swissmedic

Guidance document
for requesting product certificates (CPP)

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1 Introduction

Swissmedic issues confirmations on request for companies in Switzerland that hold a valid pharmaceutical establishment licence issued by Swissmedic. One type of confirmation is what is known as a product certificate (official term: Certificate of a Pharmaceutical Product; CPP), as described by the World Health Organization (WHO). Swissmedic issues CPPs according to the new format for product certificates (TRS 1033 - 55th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations; Annex 9). The CPP is an official confirmation for foreign regulatory bodies that describes the status of the companies concerned and the authorised medicinal product in a structured form.

Only authorisation holders or their authorised representatives can request CPP from Swissmedic. This applies both to authorisations for the Swiss market and to export licences. CPP cannot be issued for medicinal products that are manufactured but not authorised in Switzerland.

The applicant undertakes to provide only information that has been confirmed in a decision taken by Swissmedic and communicated to the authorisation holder. If different information is required, the status of the authorisation must first be updated by means of a separate application to Swissmedic. This applies, for example, to details of the manufacturer, composition of the medicinal product, shelf-life, dispensing category, etc.

Swissmedic generates the required CPP on the basis of the information in the request. However, Swissmedic reserves the right to check on a random basis that the information in the request is consistent with the authorisation dossier in Swissmedic's possession. Should discrepancies be found, the request for the CPP will be rejected and the company will be asked to update the authorisation status of the medicinal product by means of one or more applications for change before the CPP can be issued.

The form for requesting CPP and the guidance document for completing the form is available on the Swissmedic website at www.swissmedic.ch. The form is a file in Excel format with the extension xlsx. The extension and structure of the form used must not be changed, otherwise the order will be rejected. However, the name of the file can be chosen freely. The person placing the order must ensure that the currently valid published form is used.

The information in the request form is processed electronically at Swissmedic and converted directly into the CPP format defined by the WHO. Since the process is largely automated, it is particularly important that the information in the form is correct in order to avoid errors in the CPP.

This guidance is intended to guide you through the process of completing the request form. Comments are provided for each of the sections that are not self-explanatory and a reference is provided to the relevant section of the WHO format for CPP. They can also be found in the attachments to this guidance in English, Spanish and French.

2 Basic rules

- A separate request form must be completed for each product and dosage strength (sequence number), importing country and certificate language. The available certificate languages are English, Spanish or French.

- The content, form and language of all information in the request form will be transferred as it appears in the form. The only way of correcting the resulting CPP is by submitting a new corrected request form.

- Some of the information requested in the order form is mandatory, other items can be provided as necessary. Mandatory fields are marked in the guidance document and on the request form in *red italics*. If for a specific reason no information is available for a mandatory field, please insert the character ” - “ in the respective mandatory field. If a mandatory field is not filled, the order will be rejected.

- The order form contains fields for questions to which the answer is "Yes" or "No". If the answer is "Yes" an x must be entered. If the answer is "No" the field must be left blank.

- Fields that have not been completed do not appear in the CPP or the Annexes.

- The length of character strings entered can exceed the visible field under column <C> of the form. Only letters, numbers and special characters may be entered, **but not line breaks and control characters**. All attributes to characters (i.e. superscript, italic, bold) will not be transferred to the printed CPP.

- If there is more space needed to submit all APIs, excipients or addresses of manufacturers respectively, please refer to Annex 10 for further information.

- It is recommended that applicants consult the following WHO instructions before completing a request form for the first time (Annex 1 and 2: English, Annex 3 and 4: Spanish, Annex 5 and 6: French). These can be found as Annexes to this guidance and have been provided by the WHO (www.who.int).

- The fees are calculated on the basis of the Ordinance on Fees for Therapeutic Products (Verordnung des Schweizerischen Heilmittelinstituts über seine Gebühren, GebV-Swissmedic; SR 812.214.5). The fee for the basic certificate is currently CHF 200.00 (Annex 1, Ziff. VI Abs. 1 GebV-Swissmedic), the fee for each Annex CHF 100.00 (Annex 1, Ziff. VI Abs. 2 GebV-Swissmedic).

- The invoice shows for each CPP its number, the product licence number (item 13), the price, and the first 40 characters of reference 2 (item 7).

