EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Certificates of medicinal products		
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1. Purpose

Enabling the production of the European Medicines Agency (EMA) certificates of a medicinal product for human and veterinary use in a consistent way.

2. Scope

This SOP applies to the Compliance and Inspection Sector. This SOP should be read in conjunction with information, documents and forms made available on the internet.

3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within his/her 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

Extensive revision to the SOP.

5. Documents needed for this SOP

- All the following templates are available on the EMA website: Home > Regulatory > Human medicines > Post-authorisation > Certificates for products > Requesting certificates:
  - Application form for European Medicines Agency certificates of medicinal products.

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  - Statement of quantitative composition.
  - Template for letter from marketing-authorisation holder (MAH) permitting the Agency to send certificates elsewhere than to MAH address.
- WIN/INSP/2029 Recording, validation and production of certificates of medicinal products.

6. Related documents

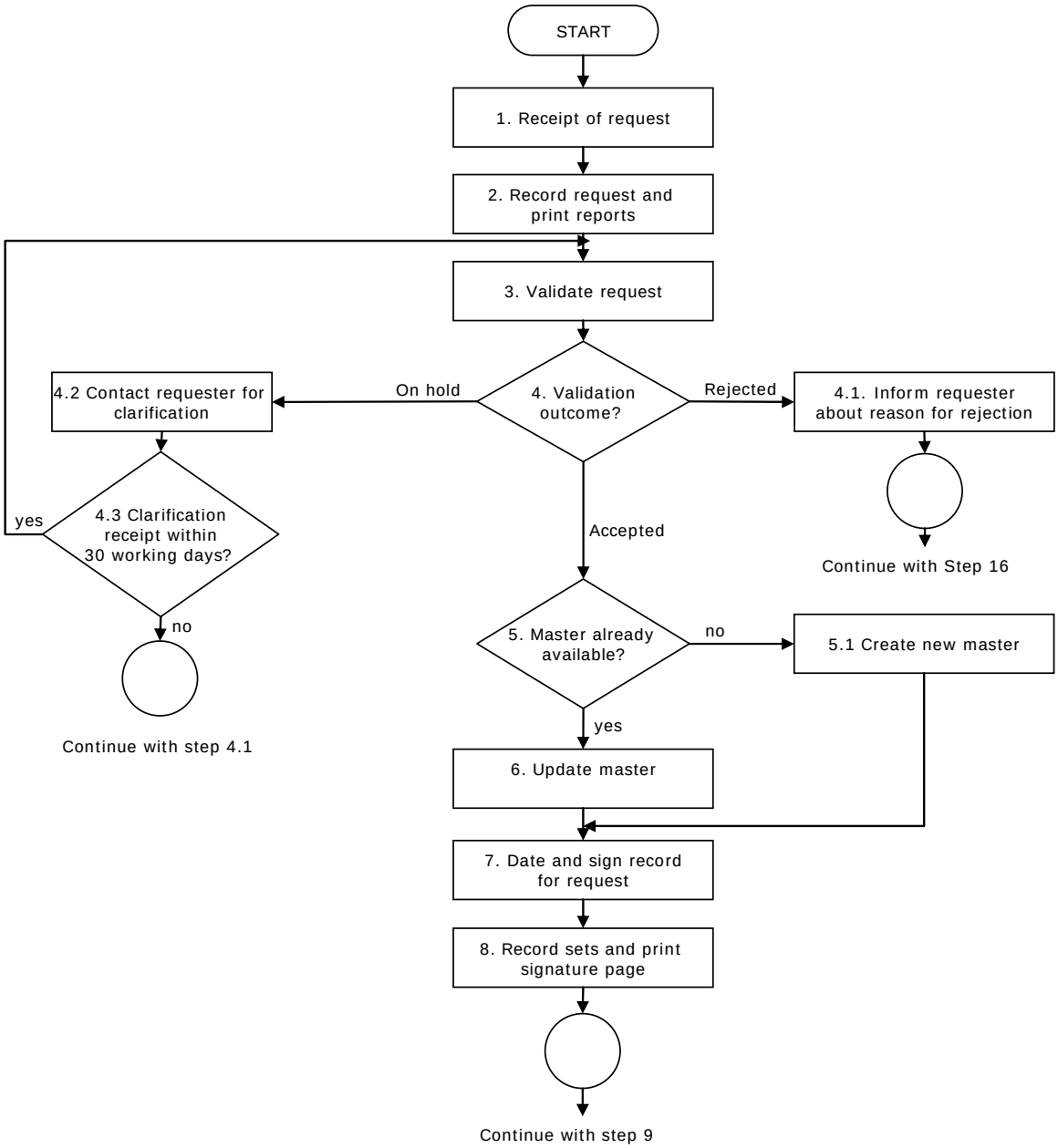
- Information package for certificates of medicinal products issued by the European Medicines Agency: Home > Regulatory > Human medicines > Post-authorisation > Certificates for products.
- European Medicines Agency certificates of medicinal products – instructions on how to fill the application form: Home > Regulatory > Human medicines > Post-authorisation > Certificates for products > Requesting certificates.
- Rules of implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures: Home > Regulatory > Human medicines > Fees.
- Explanatory note on fees payable to the European Medicines Agency: Home > Regulatory > Human medicines > Fees.

