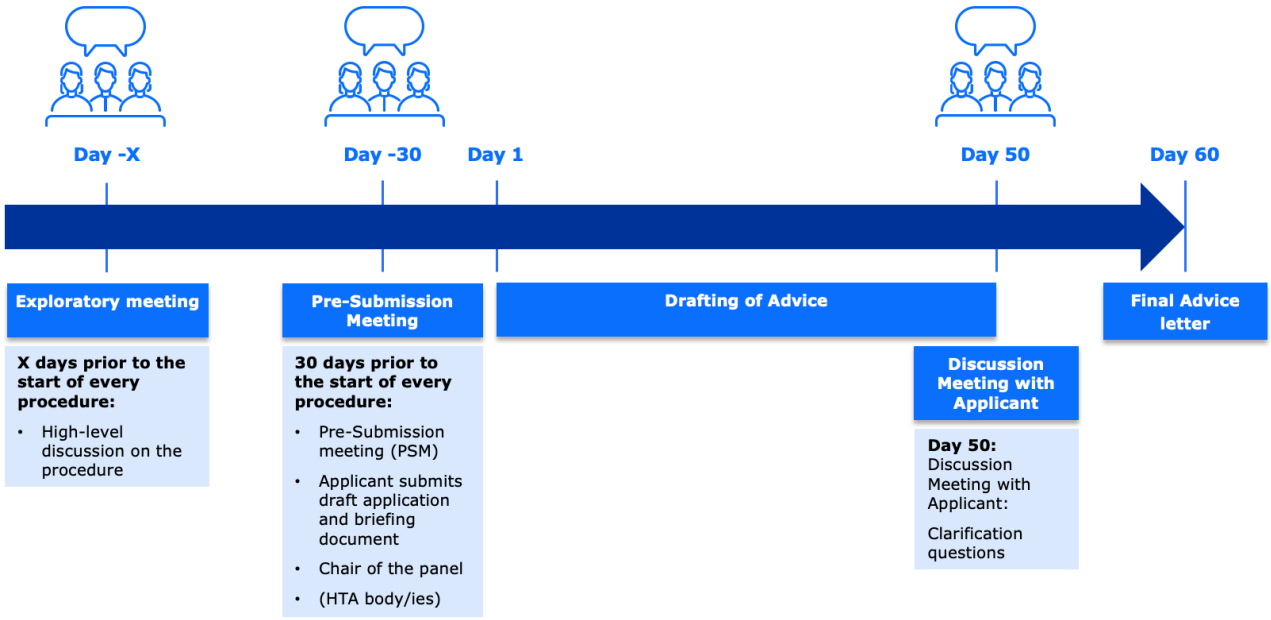
The pilot procedure for the advice to manufacturers consists of the following steps:

- Submission of the letter of interest by the applicant
- Exploratory meeting with the applicant
- Submission of the draft briefing document by the applicant
- Pre-submission meeting with the applicant: to discuss the completeness and adequacy of the briefing document
- Submission of the final briefing document (Day 1)
- Preparation of the advice by the experts
- Clarification questions from the panel to the applicant (if applicable)
- Meeting with the applicant before finalising the advice: to discuss clarification questions from the experts and any major disagreements
- Final advice letter delivery to the applicant.

Three meetings were envisaged in the process (see Figure 1). The exploratory meeting with the applicant was usually attended by the EMA secretariat (day -X) to discuss the overall regulatory status and clinical phase of development of the device. Once the applicant was ready to submit the briefing document, the EMA secretariat and Chair of the panel would attend a pre-submission meeting with the applicant (day -30) to ensure the completeness of the briefing documents.

A final meeting was organised with the entire panel, the applicant and the EMA secretariat (~ day 50) to discuss clarification questions or any major disagreements with the proposed plan. A final advice was delivered to the applicant on the questions concerning the clinical development plan or clinical investigations (~ target day 60). The advice that was provided did not preclude the applicant from seeking follow-up advice from the Expert Panel in the future.

Figure 1. Schematic representation of the advice process during the pilot



Overview of applications received during the pilot programme

The pilot programme consisted of 3 subsequent submission phases, which took place as follows:

- **First submission phase: from 27 February 2023 to 15 April 2023;**
- **Second submission phase: from 22 June 2023 to 15 September 2023;**
- **Third submission phase: from 2 April 2024 to 30 June 2024.**

The third phase included the possibility to involve Health Technology Assessment (HTA) authorities if requested by the applicant.

