10 January 2023
EMA/12375/2023
Human Medicines Division

Implementation of the new WHO certificate template – compilation of changes

On the 16th of January 2023 EMA is implementing the new WHO certificate template under the World Health Organization certification scheme for electronic certificates of medicinal products.

Please note that any request received on or after 16th January 2023 will be implemented in accordance with the new template and issuing certificates based on the old template for the requests received as of the mentioned date will no longer be possible.

The main differences compared to the previous certificate template are:

1. The format of the certificate is slightly different from the the current one and aligned with the new WHO template.

2. Certificates will no longer be space constricted and will not be limited to 4 pages only.

3. Certificates can be requested in English, Spanish, French or Portuguese language and in any combination thereof.

   Please note that Portuguese certificates will follow the same template as the certificates in English, Spanish and French.

   Please also note that countries in the address(es) of the Marketing Authorisation Holder (MAH) and manufacturing sites will no longer be translated into relevant languages and will be stated in English only.

4. Certificates will contain mutually exclusive parts "2.A" - for the centrally authorised products and "2.B" - for products under consideration and Medicines 4-All products (formerly Art.58). Only the relevant section will show in the certificate based on the status of the product requested.

5. New edited explanatory notes will be attached to the certificate(s) in relevant language(s).

6. Certificates will include a hyperlink to EMA EPAR webpage for the product (UPD for veterinary products) where the latest information, any recent press release or safety restriction can be found.

   Please note that in case of patient safety warning, press releases or safety communications will no longer be attached to the certificates. EPAR can be attached upon request.

7. Manufacturing sites' activities: Each manufacturing activity that can be requested in the application form has a corresponding letter assigned to it and will be stated as such in the certificate, next to the name and address of the manufacturing site (no longer stated as free text).

   a) manufacturing of all steps of the finished medicinal product
   b) manufacturing of the bulk finished product

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

c) manufacturing of solvent and diluents
d) quality control of the finished medicinal product
e) batch release of the finished medicinal product in the EU
f) primary packaging of the dosage form
g) secondary packaging of the product
h) other(s)

8. Stating the MAH status in the certificate will follow the same lettering as manufacturing sites' activities (please refer to point 7).

   E.g., if the MAH is responsible for manufacturing of the bulk finished product, the status of the MAH will be stated as "b" in the certificate (as opposed to "a" in the previous certificate template).

9. Annexes to certificates: The Product information (SmPC, PL and/or labelling) will be based on the latest published EPAR on EMA website (or UPD for veterinary medicinal products) by default.

   Please note that an approved PI that has not been yet published (i.e., recently approved change) can be attached instead as Annex upon request.

10. EMA certificates are digitally signed with DocuSign and signatures comply with Regulation (EU) No 910/2014 on the electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation).

11. Issued certificates will be sent by email to the email address stated in the application form (EudraLink account no longer required).

    Please note that several emails can be received for the same request, dependent on the package size.

Annex I
Example of an English electronic certificate

EUROPEAN MEDICINES AGENCY

Certificate:
Request:

Certificate of a Medicinal Product

This Certificate conforms to the format recommended by the World Health Organization (WHO).
It establishes the status of the medicinal product and of the applicant for the certificate within the jurisdiction of the regional certifying authority at the time of issue. It is for a single product only at a given point in time since the manufacturing arrangements and approved information for different dosage forms and different strengths can vary

No. of Certificate:

Regional certifying authority:

European Union:

Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and United Kingdom (Northern Ireland)

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI

Importing (requesting) country:

<text>

1.1 Name: (International Nonproprietary Name (INN)/generic/chemical name); brand name of the medicinal product as it is declared in the marketing authorisation and used within the territory of the certifying authority and, if requested, the brand name for the foreign country as declared by the requester, (if different); and pharmaceutical form of the product

<text>

1.2 Active substance(s) and amount(s) per unit dose or unit volume:

<text>

For complete composition including excipients, see attached[1]

1.3 Is this product subject to a Community Marketing Authorisation?

<text>

1.3.1 Are there restrictions of the sale, distribution or administration of the product specified in the marketing authorisation?

