Human Medicines Division
EMA/182497/2024

Business process description

Title: Medical Devices		
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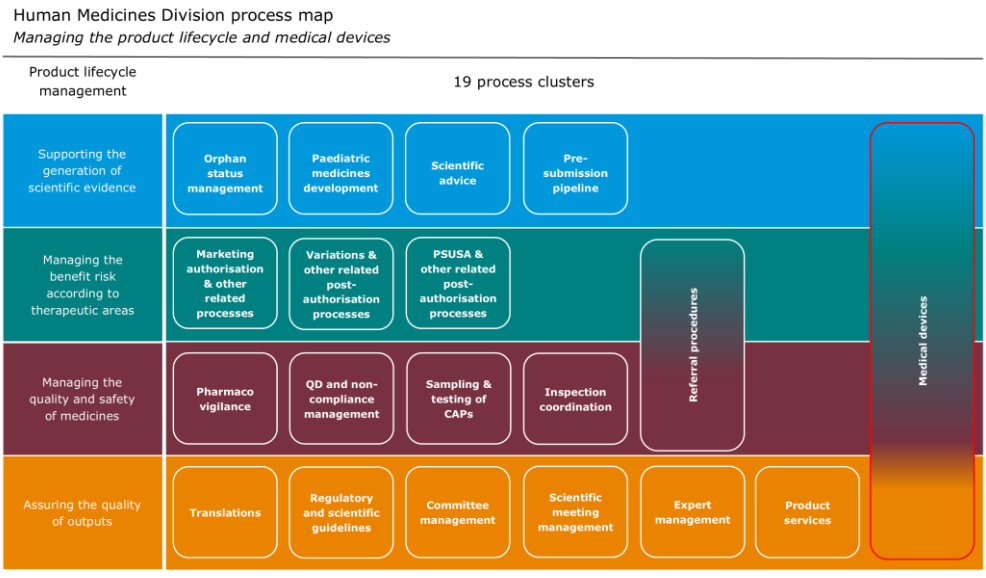
1. Introduction

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, 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, 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.



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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 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.