Number of applications received

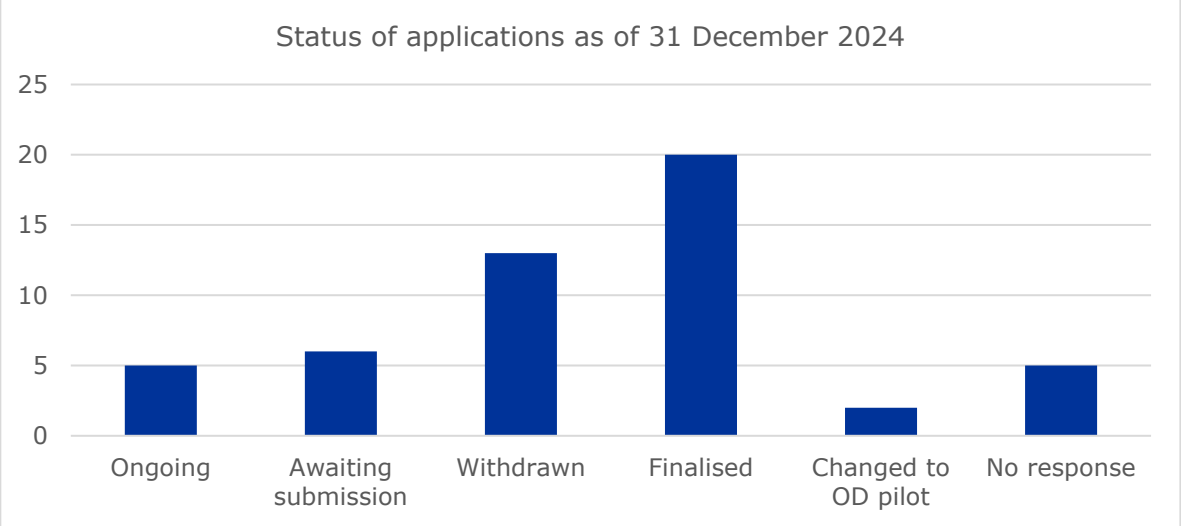
In total, 51 letters of interest were received: 26 for the first phase, 16 for the second phase, and 9 for the third phase.

Six applications were selected and prioritised for the first submission phase. For the second submission phase, all new applications as well as the initial applications not selected for the first phase were considered, and 21 applications moved forward to the advice stage. For the third phase, all applications received during the third period were considered.

Current status of applications

The status of applications across all 3 submission phases as of 31 December 2024 is shown in Figure 2. The majority of applications have been finalised with a scientific opinion given for 20 applications. A number of applications were withdrawn following the exploratory meeting, mainly because of delays in the clinical development program or of requests being out of the scope of the advice pilot. A number of manufacturers did not follow up after the first contact following the submission of the letter of interest. As of 31 December 2024, there were 5 applications ongoing and 6 applications that were still awaiting submission.

Figure 2. Summary of the applications received for the Pilot on Expert Panels' advice to medical device manufacturers



Legend:

- Ongoing: the final briefing document was received and the advice procedure is ongoing;
- Awaiting submission: the applicant confirmed that the final briefing document would be sent to EMA, the procedure has not yet started;
- Withdrawn: the applicant indicated that they no longer wished to pursue the advice procedure;
- Finalised: the advice has been delivered;
- Change to OD pilot: the device may qualify as an orphan device and the applicant has therefore decided to re-submit their letter of interest under the orphan medical device pilot programme;
- No response: following the first interactions between EMA and the applicant, the applicant has not followed up with their request for advice.

Categorisation of applications

The Circulatory system thematic panel received the highest number of applications with 31% of applications, followed by the Orthopaedics, traumatology, rehabilitation, rheumatology thematic panel (27%) then Neurology (14%). A breakdown of the submissions (i.e. letters of interest) received during the 3 phases per clinical area, SME status and prioritisation criteria can be found in Tables 1 to 3.

Table 1. Distribution of submissions per clinical area across all 3 submission phases

Thematic panel	# applications	%
Circulatory system	16	31
Orthopaedics, traumatology, rehabilitation, rheumatology	14	27
Neurology	7	14
General and plastic surgery and dentistry	6	12
Nephrology and urology	3	6
Gastroenterology and hepatology	2	4
Respiratory and anaesthetic devices, intensive care	1	2
Ophthalmology	1	2
Other	1	2
Total	51	100

The number of SME companies that took advantage of the pilot was high with 75% of applicants declaring meeting the SME definition. This indicates an unmet need for clinical development advice primarily for SMEs but also non-SMEs, as there are no other options in the EU to receive this premarket support to innovators for the design of their clinical investigations. Of note, 78% of applicants that withdrew their applications (including the non-responders) were SMEs, which correlated with the proportion of applications received from SMEs. This may indicate that the advice procedure is unlikely to disproportionally impact the accessibility of SMEs vs non-SMEs to the procedure, for example in terms of resource allocation or administrative burden.

Table 2. Percentage of SME companies that applied to pilot, as claimed by the applicant, across all 3 submission phases

SME	# applications	%
Yes	38	75
No	13	25
Total	51	100

In terms of prioritisation criteria, the applicant could choose more than one criterion for the eligibility to the pilot. As shown in Table 3, the majority of the applications received were for devices that were considered novel with a possible major clinical or health impact (criterion declared by 86% of applicants) followed by devices addressing an unmet medical need (criterion declared by 55% of applicants).

With regard to novel devices, the pilot revealed that manufacturers require early expert advice related to their clinical development strategies before starting their clinical investigations, and, where applicable, late advice on post-market follow-up studies that may complement and monitor the safety and effectiveness of their device once it is placed on the market. Hence, the Expert Panels provided a centric European-based expert framework that manufacturers developing innovative devices can access fairly rapidly, with the additional scientific and technical support from the EMA's experienced secretariat. In addition, manufacturers of devices that fulfil an unmet medical need and/or devices intended for orphan indications may face many challenges, e.g. limitations in generating sufficient clinical evidence, and would therefore benefit from additional support. This highlights the importance to cater to those needs and ensure that manufacturers have access to the support of clinical experts such as the Expert Panels. With their broad and extensive clinical practice experience in the EU, they can enable better, safer and more efficient clinical developments of those specific types of devices that will bring meaningful benefits and improve the lives of patients with very few available treatment or diagnostic options.