3 Completing request forms

Section 1: Details of request

The information in this section is used to process the order and issue the invoice. None of the information in this section is transferred to the CPP.

Item 1 The hard copy of the CPP will be posted to this Swiss address (no legalization offices).

Item 3 Enter a valid E-Mail address for a contact person of the company

Item 2, 4 – 7 These fields are used solely for communication between the applicant and Swissmedic and may be left blank.

Item 8 Enter a billing address in Switzerland.

Section 2: Basic part of the CPP

Please note that all the following text entries will be transferred directly to the CPP without translation.

Item 9 The specification of the product name in the importing country is required by some countries and is therefore added to the CPP in the form of an informative statement.

Item 10 Select the language for the certificate (English, Spanish or French) here. Only one language is permitted per request form. Put an " x " in the respective cell.

Item 11 You are recommended to use the official name of the importing country. Swissmedic does not check or correct this information.

Item 12 Enter the full name of the medicinal product, including the name of the dosage form as authorised by Swissmedic for Switzerland or for an export licence. (WHO ref.: 1.1).

Item 13 Enter the three-, four- or five-digit authorisation number and the two-digits for the dosage strength (sequence number) in the format <nnn nn>, <nnnn nn> or <nnnnn nn>. WHO ref.: 2.A.1.).

Item 14 Enter the date of issue or the date of renewal of the authorization by Swissmedic in the format <dd.mm.yyyy>. If this is a product that has been newly approved, the date of first registration must be used.

Item 15 State whether the medicinal product is authorised for the Swiss market (enter x) or only a so-called export licence (leave this field blank). This answer is extremely important for issuing the CPP and for the information under items 18 and 19 (WHO ref.: 1.3.).

Item 16 If the product has been authorised for the Swiss market, the actual availability in the distribution channels in Switzerland must be stated. For export licences (item 15 = blank) the field under item 16 must also be blank since a medicinal product that is not authorised for Switzerland cannot be on the Swiss market (WHO ref.: 1.4.).

Item 17 Enter x (yes) if the product is authorized for export only (item 15 = blank) and leave the field blank if the product is authorized for the Swiss market (item 15 = filled out) (WHO ref: 1.3.1).

Item 18, 19 **Case 1 (WHO ref: 2.4):** The applicant has **marketing authorisation** for the product for the Swiss market (item 15= filled out, item 16 = filled out or blank, item 17 = blank).

- Enter the authorisation holder under item 18 (as shown in the authorisation issued by Swissmedic; WHO ref.: 2.A.2.) and select its role in the manufacture of the dosage form under item 20 (WHO ref.: 2.A.3.). If the authorization holder does not have an address line 1 (Adress 1 of Position 18) according to the Commercial Register, the corresponding field must be filled with a "-".
- If the product is being submitted for authorisation in another country by the authorisation holder, nothing is entered under item 19.
- If the product is not being submitted for authorisation in another country by the authorisation holder, enter the details of the company that is submitting the product for authorisation in another country under item 19 (WHO ref.: 2.A.6.).

Item 18, 19 **Case 2:** If an **export authorisation** has been issued by Swissmedic (item 15 = blank and item 16 = blank, item 17 = filled out).

- Please enter name and address of the license holder in Switzerland under item 18 (this information will be printed in the CPP, cf. annex 9 of this document). The details of the applicant for authorisation abroad are entered under item 19 (WHO ref.: 2.B.1.) and its role in the manufacture of the dosage form under item 20 (WHO ref.: 2.B.2.).

Item 20 For the Authorisation Holder (marketing authorisation, Item 18) or the Applicant (export authorisation, Item 19) the status of product license holder/applicant must be attributed under Item 20 (choose one item in the list or specify by typing in).

Item 21 Name of the active ingredients in the product. The active ingredients can be entered in English, Spanish, French, Latin or using their INN designation (WHO ref.: 1.2.). The WHO instructions give the "unit dose" as the reference size.
If the number of active ingredients exceeds the available fields in Table 1, please use Table 2 and, if necessary, Table 3.

Item 22 Name of the exipients in the product. The exipients can be entered in English, Spanish, French, Latin or using their INN designation (WHO ref.: 1.2.). The WHO instructions give the "unit dose" as the reference size.
If the number of excipients exceeds the available fields in Table 1, please use Table 2 and, if necessary, Table 3.

