Human Medicines Division
EMA/224726/2024

Business process description

Title: Translations		
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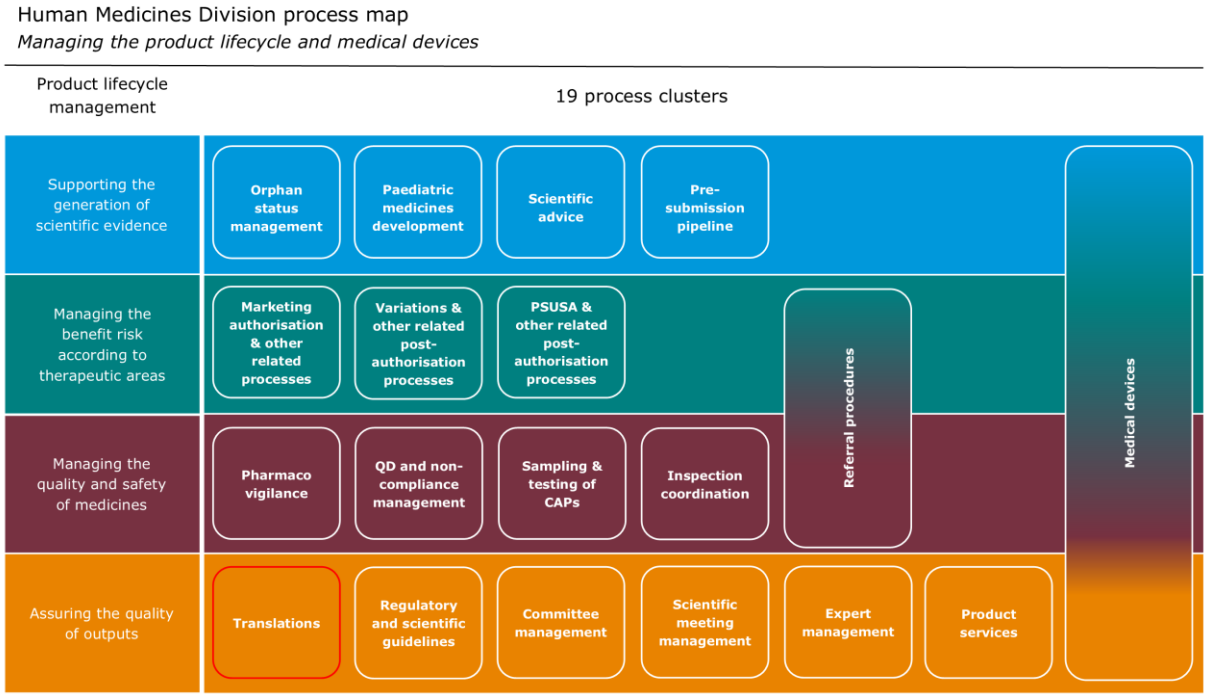
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the translations, which ensures consistency and harmonisation as well as accessibility and transparency across the multilingual European Union and European Economic Area.

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.



Translations process:

It describes the processes for:

- The translation workflow of product and non-product related documents
- The linguistic review of product information annexes

