HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Distribution of ~~Cosmetic Products~~cosmetic products in Ireland

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~~10 OCTOBER 2022~~
~~This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.~~

CONTENTS

1 SCOPE

Every cosmetic product that is made available for sale in any country in the European Economic Area (EEA) must have an entity or person located within the EEA that is responsible for the product on the EEA market. This person is known as the responsible person (RP). (See section 3.1 of this guide).

EEA countries include all EU Member States, as well as Iceland, Liechtenstein and Norway.

A 'distributor' is any person within the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Irish market in the course of a commercial activity, whether in return for payment or free of charge. This definition ~~could~~ also ~~include the retailer~~includes retailers.

Accordingly, this guidance is relevant to distributors of cosmetic products who are:

- persons placing cosmetic products on the market in Ireland for which an RP has already been designated
- persons importing cosmetic products into the EEA for which an RP has already been designated within ~~Europe~~the EEA or Northern Ireland
- retailers of cosmetic products including professionals supplying cosmetic products as part of a service.

However, note that persons importing cosmetic products from outside the EEA where no RP has been designated may also be considered to be the RP in addition to being an importer and distributor (see section 3.1 of this guide). An RP must be designated for each product distributed.

This guide is intended to provide supplementary guidance to distributors in ensuring compliance with Regulation (EC) 1223/2009 on cosmetic products, which is effective from July 2013. It sets out the Health Products Regulatory Authority's (HPRA) recommendations for best practice and other considerations for distributors of cosmetic products.

2 INTRODUCTION

The role of the HPRA, as the ~~Competent Authority~~competent authority for cosmetic products, is to ensure that all cosmetic products on the Irish market meet the requirements of the cosmetic product legislation and in doing so, do not compromise the health and safety of the consumer and any other person using or coming into contact with such products. Please note that products for professional use expose both the professional and the client to the cosmetic product.

The HPRA, in conjunction with the HSE, conducts a surveillance programme of cosmetic products on the Irish market which contributes to ensuring regulatory compliance. This surveillance involves proactive and reactive:

- cosmetic product sampling and analytical testing
- review of cosmetic product labelling
- review of cosmetic product information files and associated safety data
- inspection of responsible persons, manufacturers, importers and distributors of cosmetic products

3 LEGISLATION

This guide refers to Regulation (EC) 1223/2009 on cosmetic products ('the Regulation'). Distributors should work to this regulation to ensure compliance with its provisions. The Regulation was transposed into national legislation as European Union (Cosmetic Products) Regulation 2013 S.I. No. 440 of 2013 ('the S.I.').

It should be noted that for the purposes of market surveillance activities, authorised officers within the HPRA and HSE have powers to enter and search any premises where manufacture, distribution or supply of a cosmetic product may be taking place. Samples may be taken without payment for analysis and/or products and documentation may be detained.

3.1 Responsible Person

Every cosmetic product that is made available for sale in any country in the EEA must have an entity or person located within the EEA (or Northern Ireland) that is responsible for the product on the EEA market. This person is known as the responsible person (RP). The Regulation outlines the scenarios of becoming a RP in Article 4, and the associated obligations in Article 5. In general, the manufacturer of a cosmetic product would be considered to be the RP. This includes:

- Where the product is manufactured and distributed within the EEA, the manufacturer established within the EEA or Northern Ireland is considered the RP.
- Where a product is distributed in the EEA, and the manufacturer is established outside the EEA, the manufacturer must designate a person established within the EEA or Northern Ireland to act in the capacity of RP. The designation by the manufacturer and the acceptance of the role by the RP must be formally set out in writing.

Under the Regulation ~~(EC) No. 1223/2009~~, as amended, a distributor may also be considered to act as the RP ~~as follows: the distributor is the RP~~ where ~~he/she places~~they place a cosmetic product on the market under ~~his/her~~their name or trademark or ~~modifies~~modify a product already placed on the market in such a way that compliance with the applicable requirements may be affected (for example: re-labelling a product with their own name and contact details).

It is ~~very~~ important for an Irish distributor/retailer of a cosmetic product to establish if they may be required to act as the RP for a cosmetic product they distribute or sell. This can be established as follows:

- If they receive a cosmetic product from a supplier located outside the EEA, then they are not only a distributor but also an importer.

- If they are an importer, a check should be performed to identify if the product labelling lists ~~a European contact~~an EEA/Northern Irish address.

