EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Preparation of question-and-answer documents for withdrawals of marketing authorisation applications by the Medical Information Sector		
Status: **PUBLIC**		Document no.: SOP/H/3137
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1. Purpose

The purpose of this SOP is to describe the process for preparing question-and answer documents (q-and-a) following the withdrawal of an application for marketing authorisation (MAA), an application for a line extension linked ton extension of indication or an application for a Type II variation for an extension of indication for human medicines.

2. Scope

This SOP applies to the Safety and Efficacy of Medicines (H-SE) and Quality of Medicines (H-QM) sectors in the Human Medicines Development and Evaluation (H) unit and to the Regulatory, Procedural and Committee Support (P-R) and Medical Information (P-MI) sectors in the Patient Health Protection (P) unit.

3. Responsibilities

It is the responsibility of each Section Head, Head of Sector and Head of Unit to ensure that this procedure is adhered to within their own section/sector/unit. The responsibility for the execution of each step is identified under **9. Procedures**.

4. Changes since last revision

Update to reflect the new organisational names in the Agency.

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5. Documents needed for this SOP

Template 1: letter of withdrawal of application (for applicant)

See X:\Templates\Filenew\H-AR-LoQ-LoOI-SmOP

Template 2: q-and-a on withdrawal of application (initial)

Template 3: q-and-a on withdrawal of application (extension of indication, line extension)

