European Medicines Agency
Standard Operating Procedure

Title: Handling of a request for accelerated assessment of initial marketing authorisation applications (human use)		
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1. Purpose

This SOP describes the steps to follow when a request for accelerated assessment of a marketing authorisation application is made to the CHMP for a product to be assessed through the centralised procedure. Article 14 (9) of regulation (EC) No 726/2004 provides the legal basis for the request for an accelerated assessment procedure. **The time limit for the assessment is reduced to 150 days**.

This SOP covers the handling of the request for accelerated assessment and should be read together with SOP/H/3004, which describes in detail the steps to follow prior to and during the evaluation of the accelerated assessment and following a negative or positive opinion trend by the CHMP at Day 120 of the centralised procedure.

2. Scope

This SOP applies to the Unit for the Pre-Authorisation Evaluation of Medicines for Human Use.

3. Responsibilities

It is the responsibility of the Head of Sector to ensure that this procedure is adhered to within his/her own sector. The responsibility for the execution of specific tasks in this procedure is identified in the right-hand column of **9. Procedure**.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

Templates related to the accelerated assessment procedure only:

1. Briefing notes and rapporteurs and co-rapporteurs recommendation for an accelerated review (located at:WORD/File/new/H-AA/New (Co-)Rapporteur template AA)
2. Fax correspondence for the rejection of an accelerated assessment review of the application (located at: WORD/File/new/H-AA/Outcome fax – rejection AA template)
3. Fax correspondence for the accepteance of an accelerated assessment review of the application (located at: WORD/File/new/H-AA/Outcome fax – acceptability AA template)

Refer to SOP/H/3004 for all additional templates used in the 210-day centralised procedure (Day 80 assessment report, peer review phase, EPAR, etc…).

6. Related documents

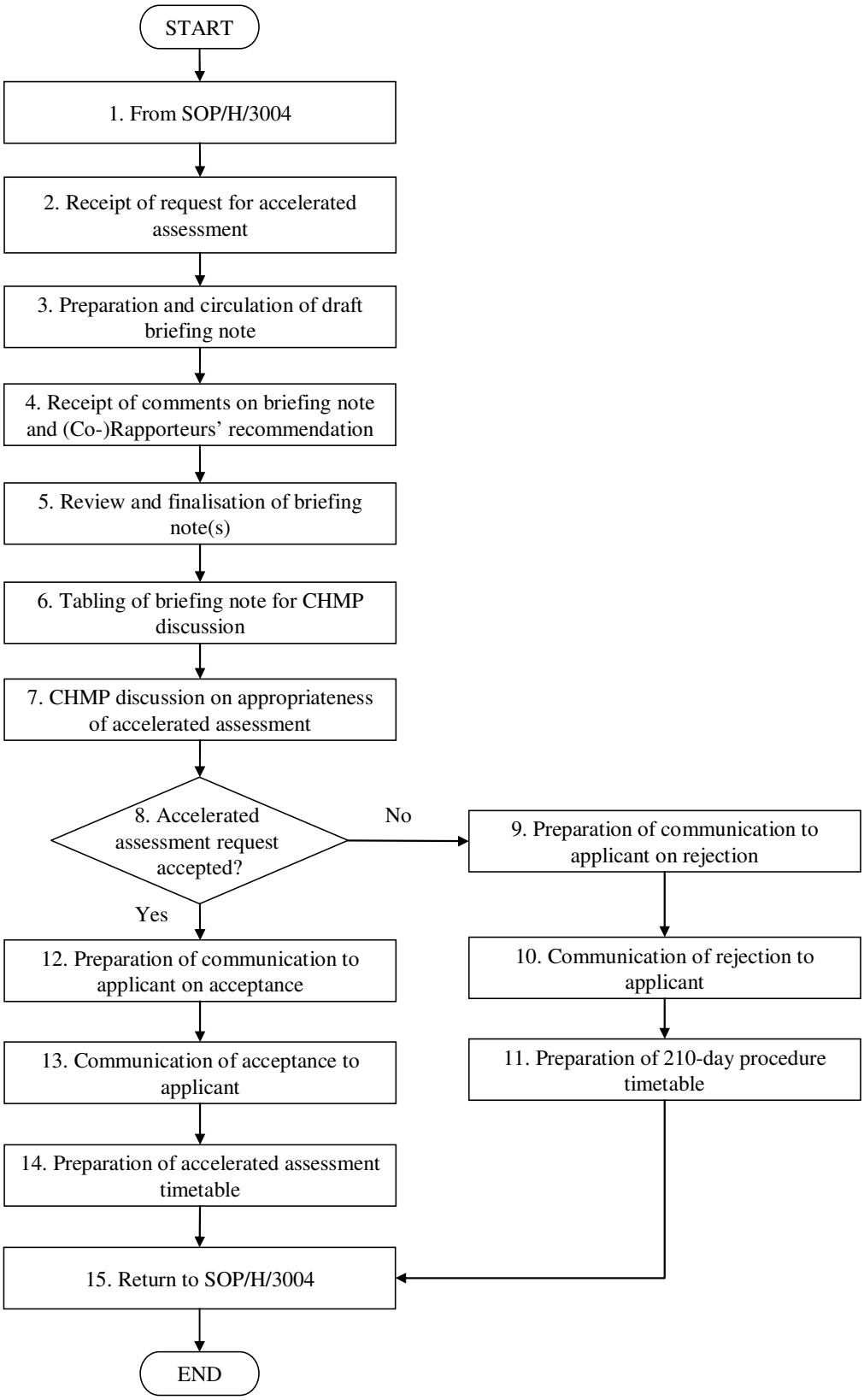
1. SOP/H/3004 on Tasks of the product team on the handling of the initial marketing authorisation application
2. WIN/H/3109 on Creation and maintenance of core master files