Item 23, 24 In the case of an export authorization (item 15 = blank), the reason why a Swiss authorization is missing must be specified under item 23. If the reason is “not requested” please fill in item 24.

Item 25-32 The manufacturers for various activities can be entered here (WHO ref: 3.1). However, it is only permitted to state manufacturers who have been approved by Swissmedic for the respective product (details of manufacturer). Fields that have not been completed do not appear in the CPP.
One or multiple activities may be assigned to a manufacturer. Activities must be entered using the activity codes A to H. Multiple activity codes must be separated by "/" (e.g. B/D/E). At least one activity must be entered for each manufacturer.
Activity A may only be used alone or in combination with activity H. Activities B to G may be combined freely. Activity H may be combined with any other activity code.
Only the activity codes A to H may be entered. Free text is only permitted for activity H and is mandatory whenever activity H is used. **If used, activity H must always be the last activity code and must be entered directly before the free text** (e.g. A/H manufacturing of API or H manufacturing of API).

Section 3: Annexes

In addition to the basic CPP defined by the WHO, specific Annexes may also be provided. Swissmedic offers a total of three different Annexes that can be selected by the applicant.

Item 33, 37, 39 Enter an x under these items to order the Annexes you require. Annexes that are not requested do not appear in the CPP. Neither can it be seen from the CPP that this type of Annex could have been provided but was not requested.

Annex: Supplementing licensing information

Item 33 Enter whether the Annex is being requested.

Item 34 Enter the date of first authorisation by Swissmedic. If the field is left blank, the complete line in the Annex will be truncated.

Item 35 Enter the shelf life as authorised for Switzerland by Swissmedic. Select the relevant time unit (years, months, weeks, days, or hours) and specify the corresponding quantity. By default, the time unit is months. If the field is left blank, the complete line in the Annex will be truncated.

Item 36 Enter x in the upper field to identify the medicinal product as "prescription only" (prescription only/solo con prescripción/sur prescription) for the Swiss market. Enter x in the lower field to identify the medicinal product as "over the counter" (over the counter / sin prescripción / sans prescription) for the Swiss market. If both fields are left blank, the complete line in the Annex will be truncated. Only one of these two fields may be chosen.

Annex: Product information for professionals and for patients

Item 37, 39 Enter whether the Annexes are being requested.

Item 38, 40 On the request form, only the language version approved by Swissmedic during the authorisation procedure may be selected. Swissmedic will take this language version from the AIPS system and integrate it into the Annex of the CPP. It is the responsibility of the applicant to ensure that the current and valid versions have been published in the AIPS system before the CPP is requested. If the requested version does not exist, the order will be rejected.

Exceptions:

- For products which have been registered in Switzerland for export only (item 15 = void) and which are therefore not published in the AIPS system, a printable copy of the information in PDF-format most recently approved by Swissmedic must be submitted together with the ordering form.
- For veterinary medicines a printable copy of the information on veterinary medicines most recently approved by Swissmedic must be submitted with the ordering form.

Items 37 and 38 are used to request the Information for healthcare professionals (IHP), items 39 and 40 to request the patient information (PI). This mechanism can be used to request the IHP and PI together or just the IHP or PI. Only the language version approved by Swissmedic may be requested in each category (IHP, PI). If one of the two Annexes is requested, the attribute "yes" / "sí" / "oui" will automatically be generated under WHO ref.: 2.A.5.; otherwise the attribute "not provided" / "no se proporciona" / "pas fournie" will appear.

Completion

Item 41-43 This information is mandatory but does not appear in the CPP. In providing this information, the responsible applicant accepts personal responsibility for the accuracy of the information and for its consistency with the current elements as approved by Swissmedic in the course of the authorisation procedure.

Swissmedic (please leave blank)

Item S1-S4 Please leave these fields blank. Swissmedic needs them to manage the request procedure.