- If ~~a European contact~~an EEA/Northern Irish address is present, they should be contacted to confirm that they are the RP for the product in question, and to notify the RP that you are importing the product into the EEA. This must be accepted in writing.

If no ~~European contact~~EEA/Northern Irish address is present, the importer takes on the role of RP. Note, however, that the product cannot be placed on the EEA market before complying with all requirements of the RP as outlined in ~~HPRA's~~HPRA 'Guide to ~~Cosmetic Products~~cosmetic products for ~~Responsible Persons~~responsible persons.' ~~Please see~~, available on the ~~'Publications~~HPRA website under 'Regulation' and ~~Forms' section of www.hpra.ie~~'Guidance documents'.

3.2 Impact of Regulation (EC) 1223/2009 on distributors

~~The implementation of Regulation (EC) No. 1223/2009 consolidates legal obligations of economic operators in the cosmetics sector into a single legal text, thereby simplifying the regulatory framework.~~

Article 6 of the Regulation ~~(EC) No. 1223/2009~~ outlines the obligations of the distributor, including:

- to act with due care in relation to applicable requirements

- to verify that certain labelling information is present (see section 5.4 of this guide)

- to take corrective measures to bring a non-compliant product into conformance or recall/withdraw the non-compliant product

- to take preventative measures where relevant

- where a product poses a risk to human health, to inform the RP and ~~Competent Authority (the HPRA)~~competent authority

- to ensure that storage or transport conditions do not negatively impact the product's compliance while under their responsibility

- to cooperate with the ~~Competent Authority (the HPRA)~~competent authority

3.3 ~~The~~ Product ~~Information File~~information file

Prior to placing a cosmetic product on the European market, the RP is required to prepare a product information file (PIF). Article 11 of the Regulation ~~(EC) No. 1223/2009~~ lists the requirements for the PIF. The RP should maintain this file throughout the lifecycle of the cosmetic product and update it as required, including any undesirable effects (UEs) reported. Therefore, it is important to refer any information on ~~undesirable effects~~UEs to the RP for investigation (see section 8 of this guide).

The PIF should be accessible ~~at~~to the ~~address which appears~~competent authority within 48 hours of a request and maintained for 10 years post placing the last batch on the ~~cosmetic product label.~~market.

4 SUPPLIER APPROVAL AND TECHNICAL AGREEMENTS

It is recommended that a distributor of a cosmetic product has a technical agreement in place with their supplier. A technical agreement between a distributor of cosmetic products and their supplier should include but is not limited to:

- relationship of parties and relevant contact details

- responsibilities for regulatory compliance of cosmetic ingredients
- products covered by the agreement and any specific requirements relating to their sale, e.g. professional use only products~~.~~

- transport specifications

- details of distributor sales, service and storage facilities

- product traceability requirements

- responsibilities and procedural aspects in terms of recall/withdrawal procedures, handling returns, complaints and/or undesirable effects

- contact details of the RP and location of the PIF for each product supplied

- additional packaging requirements, for example, where a label, tag, tape or card is required (see section 5.4~~) or products are intended for professional use~~ of this guide)

- ~~review provision for~~ ensuring roles and responsibilities are maintained for the ~~agreement maintains relevance to~~life cycle of the ~~ongoing operation~~product

5 DUE CARE AND OPERATION OF A QUALITY SYSTEM

~~In order to~~To meet the due care requirements and to ensure that only cosmetic products that comply with the legislation are made available for supply, it is recommended that distributors have a quality system in place. An effective quality system provides assurance that only ~~product~~products which ~~complies~~comply with legislative requirements ~~is~~are distributed; that defective or unsuitable ~~product~~products can be detected, that traceability of all products is maintained, and that non-conformances and the introduction of changes are controlled. Written standard operating procedures (SOPs) and appropriate records/evidence of compliance with the Regulation should be generated and maintained for all aspects of the business.

There should be an effective recall procedure in place that allows the prompt removal of defective or unsuitable product from in-house or distributed stock. ~~In order to~~To do this, records should be kept that allow for traceability of product including:

- details of the dispatched product

- details of where the product has been supplied from and distributed to ~~and supplied from~~, and

- full product reconciliation.

Article 7 of the Regulation ~~(EC) No.1223/2009~~ details the requirements for identification of product within the supply chain.

5.1 Goods-in checks

It is recommended that deliveries are examined at receipt to include checking for damage and appropriate remaining shelf life. ~~A written standard operating procedure (SOP~~An SOP (including appropriate records/forms as evidence) should be in place to enable any defective product to be detected and quarantined.

