An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Applications for Certificates of Free Sale for Cosmetics

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 SCOPE

This document outlines the information and documentation required when making an application to the Health Products Regulatory Authority (HPRA) for certificates of free sale for cosmetic products.

2 INTRODUCTION

You may submit requests for certificates of free sale for export purposes for cosmetic products. Each certificate is issued in respect of a specified cosmetic product or products. The content will vary depending on whether you are a manufacturer or designated responsible person.

The HPRA can only issue a certificate of free sale when:
- A company declaration and company registration certificate are provided for the products concerned.
- The manufacturer or designated responsible person is located in Ireland.
- The products have been assessed and registered on the Cosmetic Products Notification Portal (CPNP).

3 DEFINITIONS

'Responsible person': there must be a designated responsible person (RP) nominated for each cosmetic product placed on the market within the European Economic Area (EEA). Regulation (EC) No. 1223/2009, details the responsibilities of the RP in Article 4. In general, the RP for a cosmetic product is one of the following:
- If the product is manufactured within the EEA, the manufacturer established within the EEA is considered the RP.
- If the manufacturer is established outside the EEA, the importer established within the EEA acts in the capacity of RP.
- If the manufacturer or importer within the EEA designates another party within the EEA to act as the RP, this designation and the acceptance of the role by the RP must be formally set out in writing.
- If a distributor of a cosmetic product (any natural or legal person in the supply chain, other than the manufacturer or the importer that makes the product available for sale in the EEA) modifies a cosmetic product in a way which compromises its compliance with the legislation and/or markets a cosmetic product under his name or trademark, the distributor takes on the role of RP.

The RP must always be based within the EEA and their address should appear on the cosmetic labelling. Importers are advised to contact their suppliers to establish if there is an existing RP for the product in question. If there is no such existing RP, then that importer must become the RP or designate an RP ~~in order~~ to place the product on the market in the EEA.

For the purposes of this guideline, the following definitions apply:
- The **manufacturer** is the organisation that manufactures cosmetic products and places them on the market under their own name or trading name.
- The **designated responsible person** is the responsible person designated by the cosmetic manufacturer or importer.
- The **site of manufacture** is the place where the cosmetic product is physically manufactured.

If you do not have a registered place of business in a European Member State, you must designate a person established in the EEA to act on your behalf.

4 MAKING AN APPLICATION

To apply for a certificate of free sale, you must fill in the 'Application for Certificates of Free Sale' form. This form can be downloaded from the Publications and Forms section of www.hpra.ie, or alternatively it is available from the Compliance department of the HPRA. The completed form should be sent electronically to exportcerts@hpra.ie. A separate listing of product codes and descriptions is also required (see below).

If you request a certificate of free sale which is the same as a previous certificate of free sale issued by the HPRA, the certificate number (in the format COS XXXX) of the previously issued certificate of free sale is required, along with the payment and confirmation of the number of copies required. This certificate number can be found on the bottom left corner of a certificate of free sale. A new certificate will be issued based on this certificate number. Please note that in this scenario only the issue date and expiry date will change. All other details will remain the same. If any other changes are required then a new full application must be submitted.

All application forms and supporting documentation for a certificate of free sale must be in English.

The HPRA will send the certificate of free sale to the Irish-based organisation stated on the application form. If you require the issued certificates to be sent to a different location, please provide the ~~postal~~ details in an email or cover letter.

There is a limit of 300 products per application form for a certificate of free sale. An application which exceeds this limit will not be accepted.

4.1 Organisational declaration

When an organisation makes its application for a certificate of free sale, proof of manufacture or proof of designation as the responsible person (in the form of a notarised document) must accompany the application and indicate conformity with the requirements of the cosmetic product legislation. The original notarised document must be sent to the HPRA by post **and** ~~also~~

by email. A notarised document is a statement made by the manufacturer on the organisation's letterhead paper, signed by a designated representative and stamped and signed by their local public notary. It should state compliance with the requirements of the cosmetic product legislation, and that products are manufactured in compliance with GMP requirements (ISO 22716 or equivalent). An example of an organisation declaration is given in Appendix 1.

5 INSTRUCTIONS ON HOW TO FILL IN THE APPLICATION FORM

The 'Application for Certificate of Free Sale' form has six sections. **You must fill in all the sections unless instructed otherwise**. The sections of the form are as follows:

Section A: Application details
Section B: Identification of the manufacturer
Section C: Identification of the designated responsible person
Section D: Service required
Section E: Certificate details
Section F: Cosmetic product details

5.1 Section A – Application details

Section A has the following three parts:

Part (i): Date of application

This is the date when you apply for the certificate of free sale.

Part (ii): Status of organisation making the application

This section indicates if the organisation making the request is a manufacturer or designated responsible person. If a manufacturer is making the request, then tick the appropriate box marked 'Manufacturer' and complete section B only. 'Manufacturer' in this context means the site physically manufacturing the product.

If the organisation making the request is the designated responsible person, then tick the appropriate box marked 'Designated responsible person' and complete sections B and C.

You cannot choose both options 'Manufacturer' and 'Designated responsible person'.

Part (iii): Payment details

This indicates which type of payment is to be made for the certificates of free sale, e.g. if paying by cheque then tick this box. Please refer to the 'Payment of Fee Instructions' in the Publications and Forms section of www.hpra.ie for more information regarding payment.

