EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Translation of product information for SME applicants of the centralised procedure		
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1. Purpose

To describe the arrangements for translating product information for micro, small and medium-sized enterprises and ensure that quality translations are provided within the decision-making timeframe of the centralised procedure.

Pursuant to Article 11 of Regulation (EC) No 2049/2005, the Agency provides for translation of product information documents required for the grant of a centralised marketing authorisation (summary of product characteristics, label, package leaflet, Annex A, Annex II and Annex IV) into all EU official languages. It is the responsibility of the applicant SME to provide the Norwegian and Icelandic translations.

2. Scope

This SOP applies to the Human Medicines Development and Evaluation Unit, the Patient Health Protection Unit, and the Veterinary Medicines and Product Data Management Unit.

3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within their own sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

New SOP.

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5. Documents needed for this SOP

All templates except for 7 to 10 can be found at: X:\Templates\Others\SME

- Template 1: informing SME applicants about translation (Translations for MAA- Information to company)
- Template 2: transferring responsibility for translation into one or more official EU languages to SME applicant (Undertaking form for SME translations)
- Template 3: requesting pre-opinion translations and post-opinion updates (by day 215) from CdT (Request for pre-opinion translations and post-opinion updates from CdT)
- Template 4: requesting day 215 translations from CdT for generic/biosimilar products (Request for translation updates for generic-biosimilar products from CdT)
- Template 5: requesting full post-opinion day 215 translations from CdT (Request for full-opinion translations from CdT)
- Template 6: updating SME applicant on translation process prior to CxMP Opinion (Translations for MAA - First contact with company)
- Templates 7 to 10: Timetables (H - Timetable - New appl.-Ext; H - Timetable SME-CdT; V - Timetable - New appl.-Ext; V - Timetable SME-CdT) (located at Word/File/New/H-Opin QRD Templates)
- Template 11: forwarding translations to company for comments (SMA H + V Day 215 email to applicant (copy PTL) about MS review)
- Template 12: forwarding translations to NCA check (QRD Pos-opinion Day 215 send to QRD SME (Hum+Vet) & Herbals)

6. Related documents

- Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from the EMEA by micro, small and medium-sized enterprises
- The New Linguistic Review Process of Product Information in the Centralised Procedure (Vet) - EMEA/5542/02/Rev 3.2 (http://www.emea.europa.eu/pdfs/vet/regaffair/v_554202en.pdf)
- The Linguistic Review Process of Product Information in the Centralised Procedure – Human EMEA/5542/02/Rev 3.3 (http://www.emea.europa.eu/pdfs/human/regaffair/554202en.pdf)
- SOP/EMEA/0009: PIQ/QRD Pre-opinion Review of Product Information for Initial Applications and Annex II Applications
- SOP/EMEA/0039: Assignment and maintenance of SME status
- SOP/EMEA/0047: QRD Post-opinion Review of Product Information for Initial Applications and Annex II Applications
- SOP/PDM/1400: SOP on the translation workflow of EMA documents
- Action List for Secretaries - Follow-up after CHMP Opinion/EMEA Notification (located at: Word/File/New/H-Opin Corr)

7. Definitions

CdT: Translation Centre for the Bodies of the European Union

CxMP: Committee for Medicinal Products for Human Use or Committee for Medicinal Products for Veterinary Use

EN: English version

EU: European Union

HoU: Head of Unit

MAA: Application for marketing authorisation

NCA: National Competent Authority

PI: Product information (summary of product characteristics, labelling and package leaflet)

PIQ: Product Information Quality

PTL: Product Team Leader (human products only)

