Medicines, medical devices and blood regulation and safety – guidance

Decide if your product is a medicine or a medical device

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Part of: Herbal and homeopathic medicines, Marketing authorisations, variations and licensing guidance, Medical devices regulation and safety and + others

How the Medicines and Healthcare products Regulatory Agency (MHRA) makes decisions on what is a medicine or medical device (borderline products).

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Overview

Some products are hard to distinguish from a medicine or a medical device, for example cosmetics, food supplements or biocidal products. These products are called borderline products until their status has been decided.

MHRA determines whether a product falls within the definition of a medicine – ‘medicinal product’ or a medical device and provides information on whether a product is a medicine or a medical device or not.

Further guidance

Types of borderline products

The types of products which may fall in to the borderline category include:

- cosmetics
- food products, including, in particular, food supplements
- herbal products
- medical devices
- biocides
- machinery/laboratory equipment

There is also a borderline between medicinal products and medical devices. In these cases it will be the claims being made and the mode of action that will decide which regulatory regime will apply.

Borderline medicines

A medicinal product is:

- any substance or combination of substances presented as having properties of preventing or treating disease in human beings
- any substance or combination of substances that may be used by or administered to human beings with a view to restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis

You can find more detailed information in Regulation 2 of the Human Medicines Regulations.

Food supplements that contain familiar substances like vitamins, amino acids or minerals are generally subject to food safety and food labelling legislation rather than medicines control. You can get advice on food and cosmetics from the Trading Standards Institute.

MHRA decides whether the claims that are made or the active substance(s) present would mean that the product is regarded to be a medicinal product.

The inclusion of herbal or ‘natural’ ingredients does not exclude a product from being a medicinal product. MHRA takes the same factors into account when deciding the status of a product with herbal ingredients.

How we decide if a product is a medicine

MHRA decides whether a product is a medicine when:

- the manufacturer is not sure if their product is a medicine or not, and they come to MHRA for advice
- MHRA receives a complaint that a product is being marketed as a medicine but does not have a marketing authorisation (formerly a product licence)

We look at:

- the claims about what the product does (explicit and implicit)
- the pharmacological, metabolic or immunological properties of the ingredients (this includes any herbal ingredients)
- the primary intended purpose of the product
- whether there are any similar licensed or registered products on the market
- how it is presented to the public through labelling, packaging, promotional literature and advertisements

See final determinations by MHRA on borderline products - August 2016 (MS Word Document, 199KB)

See final determinations by MHRA on borderline products - October 2010 to July 2014 (PDF, 112KB, 18 pages) . Previous final determinations are available on the National Archives.

Borderline medical devices

Medical devices fall into 1 of 3 categories, as each type is governed by a different EU directive:

- medical devices – covered by the Medical Devices Directive (Directive

93/42/EEC)

- in vitro diagnostic medical devices – covered by the In Vitro Diagnostic Medical Devices (Directive 98/79/EC)
- active implantable medical devices – covered by the Active Implantable Medical Devices (Directive 90/385/EEC)

MHRA can give advice if you are not sure which category your device fits into.

You should not assume that if your product is considered a medical device in countries outside the EU that it will be a medical device in the EU as well.

Decisions about whether a product is a medical device are based on the stated intended purpose of the product and its mode of action.

If the product is a medical device, the principal intended action is fulfilled by physical means.

Getting advice about your product

Borderline medicines

You can find detailed advice here in our a guide to what is a medicinal product (PDF, 678KB, 62 pages) . You should read this document before contacting MHRA.

Use our borderline advice form form to request information on a medicine if you don't find the information you need in our guidance document. Email the completed form and attachments to borderline_medicine@mhra.gsi.gov.uk.

MHRA will only respond to enquiries about up to 6 products at a time.

Borderline medical devices

If your enquiry is about the regulatory route for a medical device you

should email Devices.regulatory@mhra.gsi.gov.uk.

Further guidance

Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative

Borderlines between medical devices and medicinal products (PDF, 166KB, 12 pages)

Medicines borderlines

Borderline medicines and the internet

Medical products containing herbal ingredients (PDF, 32.8KB, 5 pages)

List of herbal ingredients and their reported uses (PDF, 429KB, 12 pages)

Medical device borderlines

Guidance on standalone software (including apps)

Borderlines between medical devices and other products (such as personal protective equipment, cosmetics and biocides) (PDF, 129KB, 12 pages)

European Commission Guidance documents (MEDDEV's)

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