HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
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.

CONTENTS

1 SCOPE

This document is an introductory guide to the cosmetics function of the Health Products Regulatory Authority (HPRA) and the legislation applicable to responsible persons (including manufacturers, importers and designated responsible persons) and distributors (including retailers) for cosmetic products.

2 INTRODUCTION

The HPRA (previously the IMB) is a statutory body established under the Irish Medicines Board Act, 1995, as amended. The HPRA is the competent authority in Ireland for medicines for human and veterinary use, medical devices, health products and in particular has the responsibility for cosmetic products.

The role of the HPRA as the 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 persons where appropriate.

The HPRA is composed of a Board, Advisory Committees to the Board and staff. The Minister for Health appoints the Board and the Advisory Committees. Expert panels are also used to assist the HPRA and where necessary, working groups may be established.

The Board acts through the Chief Executive. The Chief Executive is responsible for the day-to-day activities of the HPRA with the help of a Management Committee comprising the heads of departments.

The cosmetics function of the HPRA is integrated into the Healthcare Products Distribution section of the Compliance Department. It is also supported by the Licensing section in relation to issue of export certificates.

3 DEFINITION OF 'COSMETIC PRODUCT'

The term **cosmetic product** covers a very wide range of consumer products including: anti-wrinkle products; bath and shower preparations; creams; deodorants and anti-perspirants; emulsions; face masks; gels and oils for the skin; hair care products; lotions; make-up powders; make-up removers for the face and eyes; perfumes; products for care of the teeth and mouth; products for external intimate hygiene; products for nail care and make-up; products for tanning without sun; products intended for application to the lips; shaving products; skin-whitening products; sunbathing products; tinted bases and toilet soaps. (Note: this listing is not exhaustive.)

The key definitions stated in Regulation (EC) No. 1223/2009, on cosmetic products (as amended), is as follows:
'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;'

This definition is quite specific and does not encompass products presented as having properties for treating or preventing disease in human beings. Such activities are more in keeping with medicinal product intent. Any particular words or phrases which imply such claims will be taken into account in determining the intent behind the presentation. While not intending to be exhaustive, the following list contains examples of such words or phrases which present a medicinal intent: *cures; heals; treats; restores; prevents; clears; protects against disease; helps control the symptoms of; traditionally used for treatment of; strengthens the immune system.*

Products intended to be ingested, inhaled, injected or implanted in the human body do not come under the definition of cosmetic. Furthermore, products containing ingredients that exert a pharmacological, immunological or metabolic action are considered to be medicinal products.

4 LEGISLATION

4.1 Primary legislation

Regulation (EC) No. 1223/2009 (as amended), was published in the Official Journal of the European Union, Volume 52, on 22 December 2009, and applies in full from 11 July 2013.

The aim of the cosmetics Regulation is to safeguard public health, with due regard to the welfare of animals, and to harmonise the rules in the European Economic Area (EEA) to achieve a single market for cosmetic products.

Commission Regulation (EU) No. 655/2013 lays down common criteria for the justification of claims used in relation to cosmetic products. Guidelines on this Regulation are available on the European Commission's website.

Commission Implementing Decision 2013/674/EU provides guidance on compilation of the cosmetic product safety report (CPSR) for cosmetic products. The efficacy of sunscreen products and the claims made relating to efficacy are addressed in Commission Recommendation 2006/647/EC.

4.2 National legislation

S.I. No. 440 of 2013, European Union (Cosmetic Products) Regulations transposes the national implementing provisions from Regulation (EC) No. 1223/2009 (as amended).

4.3 Parallel legislation

Council Directive 2001/95/EC concerning general product safety and the related European Communities (General Product Safety) Regulations 2004, S.I. No. 199 of 2004, which became mandatory on 4 May 2004, make certain provisions for communication of consumer products presenting a serious risk.

The European Commission has proposed a new package of measures to improve consumer product safety and to strengthen market surveillance of products in the EU. Further details can be found on the European Commission website.

4.4 Guidance and standards

Further guidance documents relating to the regulation of cosmetic products are available on our website at www.hpra.ie. Harmonised standards in the area of cosmetic product manufacture, analysis and sun protection are published in the Official Journal of the European Union.

5 ROLE OF THE COMPETENT AUTHORITY

The competent authority is the body which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the cosmetics regulation are carried out in that particular Member State. The primary role of the competent authority is to ensure that all cosmetics on the Irish market meet the requirements of the regulation and do not compromise the health and safety of the consumer.

5.1 How the HPRA undertakes the role of competent authority

The HPRA carries out the functions of the competent authority for cosmetic products as outlined in the legislation as follows:

- ensuring the operation of an effective and broad reaching market surveillance programme in conjunction with the Health Service Executive (HSE) which involves a market sampling and analysis programme
- Review of product information files, as required;
- investigation of safety concerns arising from cosmetic product use;
- inspection of manufacturers, importers and distributors to ensure compliance with the legislative requirements;

- participation in international activities including various relevant EU working groups and committees at the EU Commission;
- issuance of certificates of free sale.

