Human Medicines Division
EMA/222507/2024

Business process description

Title: Regulatory and scientific guidelines		
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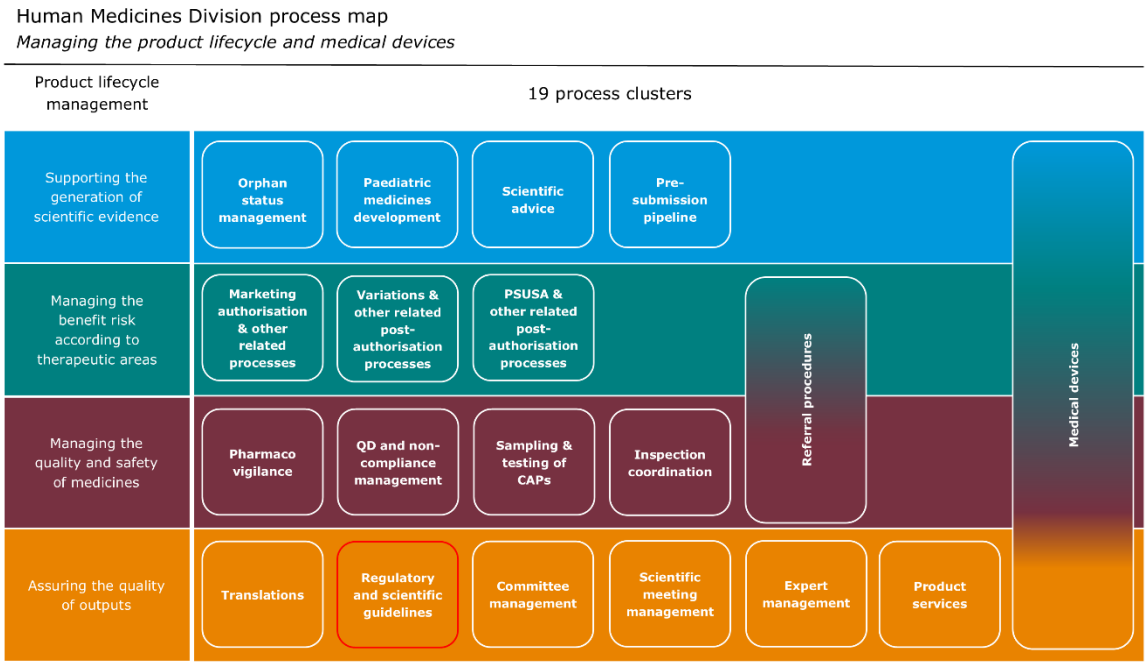
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the development of regulatory and scientific guidelines, which ensures high-quality documents which follow regulatory and scientific consistency.

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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Regulatory and scientific guidelines process:

It describes how EMA, in consultation with MSs, EU regulatory authorities, EU industry association, EU scientific societies, patients/consumer groups/healthcare professionals or other interested parties, develop guidelines to assist applicants and marketing authorisation holders with regulatory procedures, reflecting a harmonised approach on how to interpret and apply the requirements as set out in the Community legislation.