3. EMEA/274268/2006: Guideline on the procedure for accelerated assessment pursuant to article 14 (9) of regulation (EC) No 726/2004 (http://www.emea.europa.eu/pdfs/human/euleg/41912705en.pdf)
4. Request for Accelerated Assessment Pursuant to Article 14(9) of Regulation (EC) No 726/2004) (http://www.emea.europa.eu/htms/human/presub/Q08a-AA_reques_%20form.doc)

7. Definitions

CHMP: Committee for Medicinal Products for Human Use
(Co)Rapporteur: both Rapporteur and Co-Rapporteur
CIG: Central Information Group
EDMS: electronic document management system
EPAR: European public assessment report
GL: Group leader. It may be the Specialised Group Leader from the QoM Sector or the Therapeutic Group Leader from the S&E or PASE Sectors.
MAA: Marketing authorisation application
PASE Sector: Post-authorisation Safety and Efficacy Sector
PTL: Product Team Leader (The team member responsible for overall co-ordination of the procedure, including input in his/her main area of expertise. He/she is the main internal and external contact point during the procedure and is responsible for providing the product team with regular feedback on the progress of the application. In case of controversial procedural and/or scientific issues, the PTL will always keep the Group Leader(s) of the main area of expertise informed, and when necessary organise internal meetings to find a solution. In case of absence the PTL is responsible to assign his/her back up from his/her specialised/therapeutic group.)
PTM-RA: Product Team Member from regulatory affairs team
QoM Sector: Quality of Medicines Sector
RAOS Sector: Regulatory Affairs and Organisational Support Sector
S&E Sector: Safety and Efficacy Sector