6 COMPLYING WITH THE LEGISLATION

All cosmetic products placed on the market must comply with the legislation in Regulation (EC) No. 1223/2009 as amended. Some guidance on complying with the legislation is outlined below.

6.1 Nomination of responsible person

A responsible person should be nominated for each cosmetic product placed on the European market. The responsible person must be based within the EEA and their address should appear on the cosmetic labelling.

The responsible person is usually the manufacturer or, where the manufacturer is based outside the EEA, the importer. Further guidance is available in the 'Guide to Cosmetic Products for Responsible Persons'.

6.2 Confirmation that product is a cosmetic product

The responsible person must confirm that the product comes within the definition of a cosmetic product as defined in Article 2 (Definitions) of Regulation (EC) No. 1223/2009 as amended.

In cases where determination is difficult, please consult the HPRA or other relevant competent authority in Europe for classification advice.

6.3 Meeting the requirements of the legislation

Cosmetic products placed on the EEA market must meet the requirements detailed in Regulation (EC) No. 1223/2009 as amended. It is necessary for the responsible person for the cosmetic product to review all of the requirements outlined in the Regulation against their procedures and update them accordingly. The responsible person must also review the requirements regarding the information that is to be supplied with the product and determine what is appropriate for their products.

Article 6 of Regulation (EC) No. 1223/2009, as amended, 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;
- to take corrective measures to bring a non-compliant product into conformance;

- to take preventative measures where relevant;
- where a product poses a risk, to inform the responsible person and competent authority (the HPRA);
- to ensure product is not jeopardised while under their responsibility;
- to cooperate with the competent authority (the HPRA).

Further information on requirements for distribution and retail of cosmetic products are available in the 'Guide to Distribution of Cosmetic Products in Ireland'. Please see the 'Publications and Forms' section of www.hpra.ie.

6.4 Preparation of the product information file

In accordance with the requirements of Article 11 of Regulation (EC) No. 1223/2009, as amended, the responsible person must keep the product information file, demonstrating the conformity of their products with the provisions of the European regulations and related legislation that apply to them, readily accessible to the competent authority. For guidance please refer to the 'Guide to Cosmetic Products for Responsible Persons'.

6.5 Notification of cosmetic products

Article 13 of Regulation (EC) No. 1223/2009, requires that prior to placing a cosmetic product on the European market, the responsible person must submit information about the product to the European Commission by electronic means. The European Commission launched the Cosmetic Product Notification Portal (CPNP) in January 2012. This is a centralised database for the notification of cosmetic products and replaces national notification requirements. From 11 July 2013, products already on the European market must be notified by the responsible person to CPNP and notification must also occur for new products prior to placing them on the European market. Further information on the CPNP is available on the European Commission website.

6.6 Product information file/documentation availability

The responsible person must make the product information file available to the HPRA for inspection purposes if requested as part of market surveillance. This includes making the file available by a manufacturer to his designated responsible person. It also includes having the file available at the European premises indicated on the product label.

7 COMMUNICATION WITH THE COMPETENT AUTHORITY

7.1 Cosmetovigilance

An undesirable effect is an adverse reaction to a cosmetic product under normal or foreseeable conditions of use. A serious undesirable effect is an undesirable effect which results in temporary or permanent functional incapacity, disability, or hospitalisation,

congenital anomalies or an immediate vital risk or death. Article 23 of Regulation (EC) No. 1223/2009, as amended, requires all serious undesirable effects to be reported to the appropriate competent authority.

The monitoring and investigation of such reports is known as cosmetovigilance. The responsibilities of all operators involved, from the manufacture through to the supply of cosmetic products, in this area are outlined further in the 'Guide to Cosmetic Products for Responsible Persons', and the 'Guide to Distribution of Cosmetic Products in Ireland'.

To report an undesirable effect, please email cosmetics@hpra.ie.

7.2 RAPEX Notifications

Where a product presents a risk to consumers, the responsible person informs the competent authority in the European country in which the PIF is made available, giving details of the non-compliance and the corrective measures taken. Serious risks are communicated by that competent authority to all EEA countries via the RAPEX system.

The provisions of the General Product Safety Directive, and in particular the Community Rapid Information System (RAPEX) procedure (Article 12), apply to consumer products that pose a serious risk to consumers. The National Consumer Agency (NCA) is the Irish national contact point for RAPEX. The HPRA works closely with the NCA on the communications of serious risks associated with cosmetic products.

To report an issue with a cosmetic product that could present a risk to consumers, the responsible person and/or the distributor (including retailer) should e-mail cosmetics@hpra.ie.

8 CONTACT DETAILS

This guide and associated documents can be found under the 'Publications and Forms' section of the website, www.hpra.ie.

Alternatively, they can be obtained from the HPRA directly as follows:
Compliance Department,
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.
Tel: +353-1-6764971
Fax: +353-1-6344033
E-mail: cosmetics@hpra.ie

The HPRA encourages communication with the cosmetics sector. Should you have specific queries please address them to the Compliance Department of the HPRA who will endeavour to be of assistance. Communication can be made by telephone, fax, email or post to the above address.