

What do I do if a customer experiences an undesirable effect?

An undesirable effect is an adverse effect on human health that occurs from the normal or reasonably expected use of a cosmetic product. An undesirable effect is sometimes referred to as an adverse reaction. Examples of undesirable effects include irritant and allergic effects, sensitivity to light and itching.

A serious undesirable effect means an undesirable effect which results in temporary or permanent inability to function as normal, a disability, hospitalisation, birth defects, an immediate risk to life or death.

In the event of a serious undesirable effect occurring on the Irish market, the retailer must, without delay, contact the HPRA and the company at the European address on the label. You should report the following details:

- the name of the relevant cosmetic product so it can be identified;
- all serious undesirable effects that you are aware of related to this product;
- any corrective action taken. This might include stopping a product from being sold.

Report forms can be downloaded from the cosmetics section of the HPRA website.

What is the role of the Health Products Regulatory Authority?

The HPRA is responsible for the regulation of cosmetic products in Ireland. Our aim is to ensure all cosmetics on the Irish market are safe and comply with the new laws. We identify and address cosmetic product safety issues, in conjunction with the HSE, so that a cosmetic product will not compromise the health and safety of the consumer or the person applying the product.

Further information

Our *Guide to the Distribution of Cosmetic Products* contains more details. This and other guides are available from the cosmetics section of www.hpra.ie. Copies of the form used to report serious undesirable effects to the HPRA are also available.

If you have any queries about the information contained in this leaflet, or any other questions concerning the regulation of cosmetic products, please e-mail: cosmetics@hpra.ie



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A GUIDE FOR RETAILERS

Selling Cosmetic Products in Ireland

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I sell cosmetic products, why should I read this leaflet?

On 11 July 2013, new laws* came into force impacting everyone who sells cosmetic products in Ireland.

All retailers who sell cosmetic products should be aware of these new laws and the legal requirements now in place.

The Health Products Regulatory Authority (HPRA) has developed this leaflet to explain these important changes.

What are cosmetic products?

They are products generally intended to cleanse or beautify a person. Some examples include deodorants, shampoos and soaps, hair dyes, toothpaste and make-up.

*This EU law is Regulation (EC) No. 1223/2009.

What do the new laws mean for me as a retailer?

As a result of the new laws, a retailer is now required to:

- confirm that certain important information has been included on the label of a cosmetic product;
- take due care and avoid any unnecessary risks in the purchase of cosmetic products from suppliers;
- take steps to make a product safe if there is a safety concern;
- inform suppliers and/or the HPRA if a customer experiences an undesirable effect (adverse reaction) after using a cosmetic product;
- ensure products are stored and transported properly to avoid any negative impact on the safety of the products (while they are your responsibility).

What do I need to check on the product label?

- That the text on the label is in English, in Irish or both.
- That the best before date, where this is relevant to the product, has not passed.
- That the information below is present on the label:
 - An ingredient list
 - A batch number or reference ID
 - A European address

In the case of soap, bath ball or any other small product where it is not possible to list the ingredients, this information should appear on a notice immediately beside the product.

What checks must I carry out if I purchase a cosmetic product over the internet for sale in my premises?

If you are buying a cosmetic product over the internet you must carry out the same checks listed previously.

What records do I need to keep?

Retailers should keep records of all their suppliers of cosmetic products. Invoices and/or delivery dockets should be kept for three years.

What actions should I take during a product recall?

In the event that an unsafe product is placed on the Irish market, a retailer is required to cooperate with their supplier and with the HPRA in recalling the product from the market. This is when records become very important.

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