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The regulatory landscape for herbals and food supplements
27/04/2016
Alice Teague

Introduction

- Roles of key agencies and government departments
- Medical product versus Food supplement
- Key legislation

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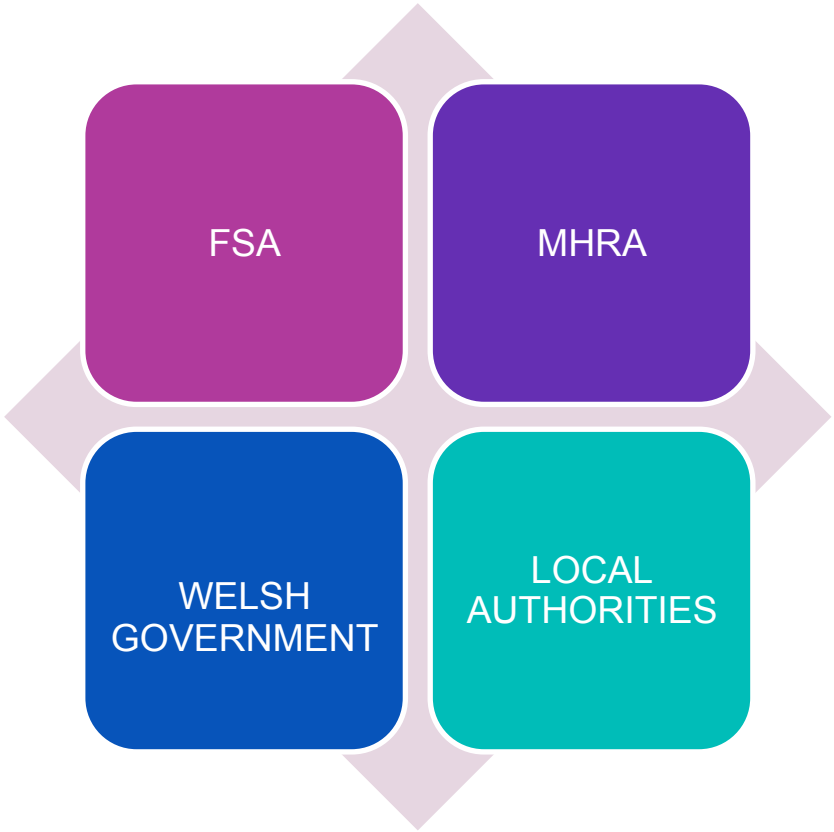
Key agencies / departments



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Definitions

Medicinal product

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

Food supplement

A concentrated source of a vitamin, mineral or other substance with a nutritional or physiological effect, alone, or in combination, sold in dose form.

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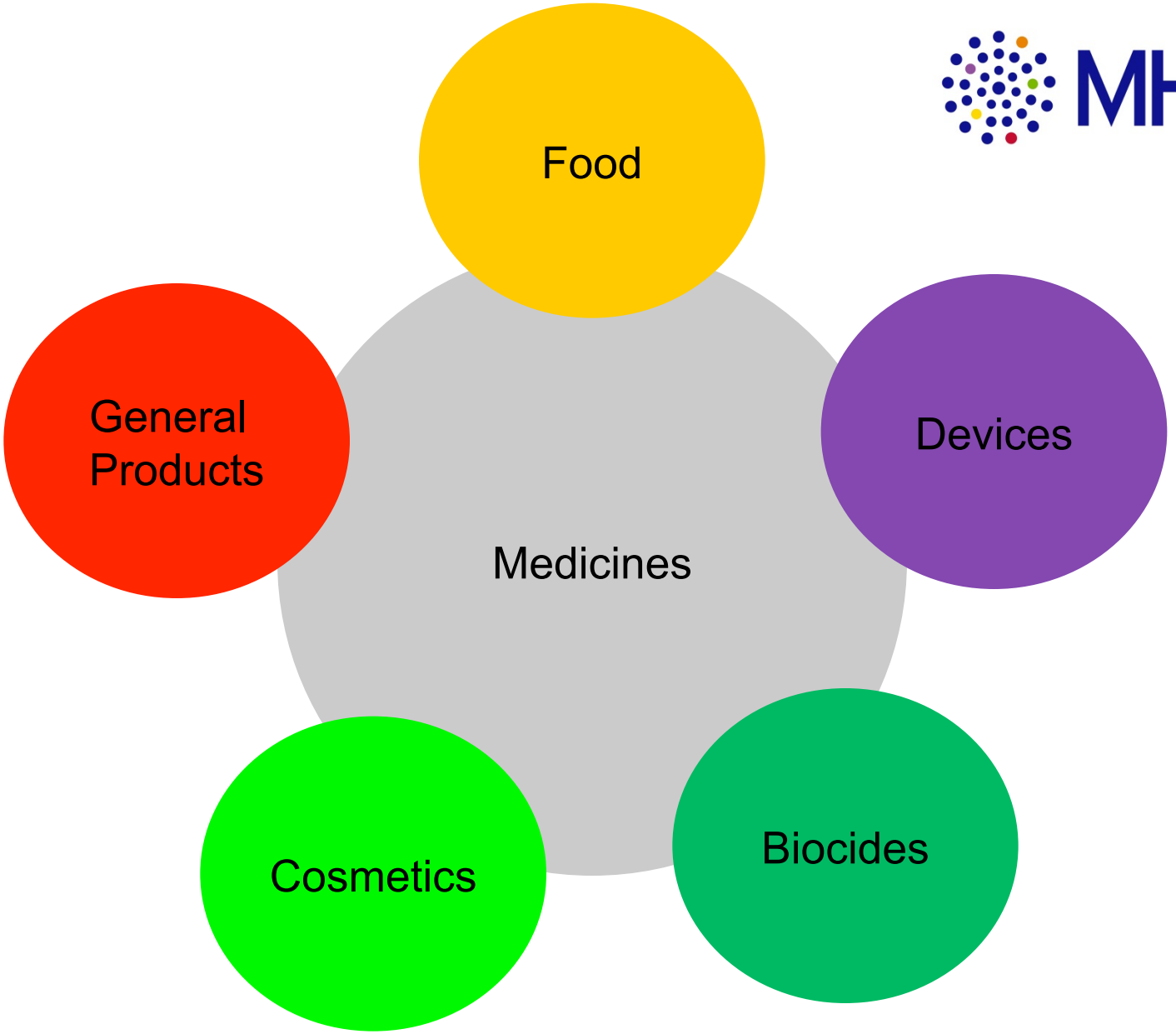
MEDICINAL PRODUCTS