2. Changes since last revision

New business process description

3. Related documents

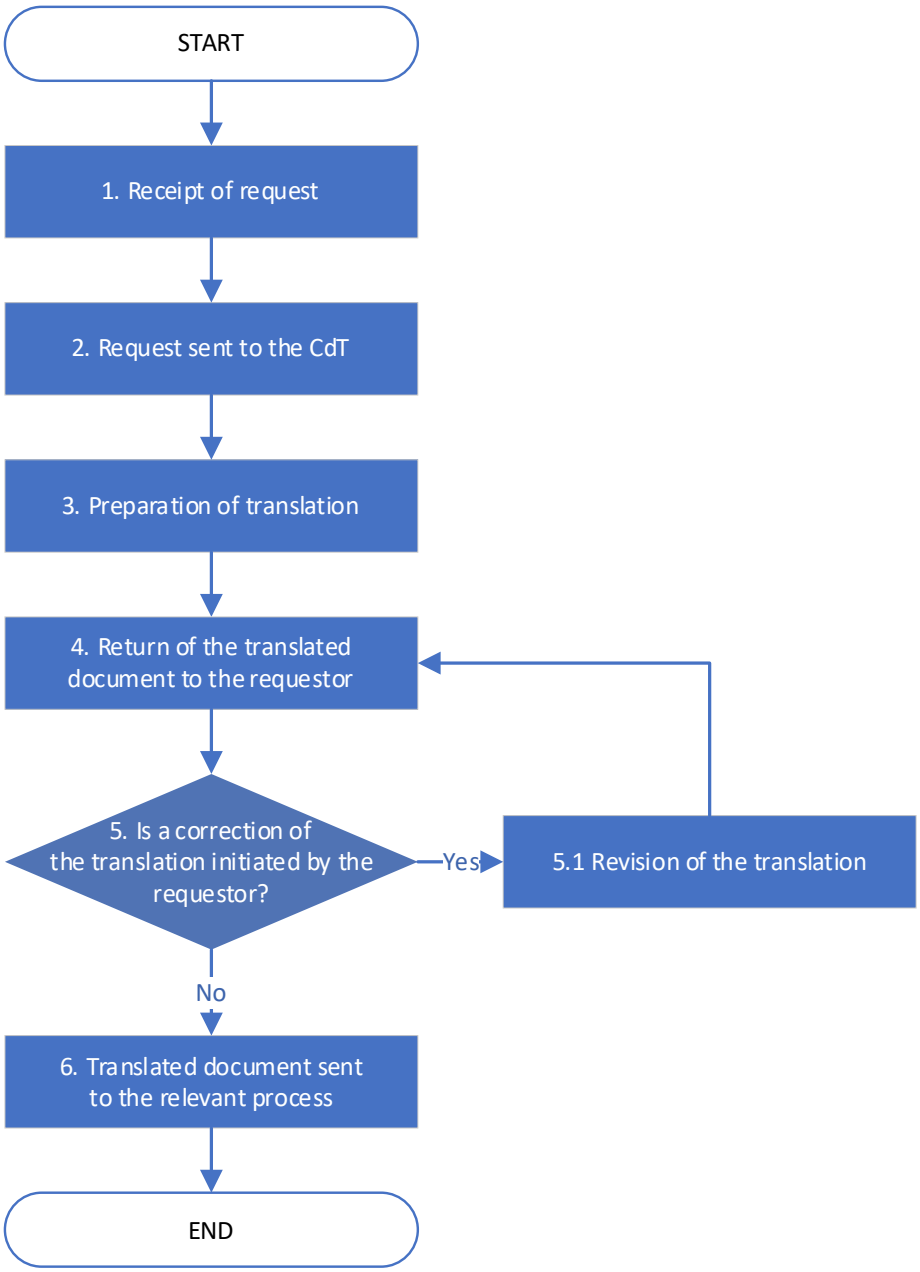
- Linguistic review - Human
- Linguistic review - Veterinary

4. Abbreviations/Definitions

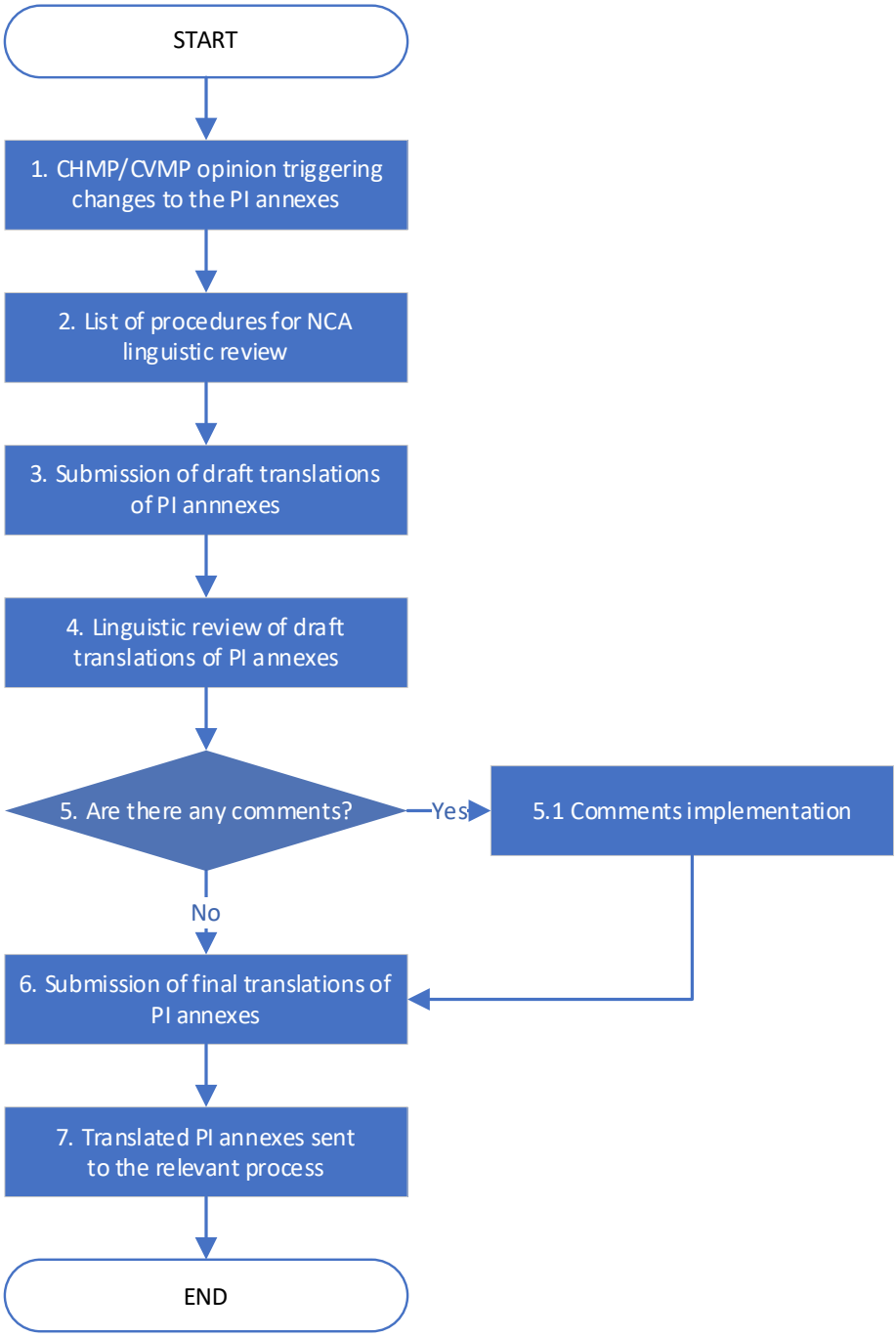
CAPs	Centrally authorised products
CdT	Translation Centre for the Bodies of the European Union in Luxembourg
CHMP	Committee for Medicinal Products for Human Use
CVMP	Committee for Veterinary Medicinal Products
EMA	European Medicines Agency
MAH	Marketing authorisation holder
NCA	National competent authority
PI	Product information
PSUSA	Periodic safety update report single assessment
QD	Quality defect
QRD	Quality Review of Documents
SME	Small and medium-sized enterprise