Annex 1: WHO-Template English

Source:
TRS 1033 - 55th report of the WHO
Expert Committee on Specifications for
Pharmaceutical Preparations; Annex 9

Certificate of a pharmaceutical product

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

No. of certificate

Certifying country or regional certifying authority:

Requesting country or regional authority:

1. Basic Information

1.1. Name: (International Nonproprietary Name (INN)/generic/chemical name); brand name of the pharmaceutical product as it is declared in the marketing authorization certificate and used within the territory of the certifying authority and, if possible, the brand name for the foreign country as declared by the requester, (if different); and, the dosage form of the finished pharmaceutical product (FPP):

1.2. Composition: active pharmaceutical ingredient name(s) using if possible, INNs or national nonproprietary names,. Unit formulation (complete quantitative composition including all excipients);[1]:

1.3. Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? *(Yes/No)*

1.3.1. Are there restrictions of the sale, distribution or administration of the product specified in the marketing authorization? *(Yes/No)*

1.4. Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? *(Yes/No)*

Sections 2A and 2B below are mutually exclusive, therefore:

- If the answer to 1.3 above is yes, continue with section 2A and omit section 2B.
- If the answer to 1.3 above is no, omit section 2A and continue with section 2B

2. Information on marketing authorization

2.A. Product that is authorized for marketing by the certifying authority.

2.A.1. Number of marketing authorization and date of issue.

2.A.2. Marketing authorization holder (name and address):

2.A.3. Status of marketing authorization holder: *(one of the options of 3.1, if manufacturer, or specify the status as importer or any other)*

2.A.4. Is a summary basis of approval appended? *(Yes/No) See attached information if answer is Yes.*

2.A.5. Is the attached officially approved product information complete and consistent with the marketing authorization? (*Yes/No) See attached information if answer is Yes.*

2.A.6. Name and address of applicant for the certificate as provided by the marketing authorization holder, if different:

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

2.B. Product that is not authorized for marketing by the certifying authority. - i. e. the product is authorized for export.

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

2.B.2. Why is marketing authorization lacking?
Not required/Not requested/Under consideration/Refused/Withdrawal for commercial reasons/Withdrawal for sanitary reasons

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

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

(b) The product has been reformulated - please specify:

(c) Any other reasons - please specify:

3. Information on manufacturing and inspections

3.1. List of name and address of the manufacturing site(s) and activities:

a) manufacturing of all steps of the finished pharmaceutical product (FPP);
b) manufacturing the bulk finished product;
c) manufacturing of solvent and diluents;
d) quality control of the FPP;
e) batch release of the FPP;
f) primary packaging of the dosage form;
g) secondary packaging of the product;
h) other(s) (specify and list in new arrows).

Name of manufacturing site 1 Adress	Activity
Name of manufacturing site 2 Adress	Activity
Name of manufacturing site etc. Adress	Activity

3.2. Does the certifying authority arrange for periodic inspection of the manufacturing site plant in which the FPP is produced? *(Yes/No)*

3.3. Periodicity of routine inspections:

3.4. Has the manufacturer of the dosage form of the FPP been inspected? (*Yes/No). If Yes, when feasible, insert date of inspection(s)(dd/mm/yyyy).)*

3.5. Do the facilities and operations of the manufacturer of the FPP conform to good manufacturing practices (GMP) as recommended by WHO?[3] *(Yes/No).*

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

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? *(Yes/No)*[4].

Explanatory Notes

1. Details of quantitative composition are preferred but their provision is subject to the agreement of the marketing authorization holder.
2. Not applicable means that 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.
3. The requirements for good practices in the manufacture and quality control of pharmaceutical products referred to in the certificate, are those included in the Thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series, No. 986, 2014, Annex 2 *(WHO Good manufacturing practices for pharmaceutical products: main principles).* Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization *(WHO Good manufacturing Practices for biological products,* WHO Technical Report Series, No. 996, 2016, Annex 3).
4. It is of particular importance when contractors are involved in the manufacture of the product. The applicant should supply the certifying authority with information in order to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

Annex 3: WHO-Template Spanish

Certificado de un producto farmaceutico

Este certificado está de acuerdo con el formato recomendado por la Organización Mundial de la Salud.