Table 3. Prioritisation criteria, as claimed by the applicant, across all 3 submission phases

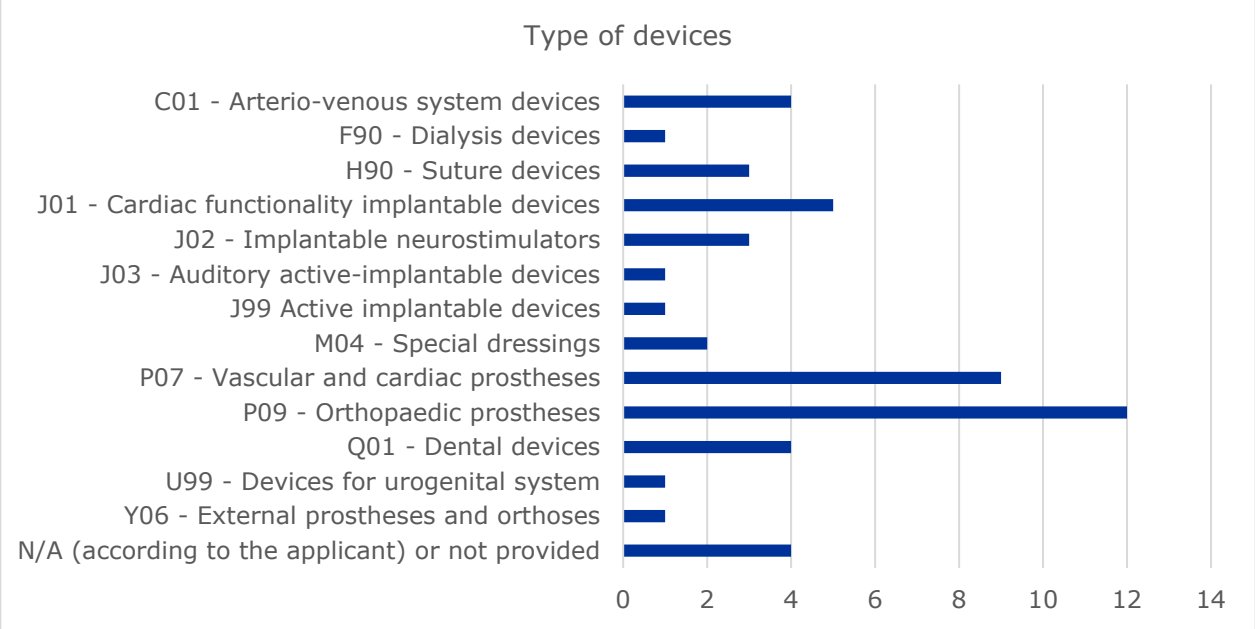
Prioritisation criteria	# applications
Novel device with a possible major clinical or health impact	44
Device for unmet medical needs	28
Device intended to benefit a relatively small group of patients	18

Overview of devices

The distribution of devices by EMDN level 2 across all 3 submission phases is presented in Figure 3. Orthopaedic prostheses and vascular and cardiac prostheses were the two types of devices most frequently submitted with 12 and 9 applications respectively, consistent with the clinical area

distribution shown in Table 1. It is noted that interest to participate in the pilot was expressed by manufacturers of a wide range of types of devices as shown in Figure 3.

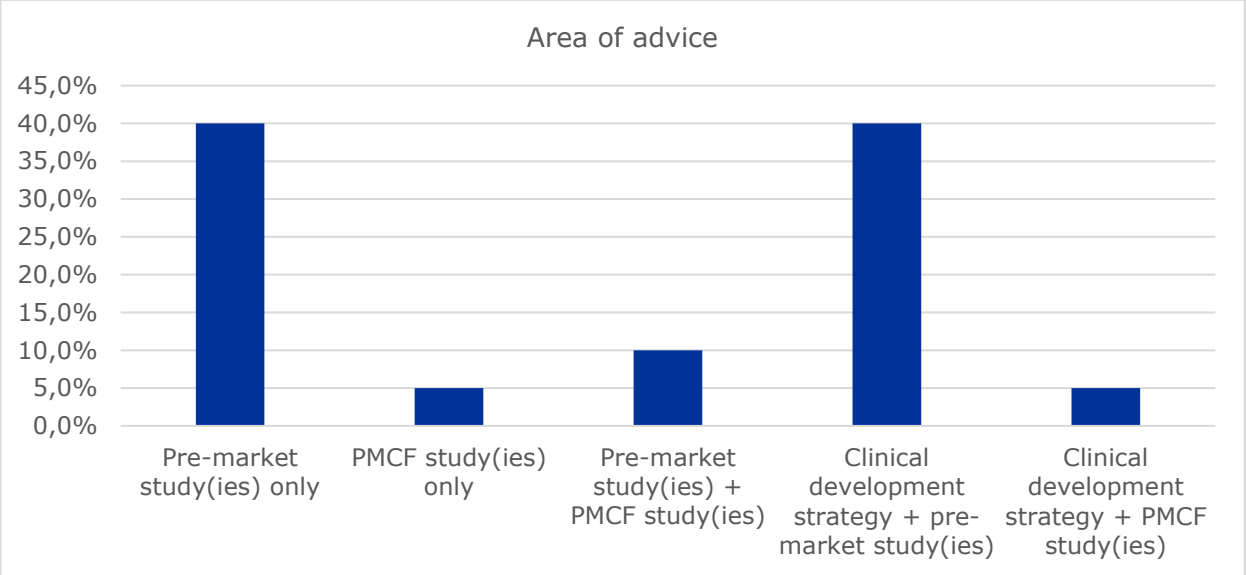
Figure 3. Summary of the types of devices, categorised per EMDN level 2, received during the Pilot on Expert Panels' advice to medical device manufacturers