Checks to be conducted include but are not limited to:

- inspection for damage
- specific storage conditions (e.g. protect from sunlight, temperature controls)
- labelling checks (see section 5.4 of this guide)
- record of the expiry date
- consignment received from an approved supplier (see section 4 of this guide)
- ~~It is preferable that~~ a record of the batch number is ~~made or~~ maintained ~~through other means~~ to assist with traceability~~.~~

~~Material safety data sheets and/or~~Batch release criteria documentation such as certificates of analysis may be examined where appropriate.

Professional use only products may require segregation from general sale products to ensure they are not incorrectly supplied.

Appropriate checks should be considered for returned products to ensure that they are legitimate and as supplied.

5.2 Documentation and record keeping

Distributors should keep adequate records, including records of customers to whom product has been distributed (including but not limited to product name and/or code, quantities and delivery date). This information is especially important in the event of a recall/withdrawal from the market.

For transactions between manufacturers and distributors, and for transactions between two distributors, there must be traceability of the origin and destination of products, for example, copies of invoices should be kept. It is considered best practice to record batch numbers or unique identifiers for cosmetic products received and supplied. In the event a recall of a particular batch is required, failure to record the batch numbers involved in transactions may result in a full product recall being required.

Records to be maintained by the distributor include:

- copies of invoices relating to the receipt and supply of a cosmetic product
- copies of orders relating to the receipt and supply of a cosmetic product
- a list of approved product suppliers and details of the relevant products
- customer list to include contact details of all customers to whom product was supplied
- records of checks carried out at receipt (for example labelling checks) and the approval of product into saleable stock

These records should be kept for up to three years following the date of receipt of the last batch and may be requested by an ~~Authorised Officer~~authorised officer of the HPRA or HSE, as referred to in section 3 of this guide, as part of market surveillance activities.

SOPs should be established to clearly describe how key activities are carried out~~.~~ and who is responsible for each activity. Forms should be used to capture relevant information such as goods receipt checks and labelling checks.

5.3 Traceability

Product traceability is achieved through maintaining adequately detailed records in relation to the sourcing and supply of cosmetic products. In the event of a product recall, it may be necessary to determine the customers that received a specific batch of a product which was defective. In such cases, the maintenance of a system which includes tracking by batch number is most valuable in terms of assisting and ensuring the swift conduct of the recall. The system used to maintain product traceability should be challenged periodically to ensure that it is capable of determining stock location.

5.4 Labelling verification

When making a cosmetic product available on the market, distributors must act with due care in relation to legislative requirements.

Before making a cosmetic product available on the market, distributors are required to verify that each batch of product includes:

- The labelling is in a suitable language.
- The date of minimum durability specified, where applicable, has not passed.
- The labelling information given below is provided to consumers:
  - RP name and address within the EEA or Northern Ireland
  - batch number
  - ingredient list
  - a label, tag, tape or card displaying product information such as the ingredient list (where applicable)
  - any additional point-of-sale requirements are met (for example, soaps displayed without packaging at retail level require information such as the ingredient list to be made available to the consumer)

Further guidance on labelling requirements can be obtained through reference to the HPRA ~~'Guide to Cosmetic Products for Responsible Persons'. Please see the 'Publications and Forms' section of www.hpra.ie.~~'Guide to cosmetic products for responsible persons'.

5.5 Stock rotation and goods-out checks

Adequate rotation of stock is advised to ensure that a 'first expired first out' (FEFO) or similar stock rotation system is applied. As such the minimum date of durability should be checked at put away and routinely checked during product storage to ensure that stock with the shortest remaining period of durability is supplied first.

Checklists can be used to ensure that any point-of-sale requirements and/or additional information are distributed with the cosmetic product as required.

5.6 Corrective actions

Where distributors consider or have reason to believe that a cosmetic product is not in conformity with the requirements of the cosmetics legislation, they must contact the RP immediately and should cease distribution of the cosmetic product until it has been brought into conformity with the applicable requirements.

A distributor is also required to ensure that the corrective measures necessary to bring that cosmetic product into conformity are taken. The RP and distributor should work closely and communicate on any corrective measures to be implemented, for example, re-labelling of a cosmetic product.

Where the distributor modifies a cosmetic product already placed on the market in such a way that compliance with the applicable requirements may be affected, ~~he/she~~they will be considered to act in the capacity of the RP (see section 3.1 of this guide).