The four types of payment are:
- Cheque
- Bank draft
- Bank transfer
- Credit on account

Validation of an application cannot commence until payment has been received. Failure to submit proof of payment with the application will result in the application being returned.

5.2 Section B – Identification of the manufacturer

Section B must be completed with the details of the manufacturer (site of manufacture) in this section. The manufacturer's details provided will appear on the certificate of free sale.

5.3 Section C – Identification of designated responsible person

You must complete section C if you require the designated responsible person's details to appear on the certificate of free sale. This is required if the applicant is the designated responsible person and is not the manufacturer of the products or if the site of manufacture is not in Ireland.

5.4 Section D – Service required

Section D has three parts.

Part (i): Standard or urgent service

If you require the standard service, then please tick this box. A standard service is when the certificate of free sale is issued within five working days of receipt of a valid application form. Please note that this timeline only starts once all the correct information, documentation and payment have been validated.

If you require the urgent service, then please tick this box. An urgent service is when the certificate of free sale is issued within three working days of receipt of a valid application form in the HPRA. Please note that this timeline only starts once all the correct information, documentation and payment have been validated.

If neither box is ticked, then the standard service will apply.

Part (ii): Finished certificate type:

You can also request to have your certificate returned as printed hard copies, or as a single electronic pdf file, which is identical to a printed version and includes a verifiable signature.

Part (iii): Number of printed copies required

The number of copies required should be inserted in the box provided. A minimum of four copies of a certificate of free sale are issued for each request.

Additional copies of the certificate are available at the time of the initial request at an extra cost.

Additional copies that are requested **after** the initial request must be applied for by way of a new application and will be charged accordingly.

Part (~~iii~~iv): Delivery of a printed certificate of free sale

The HPRA will use standard mail for delivery of all printed certificates unless otherwise requested. If you wish to organise a courier to collect the certificates of free sale at your **own expense** from the HPRA, indicate this by ticking the box. You will be contacted once the certificates are completed to arrange a courier. If the checkbox for courier delivery is not selected, standard mail will be used.

5.5 Section E – Certificate details

This section of the form deals with the information to be included with the certificate of free sale application.

- Company declaration including the product listing, and
- Company registration certificate (obtained from the Companies Registration Office (CRO)).
- Importing countries: list the countries for which the certificate of free sale is intended. This list should only detail countries outside of the EEA and should only list the countries that the certificate is intended to be used for.
- Declaration of non-inclusion of material of animal origin: if the statement of non-inclusion of material of animal origin is required on the certificate of free sale, please confirm by ticking the checkbox provided that none of your products contain any material derivative from UK bovine sources or any animal-based raw material, including tissue and liquid from brain, spinal cords and eyes of cows, sheep and goats.

All original documentation must be sent by post to the HPRA.

5.6 Section F – Cosmetic product details

This lists the cosmetic products to be included on the certificate of free sale. This list should be submitted in an Excel spreadsheet listing the product code (or unique identifier) if required and product name. If the HPRA does not accept an application, the applicant will be contacted.

You must fill in the product name, as it appears on the packaging, for each cosmetic product which is to be included on the certificate. If there is more than one product code per cosmetic

product name, please list all codes for that product. For example, if there are four product codes to one cosmetic product name, state it as follows:

Product Code	Product Description
1234	Product name 1
2345	Product name 1
3456	Product name 1
4567	Product name 1
Etc.	

6 DOCUMENTATION TO BE SUBMITTED

As specified above, the following documentation should accompany the completed application form:

- Cheque or verification of payment, unless a credit-on-account facility has been set up with the HPRA. In this case, please specify your account number.
- Excel spreadsheet of products to be listed on the certificate of free sale.

The following additional documentation does not have to accompany every application. Once it has been submitted to the HPRA, it is kept on file to be used for future certificates of free sale.

- Organisation declaration notarised by a notary public.
- In the case of an application by a designated responsible person, letter of designation from the manufacturer.
- Copy of company registration certificate from the CRO.
- Product labelling is also routinely requested as part of the assessment process, this can either be in the form of actual hard copy labels or pdf files of the artwork.

7 THE PROCESS FOR REVIEW AT HPRA

The HPRA reviews the application form on receipt to ensure that all the information required has been provided. If all the required information, documentation or fee has not been received, we will contact the applicant and request the missing information, documentation or fee. The application will be put on hold for a period of one week. If the missing documentation has not been received within that timeframe the application will be cancelled and returned to the applicant.

8 CONTACT DETAILS AT THE HPRA

For general enquiries regarding applications for certificates of free sale, please contact:

Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77
Telephone: +353-1-6764971
Fax: +353-1-6764061
Email: exportcerts@hpra.ie

Information is also available from the HPRA website at www.hpra.ie.

APPENDIX 1 ORGANISATIONAL DECLARATION LETTER

PLEASE USE COMPANY HEADED PAPER

Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Ireland

<Date>

Re: Cosmetics: Organisation Declaration by the Responsible Person

Details of the Responsible Person
<Company name>
<Company address>

<Contact person>

Statement of compliance with Cosmetic Legislation

I <RP name> of <Company name> confirm that all cosmetic products for which <Company name> is acting as responsible person are manufactured in compliance with the requirements of Regulation (EC) No. 1223/2009 and in accordance with cosmetic Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices ISO 22716:2007, or equivalent.

RP Signature

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Notary Public Signature

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