Overview of questions to Expert Panels

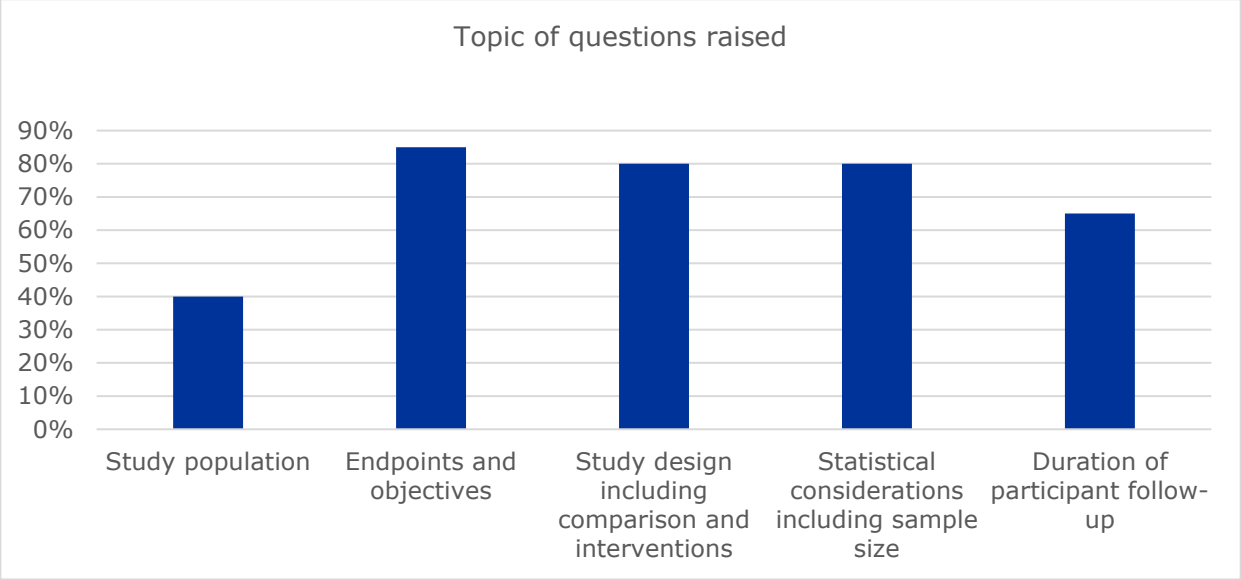
As per their legal mandate, Expert Panels can provide advice on the clinical development strategy and/or the proposals for clinical investigation from the manufacturers. The large majority of applications focused on pre-market studies (80%), with half of the applications also including more general questions on the clinical development strategy (40%). This indicates that the most pressing needs for manufacturers are mainly in the pre-market phase of the clinical development, with advice on the clinical development strategies coupled with the clinical investigations to support the conformity assessment of the high-risk device. No application pertaining to the clinical development strategy only (i.e. with no specific questions on either a pre-market study or a Post-Market Clinical Follow-up [PMCF] study) was received. An overview of the areas of advice is provided in Figure 4.

Figure 4. Summary of the area of advice provided during the Pilot on Expert Panels' advice to medical device manufacturers



Typically, applications for advice included 1-6 questions for the experts. Figure 5 shows the topics of questions raised by manufacturers on the clinical investigation(s) for which the application was submitted. These questions were quite evenly distributed between endpoints/objectives (85%), comparison and interventions (80%) and statistical considerations (80%), with fewer questions pertaining to duration of follow-up (65%) and study population and inclusion/exclusion criteria (40%).

Figure 5. Summary of the topic of questions raised by applicants in their briefing document during the Pilot on Expert Panels' advice to medical device manufacturers



Duration of the advice process

The duration of advice process is counted from the date of start of procedure, defined as the date of transmission of the briefing documents to experts, to the date of delivery of the advice to the applicant.

The pilot evaluated whether a target duration of 60 days for the advice process was feasible. For the procedures finalised before 31 December 2024, the duration from the time of submission (day 1) to the delivery of the advice ranged from 56 to 205 days, with an average of 93.5 days. Five procedures out of 20 took more than 120 days; without these procedures, the global average drops to 69.7 days.

For the first submission phase, the average was 111.8 days, with durations ranging from 64 to 205 days. Two procedures out of 5 took more than 120 days.