The range of corrective actions required to address non-compliance(s) can vary in terms of severity. However, in cases where the product presents a risk to consumers, it is necessary for the distributor to inform the competent authority of the non-compliance and corrective measures taken. It may be necessary to recall and/or withdraw batches ~~or~~of the product as appropriate (see section 5.7 of this guide).

5.7 Recall/withdrawal

For the purposes of this guidance document and in accordance with the definitions provided in Article 2 of the Regulation ~~(EC) 1223/2009~~, the following distinctions are made between the terms 'recall' and 'withdrawal':

~~A **recall** is any measure aimed at achieving the return of a product or batch of a product that has already been made available to the end user in the market place.~~

~~A **withdrawal** is any measure aimed at preventing a product in the supply chain from being made available on the market.~~

- A **recall** is any measure aimed at achieving the return of a product or batch of a product that has already been made available to the end user in the marketplace.

- A **withdrawal** is any measure aimed at preventing a product in the supply chain from being made available on the market.

In the case of the product presenting serious risk to consumer health, where it cannot be demonstrated that this risk is confined to a specific batch or batches, the market action is likely to extend to include recall as well as withdrawal.

In the event that an unsafe product is known to have been placed on the Irish market, a distributor is required to contact the HPRA at cosmetics@hpra.ie ~~before carrying out~~to inform of the initiation of any withdrawal or recall action on the Irish market and provide the following details:

- an account of the events which led to the recall/withdrawal~~/recall~~
- the reason for the recall/withdrawal
- product details (product name and brand, product code, batch number, expiry date, manufacturer, name and address of distributor, importer, RP, date of receipt)
- country of origin
- basis on which the recall is being made (e.g. voluntary, etc.)
- list of customers supplied with the affected product (including other distributors)
- mechanism of recall/withdrawal~~/recall~~
- extent of recall/withdrawal~~/recall~~ (distributor level, retail level, consumer/user level)

An effective recall/withdrawal procedure must be in place. The procedure should include:

- mechanism for the execution of the recall/withdrawal~~/recall~~ action (e.g. by letter~~, telephone~~ or ~~fax~~phone, etc.)
- timelines for carrying out and completing the recall/withdrawal
- identification of the person responsible for recording, monitoring and reconciling the stocks ~~so as~~ to facilitate liaison between the RP, manufacturer, distributor, HPRA and ~~Environmental Health Officers~~EHOs from the HSE
- contact details for the HPRA (see section 11 ~~below~~of this guide)

A recall/withdrawal summary report should be prepared detailing:

- specific corrective actions put in place as a result of the recall/withdrawal~~/recall~~ (if applicable)

- copies of notification letters sent to customers during the course of the recall/withdrawal~~/recall~~
- date of close out of recall/withdrawal~~/recall~~
- total quantity of packs placed on the market
- total quantity of packs recovered

This recall summary report should be provided to the HPRA on completion of a recall.

In the event of product disposal following a recall or withdrawal, evidence of destruction should be maintained, usually in the form of a certificate of destruction provided by a disposal company. If it is the case that there are insufficient quantities for immediate disposal, the products should be stored in a designated area of the warehouse, which is segregated and secure.

5.8 Training

Appropriate training should be provided to all personnel and conducted on an ongoing basis. Records of training should be maintained. Training could include but is not limited to:

- defined responsibilities for personnel
- access to and training on documentation relevant to their role
- storage requirements
- labelling checks and maintenance of records
- point of sale requirements (as ~~may be~~ appropriate)
- reporting of non-compliances and maintenance of records
- operation of segregated areas to minimize the risk of mix-ups
- recall/withdrawal procedures and maintenance of records
- complaints procedures and maintenance of records
- serious undesirable effects (SUE) reporting and maintenance of records (see section 8 of this guide)

6 STORAGE AND TRANSPORT CONDITIONS

Cosmetic products must be stored appropriately and in accordance with written procedure. Instructions should ~~also~~ be documented for removal of damaged/expired product from saleable stock. The instructions should state where the product is to be located. An inventory is needed for all stock including quarantined stock. The storage facility should be clean, free from litter, dust and pests.

