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Guidance Document

Certificates of Supplementary Protection

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Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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2018/09/04	Updated in accordance with the new email address and other updates made in response to stakeholder questions	1.2 1.4 2.1 2.2.1 2.2.2 2.2.4 2.2.5 2.2.7.3 2.2.8 2.5	The updates to the Guidance Document are being made following the amendment to a Health Canada email address. Additional amendments were made to correct or complete information
2019/05/15	Updated in accordance with the new Health Products and Food Branch organizational structure, new instructions on fee payment and new instructions on filing a CSP application	Throughout, for example: 1.3 1.4 2.2.1 2.5 Page 1 2.1 2.5	Change in Health Products and Food Branch organizational structure Changes to instructions on fee payment and filing a CSP application Miscellaneous changes
2021/01/06	Updated in accordance with the January 6, 2021 amendment to the <i>Certificate of Supplementary Protection Regulations</i>	2.2.2	Addition of the United Kingdom to the list of prescribed countries

2023/05/12	Updated to reflect current administrative practices and amendments to the <i>Certificate of Supplementary Protection Regulations</i>	1.4	Changes to the definition of “Authorization for sale”
		2.2.7.1	
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		Throughout, for example:	Reflect current administrative practices, such as aligning the definition of a filing date with the Management of Drug Submissions and Applications Guidance Document and how to provide a CSP application and related correspondence
		2.1	
		2.2.2	
		2.2.7.2	
		2.2.8	
		2.8	
2023/11/16	Updated to reflect new instructions on filing a CSP application	2.1	New instructions on filing a CSP application
		2.2.1	
		2.2.3	
		2.5	

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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1. Introduction

1.1 Policy objectives

In agreeing to apply the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), Canada has committed to provide up to two years of sui generis (of its own kind) protection for new pharmaceutical products protected by an eligible patent, from the expiry of the patent. Canada has implemented this commitment by introducing Certificates of Supplementary Protection (CSPs) for medicinal ingredients, applicable for Canadian pharmaceuticals, biologics and veterinary drugs.

1.2 Policy statements

The CSP regime implements Canada's commitment in CETA by providing for an additional period of protection for drugs containing a new medicinal ingredient, or a new combination of medicinal ingredients, protected by an eligible patent. This new protection, which is intended to partly compensate for time spent in research and obtaining marketing authorization, provides patent-like rights in respect of drugs containing a medicinal ingredient or combination of medicinal ingredients.

1.3 Scope and application

The purpose of this Guidance Document is to outline the CSP application process for applicants, the service standard and the roles and responsibilities of applicants and Health Canada.

1.4 Background

The Office of Patented Medicines and Liaison (OPML), within the Office of Submissions and Intellectual Property, Resource Management and Operations Directorate, Health Products and Food Branch, Health Canada, administers the CSP provisions of the Patent Act and the Certificate of Supplementary Protection Regulations (CSP Regulations).

The CSP regime is substantially defined in the amendments to the Patent Act introduced by the Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act, which came into force on September 21, 2017. However, the CSP Regulations provide various related timelines, requirements and procedures that are needed to administer the CSP regime.

In light of the requirements of the Patent Act and CSP Regulations, a CSP can issue only in respect of an eligible medicinal ingredient or combination of medicinal ingredients and an eligible patent.

Definitions

Authorization for sale means an authorization under the Food and Drugs Act, or any predecessor enactment relating to the same subject matter, that permits the sale of a drug in Canada, but does not include an interim order permitting the sale of a drug under section 30.1 of that Act, a certificate issued under section C.08.015 of the Food and Drug Regulations (FDR), an exemption under subsection C.10.002(1) or C.10.008(1) of those Regulations or an authorization under section C.05.006, C.05.008 or C.08.010 or subsection C.11.003(1) or

C.11.014(1) of those Regulations, section 67 or 71 of the Natural Health Products Regulations or section 21 or subsection 24(2) of the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations.

The definition of “authorization for sale” in subsection 1(2) applies to the CSP Regulations and for the purposes of section 104 of the Patent Act. However, section 4 of the CSP Regulations limits the prescribed kind of authorization for sale for the purpose of paragraph 106(1)(c) of the Patent Act to a Notice of Compliance (NOC) issued under section C.08.004 or C.08.004.01 of the FDR.

Filing date of the submission refers to the date that the submission is deemed administratively complete by Health Canada (i.e., once all elements and forms required for processing are completed and submitted to Health Canada). This date may differ from the date of original receipt should the submission be considered administratively incomplete at that time. This definition applies to a submission for an NOC under the FDR.

In the Drug Submission Tracking System - Industry Access, the filing date of a submission is indicated in the field “CR Date”.

Drug means a substance or a mixture of substances manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals or
- b) restoring, correcting or modifying organic functions in human beings or animals

Minister means the Minister of Health.

2. Guidance for implementation

2.1 General

How to provide a CSP application and related correspondence to Health Canada

CSP applications and related correspondence must be submitted electronically, preferably by email as outlined below, and no duplicate copy should be sent. Paper forms and other paper correspondence will not be accepted. Should applicants wish to provide information electronically by other means, please contact the OPML in order to make alternate arrangements. However, please note that CSP applications and related correspondence cannot be accepted in electronic Common Technical Document (eCTD) or “non-eCTD electronic-only” formats.

By email:

Emails must be sent to opml-bmbl@hc-sc.gc.ca.

- The sender assumes the risk of transmitting confidential or sensitive information through email.
- The maximum email size accepted by the corporate mail server is 20 megabytes.