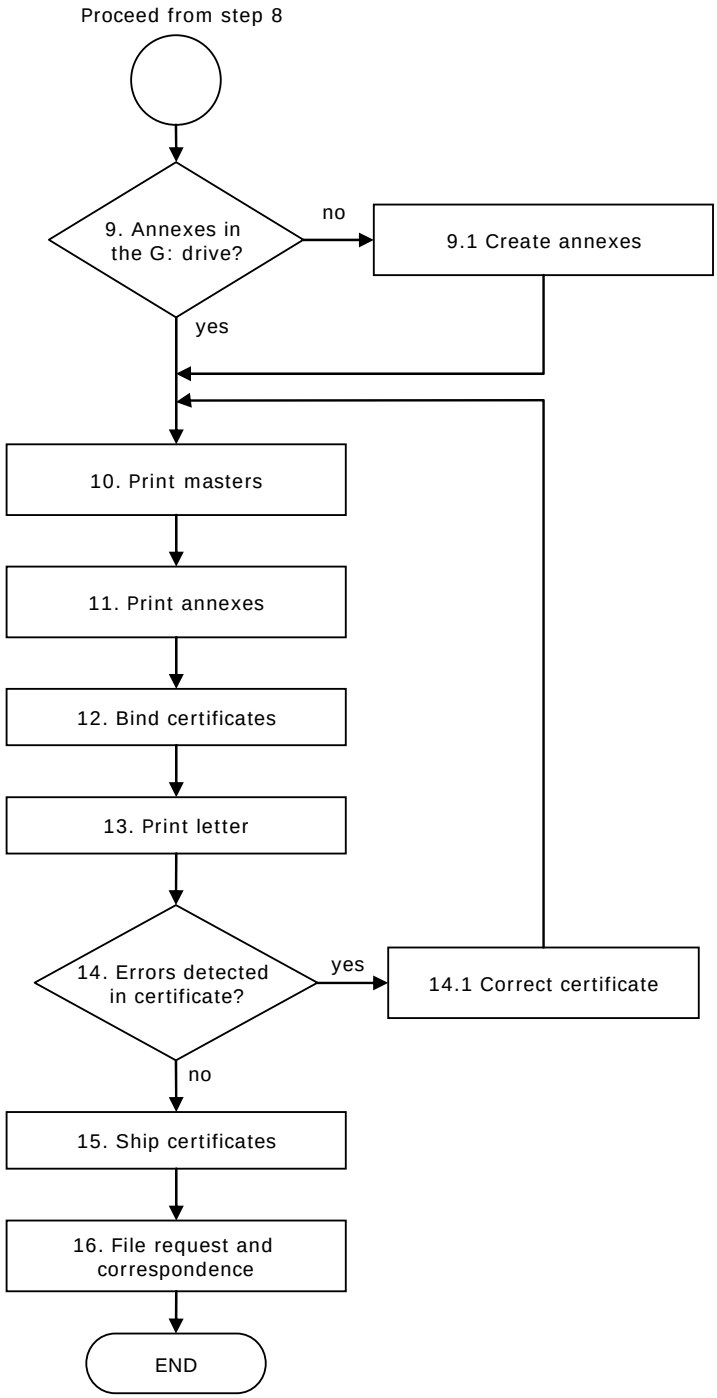
7. Definitions

Authorisation	Information and documents related to a community marketing authorisation, as amended, which is made available by the unit responsible for project management. If product is not authorised, it refers to application.
Certificate of medicinal product (CMP)	A formal document of the European Medicines Agency produced following this procedure in accordance with the WHO certification scheme for pharmaceutical products moving in international commerce. The certificate provides confirmation from the Agency on the marketing authorisation status and GMP compliance. The full title is certificate of a medicinal product (CMP). The Agency can certify a product only if a valid application for marketing authorisation or for the scientific opinion pursuant to art. 58, has been submitted to the Agency via the centralised procedure.
Certificates database	Software used for the recording and production of certificates.
Fee	It is the amount paid to the European Medicines Agency by companies requesting certificates, in accordance with the Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures.
GMP compliance	Positive outcome of periodic GMP inspection carried out in the manufacturing site producing the pharmaceutical form.
MA number	Marketing authorisation number, e.g. EU/1/XX/XXX/XXX.
Master certificate	Series of entries in the certificates database which are created/updated every time a request for certificates is received.