2. Changes since last revision

New business process description

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

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

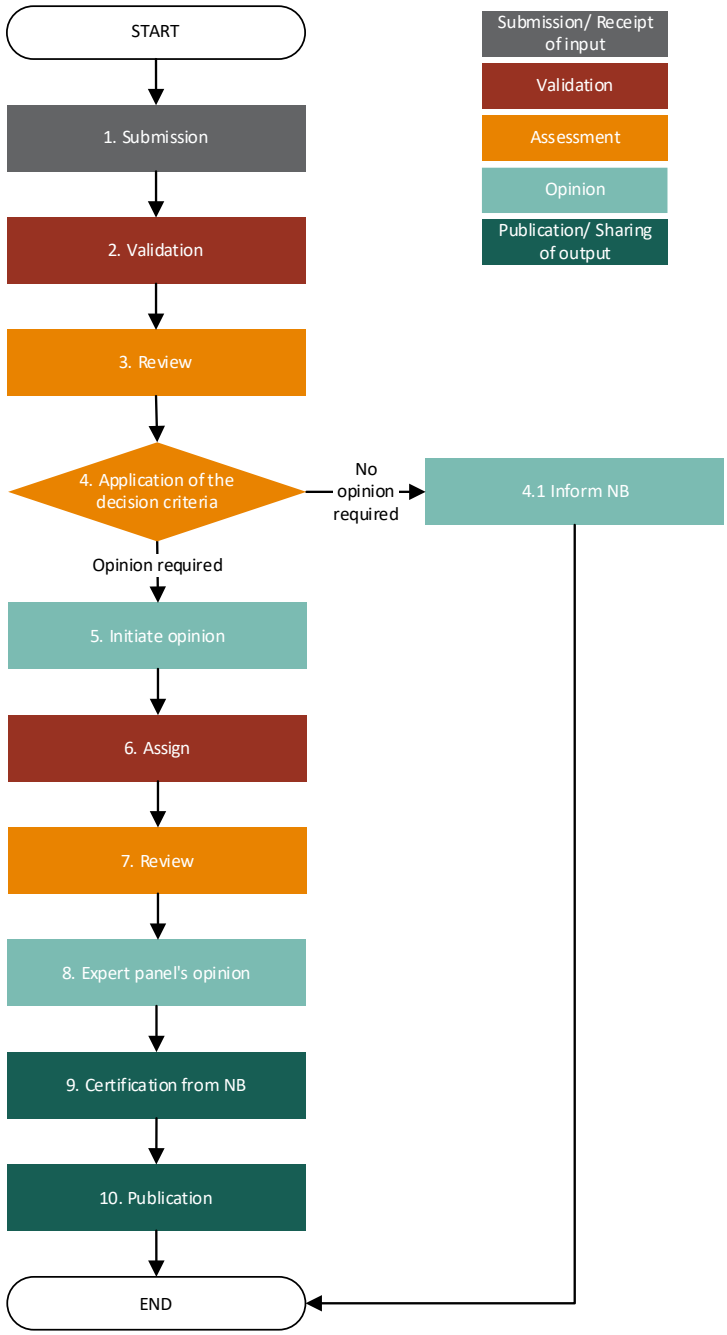
4. Abbreviations/Definitions

CAPs	Centrally authorised products
CECP	Clinical Evaluation Consultation Procedure
EC	European Commission
EMA	European Medicines Agency

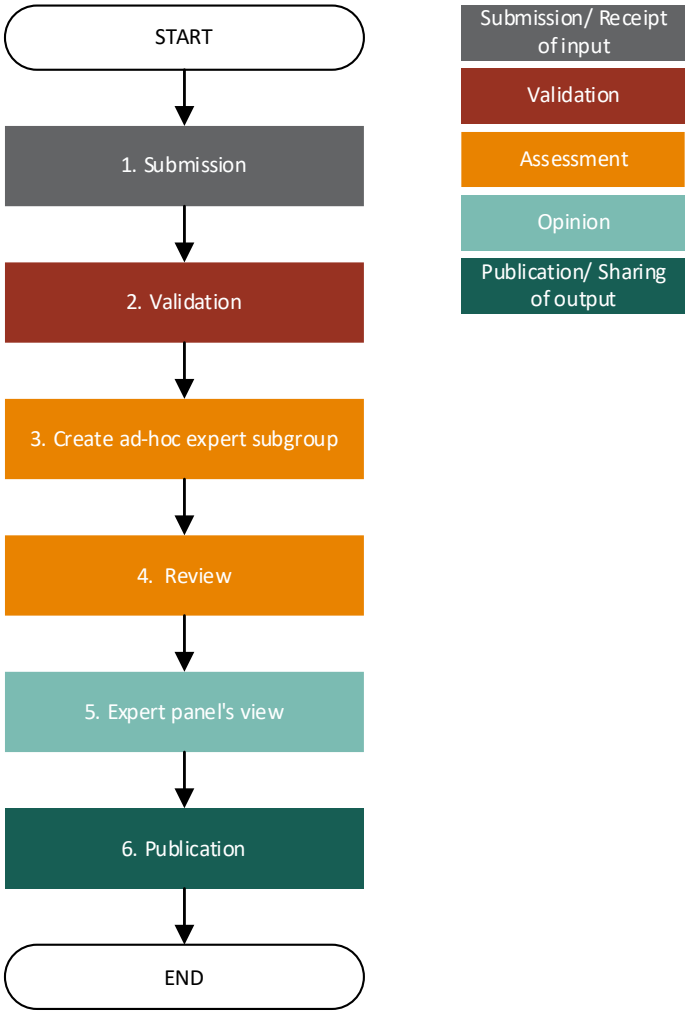
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
NB	Notified body
PSUSA	Periodic safety update report single assessment
QD	Quality defect