- The email should only contain the documents. No other information is necessary.
- Documents contained in the email should **not** be password protected.
- The subject line of the email should include **one** of the following statements:
 - “NEW CSP APPLICATION”,
 - “CSP CORRESPONDENCE FOR <Application Number (if known)>”,
 - “CSP CORRESPONDENCE FOR <Application Number and Court File Number (if known)>”.

How to provide payment information

For instructions on how to make a payment, applicants are encouraged to consult the “How to pay” (<https://www.canada.ca/en/health-canada/services/funding/cost-recovery-service-fees.html>) document available on the Cost recovery and service fees for Health Canada webpage or to contact Health Canada by phone at 1-800-815-0506 or by email at ar-cr@hc-sc.gc.ca. Anyone can pay the fee on behalf of the applicant. An agent must use the applicant’s CSP Customer Number when paying on behalf of the applicant.

In order to ensure the Minister has sufficient information to process the CSP application and to reconcile payments made with related CSP applications, the applicant’s CSP Customer Number must be inputted in the appropriate field of the CSP application form and should be included in any correspondence regarding fee payments. Please contact the OPML at the email address provided in section 2.1 of this Guidance Document in advance of a CSP application filing deadline in order to obtain a CSP Customer Number or to confirm an existing CSP Customer Number, if it is not known.

Credit card payment information cannot be included on the CSP application form or accepted by email. This requirement is to ensure that credit card payment information is not captured within Health Canada’s document repository.

2.2 Procedures

2.2.1 Filing a CSP application

In order to file a CSP application, the applicant must:

- 1) Pay the required fee
- 2) Complete the CSP application form online, including the description of the method of payment used to pay the fee, and submit the information from the form saved in .xml format

2.2.2 Timing requirements and time sensitive requirements

Attestation as to timely submission

Paragraph 106(1)(f) of the Patent Act establishes a timely submission requirement, through which the New Drug Submission (NDS) set out in the CSP application must be filed with Health Canada either before or within a 12-month period starting on the date on which the first approval was sought in one of the countries enumerated in paragraph 6(1)(a) of the CSP

Regulations for a drug containing the same medicinal ingredient or combination of medicinal ingredients as contained in the drug for which the NDS was filed.

The applicant must select one of the two timely submission attestation options on the CSP application form. The applicant must attest in the CSP application as to either:

- 1) when it filed its application for the authorization for sale in Canada (i.e. an NDS), no application for a marketing approval equivalent to an authorization for sale, with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, had been submitted in a country prescribed by paragraph 6(1)(a) of the CSP Regulations (the European Union and any country that is a member of the European Union, the United States of America, Australia, Switzerland, Japan, and the United Kingdom); or
- 2) if one or more of those applications for a marketing approval had been submitted in one or more of those countries, the NDS was filed before the end of the
 - i) 24-month period, if the application for a CSP was filed no later than the first anniversary of the day on which section 59 of the CETA Implementation Act comes into force, or
 - ii) 12-month period, in any other case,prescribed in paragraph 6(1)(b) of the CSP Regulations that begins on the date of submission of the first of those marketing approval applications.

In order to determine the filing date of the NDS in Canada, applicants should rely on the definition of “filing date of the submission” provided in subsection 1.4 above under the heading “**Definitions**”. An applicant that is also the manufacturer associated with an NDS is able to access filing date information about its own submission through the Drug Submission Tracking System – Industry Access. The filing date is listed in the “CR Date” field.

An “application for a marketing approval equivalent to an authorization for sale” is an application for approval in a prescribed foreign country permitting the regular sale of any drug that contains the same medicinal ingredient or combination of all medicinal ingredients as the drug for which the NDS was filed. In order to determine the date of submission (filing date) of an “application for a marketing approval equivalent to an authorization for sale”, the applicable regulatory provisions or practices in the foreign country in which that application was filed apply. Applicants are expected to have knowledge of the relevant provisions or practices relating to their application for marketing approval in the foreign country.

Applicants are responsible for determining the relevant “application for a marketing approval equivalent to an authorization for sale” and for making the appropriate attestation. In making a determination of what type of approval is equivalent (i.e., one that permits the regular sale and what does not), applicants should have regard to the exceptions in the definition of “authorization for sale” in subsection 1(2) of the CSP Regulations.

In determining whether the requirement of paragraph 106(1)(f) of the Patent Act has been met, Health Canada will compare the date attested by the applicant in Part 8 of the CSP application form with the filing date of the NDS in Canada.

Attestation as to applicant

The applicant must attest at the time of filing the CSP application that it is either:

- 1) the patentee and is recorded as an owner of the patent in the Canadian Intellectual Property Office (CIPO) or
- 2) a manufacturer who is authorized by the person recorded in the CIPO as the owner of the patent to file a CSP application that sets out the patent on their behalf if the Notice of Compliance was issued to that manufacturer.

Timing for applying for the CSP

In accordance with subsection 106(3) of the Patent Act and subsection 6(2) of the CSP Regulations, a CSP application must be filed before the end of the 120-day period that begins on either:

- 1) the day on which the NOC is issued in respect of the NDS identified in the application, where the application is made on the basis of a patent granted on or before that day; or
- 2) the day on which the patent is granted, where the application is made on the basis of a patent granted after the day on which the NOC is issued in respect of the NDS identified in the application.

Patent in force and not void

According to paragraph 106(1)(a) and section 113 of the Patent Act and subsection 3(1) of the CSP Regulations, at the time of filing the CSP application and at the time of CSP issuance, the patent cannot be void, rather it must still be in force. Subsection 107(2) provides that the Minister shall notify the applicant of a refusal to issue a CSP and of the grounds for that refusal if the Minister is satisfied that any of the requirements in section 106 are not met, which include that the patent not be void or expired under paragraph 106(1)(a).

