



Medicines & Healthcare products
Regulatory Agency



Guidance on legislation

Borderlines between medical devices and medicinal products

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Disclaimer

This document presents the current views of the Medicines & Healthcare Products Regulatory Agency on the interpretation of the Medical Devices Regulations and the Human Medicines Regulations as they relate to drug/device demarcation issues. It is intended as general guidance and should be regarded neither as an authoritative statement of the law nor as having any legal consequence. Manufacturers and others should therefore not rely solely on this document, but should consult the legislation referred to and make their own decisions on matters affecting them in conjunction with their lawyers and other professional advisers. The MHRA does not accept liability for any errors, omissions, misleading or other statements in this document, whether negligent or otherwise.

1 Introduction

This document sets out, in broad terms, the regulation of specific products and distinguishes those which are regulated as medical devices and those which are regulated as medicinal products, particularly where the regulation may be on the borderline between the two sets of regulations.

Whilst there are other 'borderlines' with medical devices (for example with cosmetics, personal protective equipment, biocides etc) this document relates specifically to the differentiation between medical devices and medicinal products.

Regulations

As a general rule, products making medical claims will be regulated **either** by the medical devices regulations **or** by medicines legislation.

Medical devices are regulated by a set of European directives [1] and UK laws– the Medical Devices Regulations 2002 (and amendments) [2]. We refer to these as the 'medical devices regulations' or 'MDR' in this document.

Medicinal products are regulated under the Human Medicines Regulations 2012 (SI 2012/1916) [3], referred to as 'MA' in the table in section 5.

Classification

Over time the classification of particular products has changed in accordance with changes in EC legislation. Legislation on medicinal products predated the MDR. This meant that when the MDR came into force, or was subsequently amended, many products transferred from being regulated under the medicines legislation to being regulated under the MDR. The main types of products that were subject to a change in regulatory control were:

- most wound dressings
- some dental products
- absorbable surgical materials, including sutures and bone cements
- [non-hormonal] intra-uterine contraceptive devices
- contact lens care products
- irrigation solutions intended for mechanical rinsing.

Due to the changes to the definition of a medicinal product in Directive 2004/27/EC (amending Directive 2001/83/EC), which came into force on 30 October 2005, some further products falling within the following categories are generally regulated as medical devices. However, this is determined on a case-by-case basis:

- artificial tears
- non-medicated dermatological products
- zinc oxide products (without pharmacological action, e.g. in bandages and non-medicated dermatological creams)
- aluminium sulphate / salts, astringents (dental use).

The MDR have been in place for a considerable length of time, but there may still be areas where the regulatory classification is unclear, particularly where products incorporate or are used to administer a medicinal product.

2 Definitions

Article 1 of Directive 2001/83/EC (as amended) [3] defines a 'medicinal product' as:

'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’.

Article 2(2) of Directive 2001/83/EC [3] also provides that:

‘In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a ‘medicinal product’ and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.’

Article 1.2 of Directive 93/42/EEC (as amended) [1] defines a medical device as:

‘any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means’

3 Determination of regulatory route

In order to decide whether a product is considered a medical device or a medicinal product, the following points should be considered:

- the intended purpose of the product taking into account the way the product is presented
- the method by which the principal intended action is achieved.

In the case of a medical device, the principal intended action is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions).

The action of a medicinal product is typically achieved by pharmacological, immunological or metabolic means. Note that a substance administered for diagnostic purposes, (i.e. an in vivo diagnostic substance), even though it does not act in such ways, is also usually considered to be a medicinal product.

Medical devices may contain medicinal substances which act on the body in a manner ancillary to the device. However, where such substances act in a manner that is more than ancillary, the product is regulated as a medicinal product rather than a medical device.

The appendix to this document provides a list of products with guidance as to the legislation likely to apply to such products.

4 Products that incorporate or administer a drug

Products that incorporate, or are used to administer, a drug may be regulated as either medical devices or as medicinal products, depending on the principal intended function of the product and the method by which this action is achieved.

There are three main types of medical device that incorporate, or are used to administer, a medicinal product:

a) Devices which are used to administer medicinal products

For example, a syringe marketed empty, medicine spoons, droppers etc. This category also includes devices which can be refilled with further doses of medication contained within the same pack as the medicine. All of these products are covered by the Medical Devices Regulations. If they are included separately in a pack with the medicine they will still need to comply with the MDR, including labelling provisions.

b) Devices for administering medicinal products where the device and the medicinal product form a single integral product designed to be used exclusively in the given combination and which are not re-usable or refillable

For example a syringe marketed pre-filled with a drug. These products are covered by medicines legislation, although in addition to this, the relevant essential requirements in Annex 1 of the Medical Devices Directive 93/42/EEC [1] apply with respect to safety and performance related features of the device (e.g. a syringe forming part of such a product).

c) Devices incorporating, as an integral part, a substance, which, if used separately, may be considered to be a medicinal product and where the substance is liable to act upon the body with action ancillary to that of the device.