Food
General Products
Devices
Medicines
Cosmetics
Biocides

The Definition of a Medicinal Product

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

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"

Article 1.2 Council Directive 2001/83/EEC

Classification

The MHRA reaches a determination on whether a product is or is not a medicinal product on a case by case basis, in the light of:

- the definition set out in the Directive;
- relevant ECJ and domestic Court precedents and
- following an assessment of all the available evidence.

Traditional Herbal Medicines

- Traditional Herbal Medicinal Products Directive 2004/24/EC
- Traditional herbal registration needed to market a herbal medicine
- Minor health conditions where medical supervision is not required (e.g. a cold).
- Evidence of long history (30 years) of treating stated condition

FOOD SUPPLEMENTS

EU Food Supplements Directive 2002/46

"food supplements" means 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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EU Food Supplements Directive 2002/46

- "nutrients" means the following substances:

  (i) vitamins,

  (ii) minerals.

- List of the permitted vitamins and minerals

- No positive list of other ingredients that might be present – amino acids or essential fatty acids.

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EU Food Supplements Directive 2002/46

- Not injurious to health or unfit for human consumption.
- Traceability
- Withdrawal procedures in place

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EU Food Supplements Directive 2002/46

- Labelling requirements:
  - Must be called a Food Supplement
  - Recommended daily dose
  - Warning not to exceed daily dose
  - Not a substitute for a varied diet.
  - Stored out of reach of children

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Food Information to Consumers Regulations

"Food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible.

It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any intervening material."

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Food Information to Consumers Regulations

- Name of the food
- List of ingredients
- Allergens
- Net quantity of the food
- Date of minimum durability or use by date
- Instructions for use

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Novel Food Regulations

- Foods or ingredients that do not have a significant history of consumption prior to 1997.

- Foods or food ingredients falling within the scope of the regulation must not:
  - present a danger for the consumer
  - mislead the consumer
  - differ from foods or food ingredients that they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer

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Novel Food Regulations

- Scientific assessment needed by MS to authorise a novel food.

- European Commission has published:

  – A list of authorised novel foods and novel food ingredients

  – A list of unauthorised novel foods and novel food ingredients.

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EU Nutrition and Health Claims Regulation

- Requires nutrition and health claims to be authorised at the EU level.

- Nutrition claim: states or suggests that food has beneficial nutritional properties.

- Health claim – states or suggests that health benefits can result from consuming a given food.

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EU Nutrition and Health Claims Regulation

- Positive lists of nutrition and health claims

- Rules apply to the labelling, presentation and advertising of foods ready for the final consumer or caterers.

- Claims must not:
  - Be false or ambiguous
  - Encourage or condone excess consumption of a food
  - Refer to changes in bodily functions which could give rise to, or exploit, fear in the consumer.

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THANKS FOR LISTENING

ANY QUESTIONS?