When CSP to take effect

According to subsection 116(2) of the Patent Act, a CSP takes effect upon the expiry of the term of the patent set out in the CSP if the patent remains valid until the expiry of that term.

Subsections 116(3) and (4) of the Patent Act provide details on calculating the term of a CSP. The CSP term is calculated by subtracting the Patent filing date from the NOC issuance date, minus 5 years, to a maximum of two years. Because subsection 116(3) uses the words “beginning” and “ending” on particular dates, according to subsection 27(3) of the Interpretation Act, the term includes those days.

If the term is for the maximum of two years, then the CSP term begins the day after the expiration of the underlying patent, and then the term ends two years later, including in the calculation both the “CSP Term Begins” date and the “CSP Term Ends” date. For example, if the CSP term began on September 21, 2017, and if it expires exactly two years later, the CSP would expire on September 20, 2019.

If the term is for less than two years, then the CSP term begins the day after the expiration of the underlying patent, and then it ends on the date according to the above calculation, including both the “CSP Term Begins” date and the “CSP Term Ends” date. For example, if the NOC issued on December 31, 2017 and the patent was filed on January 1, 2012, the calculation would be as follows:

CSP Term = [NOC date – patent filing date] – 5 years

CSP Term = [December 31, 2017 – January 1, 2012] – 5 years = 6 years - 5 years = 1 year

The patent will expire 20 years from the patent filing date, which is January 1, 2032. Therefore, the CSP term would begin on January 2, 2032, and if it expired exactly one year later, the CSP would expire on January 1, 2033.

Conflict timing requirements

According to subsection 113(c) of the Patent Act, Health Canada may only issue a CSP once there are no other pending CSP applications for the same authorization for sale, and of the same or higher priority. In order to avoid deemed expiry of conflicting CSP applications, action must be taken by the end of the prescribed periods to resolve the conflict by withdrawing a CSP application(s) and/or by means of proceedings under section 110 of the Patent Act. Section 110 proceedings are described in section 2.2.4 of this Guidance Document.

Timing requirement for reissuance

According to section 122 of the Patent Act and section 14 of the CSP Regulations, if there is a reissuance of the patent set out in a CSP or CSP application, Health Canada must be notified in writing of the new patent number before the end of the 30-day period that begins on the day on which the new patent is issued. Additional details on the reissuance procedure are provided in section 2.2.10 of this Guidance Document.

Time limits deemed extended

Subsection 132(1) of the Patent Act provides for prescribed or designated days. Until such time when specific days are prescribed or designated, section 26 of the Interpretation Act and its definition of “holiday” applies to any deadlines falling on a weekend or statutory holiday.

Filing date of a CSP application

According to section 7 of the CSP Regulations, the filing date of a CSP application is the date on which the information required by subsection 106(5) of the Patent Act and subsection 6(3) of the CSP Regulations is received by Health Canada. As such, the filing date for a CSP application assigned by Health Canada will be the date on which a CSP application form, which includes the description of the method of payment used to pay the application fee, is received by Health Canada.

2.2.3 Initial Processing of CSP applications

In order to ensure the Minister has sufficient information to process the CSP application, the applicant’s CSP Customer Number must be inputted in the appropriate field of the CSP

application form. The OPML should be contacted at the email address provided in section 2.1 of this Guidance Document in advance of a CSP application filing deadline in order to obtain a CSP Customer Number or to confirm an existing CSP Customer Number, if it is not known. It may take up to five business days to provide CSP Customer Number information.

Upon receipt, Health Canada will assign and insert on the CSP application form a CSP application number.

If, upon receipt it is determined that the CSP application form is incomplete or if Health Canada requires additional information, in accordance with subsection 107(1) of the Patent Act Health Canada may request any additional information from the applicant that it considers necessary to complete the processing of the CSP application. See section 2.2.9 of this Guidance Document for an explanation of the procedure for correction of obvious errors and omissions for CSP applications.

Information relating to CSP applications will be made publicly available on Health Canada's online Register of Certificates of Supplementary Protection and Applications.

Since Health Canada is required to maintain an electronic register, the applicant is encouraged to check the online Register of Certificates of Supplementary Protection and Applications to confirm that the CSP application has been received.

2.2.4 Conflict/priority scheme

The Patent Act requires that only one CSP will be granted for a given medicinal ingredient or combination. The Patent Act outlines what happens in situations where conflicting applications are submitted that set out the same authorization for sale and have the same priority.

Priority groups

CSP applications filed before the end of the 120-day period that begins on the day on which the NOC is issued in respect of the NDS identified in the application, where the application is made on the basis of a patent granted on or before that day have the highest priority and are all of the same priority regardless of the CSP application filing date or the patent grant date. CSP applications made on the basis of a patent granted after the day on which the NOC is issued in respect of the NDS identified in the application have lower priority, according to section 108 of the Patent Act. Among CSP applications where all the patents were granted after the NOC issued, a patent with an earlier grant date has priority over a patent granted on a later date, and patents granted on the same date have the same priority.

What is a conflict?

A "conflict" can be said to occur when two or more CSP applications cite the same NOC and have the same and highest priority.

