IRISH MEDICINES BOARD

The Importance of Product Classification

Wholesale Distribution Information Day, 28th September 2012

Deirdre O'Brien
Market Compliance &
Healthcare Products Inspector

Introduction

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

2. Product classifications – ***what?***

3. Practical advice – ***how?***

IRISH MEDICINES BOARD

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

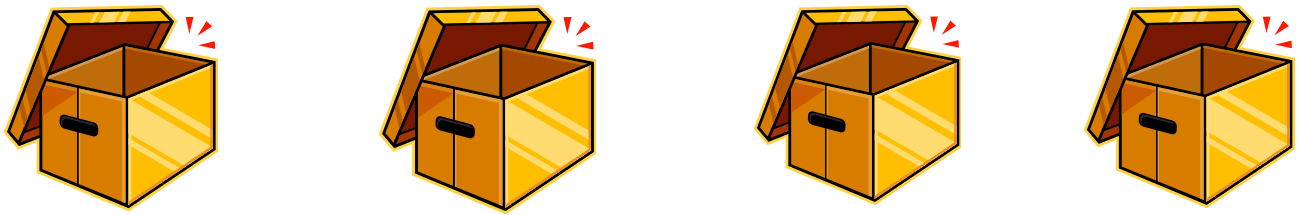
- To meet the relevant regulatory requirements
- To ensure consumer safety
- Correct & cost effective way to conduct business

IRISH MEDICINES BOARD

2. **What** are the different Product Classifications?

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

Nicola Hickie



IRISH MEDICINES BOARD

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.

IRISH MEDICINES BOARD

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

IRISH MEDICINES BOARD

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

IRISH MEDICINES BOARD

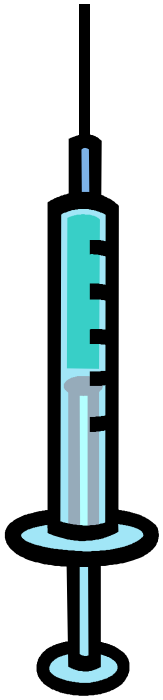
Identifying Human Medicinal Products

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

IRISH MEDICINES BOARD

Medical Devices



Definition:

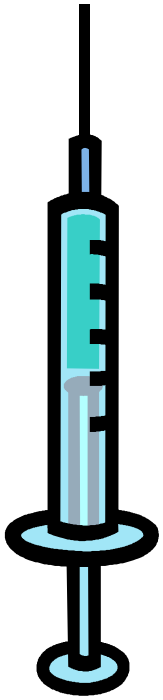
All products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability.

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

IRISH MEDICINES BOARD

Medical Devices



All medical devices authorised for distribution on the Irish market should bear a CE Mark

CE

medicaldevices@imb.ie

www.imb.ie: Medical Devices

IRISH MEDICINES BOARD

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

IRISH MEDICINES BOARD

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

IRISH MEDICINES BOARD

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

IRISH MEDICINES BOARD

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

IRISH MEDICINES BOARD

Supplier Qualification Procedure

Consider extending this procedure to all suppliers

It is important to correctly classify your product prior to procurement

IRISH MEDICINES BOARD

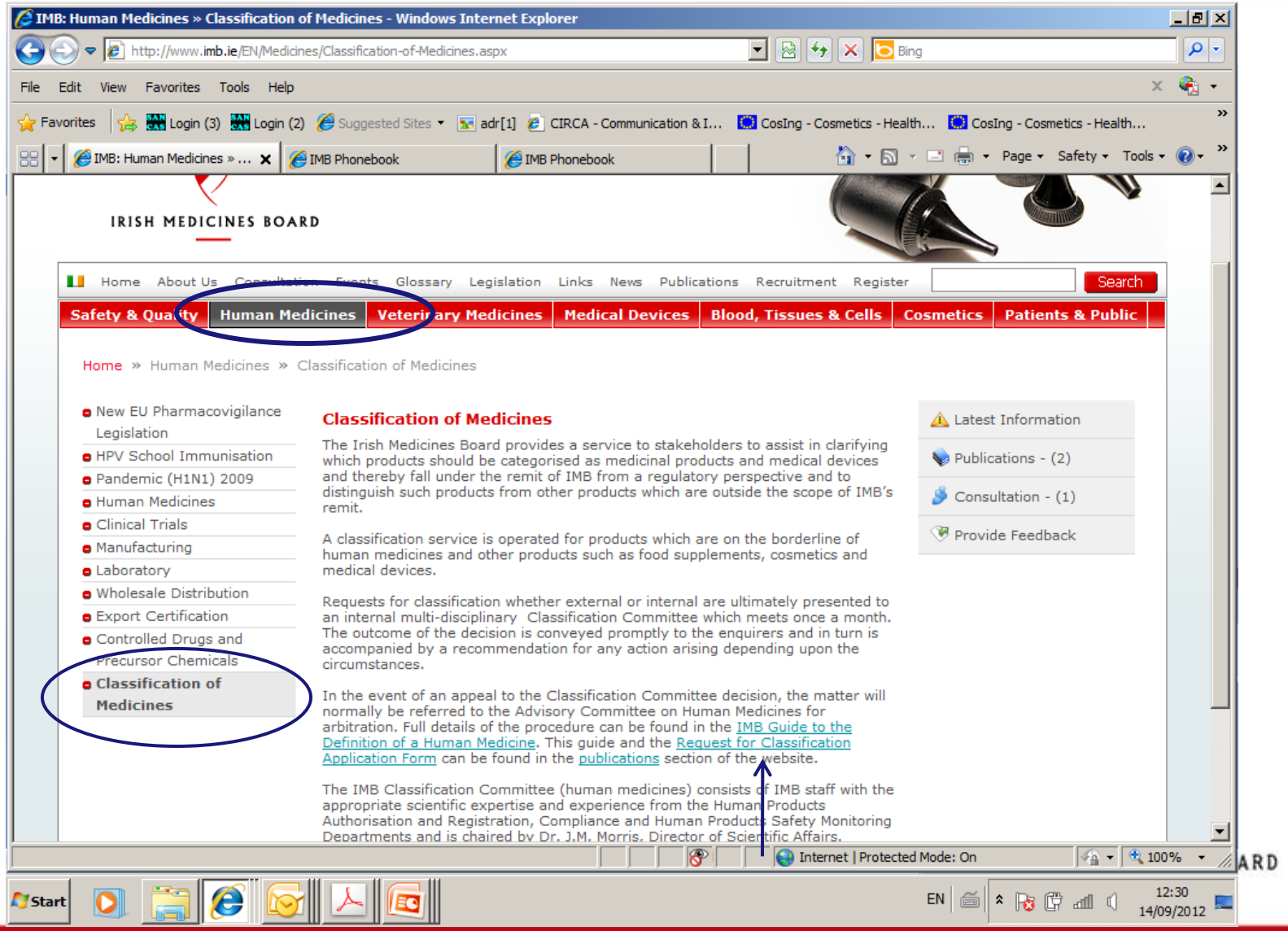
Help is available!!

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

IRISH MEDICINES BOARD

Application form 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

IRISH MEDICINES BOARD

Thank you for listening

deirdre.obrien@imb.ie

IRISH MEDICINES BOARD