



IRISH MEDICINES BOARD

The Importance of Product Classification

Wholesale Distribution Information Day, 28th September 2012

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Introduction

1. The importance of correct product classification – ***why?***
2. Product classifications – ***what?***
3. Practical advice – ***how?***



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1. **Why** is it important to classify products?

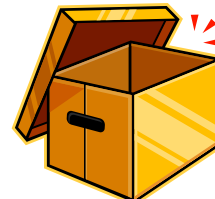
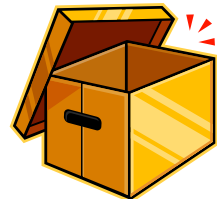
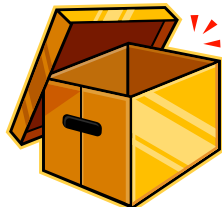
- To meet the relevant regulatory requirements
- To ensure consumer safety
- Correct & cost effective way to conduct business



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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.



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Human Medicinal Products



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



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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



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Identifying Human Medicinal Products



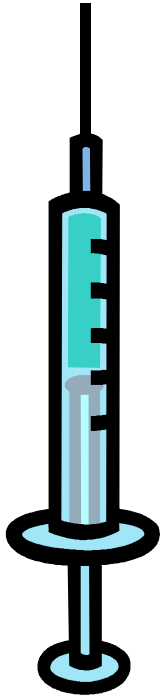
If a product fits the definition (*slide 6*)
BUT does not have the
characteristics (*slide 7*)

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



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Medical Devices



Definition:

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

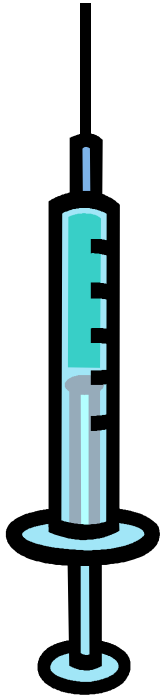
There are 3 types of medical devices outlined in the legislation.

1. General medical devices
2. Active implantable medical devices
3. *In-vitro* diagnostic medical devices



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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



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Food Supplements

Competent Authority for Food Supplements

Food Safety Authority of Ireland (FSAI)



www.fsai.ie

National Legislation

- European Communities (Food Supplements) Regulations 2007

Amended by

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



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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



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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



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Supplier Qualification Procedure

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



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Supplier Qualification Procedure



Consider extending this procedure to all suppliers



It is important to correctly classify your product prior to procurement



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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



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Application form www.imb.ie

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Safety & Quality **Human Medicines** Veterinary Medicines Medical Devices Blood, Tissues & Cells Cosmetics Patients & Public

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- New EU Pharmacovigilance Legislation
- HPV School Immunisation
- Pandemic (H1N1) 2009
- Human Medicines
- Clinical Trials
- Manufacturing
- Laboratory
- Wholesale Distribution
- Export Certification
- Controlled Drugs and Precursor Chemicals
- Classification of Medicines**

Classification of Medicines

The Irish Medicines Board provides a service to stakeholders to assist in clarifying which products should be categorised as medicinal products and medical devices and thereby fall under the remit of IMB from a regulatory perspective and to distinguish such products from other products which are outside the scope of IMB's remit.

A classification service is operated for products which are on the borderline of human medicines and other products such as food supplements, cosmetics and medical devices.

Requests for classification whether external or internal are ultimately presented to an internal multi-disciplinary Classification Committee which meets once a month. The outcome of the decision is conveyed promptly to the enquirers and in turn is accompanied by a recommendation for any action arising depending upon the circumstances.

In the event of an appeal to the Classification Committee decision, the matter will normally be referred to the Advisory Committee on Human Medicines for arbitration. Full details of the procedure can be found in the [IMB Guide to the Definition of a Human Medicine](#). This guide and the [Request for Classification Application Form](#) can be found in the [publications](#) section of the website.

The IMB Classification Committee (human medicines) consists of IMB staff with the appropriate scientific expertise and experience from the Human Products Authorisation and Registration, Compliance and Human Products Safety Monitoring Departments and is chaired by Dr. J.M. Morris, Director of Scientific Affairs.

Latest Information

Publications - (2)

Consultation - (1)

Provide Feedback

Internet | Protected Mode: On

12:30
14/09/2012

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



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Thank you for listening



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