For the second submission phase, the average was 87.4 days, with durations ranging from 56 to 192 days. Three procedures out of 15 took more than 120 days; these are statistical outliers (see Figure 6), and without these procedures the average duration is 67.8 days.

We therefore see a significant reduction of the time to deliver the advice between the first two submission phases, reflecting the gain in experience of the Expert Panels and manufacturers.

The prolonged duration for the procedures that lasted more than 120 days was due to the following factors:

- complex devices/advice requests requiring additional review time from the Expert Panel;
- company's request to extend the timelines.

Generally, flexibility was allowed for both the manufacturers and experts since the procedures were conducted under a pilot process, and also as a new initiative as part of non-legislative measures implemented by the European Commission to help support developers with the implementation of the MDR and promote innovation in the EU[7],[8]. Therefore, experts were allowed time for additional training while gaining experience on the new procedure and manufacturers were permitted more flexibility on the submission of responses to questions from the experts after the discussion meeting, before the delivery of the final advice.

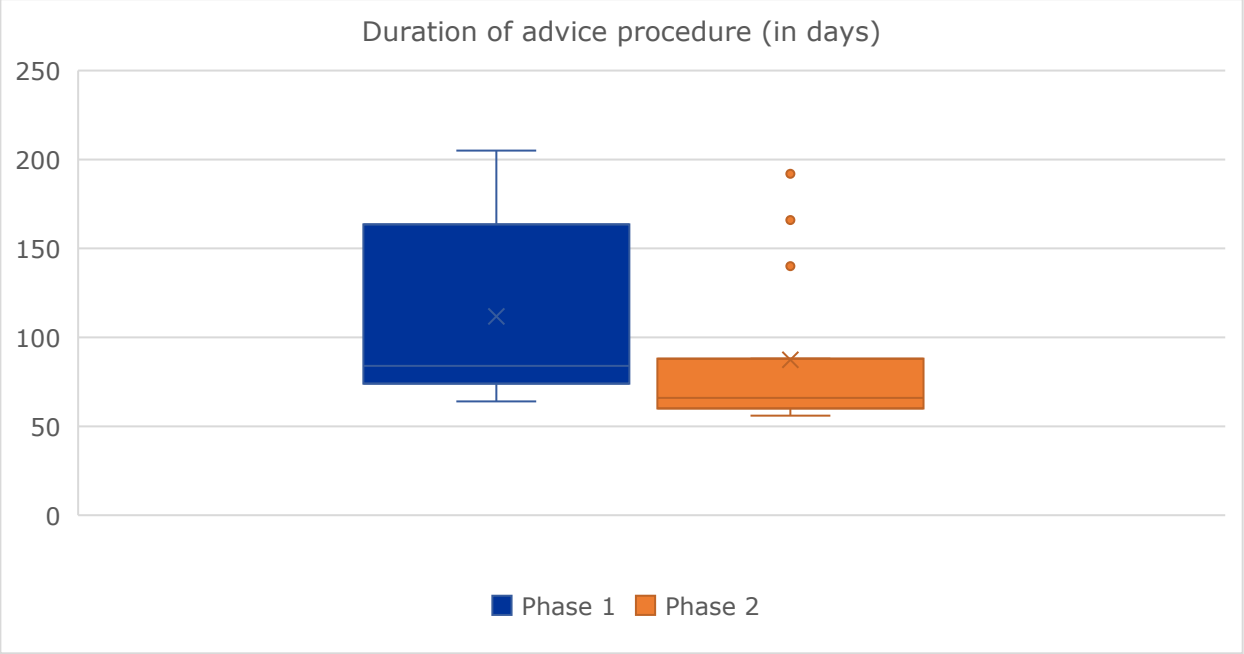
An overview of the duration of the advice procedure (days) is provided in Figure 6. This graph shows the following data for both phases:

- Within the boxes: lower/first quartile (horizontal line delineating the lower part of the box), median (horizontal line within the box), average (cross sign within the box), upper/third quartile (horizontal line delineating the upper part of the box).

- Outside the boxes: minimum excluding outliers (horizontal line at the end of the "whisker" below the box), maximum excluding outliers (horizontal line at the end of the "whisker" above the box), outliers (only for phase 2 and above the box: values greater than third quartile + 1.5 x interquartile range [IQR]). There are 3 outliers in phase 2, corresponding to duration times of 140, 166 and 192 days, respectively.

[7] https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_22_7627
[8] https://health.ec.europa.eu/document/download/d298fcf1-f1c6-477b-b798-ce0acda7c1a7_en

Figure 6. Duration of advice procedure, from start of procedure to delivery of advice to the applicant, for all finalised applications (submission phases 1 and 2) up to 31 December 2024, during the Pilot on Expert Panels' advice to medical device manufacturers