No. de este certificado

Autoridad certificadora del país o de la región:

País o autoridad regional solicitante:

1. Información básica

1.1. Nombre: (Denominación Común Internacional (DCI)/nombre genérico/denominación química); marca comercial del medicamento tal como se declara en la autorización de comercialización y se utiliza en el territorio de la autoridad de certificación y, si se solicita, marca comercial en el país extranjero declarado por el solicitante (si es diferente); y forma farmacéutica del producto:

1.2. Composición: nombre(s) del ingrediente farmacéutico activo utilizando, si es posible, las DCI o las denominaciones comunes nacionales. Formulación unitaria (composición cuantitativa completa incluyendo todos los excipientes);[1]:

1.3. ¿Está este producto autorizado por la autoridad certificadora para ser comercializado en el país certificador o dentro de la jurisdicción de la autoridad regional certificadora? *(Sí/No)*

1.3.1. ¿Existen restricciones a la venta, distribución o administración del producto especificadas en la autorización? *(Sí/No)*

1.4. ¿Està este producto realmente en el mercado del país certificador o en la jurisdicción de la autoridad regional certificadora? *(Sí/No)*

Las secciones 2A y 2B que figuran a continuación se excluyen mutuamente, por lo que:

- Si la respuesta a 1.3. es sí, continuar con la sección 2A y omitir la sección 2B.
- Si la respuesta a 1.3. es no omitir la sección 2A y continuar con la sección 2B

2. Información sobre la autorización de comercialización

2.A. Producto autorizado para su comercialización por la autoridad certificadora.

2.A.1. Número de la autorización del producto y fecha de emisión:

2.A.2. Titular de la autorización del producto (nombre y dirección):

2.A.3. Estatus del titular de la autorización de comercialización: *(una de las opciones de 3.1, si es fabricante, o especificar la condición de importador o cualquier otra)*

2.A.4. ¿Se adjunta “summary basis for approval”? *(Sí/No) Consulte la información adjunta si la respuesta es sí.*

2.A.5. La información adjunta sobre las condiciones de aprobación del producto, ¿es completa
y conforme con la autorización? *(Sí/No) Consulte la información adjunta si la respuesta es sí.*

2.A.6. Solicitante del certificado, si es diferente del titular de la autorización (nombre y dirección):

2.A.7 Enlace web a la información sobre la autorización de comercialización del producto (si está disponible)

2.B. Producto no autorizado para su comercialización por la autoridad certificadora. - es decir, el producto está autorizado para la exportación.

2.B.1. Solicitante del certificado (nombre y dirección):

2.B.2. ¿Por qué no existe una autorización de comercialización?
No necesaria/No solicitada/En evaluación/ Denegada/Retirada por motivos comerciales/ Retirada por motivos sanitarios

2.B.3. Motivo aducido por el solicitante para no solicitar el registro:
(a) El producto se ha desarrollado exclusivamente para el tratamiento de enfermedades (p. ej., enfermedades tropicales - no endémicas en el país exportador):

(b) El producto se ha reformulado, especificar:

(c) Por cualquier otro motivo, especificar:

3. Información sobre la fabricación y las inspecciones

3.1. Lista del nombre y la dirección del (de los) centro(s) de fabricación y de las actividades:

a) fabricación de todas las etapas del producto terminado;
b) fabricación del producto terminado a granel;
c) fabricación del disolvente/diluyente;
d) control de calidad del producto terminado;
e) liberación de lotes del producto terminado;
f) acondicionamiento primario de la forma farmacéutica;
g) acondicionamiento secundario del producto terminado;
h) otros (especificar)

Nombre del centro de fabricación 1 dirección	Actividad
Nombre del centro de fabricación 2 dirección	Actividad
Nombre del centro de fabricación etc. dirección	Actividad

3.2. ¿Establece la autoridad certificadora inspecciones periódicas del centro de fabricación en el que se produce la forma farmacéutica? *(Sí/No)*

3.3. Periodicidad de las inspecciones rutinarias (años):

3.4. ¿Se ha inspeccionado la fabricación de este tipo de forma farmacéutica? (Sí/No) En caso afirmativo, si es posible, indique la fecha de la(s) inspección(es). (dd/mm/aaaa).

3.5 ¿Las instalaciones y procesos cumplen con las Buenas Prácticas de Manufactura como recomienda la Organización Mundial de la Salud?[3] *(Sí/No)*

3.6 Se recomienda que, para los productos aprobados, pero no fabricados en el país de la autoridad certificadora, se declare la fuente de información que asegura el cumplimiento de las prácticas correctas de fabricación por parte del fabricante o fabricantes.

