

Human Medicines Division
EMA/182497/2024

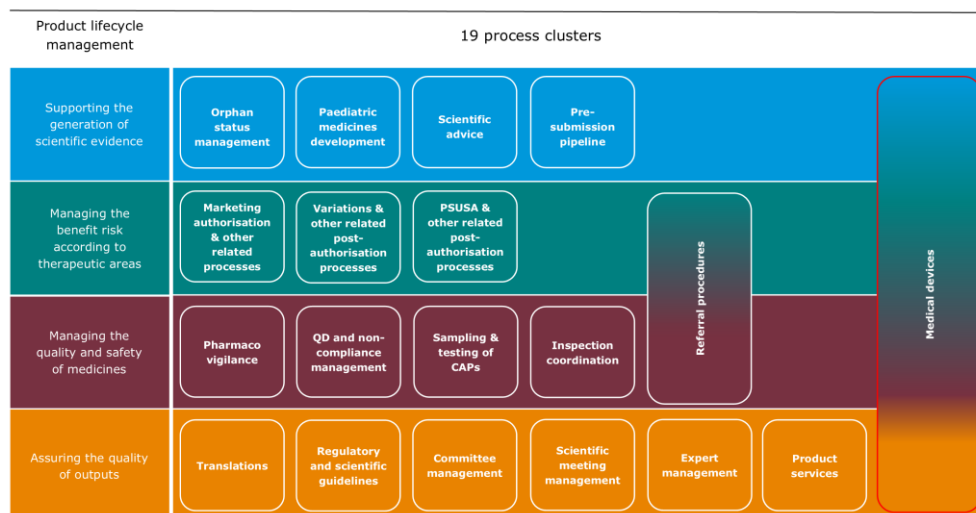
Business process description

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1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the consultation procedures for high-risk medical devices as well as advice procedures to manufacturers and notified bodies (including orphan programme), the European Commission and the Medical Device Coordination Group (MDCG). According to the current medical devices legislative framework, EMA provides scientific opinions to notified bodies through consultation procedures and advice to manufacturers (and notified bodies where requested), the European Commission, and the MDCG. EMA's regulatory role is limited to the involvement in the assessment of certain categories of medical devices and *in vitro* diagnostics, and in the context of medicinal products used in combination with a medical device.

This process is part of the Human Medicines Division's process map (image below) which provides a high-level overview of the 19 process clusters within the operating model of the Human Medicines Division.



Medical devices process:

It describes:

- the screening and opinion process of the Clinical Evaluation Consultation Procedure (CECP): An opinion on the notified bodies' assessment of the clinical evaluation, i.e., the clinical evaluation assessment report, of certain high-risk medical devices is provided, if the criteria for opinion are met as assessed during the screening phase;
- the view process of the Performance Evaluation Consultation Procedure: A view on the manufacturer's performance evaluation, i.e., the performance evaluation report, for certain high-risk *in vitro* medical devices (IVDs) is provided;
- the advice to manufacturers process: Clinical advice to manufacturers of high-risk medical devices (Class III and Class IIb active devices intended to administer or remove medicinal products) on their intended clinical development strategies and clinical investigation proposals is provided;
- the advice to European Commission and MDCG process: Scientific, technical and clinical advice to assist the Commission and the MDCG in relation to the implementation of the Medical Device Regulation (MDR) is provided;
- the advice on orphan medical devices: Advice on the designation of a medical device as an orphan medical device, and subsequent clinical advice for successfully designated orphan devices, is provided to manufacturers or notified bodies of medical devices of any class (excluding IVDs).

2. Changes since last revision

Addition of Procedural management for orphan medical device applications as a new sub-process.

3. Related documents

Guidance documents:

- [Commission guidance for the medical devices expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure \(Text with EEA relevance\) 2020/C 259/02](#)

- [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](#)
- [MDCG 2024-10 - Clinical evaluation of orphan medical devices](#)
- [Guide to manufacturers and notified bodies on the procedure for requesting advice from expert panels for orphan medical devices](#)

Policies:

- [European Commission policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices](#)

Relevant information:

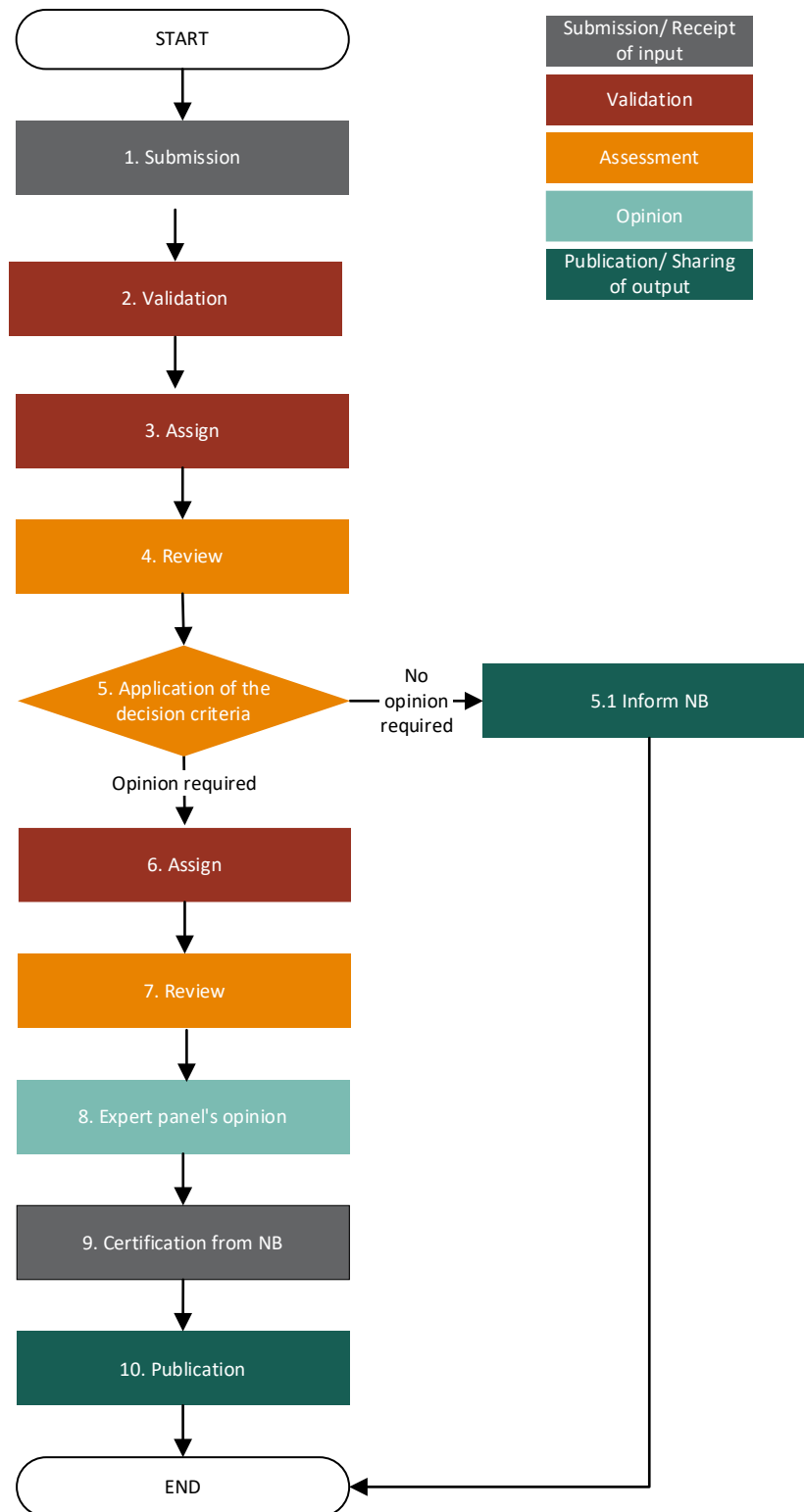
- [Rules of Procedure of expert panels](#)
- [Clarification on “first certification for that type of device” and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48\(6\) of Regulation \(EU\) 2017/746](#)

4. Abbreviations/Definitions

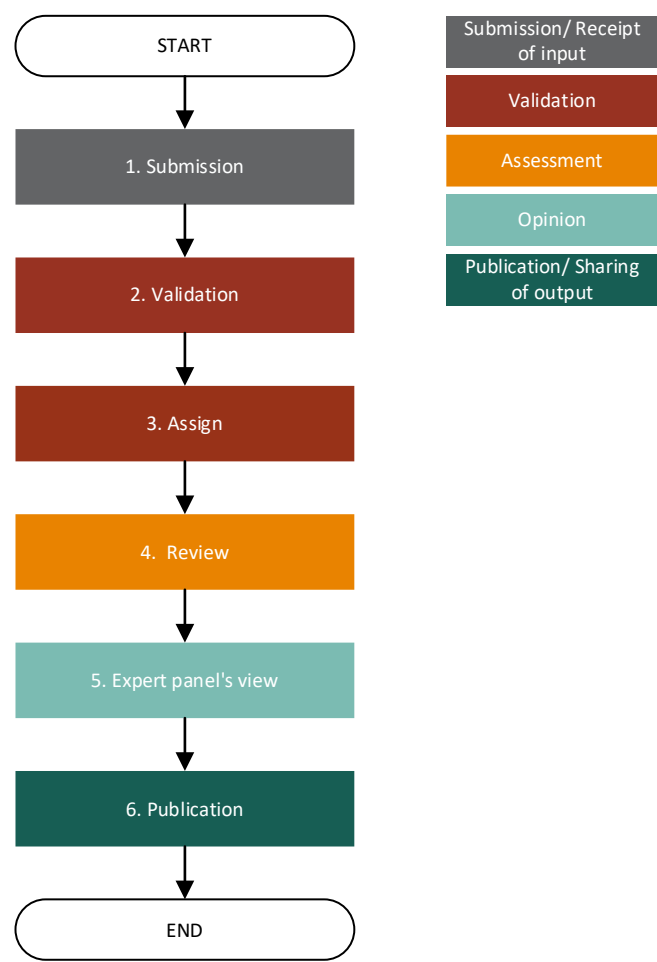
CECP	Clinical Evaluation Consultation Procedure
EC	European Commission
EMA	European Medicines Agency
IVD	<i>In vitro</i> medical device
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
NB	Notified body

