Application for an Export Certificate

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| 1. TYPE OF CERTIFICATE REQUESTED

*(tick as appropriate)*[ ]  Certificate of a Pharmaceutical Product (CPP)[ ]  Certificate of Good Manufacturing Practice – Finished Product[ ]  Certificate of Good Manufacturing Practice – API[ ]  Manufacturer Licence (certified copy)[ ]  Certificate of Free Sale of a Medicinal Product[ ]  Certification of Documents[ ]  Other (please specify): <insert here>Fast track application [ ]  Yes [ ]  NoFinished certificate type [ ]  Printed [ ]  Electronic (as pdf file)Export market: <insert here> |
| 1. APPLICANT DETAILS

Name and address of applicant:      Eircode:      Contact person:      Telephone/fax number of contact:      Email address of contact:       |
| 1. CERTIFICATE FOR AN AUTHORISED PRODUCT *(to be completed where product is the subject of a marketing authorisation (MA)/veterinary product authorisation (VPA))*

Proprietary name of product:      MA/VPA number:      MA/VPA issue date:      MA/VPA holder:      **Important:** please ensure that all applicable variations to this product authorisation have been finalised by the Human Products Authorisation and Registration Department or Veterinary Sciences Department before completion. Minor changes to the composition or manufacturing sites that are appropriately classified as Type IA variations or variations not requiring assessment which have either been recently submitted or will be submitted within the required timeframe, can be included provided a declaration is completed as outlined in Appendix III. Please see the guidance notes contained on the draft certificate of pharmaceutical product for guidance. |
| 1. CERTIFICATE FOR A PRODUCT WHICH IS NOT AUTHORISED IN IRELAND\*

Name of product:      **Each application should be accompanied by a declaration**, in the attached format (Appendix II) stating why the product is not the subject of a MA/VPA issued by the HPRA. This declaration should be signed by the Qualified Person/Head of Registration. |
| 1. CERTIFICATE OF GOOD MANUFACTURING PRACTICE

For a manufacturer licensed by the HPRA state the full name and address of the manufacturer, the licence number and expiry date.For a manufacturer of active pharmaceutical ingredients state the full name and address.Name:      Address:      Eircode:      Licence number (if applicable):      Expiry date (if applicable):       |
| 1. ATTACHMENTS TO PRODUCT CERTIFICATES

Any proposed attachment to a product certificate should be included with this application. For authorised products, any summary of composition, list of manufacturing sites, patient information leaflet (PIL), label, carton, etc., should be accompanied by a declaration (see Appendix III) signed by the Qualified Person/Head of Registration attesting that the proposed attachment is the current version authorised by the Health Products Regulatory Authority or only incorporates minor changes that are appropriately classified as Type IA variations or variations not requiring assessment that have either been recently submitted or will be submitted to the HPRA within the required timeframe.The only export certificate issued in languages other than English is the Certificate of Pharmaceutical Product, which may be provided in Spanish or French. Attachments will only be considered if they are in English and no other language.  |
| 1. DRAFT CERTIFICATES

If an application is made for a certificate of free sale or certificate of pharmaceutical product (CPP), a draft certificate must be submitted by the applicant. This is available on the ‘Publications and Forms’ section at [www.hpra.ie](http://www.hpra.ie). |
| 1. LETTER OF NO OBJECTION

If the applicant is not a subsidiary to the MA/VPA holder, a written letter of no objection for the MA/VPA holder must be submitted. |
| 1. FEES

Please refer to the HPRA guide to fees for either human or veterinary medicineson[www.hpra.ie](http://www.hpra.ie),and complete the fee application form. |
| 1. RECEIPT OF CERTIFICATE

Please indicate by ticking the relevant box if you would prefer the printed version of the certificate to be sent by post or courier (at the applicant’s expense).Post [ ]  Courier [ ]  |
| 1. DECLARATION

I hereby declare that the above particulars are, to the best of my belief, correct.**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Position/title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. CHECKLIST OF DOCUMENTS

The following information must be submitted with the application (except where not applicable).*Please tick the checkboxes below to confirm the documents have been included with the application.* [ ]  Declaration in Appendix II by Qualified Person/Head of Registration, (if applicable)[ ]  Summary of composition, if applicable[ ]  Relevant fee (copy of bank transfer document or HPRA account reference number)[ ]  Letter of no objection from MA/VPA holder, if applicable [ ]  All required attachments to the certificate, if applicable [ ]  A completed draft version of a certificate for certificates of free sale or CPPs[ ]  Signed and dated declaration within this application form at section 11**Please note that applications will not be validated unless the appropriate fee has been received.** |