<text>

1.4 Is this product actually on the market within the jurisdiction of the certifying regional authority?

<text>

2. Information of Marketing Authorisation

2.A. Product that is authorised for marketing by the certifying authority: [2]

Confidential

2.A.1 Number in the Community Register of Medicinal Products and date of issue:

<text>

2.A.2 Community Marketing Authorisation Holder (name and address):

<text>

2.A.3 Status of the Community Marketing Authorisation Holder:

<text>

For categories see section 3.1.

2.A.4 Is the European Public Assessment Report (EPAR) appended? (This refers to the document that summarises the technical basis on which the product has been authorised)?

<text>

2.A.5 Is the attached officially approved product information included in the Community Marketing Authorisation (such as the Summary of Product Characteristics – SPC- or similar)?

<text>

2.A.6 Applicant for the Certificate, if different from the Community Marketing Authorisation Holder (name and address):

<text>

2.A.7 Web-link to the product marketing authorisation information (if available):

<text>

2.B Product that is not authorised for marketing by the certifying authority: [2]

2.B.1 Applicant for the Certificate (name and address):

<text>

2.B.2 Why is a Community Marketing Authorisation lacking?

<text>

2.B.3 Reason provided by the applicant for not requesting registration:

a) The product has been developed exclusively for the treatment of conditions (e.g. tropical diseases – not endemic in the exporting country):

<text>

b) The product has been reformulated - please specify:

<text>

c) Any other reason, please specify:

<text>

Confidential

3.1 List of name and address of the manufacturing site(s) and activities: [4]

a) manufacturing of all steps of the finished medicinal product

b) manufacturing the bulk finished product

c) manufacturing of solvent and diluents

d) quality control of the finished medicinal product

e) batch release of the finished medicinal product in the EU

f) primary packaging of the dosage form

g) secondary packaging of the product

h) other(s) (specify and list in new arrows)

Name of manufacturing site	***Address***	***Activity***
<text>	***<text>***	***<text>***

3.2 Does the certifying authority arrange for periodic inspections of the manufacturing site in which the pharmaceutical form is produced?

<text>

If no or not applicable, proceed to question 4.

3.3 Periodicity of routine inspections:

<text>

3.4 Has the manufacturer of this type of pharmaceutical form been inspected? If Yes, when feasible, insert date of inspection(s) (dd/mm/yyyy):[5]

<text>

3.5 Do the facilities and operations conform to good manufacturing practices (GMP) as recommended by the World Health Organization (WHO)? [6]

<text>

3.6. It is recommended that for products approved, but not manufactured in the country of the certifying authority, the source of information that assures the GMP compliance of the manufacturer(es) is declared:

<text>

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[7]

<text>

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Telephone +31 (0)88 781 6000
E-mail certificate@ema.europa.eu **Website** www.ema.europa.eu

EUROPEAN MEDICINES AGENCY

Certificate:
Request:

Address of the Certifying Authority:

European Medicines Agency
Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
Telephone: ***+31 (0)88 781 6000***

E-mail address: ***certificate@ema.europa.eu***

Name and title of authorised person

Signature and date

Name and electronic signature from signatory

<Signature>

Authorised signatory

Stamp

Confidential

Explanatory notes

[1] Details of quantitative composition are preferred but their provision is subject to the agreement of the marketing authorisation holder.

[2] Sections 2A and 2B are mutually exclusive.

[3] In this circumstance, permission for issuing the Certificate is required from the Community Marketing Authorisation Holder. This permission has to be provided to the European Medicines Agency by the applicant (only applicable to section 2.A).

[4] This information can only be provided with the consent of the Community Marketing Authorisation Holder or, in the case of non-registered products, the applicant. It should be noted that information concerning the site of production is part of the Community Marketing Authorisation. If the production site is changed, the Community Marketing Authorisation has to be updated or it is no longer valid.

[5] Currently not feasible.

[6] The requirements for good practices in the manufacture and quality control of medicinal products referred to in the certificate, are those included in the Thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series, No. 986, 2014, Annex 2 (WHO Good manufacturing practices for medicinal products: main principles). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Good manufacturing Practices for biological products, WHO Technical Report Series, No. 996, 2016, Annex 3).

[7] It is of particular importance when contractors are involved in the manufacture of the product. The applicant should supply the certifying authority with information in order to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

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