First 120-day period that begins on the day on which the NOC is issued

According to subsection 113(b) of the Patent Act, Health Canada may only issue a CSP once the applicable period for filing a CSP application under subsection 106(3) has ended. Further, according to paragraph 106(3)(a) of the Patent Act, any CSP application made on the basis of a

patent that was granted on or before the day on which the NOC is issued in respect of the NDS identified in the application must be filed before the end of the 120-day period that begins on the day on which the NOC is issued. As such, during the 120-day period, additional CSP applications relying on a patent that was granted on or before the NOC issuance (and thus in the highest priority group) may be filed. CSP applications filed during the 120-day period will not be assessed until the 120-day period expires, at which time it becomes possible to determine with certainty if there are any other conflicting CSP applications. If, at the end of the 120-day period, there is only one application, that CSP application will be assessed for eligibility for a CSP. If the CSP application leads to issuance of a CSP, any other pending CSP applications of lower priority will expire on the CSP issuance date, according to subsection 111(2) of the Patent Act.

However, if there is more than one CSP application of the same priority pending at the end of the 120-day period, in accordance with section 109 of the Patent Act, Health Canada will send a written notice to the conflicting applicants to notify them of the conflict. This notice will include the name and contact information of the conflicting applicants, as well as the patent number set out in each CSP application. The date of the written notice is used to calculate the timeline for expiry of the conflicting applications.

No CSP applications filed during first 120-day period

If there are no CSP applications pending that were filed before the end of the 120-day period that begins on the day on which the NOC is issued in respect of the NDS identified in the application, then any subsequent CSP application will be based on a patent that was granted after the day on which the NOC is issued. As per paragraph 106(3)(b) of the Patent Act, these applications must be filed before the end of the 120-day period that begins on the day on which the patent is granted. If there is more than one such application, the CSP application with the earliest patent grant date has the highest priority. If two CSP applications set out patents that were granted on the same day after the day on which the NOC is issued and are of the highest priority, Health Canada will send a written notice of the conflict, as described above, to all conflicting applicants. Otherwise, the highest priority application will be assessed following the end of the 120-day period that begins on the day on which the patent is granted, in accordance with subsection 113(c) of the Patent Act, at which time it becomes possible to determine with certainty if there are any other conflicting CSP applications or applications of a higher priority.

Withdrawal of CSP application

A CSP application may be withdrawn according to section 112 of the Patent Act, which can be used to resolve conflicts. The withdrawal procedure is provided under section 12 of the CSP Regulations, and allows the applicant to notify Health Canada of the withdrawal. Health Canada will then make a note of the withdrawal in its records and may update the Register of Certificates of Supplementary Protection and Applications to remove the CSP application in accordance with subsection 120(2) of the Patent Act.

Expiry of CSP applications in the case of a conflict

According to section 111 of the Patent Act and section 11 of the CSP Regulations, if two or more CSP applications set out the same NOC and are deemed to have the same priority and are still pending at the end of the 90-day period that begins on the day specified in the written notice of the conflict sent under section 109 of the Patent Act, all of those CSP applications expire at the end of that period, unless conflict proceedings under section 110 are commenced before the end of the 90-day period.

Conflict proceedings under section 110 of the Patent Act

Conflicts may be resolved under section 110 of the Patent Act by seeking a declaration that a CSP application is invalid or void in the Federal Court. Only CSP applicants having CSP applications of the same priority may commence such proceedings. A section 110 proceeding must be commenced before the end of the 90-day period that begins on the day specified in the written notice of the conflict from Health Canada. If a section 110 proceeding is commenced, such CSP applications, if two or more are still pending, expire at the end of the 30-day period that begins on the day on which the last of any of the proceedings to be completed is finally disposed of. The words “finally disposed of” mean that the proceeding under section 110 has concluded and all periods for appealing the decision, or seeking leave to appeal, have ended or expired. This allows sufficient time for CSP applications to be withdrawn, should there still be more than one CSP application pending once the last of any of the proceedings to be completed has been finally disposed of. At the end of the 30 day-period, if two or more conflicting CSP applications are still pending, they will be deemed expired. If one CSP application is pending before the end of the 30-day period, it will be assessed for eligibility for a CSP. According to subsection 113(d) of the Patent Act, no CSP may issue until all conflict proceedings have been finally disposed of.

Section 110 proceeding and appeal notification to Health Canada

Anyone who commences a section 110 proceeding, or an appeal or application for leave to appeal with respect to such a proceeding, must notify Health Canada of the proceeding by providing any document that commences the proceeding and any document that marks the end of the proceeding in accordance with subsection 110(3) of the Patent Act. Notification should be sent in accordance with section 2.1 of this Guidance Document.

2.2.5 Issuance and rejection procedures

Health Canada will issue a CSP pursuant to section 113 of the Patent Act.

The subsection 113(a) analysis will not begin until the applicable period referred to in subsection 106(3) for filing the application has ended, as described in section 2.2.2 of this Guidance Document under the subheading “Timing for applying for the CSP”. In addition, timing requirements with respect to priority and section 110 proceedings must have been met.

If the CSP application is eligible for issuance, Health Canada will calculate the term of protection in accordance with subsections 116(3) and (4) of the Patent Act. The Certificate will set out the information required in section 114 of the Patent Act. A copy of the CSP will be sent to the

applicant through the contact information provided by the applicant. Health Canada will also reflect the issuance on the Register of Certificates of Supplementary Protection and Applications. According to subsection 116(2) of the Patent Act, a CSP takes effect upon the expiry of the patent set out in the CSP.

If Health Canada takes the view that a CSP application is ineligible for a CSP, the applicant will be provided with a preliminary rejection letter and a period to submit written representations. The written representations should be submitted as described in subsection 2.1 above. Upon receiving written representations from the applicant, if any, a final decision as to the eligibility of the CSP application will be rendered to either issue the CSP or finally reject the CSP application.