4. ¿La información presentada por el solicitante satisface a la autoridad certificadora en todos los aspectos de la fabricación del producto? *(Sí/No)*[4]

Annex 4: WHO-Explanatory Notes Spanish

Notas explicativas

1. Se prefieren los detalles de la composición cuantitativa, pero su provisión está sujeta al acuerdo del titular de la autorización de comercialización.
2. No se aplica significa que la fabricación tiene lugar en un país diferente del que emite el certificado y la inspección es responsabilidad de la autoridad del país de fabricación.
3. Los requisitos de Buenas prácticas de fabricación y de control de calidad de los medicamentos a los que se hace referencia en el certificado son los incluidos en el 32.º informe del Comité de expertos en especificaciones para las preparaciones farmacéuticas, serie de informes técnicos de la OMS, n.º 986, 2014, anexo 2 (Buenas prácticas para la fabricación de productos farmacéuticos según la OMS: principios fundamentales). El Comité de expertos en normalización biológica de la OMS ha formulado unas recomendaciones específicamente aplicables a los productos biológicos ((Buenas prácticas de fabricación de productos biológicos según la OMS, serie de informes técnicos de la OMS, n.º 996, 2016, anexo 3)
4. Es especialmente importante cuando participan contratistas en la fabricación del producto. El solicitante deberá facilitar a la autoridad de certificación la información necesaria para identificar a las partes contractuales responsables de cada fase de fabricación de la forma farmacéutica terminada, y el alcance y la naturaleza de los controles ejercidos sobre cada una de estas partes.

Annex 5: WHO-Template French

Certificat de produit pharmaceutique

Ce certificat est conforme à la présentation recommandée par l'Organisation Mondiale de la Santé

No. du certificat

Autorité de certification du pays ou de la région :
Autorité nationale ou régionale requérante :

1. Information de base

1.1. Nom : (Dénomination Commune Internationale (DCI)/nom générique/chimique); nom de la marque du médicament tel qu'il est déclaré dans l'autorisation de mise sur le marché et utilisé sur le territoire de l'autorité de certification et, sur demande, nom de la marque dans le pays étranger tel que déclaré par le demandeur (si différent); et la forme galénique du produit pharmaceutique fini (PPF) :

1.2. Composition: nom du ou des ingrédients pharmaceutiques actifs en utilisant si possible les DCI ou les dénominations communes nationales, Formulation unitaire (composition quantitative complète incluant tous les excipients) ;[1] :

1.3 Ce produit est-il autorisé par l'autorité de certification à être commercialisé dans le pays de certification ou dans la juridiction de l'autorité régionale de certification ? *(Oui/Non)*

1.3.1. Existe-t-il des restrictions de vente, de distribution ou d'administration du produit spécifiées dans l'autorisation de mise sur le marché ? *(Oui/Non)*

1.4. Ce produit est-il effectivement sur le marché dans la juridiction de l'autorité régionale de certification ? *(Oui/Non)*

Les sections 2A et 2B ci-dessous s'excluent mutuellement, par conséquent :

- Si la réponse à la question 1.3 est oui, passez à la section 2A et sauter la section 2B.
- Si la réponse à la question 1.3 non, sauter la section 2A et passez à la section 2B

2. Informations relatives à l'autorisation de mise sur le marché

2.A. Produit autorisé pour la mise sur le marché par l'autorité de certification.

2.A.1. Numéro de l'autorisation de mise sur le marché (AMM) et date de délivrance :

2.A.2. Titulaire de l'AMM (nom et adresse):

2.A.3. Statut du titulaire de l'AMM: *(une des options de 3.1, si fabricant, ou spécifier le statut d'importateur ou tout autre statut)*

2.A.4. Un résumé du dossier d'AMM est-il annexé? *(Oui/Non) Voir les informations ci-jointes si la réponse est Oui.*

2.A.5. L'information officiellement approuvée sur le produit annexe au présent formulaire est-elle complète et conforme aux dispositions de l'AMM? *(Oui/Non) Voir les informations ci-jointes si la réponse est Oui.*