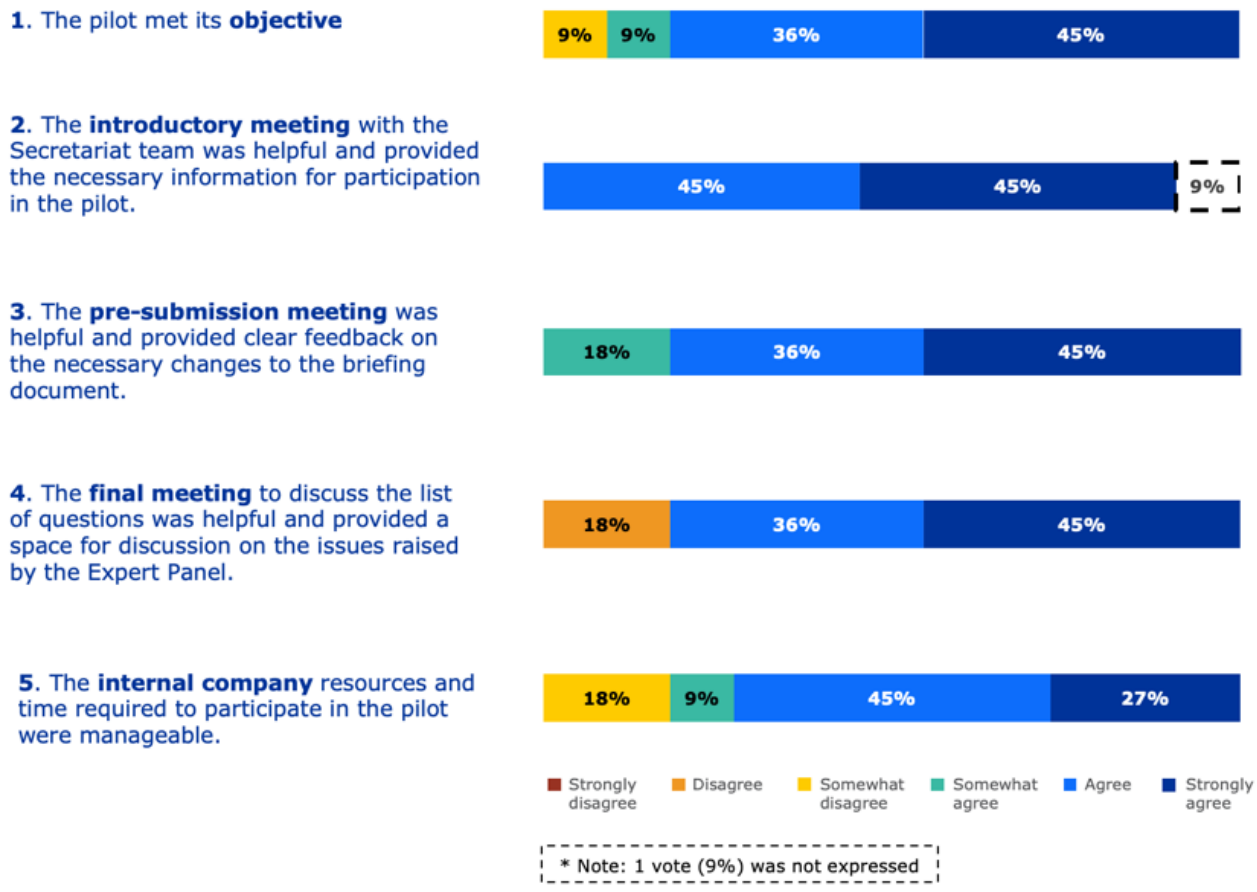
Analysis of the feedback received on the advice procedure

A voluntary survey was sent to experts and manufacturers after each completed procedure during the pilot. The aim of this survey was to gather feedback on the different aspects of the pilot, to be used as a basis for any improvement that would be required to the procedure, guidance, templates and timelines, to help further establish the regular advice for manufacturers.

Results of the survey sent to manufacturers

Responses to the survey were received from 11 applicants as of 31 December 2024. An overview of the responder's feedback on the 5 survey questions is provided in Figure 7.

Figure 7. Overview of feedback received from applicants (manufacturers) during the Pilot on Expert Panels' advice to medical device manufacturers (until 31 December 2024)



The majority of manufacturers believe that the pilot met its objectives, with 81% strongly agreeing or agreeing with the statement. Some manufacturers commented that they would also have liked to receive regulatory advice for their clinical development strategies, however, this regulatory advice was not part of the scope of the current pilot. A great majority also replied that the introductory meetings and the pre-submission meetings were helpful to understand the process and the expectations from the pilot and how to prepare the documentation to be submitted for the advice. For the discussion

meeting with the manufacturers, 81% agreed or strongly agreed that the meeting was helpful for an open exchange with the experts on the issues raised for the advice. However, some commented that they would have preferred more time for discussion and sometimes a more in-depth discussion of the topics raised in the questions. Generally, the manufacturers believe that time and internal resources required for the advice procedure were manageable, but some manufacturers commented that for SMEs, the time and resource requirements for this type of advice was unexpectedly high. Overall, manufacturers appear satisfied with the general process put in place with the Expert Panels to provide advice to manufacturers according to the provisions in Article 61(2) of Regulation (EU) 2017/745.

FEEDBACK FROM MANUFACTURERS

Areas of strength

- Unique consultation opportunity with experts for medical devices in the EU region;
- Enhance interaction with regulators and contributes to the implementation of a roadmap for CE marking;
- Clarifications on MDR evidence requirements;
- Opportunity to engage with clinical experts and support from methodology experts on clinical investigations before starting the clinical programme and in view of a future Clinical Evaluation Consultation Procedure (CECP);
- Scientific expertise of the Expert Panels;
- Collaborative and professional process;
- Quality of the discussion meeting;
- Networking with field experts outside of the specific medical device area;
- Insights into EMA's culture and support for innovation.