Addition of CSPs to the Patent Register

Once issued, all CSPs will be assessed by Health Canada for eligibility to be added to the Patent Register in accordance with subsection 4(3.1) of the Patented Medicines (Notice of Compliance) Regulations without requiring a separate form or request from the first person.

2.2.6 Service standard

There is a service standard associated with the fee prescribed in the CSP Regulations.

The service standard is 60 calendar days (average) for the first eligibility decision beginning the day there are no conflicting CSP applications of the highest priority and the time for filing a CSP application having the same or higher priority has ended.

According to this standard, Health Canada will inform the applicant either that the CSP has issued or that the CSP application has been preliminarily rejected with an opportunity to provide representations, within an average of sixty calendar days. If the CSP is issued, this represents a first and final decision regarding eligibility. If the CSP application is rejected, this represents a first decision regarding eligibility. An average of sixty calendar days was selected as the target to provide sufficient time for communications, when necessary, between the applicant and Health Canada.

If there are no CSP applications filed before the end of the 120-day period that begins on the day on which the NOC is issued in respect of the NDS identified in the application, the highest priority CSP application will be the one that sets out the patent with the earliest grant date. Measurement of the sixty calendar days will start from the day following the end of the 120-day period that begins on the day on which the patent is granted, since a CSP application will not be assessed until after it is determined that there are no other conflicting or higher priority CSP applications.

2.2.7 Eligible Medicinal Ingredients

A CSP can be issued only in respect of an eligible medicinal ingredient or a combination of all medicinal ingredients.

Eligible medicinal ingredients or combinations of medicinal ingredients must meet the requirements of paragraphs 106(1)(c), (d) and (e) of the Patent Act, applying subsections 105(3)

and (4) of the Patent Act and section 2 of the CSP Regulations. As such, in order to determine which medicinal ingredients or combinations of medicinal ingredients are eligible, it is first necessary to determine if the authorization for sale of the underlying submission was “an authorization for sale of the prescribed kind”. Once this has been established, it is necessary to determine if the authorization for sale is the first authorization for sale that has been issued with respect to the medicinal ingredient or combination of medicinal ingredients. Finally, it is necessary to confirm that no other CSP has been issued with respect to the medicinal ingredient or combination of medicinal ingredients.

2.2.7.1 Authorization for sale

Subsection 1(2) of the CSP Regulations defines an authorization for sale. However, according to section 4 of the CSP Regulations, an “authorization for sale of the prescribed kind” that can render a CSP application eligible for a CSP referred to in paragraph 106(1)(c) of the Patent Act is limited to an NOC issued under section C.08.004 or C.08.004.01 of the FDR. Eligible authorizations for sale (AFS) are therefore NOCs for drugs, biologics or veterinary drugs issued on or after September 21, 2017. The authorization for sale referred to in paragraph 106(1)(d) must be the same authorization for sale referred to in paragraph 106(1)(c). Further, the NDS in respect of which that authorization for sale was issued must have been filed in accordance with the timely filing requirement of paragraph 106(1)(f).

2.2.7.2 First authorization for sale in Canada

Once it is established that the NDS set out in the application resulted in the issuance of an NOC, then it must be determined whether that NOC is the first authorization for sale that has been issued with respect to the medicinal ingredient or combination of medicinal ingredients contained in the drug approved through the NOC. This requires a determination of whether there is a previous authorization for sale of any drug containing the same medicinal ingredient or combination of all medicinal ingredients.

Identification of medicinal ingredients

In order to determine whether the medicinal ingredient(s) has been previously authorized for sale, the medicinal ingredient(s) must first be identified. A medicinal ingredient is identified using the NOC and the pharmaceutical information in the NDS set out in the CSP application (e.g. Product Monograph) including the proper name, the chemical name, the molecular formula, the molecular mass, the structural formula and, where appropriate, the amino acid sequence. This information is then used to identify all the synonyms for the medicinal ingredient using a number of publicly available chemical databases.

Health Canada must then identify whether or not the medicinal ingredient is the same as a previously authorized medicinal ingredient in that it does not differ or differs only with respect to one or more variations.

Variations

Subsections 105(3) and (4) of the Patent Act and section 2 of the CSP Regulations provide that a medicinal ingredient is to be treated as the same as another medicinal ingredient if the

medicinal ingredients differ from each other only with respect to one or more of the following variations:

- a) a variation in any appendage within the molecular structure of a medicinal ingredient that causes it to be an ester, salt, complex, chelate, clathrate or any noncovalent derivative
- b) a variation that is an enantiomer, or a mixture of enantiomers, of a medicinal ingredient
- c) a variation that is a solvate or polymorph of a medicinal ingredient
- d) an in vivo or in vitro post translational modification of a medicinal ingredient and
- e) any combination of the variations set out in paragraphs (a) to (d)

Reference will be made to standard internationally recognized resources e.g., International Union of Pure and Applied Chemistry (IUPAC) Compendium of Chemical Terminology, when considering the structures of the appendages.

Any combinations of the prescribed variations described above are also considered to be the same medicinal ingredient (e.g., an ester and a salt; e.g., a salt and an enantiomer).

The word “appendage” in the context of medicinal ingredients, is considered to refer to a portion of the molecule that is connected or joined to a larger or more important part. It is considered to signify the non-principal part of the molecule which is not principally responsible for the mechanism of action of the medicinal ingredient.

Variations are identified by comparing the structure of the medicinal ingredient set out in the CSP application with previously authorized medicinal ingredients that have similar structures. The group of previously authorized medicinal ingredients is identified using the name of the medicinal ingredient under consideration, its mechanism of action and the therapeutic class of drugs to which it belongs.