2.A.6. Nom et adresse du demandeur du certificat, s'il est différent du titulaire de l'AMM :

2.A.7. Lien internet vers les informations relatives à l'AMM du produit (si disponible)

2.B. Produit dont la commercialisation n'est pas autorisée par l'autorité de certification. - c'est-à-dire que le produit est autorisé à l'exportation

2.B.1. Nom et adresse du demandeur du certificat :

2.B.2. Pourquoi une autorisation de mise sur le marché fait-elle défaut ?
Non exigée/Non demandée/À l'étude/Refusée/Retrait pour raisons commerciales/Retrait pour raisons sanitaires

2.B.3. Motif fourni par le demandeur pour ne pas demander l'enregistrement :

(a) Le produit a été développé exclusivement pour le traitement de maladies (par exemple les maladies tropicales – non endémiques dans le pays exportateur) :

(b) Le produit a été reformulé, veuillez préciser :

(c) Pour toute autre raison, veuillez préciser :

3. Information sur la fabrication et les inspections

3.1. Liste des noms et adresses des sites de fabrication et activités :

a) fabrication de toutes les étapes du produit fini ;
b) fabrication du produit fini en vrac ;
c) fabrication de solvants et de diluants ;
d) contrôle de la qualité du produit fini ;
e) libération des lots du produit fini ;
f) conditionnement primaire de la forme pharmaceutique ;
g) conditionnement secondaire du produit ;
h) autre(s) (préciser)

Nom du site de fabrication 1 Adresse	Activité
Nom du site de fabrication 2 Adresse	Activité
Nom du site de fabrication etc. Adresse	Activité

3.2. L'autorité certificatrice organise-t-elle des inspections périodiques de l'usine de production de la forme pharmaceutique ? *(Oui/Non)*

3.3. Périodicité des inspections de routine (ans):

3.4. La fabrication de ce type de forme pharmaceutique a-t-elle été inspectée? *(Oui/Non) Si oui, lorsque c'est possible, indiquez la date de la ou des inspections. (jj/mm/aaaa).*

3.5. L'établissement pharmaceutique et les opérations sont-ils conformes aux Bonnes Pratiques de Fabrication (BPF) recommandées par l'Organisation Mondiale de la Santé (OMS) ?[3] *(Oui/Non)*

3.6. Il est recommandé, pour les produits approuvés mais non fabriqués dans le pays de l'autorité de certification, de déclarer la source d'information qui garantit la conformité aux BPF du ou des fabricants.

4. L'information présentée par le demandeur satisfait-elle l'autorité certificatrice quant à tous les aspects de la fabrication du produit? *(Oui/Non)*[4]

Annex 6: WHO-Explanatory Notes French

Notes explicatives

1. La composition qualitative détaillée devra si possible être indiquée, sous réserve de l'accord du titulaire de l'AMM.
2. Sans objet signifie que le produit est fabriqué dans un pays autre que celui qui délivre le certificat de produit et que l'inspection est conduite sous la responsabilité du pays de fabrication.
3. Les exigences relatives aux Bonnes Pratiques en matière de Fabrication et de contrôle de la qualité des médicaments mentionnées dans le certificat sont celles incluses dans le 32ème rapport du Comité d'experts sur les Spécifications des Préparations Pharmaceutiques, Série des Rapports Techniques de l'OMS nº 986, 2014, Annexe 2 (Bonnes Pratiques de Fabrication des Médicaments de l'OMS: principes généraux). Des recommandations spécifiquement applicables aux produits biologiques ont été formulées par le Comité d'experts sur la Standardisation Biologique de l'OMS (Bonnes Pratiques de Fabrication des produits biologiques de l'OMS, Série des Rapports Techniques de l'OMS nº 996, 2016, Annexe 3).
4. Elle revêt une importance particulière lorsque des contractants sont impliqués dans la fabrication du produit. Le demandeur doit fournir à l'autorité de certification des informations permettant d'identifier les parties contractantes responsables de chaque étape de la fabrication de la forme pharmaceutique finie, ainsi que l'étendue et la nature des contrôles exercés sur chacune de ces parties.