5. Process map(s)

5.1 The translation workflow of product and non-product related documents



5.2 The linguistic review of product information annexes



6. Procedure

6.1 The translation workflow of product and non-product related documents

Step	Description
1.	**Receipt of request** • An internal request for translation of a document is received
2.	**Request sent to the CdT** • The request for translation is sent to the CdT within the required timeframe
3.	**Preparation of translation** • The CdT performs the translation of the document
4.	**Return of the translated document to the requestor** • Upon receiving it, EMA internally forwards the translation to the requestor
5.	**Is a correction of the translation initiated by the requestor?** • If yes, go to step 5.1 • If no, go to step 6
5.1	**Revision of the translation** • The translation of the document is revised by the CdT according to the requested corrections (go to step 4)
6.	**Translated document sent to the relevant process**

6.2 The linguistic review of product information annexes

Step	Description
1.	**CHMP/CVMP opinion triggering changes to the PI annexes** • CHMP/CVMP adopts an opinion within the framework of a regulatory process which triggers changes to the PI annexes
2.	**List of procedures for NCA linguistic review** • The list of procedures, featuring PI annexes set for linguistic review by the NCAs, is completed
3.	**Submission of draft translations of PI annexes** • The applicant/MAH submits the draft translations of the PI annexes to the NCAs/EMA by day 215 or day +5 (depending on the regulatory process) *Note: If the applicant is an SME, they are only required to submit Icelandic & Norwegian translations to the EMA, while translations into other EU languages are coordinated by the EMA and the CdT*
4.	**Linguistic review of draft translations of PI annexes** • The NCAs perform the linguistic review of the draft translations of the PI annexes and send their feedback to the applicant/MAH *Note: If the Applicant is an SME, the NCAs send their feedback on the translations into other EU languages to the CdT.*
5.	**Are there any comments?** • If yes, go to step 5.1 • If no, go to step 6
5.1	**Comments implementation** • The applicant/MAH implements the comments on the translations of the PI annexes (go to step 6) *Note: If the Applicant is an SME, the CdT implements the comments on the translations of the PI annexes.*
6.	**Submission of final translations of PI annexes** • The applicant/MAH submits the final translations of the PI annexes to the EMA, including the QRD form 2, by day 235 or day +25 (depending on the regulatory process) *Note: If the applicant/MAH is an SME, they are only required to submit Icelandic & Norwegian translations to the EMA, while translations into other EU languages are submitted by the CdT*
7.	**Translated PI annexes sent to the relevant process**