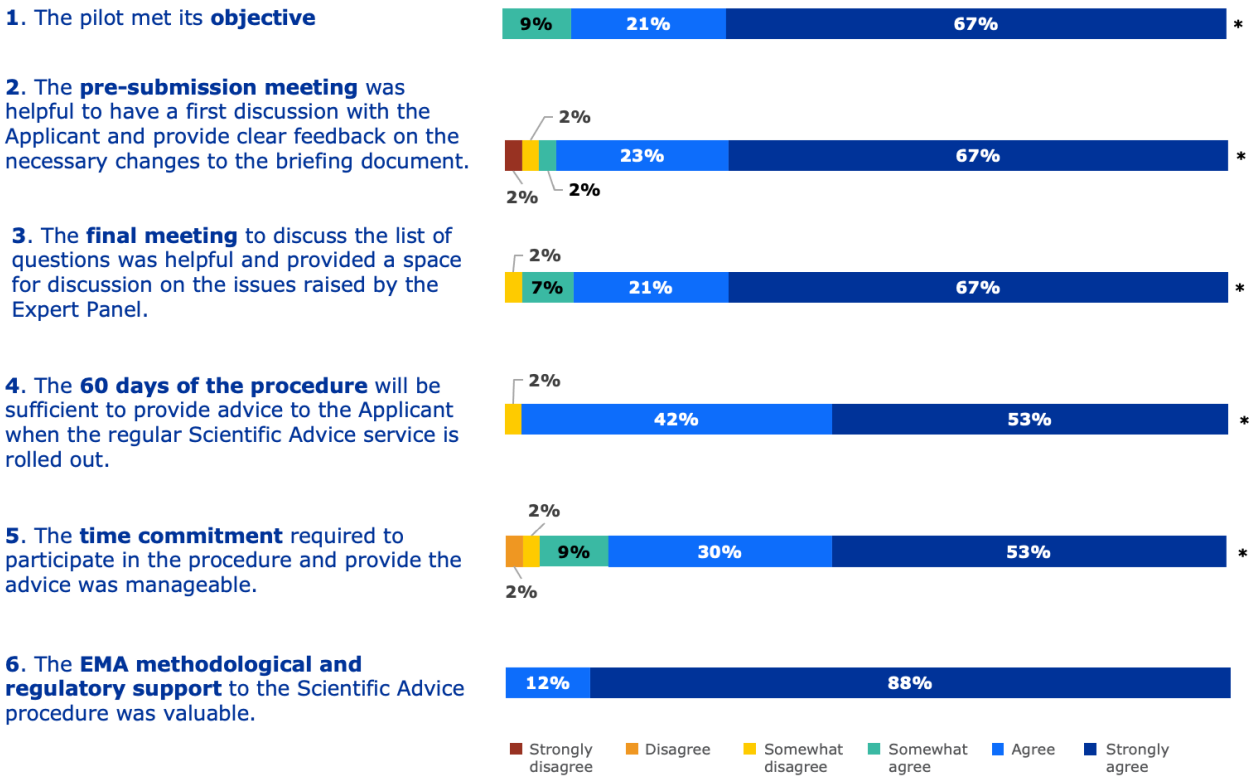
Areas of improvement

- Clarity and completeness of the clarification comments raised and advice received from the experts;
- Clearer scope for the advice (type of questions that can be answered by the Expert Panels);
- Longer meetings with experts and more focused discussions;
- Clarity on expected time commitment, requirements for documentation to be submitted and workload;
- More communication from the Secretariat about the status of the procedure;
- Fixed advice timeline and timetable;
- Improvement to the platform used for submission and communication.

Results of the survey sent to the experts

Responses to the survey were received from 43 experts as of 31 December 2024. An overview of the responder's feedback on the 6 survey questions is provided in Figure 8.

Figure 8. Overview of feedback received from experts during the Pilot on Expert Panels' advice to medical device manufacturers (until 31 December 2024)



*** Note: 1 vote (2%) was not expressed**

In general, the experts involved in the procedures during the pilot showed a high degree of satisfaction with the procedure, with 88% strongly agreeing or agreeing that the pilot met its objectives. Most experts felt that the pre-submission meeting, which is organised at least one month before the submission of the briefing documents, was important to ensure that the documentation presented to the Expert Panel was complete and acceptable. The experts also believed that, in general, the 60-day timetable was sufficient to provide the advice, with some experts preferring shorter timelines while others requesting longer periods to draft the advice, depending on the complexity of the advice. All experts responded that the involvement of EMA in providing methodological and regulatory support was very valuable for the success of the procedure.

FEEDBACK FROM EXPERTS

Areas of strength

- Teamwork and quality of discussions with experienced peer colleagues;
- Collaboration with EMA officers and methodological support;

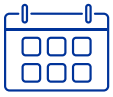
- Professional interactions with applicants;
- Gaining insight into manufacturers' development plans, involvement in early stages of new devices;
- Understanding and contributing to the advice process with their own clinical expertise;
- Sense of contribution to the development of innovative medical devices for the benefit of patients.