QRD: Quality Review of Documents

SME: Small and medium-sized enterprise

SmPC: Summary of product characteristics

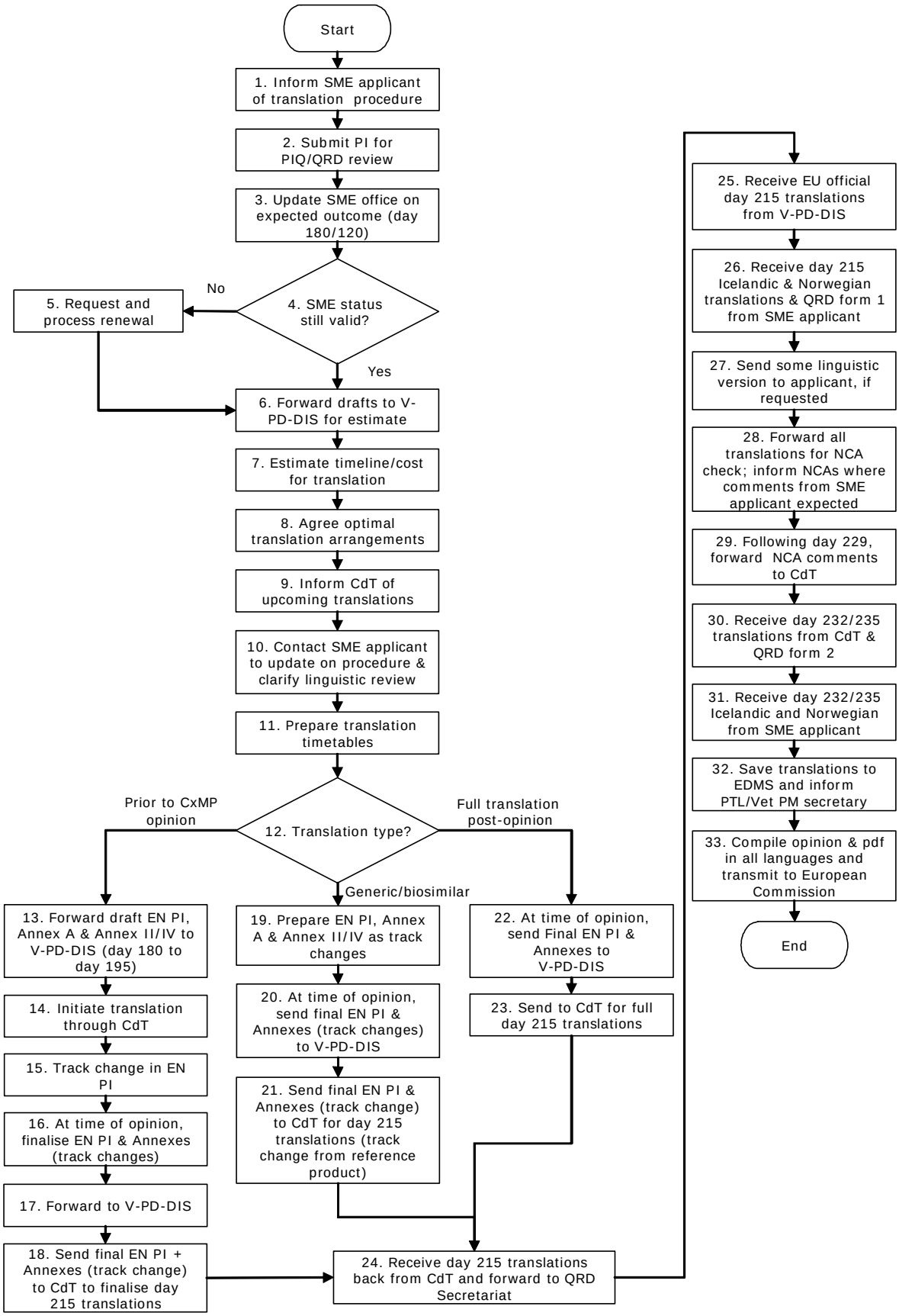
SOP: Standard Operating Procedure

Vet: Veterinary

Vet PM: Project manager (veterinary products only)

V-PD-DIS: Document and Information Services Section

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
	Pre-submission/Validation phase	
1	Inform SME applicants about translation procedure, noting the exclusion of Icelandic and Norwegian from process and possibility of taking over responsibility for certain EU official languages upon request (template 1, template 2, if applicable).	SME Office
	Prior to CxMP Opinion	
2	Submit PI for PIQ/QRD review in accordance with SOP/EMEA/0009.	PTL/Vet PM
3	One month prior to expected CxMP opinion (day 180 or day 120 for accelerated assessment), contact SME office to update on expected outcome and discuss specific arrangements to provide for translations.	PTL/Vet PM
4	Check whether the SME status of the applicant company requiring translation assistance is still valid. If no, go to step 5. If yes, go to step 6.	SME Office
5	Contact applicant to request SME status renewal in accordance with SOP/EMEA/0039 and once renewed go to step 6.	SME Office
6	Forward latest draft PI, Annex A and Annex II/IV, where available, to "translations requests" inbox for size/time/cost estimates.	PTL/Vet PM
7	Estimate size/timeline/cost for CdT translation based on latest draft.	V-PD-DIS
8	Agree optimal translation arrangements for each application in consultation with PTL, QRD Secretariat & V-PD-DIS, with internal meeting where necessary.	SME Office
9	Inform CdT of upcoming translation(s) and timetable(s) (templates 3, 4, 5).	V-PD-DIS
10	Contact SME applicant to update on translation process and clarify languages (if any) that applicant would like to be given opportunity to comment on during NCA review (template 6) and inform QRD Secretariat.	PTL/Vet PM
11	Prepare timetables for finalisation of translations (templates 7 & 8 for EU languages for Human and Vet and templates 9 & 10 Icelandic/Norwegian for Human and Vet)	Secretary of PTL/Vet PM
12	If agreed to initiate translations prior to CxMP opinion, go to step 13. For generic/biosimilar products, go directly to step 19. For full translation post-opinion (excluding generics), go to step 22.	Secretary of PTL/Vet PM or PTL/Vet PM

