Product Classification

Borderlines between medicines, cosmetics and biocidal products

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Overview

• Key aspects – define your product
• Some examples of borderlines
  • Hair loss products
  • Antibacterial hand washes
  • Tooth Whitening Products
• Reference/ Guidance Documents
Key aspect to classification ...

1. Define product
2. Apply Regulatory Framework
3. Ensure compliance (documentation, records, licences etc)
4. Place on the market
## Define Product

<table>
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<th>IMB responsibility</th>
<th>Other agencies</th>
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<tbody>
<tr>
<td>Human &amp; Veterinary Medicines (Including THMPs)</td>
<td>Biocides (PRCD, Dept of Agriculture Food and the Marine)</td>
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<tr>
<td>Medical Devices</td>
<td>General Products (National Consumer Agency)</td>
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<td>Cosmetics</td>
<td>Food Supplements (FSAI)</td>
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Need to refer to legal text for product definitions

- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

- Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Cosmetic Product Definition

Article 1 of Directive 76/768/EEC

• ...substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous membranes of the oral cavity,

with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition...
Key differences between medicine and cosmetic …

Cosmetic product

- Must not exert a pharmacological, immunological or metabolic action
- Must not be presented as having properties for treating/preventing a disease
- External application
- Cannot be ingested, implanted or inhaled
Biocide definition

Article 2 of Directive 98/8/EC

- Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.
Article 2 of Directive 2001/95/EC

- Any product – including in the context of providing a service – which is intended for consumers ... and is supplied or made available ... in the course of a commercial activity, and whether new, used or reconditioned.
Borderline cases...

Dental Floss
Facial Wipes
Dermal Patch

Are these cosmetic products?
1 – Yes
2 – No
3- It depends
Borderline cases ...

Lip Plumper

Eyelash Growth Enhancer
Childrens Cosmetics

Chewing Gum releasing agents

Manual on the scope of application of the Cosmetics Directive, version 8:
Hair loss products

Claims include:
- Treat or prevent hair loss
- Stimulate hair growth
- Stop, slow down or reverse hair loss

Do you consider the claims listed to be associated with:

1. a cosmetic product or
2. a medicinal product?
Non-medicinal claims for hair care products

- Promote or strengthen existing hair growth
- Nourish thinning hair
- Consider route of administration - cosmetic Vs food supplement
Antibacterial hand washes – classification?

Cosmetic Vs Biocide Vs Medicine?
Intended Use?
Ingredient list?
Claims?

**Intended Use**
In line with a cosmetic product definition or is it to prevent cross contamination?

**Ingredient List**
Biocidal active ingredients?
Meet the restrictions of Directive 76/768/EEC?
Antibacterial hand washes – examples of claims

- Kills 99.9% bacteria
- Germ kill
- Kills bacteria, fungi, viruses
- Suitable for hand disinfection
- Disinfectant

Would you consider the above claims to be associated with:

1 - A Cosmetic product, or
2 - A Biocidal product?
Antibacterial products – classification?

- Cosmetic, medicinal, biocide?
- Antiseptic claims – used to treat or prevent infections
- Disinfection claims – for hygiene purposes/ prevention of cross contamination
- Clean, protect, correct body odours - Cosmetic
Status of cosmetic – biocide borderline products

- National guidance was drafted in 2011
- Outcome of Public Consultation – query to EU Commission on secondary claims
- EU Commission currently in discussions
- Hope to have clarification over the coming months
- IE – consider the product presentation, intended use and composition – if in doubt, contact the IMB and PRCD for guidance.
Hydrogen Peroxide in Tooth Whitening products

Before

After
The use of **toothpastes, mouth rinses** and tooth whiteners containing **up to 0.1% hydrogen peroxide** does not pose a risk to the health of the consumer. Toothpastes and mouth rinses should not contain more than 0.1% hydrogen peroxide.
Key area for 2012

- Products containing up to 0.1% $\text{H}_2\text{O}_2$ can be made available to the consumer
- Products containing between 0.1% and 6% $\text{H}_2\text{O}_2$ can only be made available to dental practitioners
- Products containing $>6\% \text{H}_2\text{O}_2$ **Prohibited**
- Distributors must ensure product meets requirements in terms of labelling and must only supply to dental practitioners
Labelling requirements for $\text{H}_2\text{O}_2 > 0.1\%$

- Contains hydrogen peroxide
- Concentration of $\text{H}_2\text{O}_2$ present or released indicated as %
- ‘Avoid contact with eyes, rinse immediately if product comes into contact with them’
- Not to be used on a person under 18 years of age
- **To be only sold to dental practitioners.**
- For each cycle of use, the first use to be carried out only by dental practitioners
Summary

- Ensure product classification is appropriate
- Apply appropriate regulatory framework
- If in doubt – seek advice
- Place safe, compliant product on the market

Guidance Documents:

http://www.imb.ie/EN/Cosmetics.aspx
Borderline Products Guidance

In practice, it may sometimes be unclear whether a product is a cosmetic product in the sense of the Cosmetics Directive or whether it falls under other sectoral legislation. This decision is to be taken on a case-by-case basis.

However, the Commission has published a number of guidance documents to facilitate the application of Community legislation in these cases. These include a “manual” on the application of Art. 1 Cosmetics Directive, i.e., the definition of “cosmetic product” (see below) and various guidelines on the borderline other sectoral legislations.

Please note, however, that only the text of the Directives is authentic in law. The text of the Directives is applicable where there are differences between the provisions of a directive and the contents of these guidance documents. The interpretation of Community law is ultimately the responsibility and privilege of the European Court of Justice. The analysis set out in these guidance documents does not in any way prejudice a different interpretation by the European Court of Justice in a particular case, and does not in any way commit the European Commission.


Guidance documents on “borderline products”:

- Guidelines on the demarcation between the Cosmetic Products Directive 76/768/EEC and the Medical Products Directive 2001/83 as agreed between the Commission services and the competent authorities of Member States

Cosmetics

Cosmetic Product

A cosmetic product is any substance or preparation intended to be placed in contact with the various 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 and/or correcting body odours and/or protecting them or keeping them in good condition.

Substances intended to be inhaled, inhaled, injected or implanted in the human body, are not considered cosmetics.

Cosmetic products placed on the EU market must meet the requirements outlined in the Cosmetic Directive 76/768/EEC. This has been transposed into Irish law by S.I. 870 of 2004 European Communities (Cosmetic Products) Regulations, as amended. This legislation has been reviewed and updated in recent years and, from July 2013, will be replaced with Regulation (EC) No. 1223/2009. From July 2013, all cosmetic products placed on the EU market must comply with this regulation.