See X:\Templates\Others\H – Q and A documents

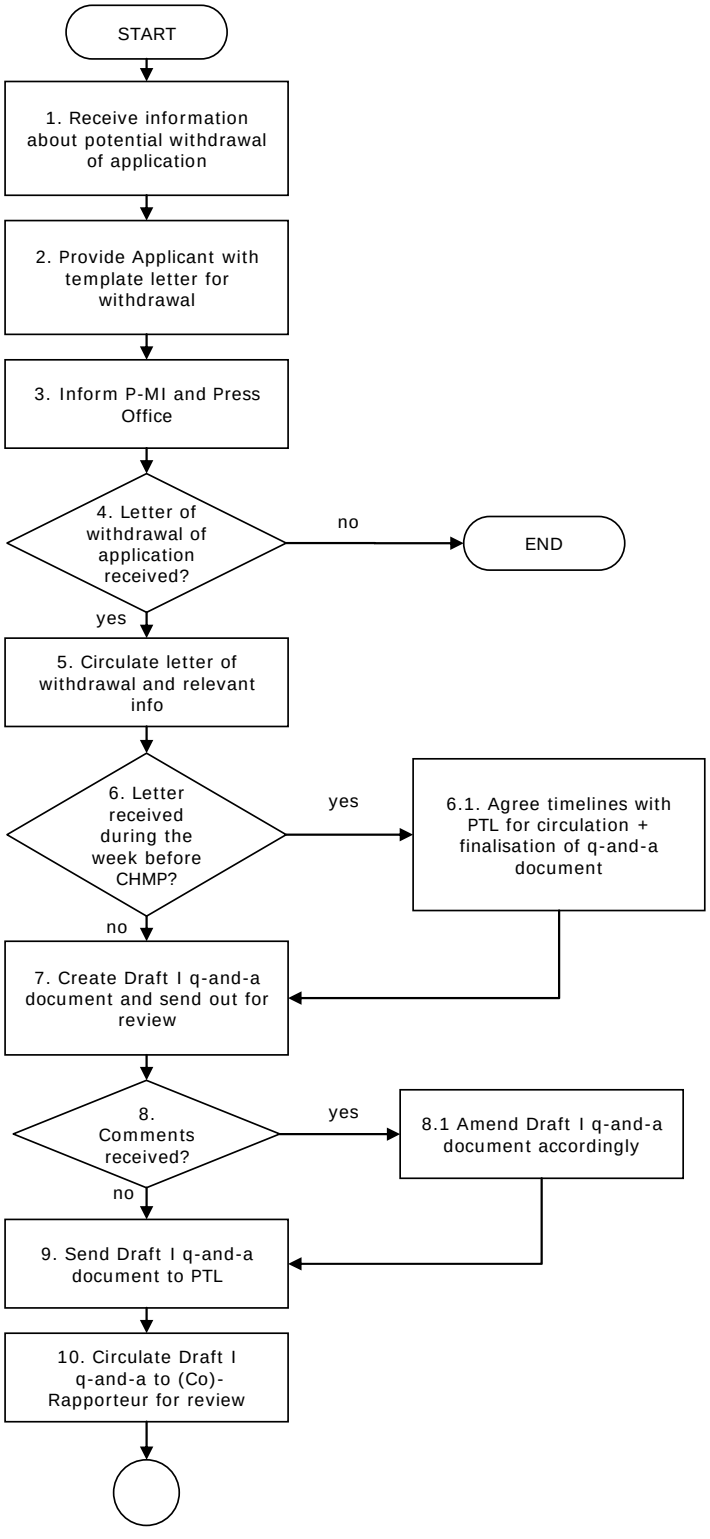
6. Related documents

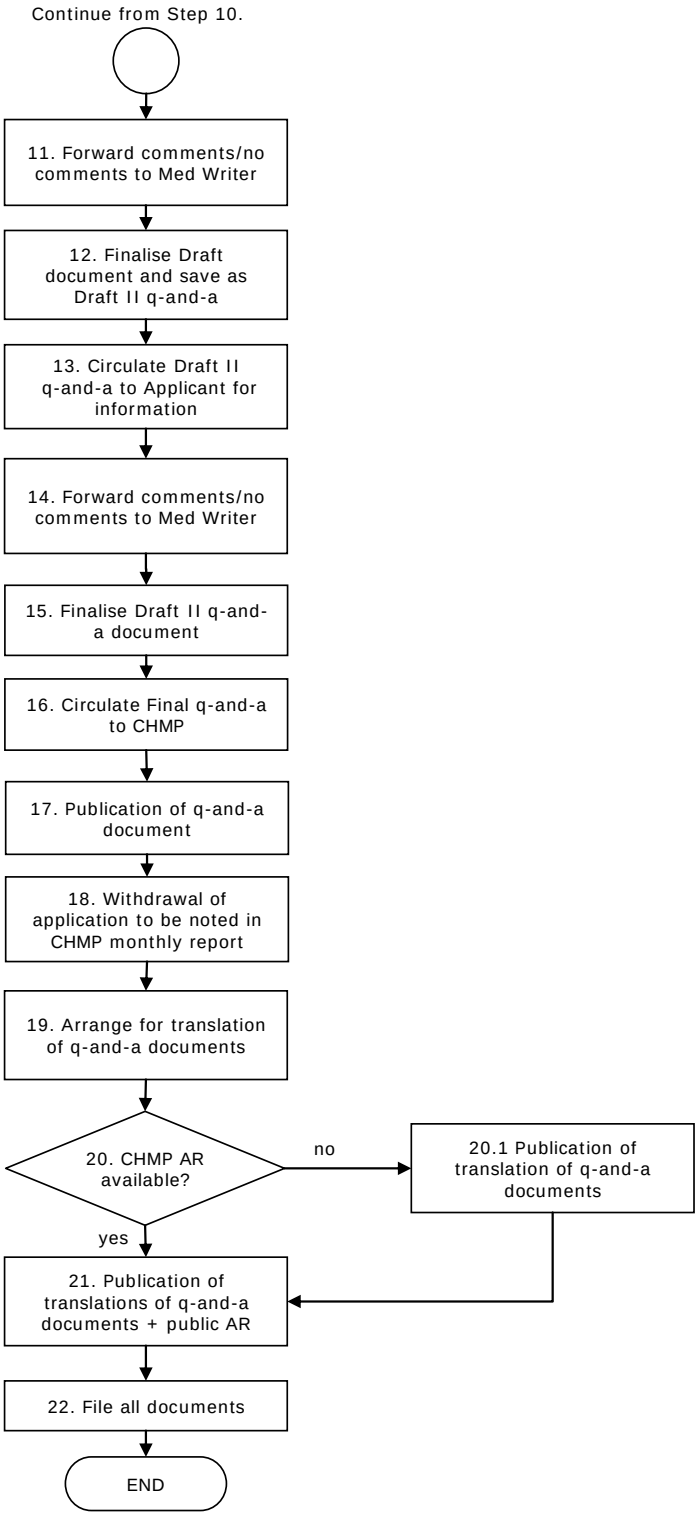
- Reflection Paper on Publication of Withdrawals of Marketing Authorisation Applications for Human Medicinal Products (EMA/239350/2005) http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005061.pdf)
- SOP/H/3224 - Preparation of a European Public Assessment (EPAR) following a withdrawal of application
- Guidance on the Handling of EPAR files Human Products (EMA/447123/2006 – working document)

7. Definitions

AR	Assessment report
CdT	Centre de Traduction (Translation Centre of the EU Institutions)
MAH	Marketing Authorisation Holder
MedW	Medical Writer
P-MI	Medical Information Sector
PTL	Product Team Leader
PTM	Product Team Member
q-and-a	Question-and-answer document

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




Continue from Step 10.
11. Forward comments/no comments to Med Writer
12. Finalise Draft document and save as Draft II q-and-a
13. Circulate Draft II q-and-a to Applicant for information
14. Forward comments/no comments to Med Writer
15. Finalise Draft II q-and-a document
16. Circulate Final q-and-a to CHMP
17. Publication of q-and-a document
18. Withdrawal of application to be noted in CHMP monthly report
19. Arrange for translation of q-and-a documents
20. CHMP AR available?
no
20.1 Publication of translation of q-and-a documents
yes
21. Publication of translations of q-and-a documents + public AR
22. File all documents
END