Areas of improvement

- Clarity on expected time commitment, timelines and expectations for experts;
- Strengthening instructions to applicants regarding scope of the advice and expectations;
- Streamlining the process (more focused timelines, replacement of meetings by written exchanges where appropriate, improvement in drafting and review of the advice);
- Management of the team of experts when replacements are needed.

Recommendations for process improvement and new measures for the efficient implementation of the standard procedure for advice to manufacturers

Based on the interim feedback received from experts and applicants, a careful analysis of the preliminary results of the survey was conducted and the following adjustments were considered appropriate to be applied for the implementation of the standard procedure for advice:

	Learnings	Recommendations
Improvement of the process with streamlining of communication 	• Streamlining the process (more focused timelines, replacement of meetings by written exchanges where appropriate)	• Meetings during the procedure are now all optional, to leave the flexibility to have exclusively written exchanges, where appropriate.
Regulatory context and timelines 	• Clarity on expected time commitment, timelines and expectations for both experts and applicants • Clearer scope for the advice • Clearer requirements of the documentation to be submitted	• A guide to experts and a guide to applicants including respective expectations and instructions have been developed and published. • A template for the briefing document with detailed instructions for applicants has been developed and published.
Increase predictability and transparency 	• Fixed advice timeline and timetable	• A fixed timing for the advice (60 days from submission of final briefing document) has been implemented, along with a published timetable with defined submission slots for applicants.
Increase collaboration and communication 	• More communication from the Secretariat about the status of the procedure	• Standard communications are sent to the applicants and experts at each step of the process.

It is planned to continue collecting feedback for at least a year while the standard process for the regular advice procedure is implemented, and to further conduct periodic adjustments and improvements to the procedure.

Conclusion and next steps

In a pioneering initiative for medical devices in the EU, the Expert Panels took part in a pilot on advice to manufacturers on the clinical development strategy and/or proposals for clinical investigation for certain high-risk medical devices. The pilot was launched by EMA in February 2023 and is now in its closing phase. This is the first time in the EU that manufacturers have access via a dedicated regulatory procedure to experts that will advise on the best possible way to design and conduct clinical investigations.

In this interim report, a summary of the preliminary results of the pilot have been presented. The pilot prioritised proposals that covered different medical areas and types of devices with a high proportion of proposals presented by SME manufacturers. The ratio of withdrawn applications versus submitted applications is equivalent for SMEs and non-SMEs. This indicates that the advice procedure does not disproportionately impact SMEs, which is a positive indicator for these companies which are in many cases at a disadvantage due to their limited resources. This may also reflect the need to support SMEs in the medical device technology sector on their clinical strategies for innovative devices and to improve availability of EU expertise in clinical areas of interest. The main objective is to eventually create a system that promotes innovation together with the generation of meaningful clinical data for the conformity assessment, which will lead to faster access to safe and effective novel devices for patients and healthcare professionals.

The highest number of applications was received in the Circulatory system thematic panel with 31% of applications. Orthopaedic prostheses and vascular and cardiac prostheses were the two types of devices most frequently submitted with 12 and 9 applications respectively. The majority of the applications received were for devices that were considered novel with a possible major clinical or health impact. The involvement of the Expert Panels in those critical clinical areas can help build standardisation of the advice on specific devices in the long term and trust between manufacturers and healthcare professionals on the performance and safety of high-risk devices. It can also reassure that the investments made are consistent with the efficient use of the limited resources.

The pilot evaluated whether a target duration of 60 days for the advice process was feasible. During the pilot, the duration of the procedure ranged from 56 to 205 days, with an overall average of 93.5 days. However, of note that without outliers, the average in the second phase of the pilot drops to 67.8 days, which is very close to the 60-day target procedural timelines set for the pilot. These preliminary findings are promising and highlight the possibility of the application of a streamlined procedure.

A voluntary survey was sent to experts and manufacturers after each completed procedure during the pilot and shows an overall high level of satisfaction with the procedure and involvement of the Expert Panels, both from the perspective of the experts and from manufacturers. The flexibility of this process offers the opportunity to foster further engagement with stakeholders, such as the pilot programme on orphan devices and the future Parallel HTA/EMA joint scientific consultation (JSC) for high-risk medical devices. Based on the preliminary results from the pilot, the positive feedback received, and the actions implemented as the result of the process improvement activities, the advice to manufacturers was fully implemented as of February 2025. Further information and documents can be found at the following link: https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices#scientific-advice-for-high-risk-medical-devices-13045.

The pilot applications that are not yet finalised will continue running in parallel of the full implementation of the advice to manufacturers programme until advice is delivered on all pilot applications. A final report on the pilot will be published once all pilot procedures are finalised.

Glossary

EMA	European Medicines Agency
EMDN	European Medical Device Nomenclature
EU	European Union
HTA	Health Technology Assessment
IVDR	*In Vitro* Diagnostic Medical Devices Regulation
MDR	Medical Devices Regulation
OD	Orphan Device
PMCF	Post-Market Clinical Follow-up
SME	Small and Medium-sized Enterprise
UMN	Unmet Medical Need

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