5. Process map(s)

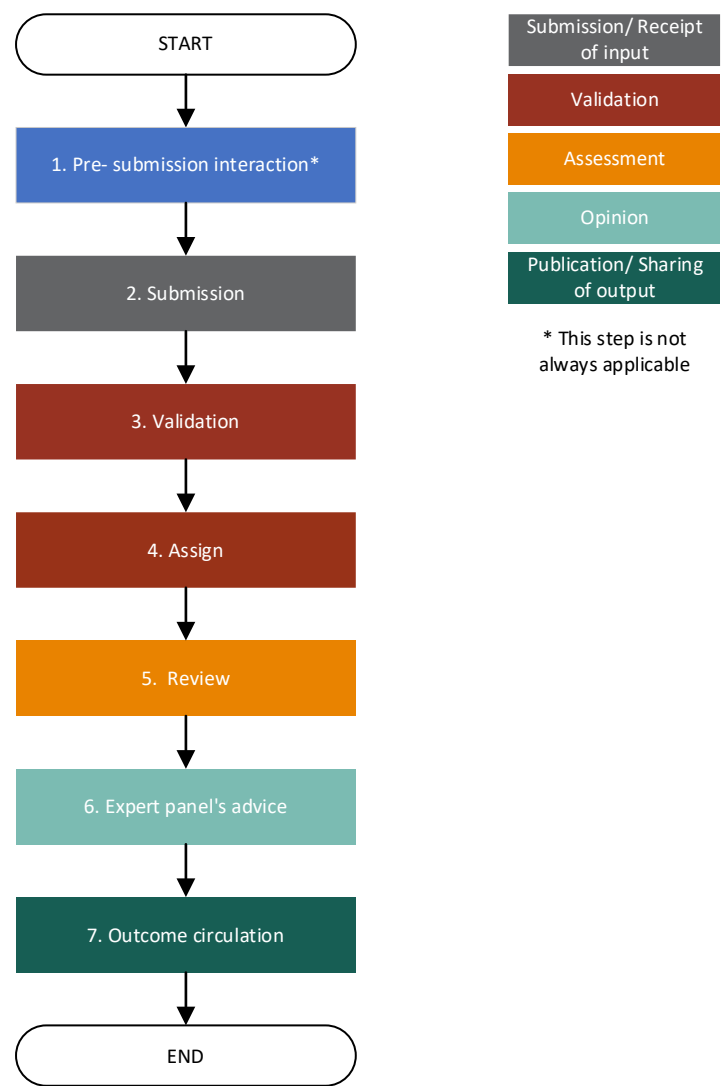
5.1 The screening and opinion process of the Clinical Evaluation Consultation Procedure



