LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Issue of export certificates for medicinal products

Content

Introduction

The Danish Medicines Agency (LMST) authorises certificates for medicinal products to be exported. The certificates are generally designed in accordance with the WHO Certification Scheme certification formats. Additional information is provided to ensure the best possible information on individual medicinal products.

1. Legal basis

Ministry of Health Circular No. 14 of 29 January 1998 on the regulation of the Danish Medicines Agency's export register for medicinal products, etc.

2. Application for an export certificate and processing time

In the following we describe the process of application, case processing and processing time when issuing export certificates.

1) Digital templates for export certificates can be found on the Danish Medicines Agency's website. Here, the company can download relevant templates and fill them out electronically. The templates are available as restricted documents, where filling out forms is allowed.
2) Completed certificates must be submitted via a form available via the link: digital formular til eksportcertifikater . English version: digital form for export certificates.
3) You must write your contact details with your company name, contact name and e mail. You must write who is the recipient of the export certificate if it is different from the company's contact details. If you wish to collect the certificate or certificates from the Danish Medicines Agency, this must be ticked.
4) You must request the type of export certificate to be requested (OBS can only be requested one type of certificate per request). Maximum attachments up to 10 items with a total limit of 50 MB can be attached.
5) At the end of the form, please tick that you declare that the information you submit in the attached material is correct and in accordance with the conditions of your company.
6) There must be a power of attorney if the applicant is different from the registration holder for the medicinal products concerned.
7) LMST has a processing time of up to 7 working days from the day we receive the request. LMST certifies the completed certificate digitally, prints it on certificate paper, prints any attachments on plain paper, and collects the documents with an oblate. We will then return the certificate to the recipient mentioned in point 3).

Questions about export certificates and their issuance can be asked at certificates@dkma.dk.

3. What types of export certificates does the Danish Medicines Agency issue?

3.1. Certificate of a Pharmaceutical Product (CPP-1 and CPP-2)

CPP-1 and CPP-2 are part of the WHO Certification Scheme.

CPP-1 is used for medicinal products wholly or partly manufactured in Denmark that are released in Denmark, which have a marketing authorisation in Denmark, or where the medicine is included in the export register. Medicinal products exclusively manufactured and released abroad may also obtain a CPP-1, if applicable.

CPP-2 can be granted for medicinal products that are wholly or partly manufactured and/or released in Denmark, but where there is no marketing authorisation in Denmark or entry in the export register. If such a product is manufactured or released only abroad, CPP-2 must be sought in that country.

CPP-1 and CPP-2 provide information on whether or not

- there is a marketing authorisation in DK or entry in the export register
- the drug is on the Danish market
- Danish manufacturing site is subject to regular inspections
- the Danish manufacturer meets the established requirements for GMP and quality control
- the product information is approved in Denmark

CPP-1 is available in English and Spanish, while CPP-2 is only available in an English version.

The certificates are completed by the applicant in accordance with "Explanatory Notes", which can be found on the Danish Medicines Agency's website. Only one product form/strength per certificate may be indicated.

When completing the certificates, attention should be drawn to the following:

- The MT number (EU or DK) or Export Reg. number shall be used, whereas the DSP or SPN number shall not be indicated. The EMA reference number, if applicable, may be added as a supplement, but may not stand alone.
- When indicating the date of marketing authorisation, the date in the approved SPC shall be used. The date of registration of new packages shall not be indicated.

For CPP-1 and CPP-2, additional product-relevant information may be attached, such as the indication of composition or summary of product characteristics/catalogue text from the export register (or extracts thereof). GMP certificate can also be attached for any foreign manufacturers of the drug.

3.2. Statement on Licensing Status of Pharmaceutical Products (LSPP)

LSPP is part of the WHO Certification Scheme and can be granted for medicinal products that have a marketing authorisation in Denmark or are entered in the export register. The LSPP is completed by the applicant.

When indicating the date of registration, the date in the approved SPC shall be used. The date of registration of new packages cannot be indicated.

3.3. Statement on Good Manufacturing Practices (CGMP)

- Pharmaceutical Products (CGMP-PP)
- Pharmaceutical Starting Materials (API), voluntary inspection (CGMP-API)
- Pharmaceutical Starting Materials (API), non-voluntary inspection (CGMP-API-NV)
- Antiseptics and Disinfectants (CGMP-AD)
- Non-pharmaceutical products (CGMP-NP)
- GMP Compliance non-EC/EEA Countries (CGMP-3.country)

CGMP is part of the WHO Certification Scheme. Please note that the current pharmaceutical forms must be covered by the company's manufacturing authorisation or be subject to voluntary inspections. All CGMPs are available in English, although CGMP-PP is also available in Spanish.

The Danish Medicines Agency automatically issues GMP certificates according to harmonised procedures within the EU after any completed inspection with satisfactory follow-up – both in Denmark and in third countries (non-EU/EEA). The Danish Medicines Agency will phase out the issuance of CGMP as these EU GMP certificates become widely used and recognised in those countries that require evidence of GMP compliance.

