Stakeholder Instructions: Requesting a Certificate of a Pharmaceutical Product and Good Manufacturing Practice Certificate during COVID-19

Introduction

This document provides instructions and information to assist with submitting a Certificate of a Pharmaceutical Product (CPP) and Good Manufacturing Practice (GMP) Certificate application during the COVID-19 pandemic.

These instructions should be used for all certificate requests at the present time and are applicable for the duration of COVID-19 pandemic conditions, until further notice.

Health Canada is launching a pilot to implement the electronic issuance of CPPs and GMP Certificates effective **October 5th 2020** to continue meeting our obligations set out in the WHO Certification scheme on the quality of pharmaceutical products moving in international commerce during the COVID-19 pandemic. All aspects of an application will now be electronic (i.e. applications can only be submitted electronically and certificates can only be issued and sent electronically) and certificates will no longer be issued using a wet signature.

This new process will replace the interim signed letters, which were attesting to the compliance of the Canadian manufacturer in place of the paper certificate process, which was put on hold in early March. Furthermore, as of October 1st, Heath Canada will no longer be sending electronically signed interim letters and a formal electronic certificate application should be submitted if necessary.

What to expect

Certificates will continue to be issued in either English or French as requested by the applicant. If the certificate is required in another language, it is the responsibility of the applicant to provide a notarized translation to the importing authority.

The CPP will also continue to be issued in the format as recommended by the WHO Certification Scheme on the quality of products moving in international commerce and will include a statement to this effect. The GMP Certificates will not include such statement, as they are not part of the WHO certification scheme.

The CPP and GMP Certificates will continue to be valid for a maximum period of one year from the date they are issued.

Explanatory Notes will now be attached to the last page of the certificate instead of a separate document included in the package (see example in Appendix B).

Features of an Electronic CPP and GMP Certificate

Electronic CPP or GMP Certificates will be signed with an electronic signature that uses a certificate-based digital ID to authenticate the signer's identity and demonstrate proof of signing. The validity of the signature can only be viewed electronically. The certificate will also be locked to:

- Protect the integrity of the certificate and prevent any modifications to the document from being made after it is signed.
- Prevent the content in the certificate from being copied.

All electronically signed certificates will be sent **by email only** to the email address which was used to submit the application.

Letter of Authorized Signatories

A Letter of Authorized Signatories will be included with all issued CPP and GMP Certificates in order to validate the signature found on the certificates.

Stamping documents and Affidavits

During the first phase of this pilot, all copies of product information, including notarized Request for Stamping Form product labels, product information, product monographs, lists of excipients and others which are generally submitted to support an application for a certificate and intended to be appended to the certificate will **not be accepted** until further notice. Requests for Affidavits will also **not be accepted** at this time.

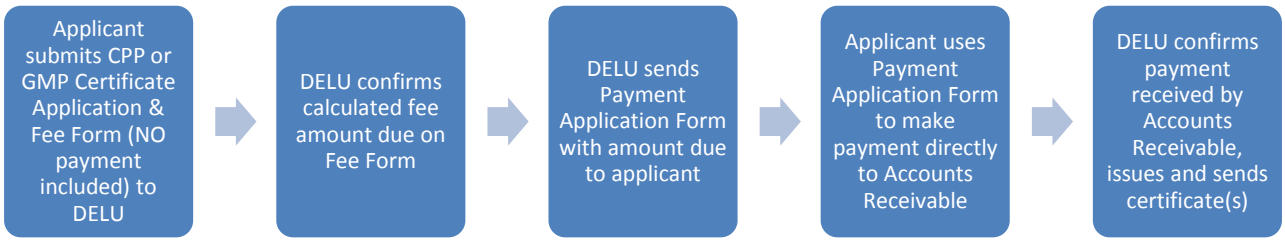
Paper certificate requests

All applications that were mailed to Health Canada from March 13, 2020 to present must be resubmitted electronically following the new process.

All applications that were received and pending issuance before March 13, 2020 for which payments have already been processed must be resubmitted electronically but will not be subject to additional charge. Please mention if you fall under this category within your cover letter. If you no longer require the certificate(s) for which payment was already processed, please contact us at hc.cpp.questions.sc@canada.ca to arrange a refund of payment.

How to apply

The diagram below illustrates the new process for obtaining electronic CPP and GMP Certificates. Instructions on how to apply and make a payment are detailed below.