8. Process Map(s)/ Flow Chart(s)



9. Procedure

This SOP must be followed in parallel with SOP/H/3004

Step	Action	Responsibility
Request for accelerated assessment procedure		
	The timelines in the pre-submission phase are approximate and serve only to provide a general guidance	
1	From SOP/H/3004: Pre-submission phase	
2	**Generally, one month prior to the submission of the MAA** - Receive the request for an accelerated assessment including supporting documentation from the applicant *(Note: The submission of the MAA will happen separately)*	CIG
3	**Preparing the Briefing Note** - Prepare a draft briefing note by summarising the relevant information with the applicant's justification (Template 1) - Send the draft briefing note with the supporting documentation provided by the applicant to the (Co)Rapporteurs	PTL
4	**Receipt of comments on the Briefing Note and recommendation** - Receive the draft briefing notes with the (Co)Rapporteurs' comments and the recommendation for an accelerated review based on the appropriateness/applicability of an accelerated assessment from the (Co)Rapporteurs	PTL
5	**Finalising the Briefing Note** - Review the briefing notes with the supporting data/evidence found in the application that provide the justification for an accelerated assessment (optional) - Prepare a final briefing note by combining the recommendation of (Co)Rapporteurs into a single document, if possible. Otherwise, leave briefing notes as two separate documents - If required, send back for review by the (Co)Rapporteurs	PTL
6	**Tabling of Briefing Note(s) for CHMP discussion** *(Note: Briefing note(s) is/are generally tabled for discussion at the CHMP meeting which directly follows the submission of the request for accelerated assessment)* - Provide the briefing note(s) to the CHMP secretariat for circulation at CHMP according to the relevant procedure - Check the CHMP agenda to ensure that the application for accelerated opinion is scheduled for discussion - Check that the briefing note(s) has/have been tabled for discussion	 PTL/PTLS PTL PTL
Evaluation of the Accelerated Assessment Request		
7	**CHMP considers accelerated assessment request** - Attend the CHMP discussion on the appropriateness of the accelerated assessment request submitted by the applicant, taking into account the recommendation(s) from the (Co)Rapporteur	PTL
8	**Does CHMP accept/reject the accelerated assessment request?** - If the CHMP rejects the request for accelerated assessment, go to step 9. - If the CHMP accepts the request for accelerated assessment, go to step 12.	
9	**Preparing communication on rejection of accelerated assessment request** - Prepare a letter informing the applicant of the CHMP outcome (Template 2) - Prepare a brief summary of the reasons for rejecting the accelerated assessment request based on the discussion at the CHMP meeting - Provide the letter for reviewing by GL and PTM-RA	 PTLS PTL PTLS

Step	Action	Responsibility
10	**Communicating a rejection of accelerated assessment request with the applicant**	
	- Obtain a signature for the rejection letter from the Head of Sector, RAOS	PTL/PTLS
	- Fax the rejection letter to the applicant	PTL/PTLS
	- Archive a copy of the letter electronically in EDMS	PTL
	- Archive the original signed copy in the product master file (WIN/H/3109)	CIG
	Note: In case any correspondence is received from the applicant regarding the refusal, these will be tabled at the next CHMP solely "For information".	
11	**Preparing a normal 210-day procedure timetable for CHMP adoption**	
	- Prepare a timetable based on the 210-day procedure for adoption by CHMP	CIG
	- Inform the applicant by email/fax of the new timetable	
	Go to step 15	
12	**Preparing communication on acceptance of accelerated assessment request**	
	- Prepare a letter informing the applicant of the CHMP outcome (Template 3)	PTLS
	- Prepare a brief summary of the reasons for accepting the accelerated assessment request based on the discussion at the CHMP meeting	PTL
	- Provide the letter for reviewing by GL and PTM-RA	PTLS
13	**Communicating the acceptance of accelerated assessment request with the applicant**	
	- Obtain a signature for the acceptance letter from the Head of Sector, RAOS	PTL/PTLS
	- Fax the acceptance letter to the applicant	PTL/PTLS
	- Archive a copy of the letter electronically in EDMS	PTL
	- Archive the original signed copy in the product master file (WIN/H/3109)	CIG
14	**Preparing an accelerated assessment timetable for CHMP adoption**	
	- Prepare a timetable for the accelerated assessment procedure for adoption by CHMP	CIG
	- Inform the applicant by email/fax of the new accelerated timetable	
15	Return to SOP/H/3004	

10. Records

Electronic records generated during the process are saved in EDMS. E-mail correspondence is saved in the product-specific Outlook folder. Paper records are filed in the product master file.