2. Changes since last revision

New business process description

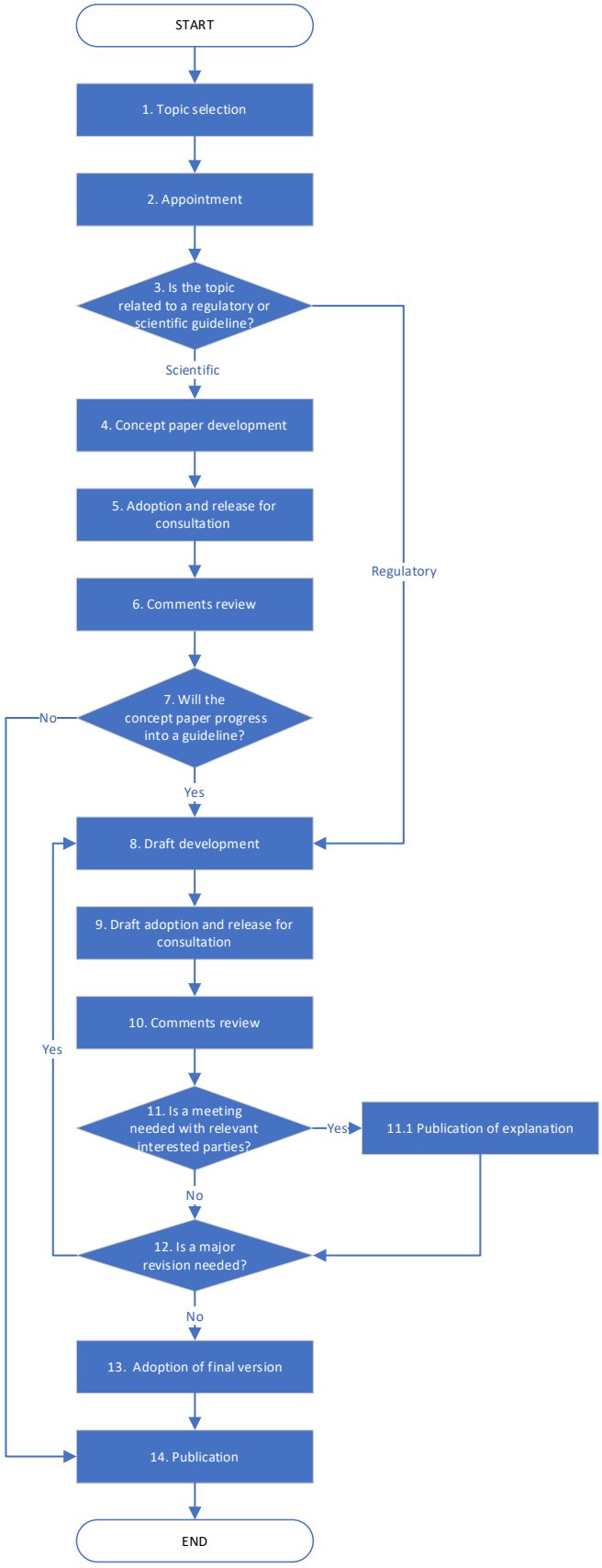
3. Related documents

- General: Regulatory and procedural guidance
- Guidelines Consistency Group | European Medicines Agency (europa.eu)
- Scientific guidelines

4. Abbreviations/Definitions

CAPs	Centrally authorised products
Concept paper	A document prepared by a European Medicines Agency working party prior to the drafting of a guideline, setting out the problem, the scope of the work, the resources needed and the timeframe
EC	European Commission
EMA	European Medicines Agency
EU	European Union
MSs	Member States
PSUSA	Periodic safety update report single assessment
QD	Quality defect
WG	Working group
WP	Working party

5. Process map(s)



6. Procedure

Step	Description
1.	**Topic selection** • The topic is selected and included in the relevant work programme of the relevant scientific committee, WP, or WG • Input for topics may also be received from MSs, from members of the scientific committees, within the framework of international activities, as well as from interested parties (e.g. the European pharmaceutical industry, European human and animal health professional groups, learned societies, patients' associations, etc.)
2.	**Appointment** of sponsor (and co-sponsor if appropriate)
3.	**Is this topic related to a regulatory or scientific guideline?** • If scientific, go to step 4 • If regulatory, go to step 8
4.	**Concept paper development** • The concept paper is drafted by the drafting group
5.	**Adoption and release for consultation** • The draft concept paper is adopted by the relevant committee/ WP/ WG before being released for public consultation (patients' groups, healthcare professionals, other interested parties)
6.	**Comments review** • Following the public consultation and collection of comments, the drafting group reviews the received comments and implements changes if needed
7.	**Will the concept paper progress into a guideline?** • If yes, go to step 8 • If no, go to step 14 (in some cases an explanation note reflecting the reasons for this decision, might be published too)
8.	**Draft development** • The guideline is drafted by the drafting group • Comments from the concept paper revision are taken into account (applicable only for scientific guideline) • Consultation with relevant committee/ WPs/ WGs and interested parties takes place, where relevant
9.	**Draft adoption and release for consultation** • The draft guideline is adopted by the relevant committee/ WP/ WG/ EC/ European Pharmacopoeia before being released for public consultation (patients' groups, healthcare professionals and/or other interested parties)

Step	Description
10.	**Comments review** • Following the public consultation and collection of comments, the drafting group reviews the received comments • Comments are expected from MSs, regulatory authorities, EU industry association, EU scientific societies, patients/consumer groups/healthcare professionals, other interested parties • Collected comments are systematically published on the relevant website unless they contain commercially confidential information and/or the author has specifically objected to their publication
11.	**Is a meeting needed with relevant interested parties?** • If yes, go to step 11.1 • If no, go to step 12
11.1	**Publication of explanation** • After the meeting, a justification will be published regarding the acceptance or the rejection of the comments (go to step 12)
12.	**Is a major revision needed?** • If yes, go to step 8 (When significant changes are required, a revision of the draft is prepared) • If no, go to step 13
13.	**Adoption of final version** • The final version of the guideline is prepared by the drafting group before it is presented to the relevant committee/ WP/ WG and/or EC for adoption with a proposed date for implementation
14.	**Publication** • The adopted guideline and the adopted concept paper (applicable only for scientific guideline) are published on the EMA corporate website *Note: In the event that a concept paper does not progress into a guideline, only the adopted concept paper is published.*
NB	*In case of new developments, changes in priorities, or concerns raised during consultation, the concept paper or draft guideline can be withdrawn and removed from the relevant work programme, and an announcement would be published.*