In **the case of the LSPP and the CGMP**, additional information shall be allowed to the extent that it can be accommodated on the back of the certificate in the case of:

a) indication of composition – i.e. "official" LMST information;
b) indications – i.e. summary of product characteristics or catalogue text from the export register (or extract thereof)

This additional information shall be provided as a separate document, which shall not exceed one page. Information will not be certified.

3.4. Statement on Good Distribution Practices (CGDP)

CGDP is not part of the WHO Certification Scheme, but aims to confirm that a wholesale distributor is approved and thus subject to routine GDP inspection by LMST.

3.5. Batch Certificate of a Pharmaceutical Product (BCPP)

BCPP is recommended by the WHO and can be trusted by LMST. The certificate shall be drawn up by the undertaking, on the company's own logo paper and with the company's signature. The company chooses whether these BCPPs are submitted by e-mail or whether the document should be credibly stamped on the company's original letterhead. In this case, the documents may be submitted to the Danish Medicines Agency, Axel Heides Gade 1, DK-2300 Copenhagen S. The envelope is requested to bear the label "Export certificates for medicinal products".

Examples of the certificate can be found on the WHO and EMA websites.

3.6. TSE certificates

TSE certificates are different declarations that can be certified by LMST. The text of the declaration depends on how the information for the given medicinal product has been evaluated:

a) Type I preparations:

The raw materials of ruminant origin used for production of have been granted a certificate from EDQM. This means that after examination of the information provided on the origin of raw material, type of tissue used and on the manufacturing process, the EDQM certify that this substance meets the criteria described in the monograph "Products with risk of transmitting agents of animal spongiform encephalopathies" (Ph.Eur. current edition at the time of issue of the certificate).

b) Type II preparations:
"Examination of the information provided on the origin of raw material, type of tissue used and the manufacturing process for the raw materials of ruminant origin used in has shown that the criteria described in the monograph "Products with risk of transmitting agents of animal spongiform Encephalopathies" (Ph.Eur. current edition at the time of issue of the certificate) are fulfilled."

c) Type III preparations:
The company has informed The Danish Medicines Agency that does not contain raw materials of ruminant origin covered by the monograph "Products with risk of transmitting agents of animal spongiform encephalopthies" (Ph.Eur. current edition at the time of issue of the certificate).

d) Preparations not yet voted under the new TSE Directive/guideline (Type 0):
"(Name of the preparation) is currently being evaluated according to the requirements in the Ph.Eur. Monograph "Products with risk of transmitting agents of animal spongiform encephalopathies" (Ph.Eur. current edition at the time of issue of the certificate).'

TSE declarations shall be issued by LMST at the written request of the company and the professional decision of LMST on the type of the medicinal product concerned.

4. Credential stamping

In addition to certificates, the company's own relevant documents can be trusted by LMST. For example, certificates of analysis for a current batch, written on the company's own logo paper and signed by a responsible person in the company. However, this requires the company to have a valid manufacturer's license from LMST.

The company chooses whether documents that are to be trusted are submitted by e-mail or whether the document should be stamped with credibility on the company's original letterhead. In this case, the documents may be submitted to the Danish Medicines Agency, Axel Heides Gade 1, DK-2300 Copenhagen S. The envelope is requested to bear the label "Export certificates for medicinal products".

5. English version of marketing authorisation

In case of a certified English version of a marketing authorisation, the translation must be prepared by the company itself. The translation should be sent by e-mail to certificates@dkma.dk together with a copy of the Danish permit. We check the translation and transfer it to our own logo paper. After certification, we return the translation to the company.

6. Fees

The issue of export certificates for medicinal products is exempt from the fee.

7. Other information

The certificates shall be stamped and certified electronically in the LMST. To protect against counterfeiting, the certificates are printed on special certificate paper, which is supplied with our oblate.

The Danish Medicines Agency reserves the right to revoke issued export certificates if it turns out that the information is no longer correct.

8. Summary of export certificates and declarations for medicinal products

- ***Certificate of a Pharmaceutical Product,*** CPP-1 and CPP-2
- ***Statement on Licensing Status,*** LSPP
- ***Statement on Good Manufacturing Practices***
- CGMP-PP (Pharmaceutical Products)
- CGMP API (Pharmaceutical Starting Materials (API) – voluntary inspection)
- CGMP-API-NV (Pharmaceutical Starting Materials (API) – non-voluntary inspection)
- CGMP-AD (antiseptics/Disinfectants)
- CGMP-NP (Non-pharmaceutical Products)
- CGMP-3 rd country (Non-EU/EEC Countries)
- ***Statement on Good Distribution Practices,*** CGDP
- ***Batch Certificate of a Pharmaceutical Product,*** BCPP
- **TSE certificates**
- **Credibility statements**

9. Change log

Date	Version	Change
02-10-2023	Export certificates	General update of the guide.