Step	Action	Responsibility
	Initiation of translations pre CxMP opinion (where applicable)	
13	Depending on agreed timeline, between day 180 to day 195 (day 120 to 135 for accelerated assessment), send latest draft of PI, Annex A and Annex II/IV where available to "translations requests" inbox.	Secretary of PTL/Vet PM
14	Forward draft of PI and available Annexes to CdT to initiate translation (via CdT electronic worksheet and Eudralink) and request return of all EU official language versions by day 3 of CxMP meeting at the latest.	V-PD-DIS
15	On day translations are initiated, inform SME applicant that any changes will need to be tracked in EN version of PI (track changes from version transmitted to CdT for initial translation).	PTL/Vet PM
16	At time of CxMP opinion, finalise EN PI, Annex A & Annex II & Annex IV (if applicable) with SME applicant, if possible by day 3 of CxMP meeting.	PTL/Vet PM
17	Send the final EN PI (track changes) and available Annexes to "translation requests" inbox.	Secretary of PTL/Vet PM
18	Send the EN PI including all Annexes (as track changes from version translation initiated) to CdT together with all initial draft EU official language versions of PI to request modification and finalisation of day 215 translations (via CdT electronic worksheet and Eudralink). Go to step 24.	V-PD-DIS
	Generic/biosimilar products (where applicable)	
19	Prepare EN PI, Annex A and Annex II/IV, as track changes from reference PI.	PTL/Vet PM
20	At time of CxMP opinion, if possible by day 3 of CxMP meeting, send final EN PI (as track changes from reference PI) and any Annexes to "translation requests" inbox.	Secretary of PTL/Vet PM
21	Send the EN PI, including all Annexes, (as track changes from reference PI) to CdT together with all EU official language versions of reference PI (via CdT electronic worksheet and Eudralink) to request day 215 translations as modification with track changes from reference PI. Go to step 24.	V-PD-DIS
	Full translation post-opinion (where applicable), excluding generic/biosimilar products	
22	At time of CxMP opinion, if possible by day 3 of CxMP meeting, send final EN PI and any Annexes to "translation requests" inbox.	Secretary of PTL/Vet PM
23	Forward final EN PI and any Annexes to CdT to request full day 215 translations (via CdT electronic worksheet and Eudralink).	V-PD-DIS
	Finalisation of translations	
24	Receive “day 215 translations” back from CdT and forward to QRD	V-PD-DIS

Step	Action	Responsibility
	Secretariat.	
25	Receive EU official language day 215 translations from V-PD-DIS	QRD Secretariat
26	Receive draft Icelandic and Norwegian day 215 translations and QRD form 1 from applicant.	QRD Secretariat
27	Where requested, forward certain EU linguistic versions to the SME applicant for comments within 3 calendar days (template 11).	QRD Secretariat
28	Forward "day 215 translations" for NCA check in accordance with agreed timetable. Where SME applicant will be providing comments on some linguistic versions, inform relevant NCAs that they will receive comments from SME applicant and review should only be completed once comments are received (template 12).	QRD Secretariat
29	Following "day 229 comments", forward NCA comments to CdT (client.coordination@cdt.europa.eu) for implementation and finalisation of translation in accordance with agreed timetable.	QRD Secretariat
30	Receive "day 232[1]/235[2] translations" from CdT (Client Coordination Section) together with QRD form 2.	QRD Secretariat
31	Receive "day 232[1]/235[2] Icelandic and Norwegian translations" from SME applicant and QRD form 2.	QRD Secretariat
32	Save translations to EDMS product folder and inform PTL/Vet PM secretary.	QRD Secretariat
	Transmission to European Commission	
33	Compile the opinion with pdf versions of translations in all languages and send to European Commission, Standing Committee and applicant (pdf + Word versions for applicant), in accordance with Action List for Secretaries - Follow-up after CHMP Opinion/EMEA Notification.	Secretary of PTL/Vet PM

10. Records

Translations and related forms are saved in accordance with SOP/EMEA/0009, SOP/EMEA/0047 and SOP/T/1400. Translation related correspondence between SME Office and applicants are saved in the appropriately labelled folder in EDMS.

[1] For medicinal products for human use
[2] For veterinary medicinal products