1. Email the Drug Establishment Licensing Unit (DELU) within Health Canada at hc.cpp.questions.sc@canada.ca.

2. Fill out the following electronic fillable forms that are sent automatically through the auto-reply:

    - Application Form: Certificate of a Pharmaceutical Product (FRM-0454) if the request is specific to a pharmaceutical product.
    - Application Form: Good Manufacturing Practices Certificate (FRM-0455) if the request is not specific to a single product.
    - NEW Fee Form-Certificate of a Pharmaceutical Product and Good Manufacturing Practice Certificate (FRM-0456)
        - Fill out the "Bill To" information and calculate the amount due for your application using the calculation found in appendix A. One fee form should be submitted when applying for multiple certificates at the same time.

3. Sign the application forms electronically and save them in PDF format only.

4. Include Letter of Authorization if the applicant is not a DIN holder (for a CPP) or a DEL holder (for a GMP certificate) or if you are a consultant representing the DIN or DEL holder.

Health Canada will require a written authorization from both DIN or DEL holder since information on the certificates is confidential.

If the applicant does not provide such confirmation, the application will be rejected.

5. Ensure that applications are not locked or protected with a password.

6. Submit your CPP and GMP Certificate application with the following subject line: “CPP Application(s)”, “GMP Certificate Application(s)” or “CPP and GMP Certificate Application(s)” to DELU by email at: hc.cpp.questions.sc@canada.ca. Please indicate the number of certificates (including number of supplemental certificates requested in the application).

Tip: Please ensure that the application form(s), letter of authorization (if applicable) and the fee form are all sent in the **same** email.

Application Checklist

To ensure all documents are adequately completed, signed and submitted in the email, refer to the checklist below before submitting the application. Following this checklist will ensure that certificates can be issued without delay.

Type of Application	Sections to be completed
☐ CPP application	☐ Cover letter (recommended) ☐ Application form completed and signed (PDF format) ☐ Fee form completed and signed (PDF format) ☐ Letter of authorization if the applicant is not the DIN owner or you are a third party representative
☐ GMP Certificate application	☐ Cover letter (recommended) ☐ Application form completed and signed (PDF format) ☐ Fee form completed and signed (PDF format) ☐ Letter of authorization if the applicant is not the DEL holder or you are a third party representative

How to submit payment

DELU will **no longer be accepting payments with CPP and/or GMP Certificate applications.** The payments will now be **sent directly to Accounts Receivable**.

Once the submitted Fee Form (FRM-0456) is verified and confirmed by DELU, the applicant will be emailed a **Payment Application Form** with the confirmed amount due and instructions on how to **submit this payment to the Accounts Receivable Unit** at Health Canada.

Important: If payment is received with the application directly by DELU, applicants will be notified that the application will not be processed until payment is submitted to Accounts Receivable.

Fees can be paid to **Accounts Receivable** using any payment method, including any existing credit on a Health Canada account. Applicants are encouraged to pay using online banking via a Canadian financial institution, credit card **by telephone or fax,** or lump sum payment to prevent any delays in the issuance of a certificate. Certificate(s) will only be issued to the applicant when payment has been received and confirmed by Health Canada.

***Only one Fee Form is required if CPP and GMP certificate applications are being submitted together.**

Certificate Processing

Health Canada aims to issue CPP or GMP Certificates within 15 business days from receipt of a request. Certificate(s) will only be issued to the applicant when payment has been received and confirmed by Health Canada.

If a regulatory authority of the importing country has any questions or doubt with respect to the authenticity, integrity or validity of an electronic certificate issued by Health Canada, they can contact DELU directly at hc.cpp.questions.sc@canada.ca. The request must include the electronic certificate provided to the regulatory authority of the importing country for which the authenticity, integrity or validity is sought.

Health Canada aims to reply to request for authenticity, integrity or validity of an electronic certificate as soon as possible or within 5 business days of receipt of request. DELU will respond by providing a copy (electronically marked as duplicate) of the electronic certificate directly to the importing authority.

If Health Canada discovers or receives information that a product, which has been exported under the WHO Certification Scheme, has any new serious hazards associated with it or if any criminal abuse of the Scheme is found, such as export of false or forged certificates, falsely labelled, deceitful, counterfeited or substandard pharmaceutical product, Health Canada will notify WHO and importing authorities immediately.

Contact Us

For any questions, information or help with the electronic CPP or GMP Certificate application process, please contact the Drug Establishment Licensing Unit by email at hc.cpp.questions.sc@canada.ca.

For help determining your customer number or how to make payments please contact Accounts Receivable at:

Telephone: 1-800-815-0506 or (613) 957-1052
Facsimile: (613) 957-3495
Email: hc.ar-cr.sc@canada.ca

Appendix A

The fee for a CPP and GMP certificate application can be calculated as follows:

Application Fee = number of certificates requested x Fee for a CPP and/or GMP Certificate + applicable taxes (found in table below).