Once the group of previously authorized medicinal ingredients with possible structural similarities has been identified, side-by-side comparisons are performed between the chemical structures of the medicinal ingredient under consideration and the previously authorized medicinal ingredients. Differences due to ester appendages, salt appendages, complex appendages, chelate appendages, clathrate appendages, any non-covalently bonded appendages and post-translational modifications (PTMs) are identified at this point.

Enantiomers, solvates and polymorphs are typically identified by comparing the name of the medicinal ingredient under consideration with the names of the previously authorized medicinal ingredients. However, whether a medicinal ingredient is an enantiomer, a solvate or a polymorph of a previously authorized medicinal ingredient can be confirmed through a side-by-side comparison of the chemical structures, which also allows an assessment of whether other variations are present.

PTMs are typically identified by comparing the name of the medicinal ingredient under consideration with the names of the previously authorized medicinal ingredients. The molecules will be compared to identify any differences in the structure that are due to PTMs (e.g., glycosylation, PEGylation).

Previous authorizations

The analysis of whether or not the medicinal ingredient has been previously authorized involves a search of Health Canada's databases to identify previous authorizations of the medicinal ingredient or combination of medicinal ingredients under consideration. All known names and synonyms of the medicinal ingredient are input as search criteria into the various databases.

Only certain types of previous AFSs can disqualify a CSP application from eligibility. An AFS is defined in subsection 1(2) of the CSP Regulations. This definition of AFS is intended to capture not only NOCs, but also other authorizations granted under predecessor enactments before the time when NOCs were granted, that allowed the regular sale of a drug in Canada (e.g., by way of an NOC, Drug Identification Number, or Natural Health Product Number). AFS includes any authorization that permitted the regular sale of a drug in Canada. Accordingly, the following limited purpose authorizations are excluded from the definition of AFS:

- an interim order permitting the sale of a drug under section 30.1 of the Food and Drugs Act
- the sale of a drug under a clinical trial application (FDR C.05.006 and C.05.008)
- the authorization to sell a drug for emergency treatment (e.g., Special Access Program (FDR C.08.010))
- the authorization for limited sale of a new drug for use in animals (experimental studies certificate) (FDR C.08.015)
- the sale of a drug imported into Canada to address an urgent public health need, including a drug shortage (FDR C.10.002(1) and C.10.008(1))
- the authorization for the sale of a specified quantity of a drug to address an actual, imminent or potential emergency, event or incident affecting public health or the health of members of the Canadian Armed Forces, including to a practitioner for use in the emergency treatment of a person under the care of that practitioner (FDR C.11.003(1) and C.11.014(1))
- the sale or import of a natural health product for the purposes of a clinical trial (sections 67 and 71 of the Natural Health Products Regulations) and
- The authorization or amendment to an authorization of a COVID-19 drug for the purposes of a clinical trial (section 21 and subsection 24(2) of the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations).

2.2.7.3 Previous CSP

Once it is established that the NOC is the first authorization for sale that has been issued with respect to a medicinal ingredient or combination of medicinal ingredients, for use in humans or in animals, as the case may be, there must be a determination that no other CSP has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be, in accordance with paragraph 106(1)(e) of the Patent Act.

According to subsection 106(2) of the Patent Act, a CSP is considered to have been issued even if that CSP is subsequently held to be invalid or void or it never takes effect or ceases to have effect. Health Canada will consult the Register of Certificates of Supplementary Protection and Applications in making this determination. In considering previous CSPs, regard must be paid to

subsections 105(3) to (6) of the Patent Act, which specify that a CSP may issue for human use and a separate CSP may issue for veterinary use for a medicinal ingredient or combination of medicinal ingredients that would otherwise be considered the same. It is possible, but not required, that both such CSPs may be based on the same patent.

2.2.8 Eligible Patents

A CSP can be issued in respect of an eligible patent that meets the requirements in paragraph 106(1)(c) of the Patent Act and subsection 3(2) of the CSP Regulations.

As such, the patent set out in the CSP application must pertain to a medicinal ingredient, or the combination of all medicinal ingredients, contained in a drug for which an NOC was issued on or after the day on which paragraph 106(1)(c) of the Patent Act came into force. Only one eligible claim is required to obtain a CSP. In addition, eligible patents must contain at least one of the following:

- a claim for the medicinal ingredient (in the case of a drug containing only one medicinal ingredient) or combination of all the medicinal ingredients (in the case of a drug containing more than one medicinal ingredient) contained in a drug for which the authorization for sale set out in the CSP application was issued
- a claim for the medicinal ingredient (in the case of a drug containing only one medicinal ingredient) or combination of all the medicinal ingredients (in the case of a drug containing more than one medicinal ingredient), as obtained by a specified process (product by process claim) contained in a drug for which the authorization for sale set out in the CSP application was issued or
- a claim for a use of the medicinal ingredient (in the case of a drug containing only one medicinal ingredient) or combination of all the medicinal ingredients (in the case of a drug containing more than one medicinal ingredient) contained in a drug for which the authorization for sale set out in the CSP application was issued

For patents that claim “a use” of the medicinal ingredient or combination of all the medicinal ingredients, the claimed use does not need to match the use approved by the NOC for the NDS set out in the CSP application, so long as the claimed use includes use in humans or animals, as the case may be.

Claims that are directed to a formulation containing the medicinal ingredient, including compositions, preparations or similar claim types, do not make a patent eligible for a CSP. A claim to a formulation does not protect the medicinal ingredient or combination of all the medicinal ingredients per se because a claim to a formulation includes other elements in addition to the medicinal ingredient(s). A claim to a formulation may be directed, for example, to the improvement of the stability of those medicinal ingredients. This is consistent with CETA, which only requires the protection of the medicinal ingredient or combination of medicinal ingredients “as such”.