5. Process map(s)

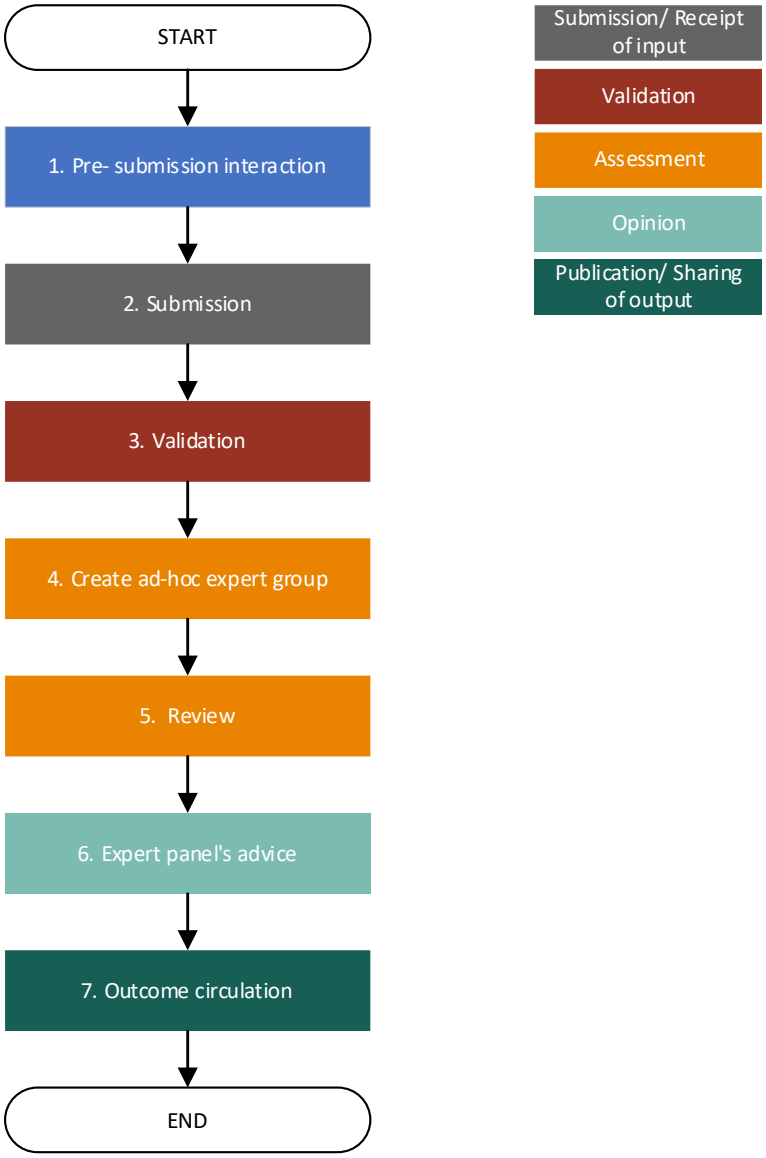
5.1 The screening and opinion process of the Clinical Evaluation Consultation Procedure



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



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.	**Review** • Experts (rapporteur and co-rapporteur) perform the review
4.	**Application of the decision criteria** Apply the decision criteria to determine whether opinion is required: • If an opinion is required, go to step 5 • If no opinion is required, go to step 4.1
4.1	**Inform NB** of the experts' decision Then the process ends.
5.	**Initiate opinion** • CECP thematic panel receives decision from the screening panel
6.	**Assign** rapporteur, co-rapporteur and reviewing member(s)
7.	**Review** • Experts (rapporteur, co-rapporteur and reviewing member(s)) perform the review of the application
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 *Note: If the opinion is not (fully) followed by NB, NB will send a justification, which will be provided to EC and subsequently published*

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.	**Create ad-hoc expert subgroup**
4.	**Review** • Experts (rapporteur, co-rapporteur and reviewing member(s)) perform the review of the application
5.	**Expert panel's view** • Inform NB of the expert panel's view
6.	**Publication** • Publish the view

6.3 Advice to manufacturers on intended clinical development strategy and proposals for clinical investigation

Step	Description
1.	**Pre-submission interaction** • Receive letter of interest from the company • 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 experts and comments are provided to the applicant in writing
2.	**Submission** • The applicant submits the application for advice
3.	**Validation** • Validate the submission *Note: Once the validation is positively concluded, the procedure starts*
4.	**Create ad-hoc expert group**
5.	**Review** • Experts (rapporteur, co-rapporteur and reviewing member(s)) perform the review of the application • 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
2.	**Validation** • Check if the all the required information is present in the mandate *Note: Once the validation is positively concluded, the procedure starts*
3.	**Create ad-hoc expert group**
4.	**Review** • Experts (rapporteur, co-rapporteur and reviewing member(s)) perform the review of the application based on the available evidence
5.	**Third-party consultation** • Experts take input from the third-party consultation into consideration to finalize their advice *Note: This step is applicable if EC has requested a third-party consultation at the time of the request for advice*
6.	**Expert panel's advice** • The expert panel adopts the advice
7.	**Publication** • The advice is published on the expert panel website