The Importance of Product Classification

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Introduction

1. The importance of correct product classification – *why?*

2. Product classifications – *what?*

3. Practical advice – *how?*
1. **Why** is it important to classify products?

- To meet the relevant regulatory requirements
- To ensure consumer safety
- Correct & cost effective way to conduct business
2. **What** are the different Product Classifications?

- Medicinal Products
- Medical Devices
- Food Supplements
  - Herbal Medicinal Products - *Pat Walsh*
  - Cosmetics
  - Biocides - *Nicola Hickie*
Human Medicinal Products

Article 1 of Directive 2001/83/EC, as amended by 2004/27/EC – Definition:

- 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.
1. Presentation
   • Label claims – cure, alleviate or prevent disease
   • Intended action - pharmacological, metabolic or immunological
   • Labelling, packaging, form, promotional material, intended audience implies medicinal use.

2. Purpose
   • Any product containing a substance with a known pharmacological effect

3. Composition
   • Substance confined to supply on a medical prescription

Guide to the Definition of a Human Medicine
Identifying Human Medicinal Products

All products authorised for distribution on the Irish market

- PA / EU / PPA / DPR Number
- TR, HOR, HOA
- Name, strength, form
- Active Ingredient
- Batch Number
- Expiry Date
- Manufacturer name & address
Identifying Human Medicinal Products

If a product fits the definition *(slide 6)* BUT **does not** have the characteristics *(slide 7)*

- Do not place product on the market
- Discuss with supplier
- Discuss with relevant regulatory authority to confirm classification
- Take the necessary steps to comply
Definition:

All products, except medicines, used in healthcare for the **diagnosis, prevention, monitoring** or **treatment** of illness or disability.

There are 3 types of medical devices outlined in the legislation.

1. General medical devices
2. Active implantable medical devices
3. *In-vitro* diagnostic medical devices
All medical devices authorised for distribution on the Irish market should bear a CE Mark.

medicaldevices@imb.ie

www.imb.ie: Medical Devices
Competent Authority for Food Supplements

Food Safety Authority of Ireland (FSAI)

www.fsaí.ie

National Legislation

- European Communities (Food Supplements) Regulations 2007

Amended by

- European Communities (Food Supplements) (Amendment) Regulations 2010
Food Supplements

Definition:

foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as:

- capsules
- pastilles
- tablets
- pills and other similar forms
- sachets of powder
- ampoules of liquids
- drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities
3. **How** can you ensure you are classifying products correctly?

When entering into a new contract or expanding an existing contract with a supplier, follow your Supplier Qualification Procedure

Requirement of New GDP Guide – Chapter 5
Supplier Qualification Procedure should include:

- **Product Classification**
  - Assessment of Products
  - Product Definitions
  - Determine if it’s a medicine
  - If not, what ‘box’ does it fall into?
  - Sources of Guidance

- **Formal record of the decision**
Consider extending this procedure to all suppliers.

It is important to correctly classify your product prior to procurement.
Help is available!!

IMB Classification Committee

- Classification service for borderline products
- Multidisciplinary in-house scientific committee
- Application form on IMB website
- Enclose all labels, leaflets & promotional material (websites)
- Application fee (€250)
- Response within ~ 28 days
Application form [www.imb.ie](http://www.imb.ie)
Key Message

- Correct product classification is important to meet regulatory requirements & ensure consumer safety
- Do not assume a product is not a medicine!
- If in doubt – seek advice (Supplier or Regulator)
- Take a proactive approach to product classification
Thank you for listening

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