9. Procedure

Step	Action	Responsibility
1.	**PTL receives information about potential withdrawal of application** PTL is informed by the Applicant/MAH of a possible withdrawal of application.	PTL
2.	PTL ensures that Applicant uses the appropriate template for the letter of withdrawal (template 1).	PTL
3.	PTL informs P-MI and the Press Office as soon as possible directly by e-mail.	PTL
4.	**Letter of withdrawal received?** • If the letter of withdrawal is received go to step 5. • If the letter of withdrawal is not received the process ends.	PTL
5.	**Circulate letter of withdrawal and relevant info** PTL to circulate: • the letter of withdrawal to P-MI and Press Office; • the latest adopted CHMP assessment report, if available (after Day 120 for initial applications/line extensions and after Day 90 for extension of indication), and the latest available product information to P-MI	PTL
6.	**Has the letter of withdrawal been received the week before CHMP?** • If the letter of withdrawal is received the week before the CHMP, go to step 6.1. • If the letter of withdrawal is received at any other time, go to step 7.	PTL
6.1	**Agree timelines with PTL** If the letter of withdrawal is received the week before CHMP, fast timelines need to be agreed with the PTL for circulation and finalisation of the q-and-a by the following Thursday (last day of CHMP).	MedW
7.	**Create Draft I q-and-a document and send it for internal review** The MedW write the Draft I q-and-a using template 2 or template 3, as appropriate. The MedW sends a link to the Draft I q-and-a to P-MI, PTL/PTM and Press Office, asking for feedback within 2 working days.	MedW
8.	**Have any comments been received?**	MedW

Step	Action	Responsibility
	• If any comments have been received go to step 8.1. • If no comments have been received go to step 9.	
8.1	**Amend Draft I q-and-a document accordingly** Finalise Draft I q-and-a document by incorporating any comments received within one working day.	MedW
9.	**Send Draft I q-and-a document to PTL** MedW sends the Draft I q-and-a document to PTL ready for review by rapporteur(s).	MedW
10.	**Circulate Draft I q-and-a document for review to Rapporteur/Co-Rapporteurs** PTL will send the Draft I q-and-a document to the Rapp and Co-Rapp for brief consultation phase. Comments are to be received no later than Friday before CHMP week. Note: this step may be delegated by PTL to MedW if appropriate (e.g. tight timelines). In such case, the PTL provides the MedW with the contact names and step 11 is not needed.	PTL
11.	**Forward comments from Rapporteur/Co-Rapporteur** If comments/no comments are received from Rapporteur/Co-Rapporteur these are forwarded by the PTL to MedW in MIS so that they can be taken into account and incorporated as appropriate.	PTL
12.	**Finalise Draft I q-and-a document** On receipt of comments from Rapp/Co-Rapp, the MedW finalises Draft document and saves it as Draft II q-and-a forwards it back to PTL.	MedW
13.	**Circulate Draft II q-and-a document for information to Applicant/MAH** PTL circulates the Draft II q-and-a for comments to the Applicant/MAH, no later than Monday of the CHMP. Comments should be received within 24 hours.	PTL
14.	**Forward feedback to Medical Writer** If comments/no comments are received from Applicant/MAH these are forwarded by the PTL to MedW in P-MI so that they can be taken into account and incorporated as appropriate.	PTL
15.	**Finalise Draft II q-and-a document** Incorporate any relevant comments from the Applicant/MAH, as appropriate, to create the final q-and-a document for publication and forward it back to PTL.	MedW

Step	Action	Responsibility
16.	**Circulate final q-and-a document to CHMP for information** PTL tables the final q-and-a to the CHMP for information during CHMP meeting.	PTL
17.	**Publication of the q-and-a document (EN version)** The withdrawal letter from the Applicant and the q-and-a document (EN version) are published on the EMA website in time for the CHMP monthly report, i.e. Tuesday after CHMP at the latest. The letter of withdrawal should have all personal data blanked out (deletion of names and personal e-mail/phone for company signatory(ies) and EMA staff).	PTL Secretary
18.	**Reference the withdrawal of the application within the CHMP monthly report.** The CHMP monthly report will reflect the withdrawal, along the same lines as the initial press-release. The report will make reference to the published q-and-a.	CHMP Secretariat
19.	**Translation of q-and-a document** The PTL secretary is responsible for requesting from V-PD-DIS the translations of the q-and-a document (EN version) into all EU languages by the CdT.	PTL Secretary
20.	**Is the CHMP assessment report available (after Day 120 for initial applications/line extensions and after Day 90 for extension of indication)?** • If the CHMP AR is not available, go to step 20.1. • If the CHMP AR is available, go to step 21.	PTL Secretary
20.1.	**Publication of translations of q-and-a document if CHMP AR is not available** PTL secretary to publish the translations of the q-and-a as soon as received from the CdT.	PTL Secretary
21.	**Publication of translations of q-and-a if CHMP AR is available** PTL secretary to publish the translations of the q-and-a document at the same time as the Application withdrawal assessment report (prepared according to SOP H/3224).	PTL Secretary
22.	**File all documents** PTL secretary to file all the documents.	PTL Secretary

10. Records

Withdrawal q-and-a and all correspondence relating to them are part of the Master File and should be kept according to SOP/PDM/1004.