5.2 The view process of the Performance Evaluation Consultation Procedure

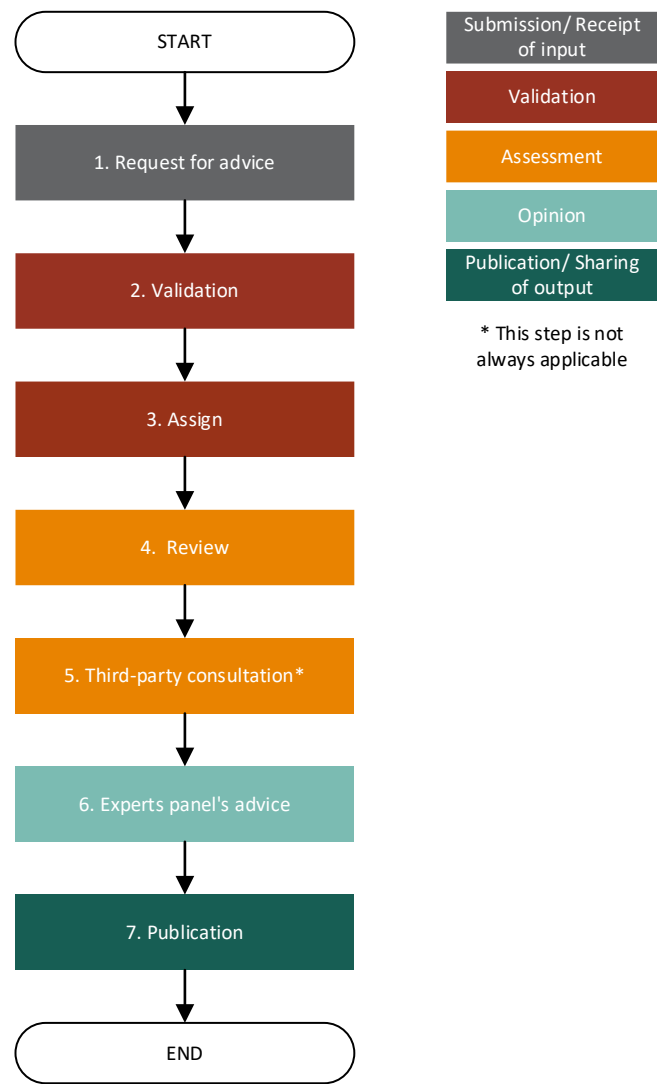


5.3 Advice to manufacturers on intended clinical development strategy and proposals for clinical investigation & advice to manufacturers and notified bodies on orphan status or on intended clinical development strategy and proposals for clinical investigation for a designated orphan device



Note: Blue colour represents other steps of a process that are not covered by the above legend

5.4 Advice to the European Commission and the Medical Device Coordination Group



6. Procedure

6.1 The screening and opinion process of the Clinical Evaluation Consultation Procedure

Step	Description
1.	Submission Receive submission from NB
2.	Validation Check for completeness and validate the submission
3.	Assign Assign screening rapporteur and co-rapporteur
4.	Review Experts (rapporteur and co-rapporteur) perform the review
5.	Application of the decision criteria Apply the decision criteria to determine whether opinion is required: - If an opinion is required, go to step 6 - If no opinion is required, go to step 5.1
5.1	Inform NB of the experts' decision Then the process ends.
6.	Assign Create ad hoc expert group (Chair, rapporteur, co-rapporteur and reviewing member(s))
7.	Review Experts perform the review
8.	Expert panel's opinion Inform NB of the expert panel's opinion
9.	Certification from NB Receive confirmation about the issued certification from NB
10.	Publication Publish the opinion after redaction where necessary <i>Note: If the opinion is not (fully) followed by NB, NB will send a justification, which will be provided to EC and subsequently published</i>

6.2 The view process of the Performance Evaluation Consultation Procedure

Step	Description
1.	Submission • Receive submission from NB
2.	Validation • Check for completeness and validate the submission
3.	Assign • Create ad hoc expert group (Chair, rapporteur, co-rapporteur and reviewing member(s))
4.	Review • Experts perform the review
5.	Expert panel's view • Inform NB of the expert panel's view
6.	Publication • Publish the view after redaction where necessary

6.3 Advice to manufacturers on intended clinical development strategy and proposals for clinical investigation & advice to manufacturers and notified bodies on orphan status or on intended clinical development strategy and proposals for clinical investigation for a designated orphan device

Step	Description
1.	Pre-submission interaction • Receive letter of interest from the company (manufacturer for advice to manufacturers; manufacturer or notified body for orphan procedures) • An explanatory meeting with the applicant might be organised to clarify process related questions and/or • A pre-submission meeting might be held with the Chair and comments are provided to the applicant in writing
2.	Submission • The applicant submits the application for advice
3.	Validation • Validate the submission <i>Note: Once the validation is positively concluded, the procedure starts</i>
4.	Assign • Create ad hoc expert group (Chair, rapporteur, co-rapporteur and reviewing member(s))

Step	Description
5.	Review - Experts perform the review - A discussion meeting with the applicant will be held in cases where a list of questions has been raised by the experts
6.	Expert panel's advice The expert panel adopts the final advice letter
7.	Outcome circulation Send the final advice letter to the applicant

6.4 Advice to the European Commission and the Medical Device Coordination Group

Step	Description
1.	Request for advice Receive the mandate from the EC/MDCG
2.	Validation Check if the all the required information is present in the mandate <i>Note: Once the validation is positively concluded, the procedure starts</i>
3.	Assign Create ad hoc expert group (Chair, rapporteur, co-rapporteur and reviewing member(s))
4.	Review Experts perform the review
5.	Third-party consultation Experts take input from the third-party consultation into consideration to finalise their advice <i>Note: This step is applicable if EC has requested a third-party consultation at the time of the request for advice</i>
6.	Expert panel's advice The expert panel adopts the advice
7.	Publication The advice is published on the expert panel website