Annex 9: Information for authorisations for export only

Attachment: Information on the marketing authorisation

The Swiss marketing authorisation system allows a marketing authorisation holder to register a product for export only. The requirements are identical to the ones for a marketing authorisation of a product to be placed on the Swiss market. Exempt are only the patient information leaflet and the secondary packaging.

The product

xxx (taken from item 12)

has the Swiss marketing authorisation number

xxx (taken from item 13)

and is registered by the following marketing authorisation holder

xxx (taken from item 18)

Apéndice: Informaciones sobre la autorización para ser puesto en el mercado

El sistema suizo de autorización de comercialización (puesta en el mercado) permite a una empresa de obtener una autorización para la exportación solamente. Las exigencias son las mismas que aplican para los productos autorizados en el mercado suizo. Las solas excepciones son con resguardo a las informaciones para los pacientes y para el empaquetado secundario.

El producto

xxx (taken from item 12)

lleva el número de autorización de comercialización siguiente

xxx (taken from item 13)

y es detenido por el titular de la autorización de comercialización

xxx (taken from item 18)

Annexe: Informations sur l'autorisation de mise sur le marché (AMM)

Le système suisse d'autorisation de mise sur le marché permet à un titulaire d'autorisation d'enregistrer un médicament pour l'exportation exclusivement. Les exigences sont identiques à celles requises pour la mise sur le marché en Suisse. La seule exception concerne le texte pour l'information des patients et pour le conditionnement secondaire.

Le produit

xxx (taken from item 12)

possède le numéro d'autorisation de mise sur le marché

xxx (taken from item 13)

et est détenu par le titulaire d'autorisation de mise sur le marché

xxx (taken from item 18)

Annex 10: Information for additional space for APIs and excipients

In some cases, the available field in <Tabelle1> is not sufficient to submit all information needed. In that case, <Tabelle2> and <Tabelle3> can be used.
No other sheets may be added or removed to the ordering form. The APIs and Excipients must be entered according to the fixed format in <Tabelle2> and <Tabelle3>. The Format of any of the sheets must remain unaltered.
If the format is altered or existing sheets are removed or additional sheets are added, the order will be rejected.
Please insert only printable characters into the cells (no control codes allowed).

Codes:

API	Additional API	cf. Item 21
EXC	Additional excipient	cf. Item 22
MAP	Manufacturer	cf. Item 25 – 32

Structure for compounds (API and excipients):

EXCEL column "A"	*EXCEL column "C"*	*EXCEL column "E"*	*EXCEL column "F"*
Code	**Name of compound**	**Amount**	**Unit**

Structure for addresses:

EXCEL column "A"	*EXCEL column "C" (red lines are mandatory)*
Code	Activities Name of company Address 1 Address 2 Address 3 ZIP-code and place Country

Change history

Version	Change	sig
12.1	Specification about empty mandatory fields Clarification on Format for filling position 13	spl
12.0	Adjustement of table3 and specification for shelf life time span Specification about missing Adress1 for Position 18 Modifications of API and Excipient entering Modification regarding additional sheets (<Tabelle2> and <Tabelle3>	spl
11.1	New layout, no content adjustments to the previous version	tsj
11.0	Modification of item 25-32 regarding entry of multiple activities. Section 3: three (not two) annexes can be selected	bja
10.0	Modification of item 25-32 regarding entry of activity H, Annex 10: Correction of description for code MAP	hul
9.0	Modifications due to adaption of CPPs according to the new format for product certificates (TRS 1033 - 55th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations; Annex 9)	hul
8.0	Modification of the specification on position 14	seb
7.0	Modification due to revision of MPLO / Medicrime	seb
6.0	General revision of the document and adaptation to current practice in the product certificate process	seb
5.0	Modification if Item 19.	hbj
4.0	Addition of Annex 10.	hbj
3.0	Item 50 – 53: information for product information concerning registrations for export only.	hbj
2.0	Changes: Chapter 2, points 3, 6, and 7; Chapter 3, item 12 und item <17/18/19>, "Case 2"; Attachment 9 added	hbj
1.0	1st edition, replaces document: *Merkblatt Produktzertifikate für verwendungsfertige Arzneimittel (gemäss WHO-Richtlinien)* and document: *Informationen zum Ausfüllen für Produktzertifikate*	cza