7 PRODUCT PRESENTING A SERIOUS RISK

A distributor is required to:

- ensure that a cosmetic product is safe prior to placing it on the market; the distributor should receive confirmation from the RP that the product meets the legislative requirements governing PIFs, and that an appropriate safety assessment has been carried out
- report products presenting serious risk to the RP and ~~Competent Authority~~the competent authority
- maintain traceability within the supply chain, for example maintenance of documentation necessary for tracing the origin of the product within a reasonable timeframe
- inform the RP, ~~Competent Authority~~competent authority and consumers of any defects and/or risks posed to consumers
- cooperate with actions taken by the RP and/or the ~~Competent Authority~~competent authority

The reporting of a cosmetic product which presents a risk to consumers must be notified to the HPRA providing the following information:

- information enabling a precise identification of the product or batch of product in question
- a full description of the risk that the product(s) in question present
- all available information relevant for tracing the product, e.g. quantities and customers supplied
- a description of the action undertaken to prevent risks to consumers

~~7.1 RAPEX~~

7.1 ~~RAPEX~~Safety Gate

Safety Gate is the EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. The ~~National~~ Competition and Consumer ~~Agency (NCA~~Protection Commission (CCPC) is the national contact point for ~~RAPEX and the NCA~~Safety Gate. The European Commission circulates ~~alerts on~~ a weekly ~~basis for all~~summary of consumer products, including ~~cosmetics~~cosmetic, which pose a risk to consumers. Distributors are encouraged to sign up

for ~~RAPEX~~Safety Gate updates on the ~~NCA website, in order~~European Commission website, to be aware of new alerts circulated for consumer products.

8 REPORTING SERIOUS UNDESIRABLE EFFECTS

An undesirable effect (UE) is an adverse effect on human health that occurs from the normal or reasonably foreseeable use of a cosmetic product. ~~Undesirable effects~~UEs do not include, for example, those resulting from abuse or misuse of the product. Examples of ~~undesirable effects~~UEs include but are not limited to: ~~irritant and allergic effects, sensitivity to light and itching.~~

- irritant and allergic effects
- sensitivity to light
- itching

A serious undesirable effect (SUE) means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death. It is important to note that the HPRA considers an adverse event, which results in significant impact to someone's physical appearance in so far as them becoming socially uncomfortable or impacting their quality of life (i.e. not being able to attend events as planned), as temporary functional incapacity.

In the event of ~~serious undesirable effects~~SUEs occurring on the Irish market, the distributor must, without delay, notify the following to the HPRA and the RP:

- all known ~~serious undesirable effects~~SUEs
- the name of the cosmetic product concerned, enabling its specific identification
- the corrective measures taken, if any

This information should be supplied by the distributor to the RP and the HPRA using SUE form A available from the ~~EU Commission website~~European Commission website. A distributor should maintain a log and records of UE and SUEs reported to them, as they are required to be able to unambiguously identify these cases, as detailed in the European Commission SUE reporting guidelines.

9 SUPPLY OF PROFESSIONAL USE PRODUCTS

The restriction of supply to professional use ensures that certain products are used by a professional only. A professional is more familiar with the health risks of a specific substance or its concentration in a cosmetic product than a consumer or has more professional expertise in applying cosmetic products correctly on the consumer. For example, tooth-

whitening products which contain greater than 0.1% and up to 6.0% hydrogen peroxide (present or released) should only be supplied to a dental practitioner.

Distributors should operate a system which enables identification of professional use only products~~,~~ and ensure that the onward distribution of these products is confined to supply to the relevant intended and qualified user groups only.

10 NOTIFICATION TO CPNP BY DISTRIBUTORS

The RP is required to inform the ~~Competent Authorities~~competent authorities and poison centres of cosmetic products which they are placing on the European market. This information is notified through the Cosmetic Product Notification Portal (CPNP).

There are a limited number of circumstances whereby a distributor is required to notify~~:~~ a product to CPNP. These include:

- where a cosmetic product is modified in a way which affects its compliance with the legislation (e.g. modification of labelling)

- where the RP is no longer placing a cosmetic product on the European market and the distributor re-introduces the product to the market

The CPNP system will 'link' the distributor's notification to that of the original RP in such cases to ensure transparency of the supply chain.

11 FURTHER INFORMATION

For queries on the distribution of cosmetic products in Ireland, contact the ~~Health Products Regulatory Authority at the following address:~~HPRA via email to cosmetics@hpra.ie or use the 'contact us' form on the HPRA website.

~~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: cosmetics@hpra.ie~~

~~Information~~Further information is also available on the HPRA website ~~at www.hpra.ie~~, under the 'Regulatory guidance documents' and the 'Cosmetics' sections.