PI	Product Information.
Request	A document in standard format (using the template available on the website) that is used by the requester to order certificates from the Agency.
Requester	Holder of (or applicant for) the community marketing authorisation or any other organisation with the permission of the MAH/MA applicant requesting certificates from the Agency.
Set	A maximum of six identical original certificates for a medicinal product with a distinct marketing authorisation number, addressed to the same importing country, issued in the same official language of the European Union and having identical annexes.
SIAMED database	Model system for computer-assisted drug registration.
Standard procedure	Procedure for issuing certificates of medicinal products (CMP) within 10 working days, starting on the following working day of receipt of request.
Urgent procedure	Procedure for issuing certificates of medicinal products (CMP) within 2 working days, starting on the following working day of receipt of request.

8. Process Map(s)/ Flow Chart(s) (numbers refer to the procedure step)




Proceed from step 8
9. Annexes in the G: drive?
no
9.1 Create annexes
yes
10. Print masters
11. Print annexes
12. Bind certificates
13. Print letter
14. Errors detected in certificate?
yes
14.1 Correct certificate
no
15. Ship certificates
16. File request and correspondence
END

9. Procedure

Step	Action	Responsibility
1	Receive CMP request in the certificates mailboxes certificate@ema.europa.eu for the standard procedure and certificate_urgent@ema.europa.eu for the urgent procedure. These mailboxes are checked at least once a day (follow WIN/INSP/2029, step 1).	Certificates assistant
2	Record request in certificates database. Send e-mail acknowledging receipt of request, start of the procedure and notify the requester about the applicable fee. Print GMP status confirmation and product status report (follow WIN/INSP/2029, steps 1 to 11).	Certificates assistant
3	Validate request (follow WIN/INSP/2029, step 12).	Certificates assistant
4	Record validation outcome (follow WIN/INSP/2029, step 12). If the validation outcome is “Accepted”, proceed with step 5. If the validation outcome is “Rejected”, proceed with step 4.1. If the validation outcome is “On hold”, proceed with step 4.2.	Certificates assistant
4.1	Inform requester about reason for rejection, update validation outcome from “On hold” to “Rejected” and proceed with step 16.	Certificates assistant
4.2	Contact requester by e-mail to ask for clarification.	Certificates assistant
4.3	Record date in “Company contact” field in certificates database. If clarification is received within 30 calendar days, proceed with step 3. If no clarification is received within 30 calendar days, proceed with step 4.1.	Certificates assistant
5	Check in the certificates database whether master certificates for requested presentations are available in the requested languages. If master is not available, proceed with step 5.1. If master is available, proceed with step 6.	Certificates assistant
5.1	Create new masters for presentations and languages requested. (follow WIN/INSP/2029, steps 13 to 14). Proceed with step 7.	Certificates assistant
6	Update the master (follow WIN/INSP/2029, steps 13 to 14).	Certificates assistant

Step	Action	Responsibility
7	Date and sign the record for request of certificates.	Certificates assistant
8	Record sets into certificates database and print out the form “certificates of medicinal products for signature” according to WIN/INS/2029 (steps 15 to 18).	Certificates assistant
9	Check if requested annexes are on G: drive (G:/SharedAreas/Certificate/Products). If requested annexes are on the G: drive, proceed with step 10. If annexes need to be created, proceed with step 9.1.	Certificates assistant
9.1	Create a folder for the requested variation under the product folder on the G: drive. Save the relevant product information from the Agency’s external website, and if not updated, from DREAM. From the product information create the requested annexes (follow WIN/INS/2029, steps 19 to 20). Proceed with step 10.	Certificates assistant
10	Print out master certificates from certificates database (follow WIN/INS/2029, step 21).	Certificates assistant
11	Print out requested annexes from G: drive (follow WIN/INS/2029, step 22).	Certificates assistant
12	Bind certificates and corresponding annexes together (follow WIN/INS/2029, step 23).	Certificates assistant
Completion of request for CMP		
13	Update certificates database with current date and “Days to issue” and print out cover letter (follow WIN/INS/2029, step 24-25). Under the **standard procedure**, certificates are to be sent within 10 working days following receipt of request, not including weekends, bank holidays and periods when the request has to be put on hold, between “Company contact” date and “Reply date”. Under the **urgent procedure**, certificates are to be sent within 2 working days following receipt of request, not including weekends, bank holidays and periods when the request has to be put on hold, between “Company contact” date and “Reply date”.	Certificates assistant
14	Perform quality review (follow WIN/INS/2029, step 26). If errors detected, return to Certificates assistant and go to step 14.1. If CMPs are correct proceed with step 15.	Certificates quality review secretary

Step	Action	Responsibility
14.1	Correct certificates and go to step 10.	Certificates assistant
15	Sign cover letter and prepare shipment of documents (follow WIN/INS/2029, step 27).	Certificates assistant
16	File request and all related correspondence (follow WIN/INS/2029, step 28).	Certificates assistant

10. Records

Requests for certificates and all the correspondence related to requests for certificates are retained by the Compliance and Inspection sector. Paper copies are filed in the certificates office for three months and after that, archived off site for 10 years. Also electronic records of CMP and annexes are kept in the certificates database and G:drive (G:\SharedAreas\Certificate\Products).