The CSP Regulations prescribe that a combination may be an eligible claim type only when the claim is for the combination of **all** the medicinal ingredients, or uses thereof. Each of the medicinal ingredients must be specified in the claim. A medicinal ingredient may be specified, for example, in the following ways:

- name
- structure or sequence
- structure with defined R groups
- amino acid sequence found in the complementarity-determining regions of an antibody

A patent eligible for a CSP cannot be void according to paragraph 106(1)(a) of the Patent Act. A patent eligible for a CSP must be in force according to subsection 3(1) of the CSP Regulations.

As permitted in section 5 of the CSP Regulations, in conducting the assessment of patent eligibility, Health Canada may consult with the CIPO regarding any matter relating to the patent. The CIPO and/or the patent information recorded on the CIPO online Canadian Patents Database may also be consulted to verify that a patent is in force.

2.2.9 Correction of errors

According to subsection 15(1) of the CSP Regulations, either on the written request of the applicant or with the applicant's written consent, Health Canada may correct an obvious error or omission on the CSP application, and will notify the applicant when the correction has been made. However, no correction may be made to an erroneous patent number set out in the CSP application after the expiry of the 90-day period for commencing a proceeding referred to in subsection 110(2) of the Patent Act. If Health Canada identifies an obvious error or omission, it will request the applicant's written consent to make a correction, prior to making any correction.

According to subsection 15(2) of the CSP Regulations, Health Canada may also correct any obvious error or omission in a CSP on the basis of information that Health Canada had, or could have obtained, on the day of its issuance.

2.2.10 Reissuance procedure

According to section 122 of the Patent Act and section 14 of the CSP Regulations, if there is a reissuance of the patent set out in a CSP or CSP application, the CSP holder or applicant must notify Health Canada of the new patent number before the end of the 30-day period that begins on the day on which the new patent is issued. If more than one new patent is issued under the reissuance provision(s), the applicant shall provide the number for only one of the new patents.

If reissuance occurs at the CSP application stage and there are no conflict proceedings, once informed by the applicant of the new patent number, Health Canada will amend the CSP application to set out the new patent number.

According to subsection 122(5) of the Patent Act, if reissuance occurs at the CSP application stage and there are conflict proceedings, once informed by the applicant of the new patent number, Health Canada will amend the CSP application to set out the new patent number, and

provide written notice of the amendment to any other applicants who received the written notice of the conflict.

If the reissuance occurs after CSP issuance, once informed by the CSP holder of the new patent number, Health Canada will then issue a new CSP setting out the new patent number to replace the original CSP.

2.3 Scope of the CSPs

Subsection 115(1) of the Patent Act provides that the scope of the CSP is the same as that of the patent, but only with respect to the making, constructing, using or selling of any drug that contains the medicinal ingredient or combination of medicinal ingredients set out in the certificate, by itself or in addition to any other medicinal ingredient.

2.4 CSP ownership

CSP ownership follows that of the patent according to section 118 of the Patent Act. In order to transfer ownership of a CSP or a CSP application, one must transfer the ownership of the patent. The owner of the CSP or CSP application, recognized under the Patent Act and the CSP Regulations, is the owner of the patent set out in the CSP application, as recorded in the CIPO. Despite any changes of ownership recorded in the CIPO following the filing of the CSP application, Health Canada will continue to correspond with the original applicant according to the CSP application, unless Health Canada is advised otherwise in writing.

2.5 Completing the CSP application form

Applicant Information: All correspondence, other than billing correspondence (if a billing address is provided), will be sent to the applicant through the contact information provided in this section. The onus is on the applicant to keep this information up-to-date. To do so, the applicant should submit to Health Canada a request to change the contact information and provide such request in the manner described in section 2.1 of this Guidance Document.

Applicant contact information

Applicant Name: Enter the name of the applicant making the CSP application. See section 2.2.2 of this guidance document for information on the Attestation as to applicant.

Agent Name: Provide the name of the organization or person with the authority to correspond with Health Canada regarding the CSP application. Any organization or person having contact information in Canada may be named as the agent. If you are providing an agent name, then all contact information must be the agent's, except for the CSP Customer Number, which is unique to the applicant. If you wish to use the applicant's contact information, then please do not include an agent name on the application form even if you are using an agent.

CRA Business Number: Provide the nine-digit number that the Canada Revenue Agency has assigned to the applicant.

CSP Customer Number: Provide the applicant's CSP Customer Number in the appropriate field of the CSP application form. Please contact the OPML at the email address provided in section 2.1 of this Guidance Document in advance of a CSP application filing deadline in order to obtain a CSP Customer Number or to confirm an existing CSP Customer Number, if it is not known.

Names: Provide the name of a person with the authority to correspond with Health Canada on behalf of the applicant making the CSP application.

Job Title: Enter the job title of the person named.

Address (Street/Suite, City, Province, and Postal Code): Include the address in Canada at which the person named is located for purposes of the business of the applicant.

Telephone Number, Facsimile Number, and Email: Provide the telephone and facsimile number and email address of the person named whom may be contacted by Health Canada regarding the CSP application. This information will be used to contact the applicant regarding any issues with respect to the CSP application. Health Canada issues CSPs by sending an electronic certificate by e-fax to the facsimile number provided.

Billing contact information

Billing Address: Check the box, if applicable, to indicate that a different billing address will be used. The billing address will only be contacted should there be any issues with respect to the fee payment. Please note that an agent with multiple CSP applications may only have one billing address at any given time in respect of its CSP applications. The address may be updated, however multiple billing addresses are not permitted concurrently.

