Human Medicines Division
EMA/367662/2024

Business process description

Title: Scientific Advice		
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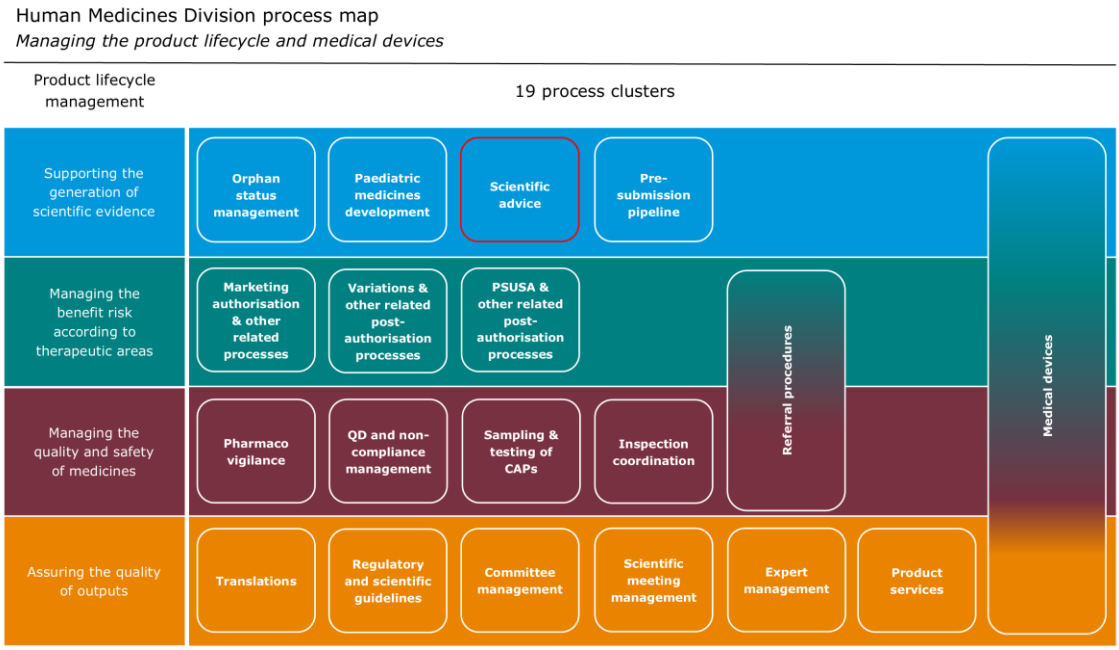
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for scientific advice, which provides product-specific guidance to developers for the timely and sound development of a medicine by helping to generate robust evidence to demonstrate its quality, efficacy and safety. This process also includes scientific advice provided to support the qualification of novel methodologies for medicines development.

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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Scientific advice process:

It describes the following sub-processes:

- scientific advice (including products for parallel scientific advice with FDA or parallel consultation with HTA bodies)
- protocol assistance (for designated orphan medicines)
- qualification of novel methodologies (qualification advice on protocols and methods intended to develop a novel method or qualification opinion on the acceptability of a specific use of a novel method)

2. Changes since last revision

New business process description

3. Related documents

- European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance
- Qualification of novel methodologies for medicine development
- Requesting scientific advice or protocol assistance from EMA
- Scientific advice and protocol assistance

4. Abbreviations/Definitions

CAPs	Centrally authorised products
CHMP	Committee for Human Medicinal Products
COMP	Committee for Orphan Medicinal Products
EMA	European Medicines Agency
FDA	Food and Drug Administration
HTA	Health Technology Assessment
PSUSA	Periodic safety update report single assessment
PR	Patient representative
QD	Quality defect
SAG	Scientific advisory group
SAWP	Scientific Advice Working Party
WP	Working party

5. Process map(s)

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

6. Procedure

Step	Description
1.	**Pre-submission interaction** • A preparatory meeting can be organised to provide guidance to the applicant *Note: This step is optional*
2.	**Submission** The applicant submits the application to EMA for: • Scientific advice • Protocol assistance • Qualification advice • Qualification opinion
3.	**Validation** • Validate the submission • Identify the need for WPs/SAGs/committees/PRs' involvement *Note: Once the validation is positively concluded, the procedure starts*
4.	**Assessment** • Coordinate the assessment of the application by SAWP and relevant WPs/SAGs/committees/PRs
5.	**Has the advice been agreed upon?** • If yes, go to step 6 • If no, go to step 5.1
5.1	**Additional information request** • Send list of issues to the applicant (or FDA/HTA if parallel scientific advice with FDA/HTA takes place) • A written response to the list of issues is received if requested by SAWP • A discussion meeting with the applicant (and FDA/HTA if parallel scientific advice with FDA/HTA takes place) is held Go to step 4 *Note: This step can only occur once*
6.	**Joint report** • Prepare joint report and incorporate comments from WPs/SAGs/committees and PRs involved

Step	Description
7.	**Adoption** • The CHMP (and COMP when significant benefit questions are raised) adopt the final advice letter • The CHMP adopts the qualification advice • The CHMP adopts the qualification opinion following public consultation
8.	**Outcome circulation** • Send the final advice letter, the qualification advice or the qualification opinion to the applicant • Publish the qualification opinion on the EMA corporate website
9.	**Are there post-advice issues raised by the applicant?** • If yes, go to step 9.1 • If no, then the process ends
9.1	**Respond to post-advice issues** • Respond to post-advice issues, consulting with the SAWP coordinators when applicable Then the process ends