Table 1: Applicable Taxes by province

Province	Type of Tax	Rate/Percentage Taxes	Total Tax Rate
Alberta	GST	5%	5%
British Columbia	GST + PST	5% + 7%	12%
Manitoba	GST + PST	5% + 7%	12%
New Brunswick	HST	15%	15%
Newfoundland and Labrador	HST	15%	15%
Northwest Territories	GST	5%	5%
Nova Scotia	HST	15%	15%
Nunavut	GST	5%	5%
Ontario	HST	13%	13%
Prince Edward Island	HST	15%	15%
Quebec	GST + QST	5% + 9.975%	14.975%
Saskatchewan	GST + PST	5% + 6%	11%
Yukon	GST	5%	5%

Appendix B – Health Canada Certificate examples and explanatory notes

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization

(Superscript numbers refer to explanatory notes located at the end of the certificate)

Exporting (certifying country): No. of certificate:

Importing (requesting country):

1. Name and dosage form of the product:

1.1. Active ingredient(s)[2] and amount(s) per unit dose[3]:

For complete composition including excipients, see attached[4]:

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] (yes/no)

1.3 Is this product actually on the market in the exporting country?

If the answer is yes, continue with section 2A and omit section 2B.

If the answer is no, omit section 2A and continue with section 2B[6]:

2.A.1. Number of product licence[7] and date of issue:

2.A.2. Product licence holder (name and address):

2.A.3. Status of product licence holder[8]: (Key in appropriate category as defined in note 8)

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is[9]:

2.A.4. Is a summary basis for approval appended?[10] (yes/no)

2.A.5. Is the attached, officially approved product information complete and consistent with the licence?[11] (yes/no/not provided)

2.A.6. Applicant for certificate, if different from licence holder (name and address)[12]:

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

2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[9]

2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)

2.B.4. Remarks[13]:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable)[14]

If not or not applicable, proceed to question 4.

3.1. Periodicity of routine inspections (years):

3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15] (yes/no/not applicable)[14]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16]: (yes/no)

If no, explain:

Address of certifying authority:

Regulatory Operations and Enforcement Branch
Health Product Compliance Directorate
200 Eglantine Driveway, Tunney's Pasture
Ottawa, Ontario
K1A 0K9

Signature: _____

Date:

Name of authorized person:

This certificate expires 1 year from the date of issue

Explanatory Notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
    a. manufactures the dosage form;
    b. packages and/or labels a dosage form manufactured by an independent company; or
    c. is involved in none of the above.
9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
    a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    b. the product has been reformulated with a view to improving its stability under tropical conditions;
    c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e. any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs 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. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information 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.

GOOD MANUFACTURING PRACTICE CERTIFICATE

(Superscript numbers refer to explanatory notes located at the end of the certificate)

Exporting (certifying country): No. of certificate:

Importing (requesting country):

1. Name and dosage form of the product:

1.1. Active ingredient(s)[2] and amount(s) per unit dose[3]:

For complete composition including excipients, see attached[4]:

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] (yes/no) N/A

1.3 Is this product actually on the market in the exporting country? N/A

If the answer is yes, continue with section 2A and omit section 2B.

If the answer is no, omit section 2A and continue with section 2B[6]:

2.A.1. Number of product licence[7] and date of issue:

2.A.2. Product licence holder (name and address):

2.A.3. Status of product licence holder[8]: (Key in appropriate category as defined in note 8)

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is[9]:

2.A.4. Is a summary basis for approval appended?[10] (yes/no)

2.A.5. Is the attached, officially approved product information complete and consonent with the licence?[11] (yes/no/not provided)

2.A.6. Applicant for certificate, if different from licence holder (name and address)[12]:

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

2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[9]

2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)

2.B.4. Remarks[13]:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable)[14]

If not or not applicable, proceed to question 4.

3.1. Periodicity of routine inspections (years):

3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15] (yes/no/not applicable)[14]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16]: (yes/no)

If no, explain:

Address of certifying authority:

Regulatory Operations and Enforcement Branch
Health Product Compliance Directorate
200 Eglantine Driveway, Tunney's Pasture
Ottawa, Ontario
K1A 0K9

Signature: _____

Date:

Name of authorized person:

This certificate expires 1 year from the date of issue

Explanatory Notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
    a. manufactures the dosage form;
    b. packages and/or labels a dosage form manufactured by an independent company; or
    c. is involved in none of the above.
9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
    a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    b. the product has been reformulated with a view to improving its stability under tropical conditions;
    c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e. any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs 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. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information 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.