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| 1. FOR OFFICE USE ONLY

Certificate and schedule prepared by:      Certificate and schedule approved by:      Certificate number(s):      HPRA reference number(s):       |

Send to:

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

Email: exportcerts@hpra.ie

APPENDIX I APPLICATION FOR EXPORT CERTIFICATE NOTES

Applications for an export certificate are issued under the following:

* Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended
* Medicinal Products (Control of Manufacture) Regulations 2007, as amended
* European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007), as amended
1. Persons/Companies entitled to receive certificates
2. In general a certificate will only be issued to the following:
* MA/VPA Holder (for an authorised product)
* Licensed Manufacturer based in the Republic of Ireland (Certificate relating to a medicinal product which is not the subject of a MA/VPA in Ireland or Certificate of Good Manufacturing Practice)
* Manufacturer of Active Pharmaceutical Ingredients
1. Where the applicant for a certificate is not the MA/VPA holder or the licensed manufacturer, as the case may be, the application must be accompanied by a declaration from the MA/VPA holder, or manufacturer, permitting the issue of the certificate to the applicant.
2. Certificate of a Pharmaceutical Product
3. The Certificate of a Pharmaceutical Product has been developed by the World Health Organisation principally for use in the registration of medicinal products in export markets. It is the preferred format of product certificate used by the HPRA. It will be issued in each of the following circumstances:
* For an authorised product, where the importing country is a signatory to the Certification Scheme of the WHO
* For a medicinal product manufactured in Ireland but which is not the subject of a MA/VPA in Ireland
1. Only one product is permitted per certificate.
2. One original certificate is issued.
3. Certificate of Free Sale
4. In general, this will be issued only where:
* The product is the subject of a MA/VPA, and
* the product is currently on the Irish market, and
* the importing country is not a signatory to the WHO Certification Scheme/or there are particular, stated reasons why a Certificate of Free Sale is required.
1. Four original certificates are issued in relation to each individual application.
2. Certificate of Good Manufacturing Practice
3. This will be issued to a manufacturing site which is licensed by the HPRA.
4. Such a certificate may also be issued to an Irish based manufacturer of active pharmaceutical ingredients if the HPRA is satisfied that the site operates in accordance with the ICH standards of Good Manufacturing Practice.
5. Four original certificates are issued in relation to each individual application.
6. Other types of Certificates
7. This could include a request for a Statement of Licensing Status of Pharmaceutical Product(s) (World Health Organisation format) or a certified copy of a manufacturer’s licence.
8. For any such certificate, one original is issued in relation to each individual application.

APPENDIX II CERTIFICATE FOR A PRODUCT WHICH IS NOT AUTHORISED IN IRELAND

**FORMAT FOR DECLARATION**

**DECLARATION**

**(Insert name of product here)**

I hereby declare that the above mentioned product is not authorised in Ireland for the following reason(s):

**(Insert reason(s) here)\***

I further declare that the above mentioned product had not been:

1. the subject of a MA/VPA application which was rejected by the HPRA (or the competent authority of another country) or withdrawn on foot of objections raised by the HPRA (or the competent authority of another country);

or

1. the subject of a MA/VPA which was revoked by the HPRA (or the competent authority of another country), or withdrawn at the request of the HPRA (or the competent authority of another country) on grounds of quality, safety or efficacy.

Signed:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Qualified Person/Head of Registration**

\*Examples of reasons why a product is not authorised in Ireland may include:

1. The product has been developed exclusively for the treatment of conditions- particularly tropical diseases – not endemic in the country of export;
2. The product has been reformulated with a view to improving its stability under tropical conditions;
3. The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
4. The product has been reformulated to meet a different maximum dosage limit for an active ingredient.

appendix III declaration letter in support of type ia variations or variations not requiring assessment

PLEASE USE COMPANY HEADED PAPER

Compliance Department

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Ireland

<Date>

**Re:** <Type IA Variation>/<Variation not requiring assessment>**: Declaration by the Senior Regulatory Affairs Manager**

**Details of the Senior Regulatory Affairs Manager**

<Company name>

<Company address>

<Contact person>

**Statement of compliance with variations legislation**

I <name> of <company name> confirm that all details in the attached application for a certificate of pharmaceutical product or certificate of free sale for medicinal products are either currently approved or relate to minor changes that are appropriately classified as <Type IA Variation>/<Variation not requiring assessment> that have been recently submitted or will be submitted to the HPRA within the required timeframe.

Please provide a brief overview of the variation change to the existing product authorisation:

**Regulatory Affairs Manager Signature**

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ADD COMPANY STAMP