Organization Name: Provide the name of the organization with the authority to correspond with Health Canada regarding billing matters in the CSP application.

Names: Provide the name of the person with the authority to correspond with Health Canada on behalf of the applicant with respect to billing matters in the CSP application.

Job Title: Enter the job title of the person named with respect to billing matters.

Address (Street/Suite, City, Province, Country, and Postal Code): Include the address at which the person named is located for the purpose of addressing billing matters in the CSP application.

Telephone Number, Facsimile Number, and Email: Provide the telephone and facsimile number and email address, of the person named whom may be contacted by Health Canada regarding the billing matters for the CSP application. This contact information will be used to address any issues with the CSP application with respect to billing matters in the CSP application.

Canadian Patent Number: Provide the Canadian patent number in relation to which the certificate is sought. One CSP application is required for each patent number.

Patent Filing Date: Indicate the Canadian patent application filing date. The filing date of the patent must be on or after October 1, 1989 according to paragraph 106(1)(b) of the Patent Act.

Patent Date Granted: Enter the date on which the patent was granted by the CIPO.

Patent Expiration Date: Enter the date on which the patent term will expire.

New Drug Submission: Enter the NDS number listed on the NOC that was issued with respect to the medicinal ingredient or combination of medicinal ingredients; the NOC must meet the requirements set out in paragraphs 106(1)(c) and (d) of the Patent Act. According to paragraph 106(1)(d) of the Patent Act, the NOC must be the first authorization for sale that has been issued in Canada with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be. According to paragraph 106(1)(c) of the Patent Act, the NOC issuance date must be on or after the day on which that section came into force, namely September 21, 2017. That NDS must also have been filed in accordance with the timely submission requirement outlined in paragraph 106(1)(f) of the Patent Act.

Notice of Compliance (NOC) Date: Enter the date that appears on the NOC issued in respect of the NDS that is set out in the CSP application. Applicants may view this information on Health Canada's online NOC database, or they may request a copy of the NOC from Health Canada by email at the email address provided in section 2.1 of this Guidance Document.

Drug Use: Check the appropriate box to indicate whether the medicinal ingredient or combination of medicinal ingredients in respect of which the CSP is being sought is for human or veterinary use.

Timing of Application: The CSP application must meet one of two timing requirements. The CSP application must be filed before the end of the 120-day period that begins on either:

- 1) the day on which the NOC is issued in respect of the NDS identified in the application, where the application is made on the basis of a patent granted on or before that day; or
- 2) the day on which the patent is granted, where the application is made on the basis of a patent granted after the day on which the NOC is issued in respect of the NDS identified in the application.

Medicinal Ingredient(s): Enter the medicinal ingredient or medicinal ingredients included in the specific drug product in the NDS set out in the CSP application. Please enter the medicinal ingredient or medicinal ingredients exactly as they appear on the NOC for that NDS. Applicants may view this information on Health Canada's online NOC database, or they may request a copy of the NOC from Health Canada by email at the email address provided in section 2.1 of this Guidance Document.

Product Name: Enter the product name (brand name) included in the NDS set out in the CSP application. Please enter the product name exactly as it appears on the NOC for that NDS. Applicants may view this information on Health Canada's online NOC database, or they may request a copy of the NOC from Health Canada by email at the email address provided in section 2.1 of this Guidance Document.

Attestation as to applicant: Check the appropriate box to indicate the applicable attestation. See section 2.2.2 of this Guidance Document for additional details.

Attestation as to Timely Submission: Check the appropriate box to indicate the applicable attestation. See section 2.2.2 of this Guidance Document for additional details.

If applicable, please enter the date on which the first application for a marketing approval equivalent to an authorization for sale with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, was submitted in a country prescribed by paragraph 6(1)(a) of the CSP Regulations. If the first of those marketing approval applications was made to a member of the European Union, please enter the name of the specific country.

Fee payment and amount: Please check the box and enter the fee amount. The fee must be paid in Canadian currency to the account of the Receiver General of Canada, according to section 9 of the CSP Regulations. Beginning April 1, 2018, the fee increases annually by an amount equal to 2% of the fee payable in the previous year, rounded up to the nearest dollar. Health Canada will publish the fee increase in the Canada Gazette Part I annually. An applicant may apply to the Minister for a CSP on the payment of the prescribed fee. One of the filing requirements for a CSP application is the receipt of a description of the method of payment used to pay the fee, which is provided to the Minister through the CSP application form. For instructions on how to make a payment, applicants are encouraged to consult the “How to pay” (<https://www.canada.ca/en/health-canada/services/funding/cost-recovery-service-fees.html>) document available on the Cost recovery and service fees for Health Canada webpage or to contact Health Canada by phone at 1-800-815-0506 or by email at ar-cr@hc-sc.gc.ca. Anyone can pay the fee on behalf of the applicant. An agent must use the applicant’s CSP Customer Number when paying on behalf of the applicant.

Method of payment: Select the method of payment used to pay the application fee in accordance with paragraph 6(3)(e) of the CSP Regulations from the drop-down list. CSP application fee payments may be made using an existing credit on the applicant’s account, a cheque, a money order, a bank draft, a payment through a Canadian financial institution, a credit card, interact online, or a wire transfer.

Certification

Name of Authorized Official: Provide the name of the person with the authority to make the attestations and certification on behalf of the applicant making the CSP application.

Job Title: Enter the job title of the person making the attestations and certification.

Date: Provide the date of the attestations and certification.