For example a heparin coated catheter. These products are subject to the MDR. In addition, the safety, quality and usefulness of the medicinal substance must be verified by analogy with the methods required in Directive 2001/83/EC [3] concerning the testing of proprietary medicinal products. Under the classification rules set out in the Medical Devices Directive (see MHRA's guidance 'The classification rules' and European Commission guidance MEDDEV 2.4/1 [4]), such a device would fall into class III under classification rule 13 of Annex IX of Directive 93/42/EEC [1]. The notified body carrying out relevant conformity assessment procedures in respect of such a device must consult a member state competent authority for medicinal products or the [European Medicines Agency](#) where appropriate, on the medicinal aspects of the device.

Note that 'medicinal product' in this context includes all substances which may be considered to be medicinal products, including herbal medicinal products (including herbal and plant extracts), constituents of medicinal products and substances derived from human blood or blood plasma.

'Integral' is usually taken to mean a single component product. However, there may be circumstances where it may be taken to mean two elements that are packaged together and combined into one product immediately prior to administration to the patient – see also MEDDEV 2.1/4 [5] which states: 'A medical device incorporates a medicinal substance as an integral part, within the meaning of Article 1 (4) MDD and Article 1 (4) AIMDD, if and only if the device and the substance are physically or chemically combined at the time of administration (i.e. use, implantation, application etc) to the patient'.

5 Drug–device demarcations

In the table below MDR indicates the medical devices regulations [2] and MA the medicines legislation

Note: Please refer to the MHRA's '[A guide to what is a medicinal product](#)' for additional information.

Product	Applicable regulation	Comment
1. Contact lens care products		
a. Disinfecting	MDR	
b. Cleaning solutions	MDR	
c. Rinsing solutions	MDR	
d. Hydrating solutions	MDR	
e. Wetting agents	MDR	
f. Comfort drops	MDR	Considered to be accessories to medical devices when specifically intended for use as a result of wearing contact lenses. Considered to be medicinal products if therapeutic claims are made and contain an active ingredient. See also section 2.
2. Other ophthalmics		
a. Artificial tears (unmedicated)	MDR	Considered to be medical devices if therapeutic claims are made. Medicated drops are considered to be medicinal products.
b. Artificial tears (medicated)	MA	
c. Other eye drops (medicated)	MA	
d. Other eye drops (unmedicated)	MDR	If claims are made to treat or alleviate damage to the eye– see the manual of decisions [6].
e. Fluorescein ocular strips	MA	
f. Injectable fluorescein	MA	
g. Rose Bengal	MA	
h. Solution for preserving corneal material prior to transplant	MDR	Will generally be regarded as Class III medical devices on the basis of European Consensus.
i. Ocular endotamponades	MDR	
j. Viscoelastic/viscosurgical products	MDR	May become medicines if additional claims are made
3. Surgical dressings		
a. Non-medicated	MDR	
b. Medicated	MDR/MA	Depends on manufacturer's claim
c. bandages containing Zinc Oxide without pharmacological action	MDR	
4. Non-medicated dermatological creams	MDR	Including those containing zinc oxide (without pharmacological action)
5. Sutures and ligatures		
a. Absorbable	MDR	
b. Non-absorbable	MDR	
c. Biological sealants	MA/MDR	Depends on mode of action

6. Resorbable bone plates/polylactic/polyglycolic acid	MDR	
7. Hard tissue scaffolds		Tissue scaffolds containing bioactive materials are likely to be medicinal products except where there is clean ancillary action, in which case they may be regulated as medical devices. Advice should be sought from MHRA.
a. Hydroxyapatite with/out collagen	MDR	
b. Calcium phosphate with/out collagen	MDR	
c. Bioglas	MDR	
d. Coral	MDR	
e. Cartilage repair systems	MA/MDR	Depends on mode of action
8. Soft tissue fillers		Human tissue derived fillers may be regulated as medicinal products, or may come within the Code of Practice for human derived therapeutic products – verify with the Medicines Borderline Section at MHRA. Note that the legislation covering human tissues and cells and regulations on advanced therapy products may also apply to such products.
a. Collagen (non human)	MDR	
b. Silicone elastomer dispersions, e.g. Bio/uroplastique	MDR	
9. Bone cements		
a. Polymethylmethacrylate with/out antibiotic	MDR	
10. Joint replacements coated with:		Coatings of human origin are not covered by the MDR
a. Hydroxyapatite/calcium phosphate	MDR	
b. Bone growth factor (beta BGF)	MDR	b and c used alone are controlled by MA
c. Genetically engineered BGF	MDR	
11. Inhalation products		
a. Prefilled metered dose inhalers	MA	
b. Chamber spacers for use with metered dose inhalers	MDR	(b), (c), (d) & (e) may be sold with medication and their performance/drug delivery will be assessed by a drug regulatory authority as part of the medicines Marketing Authorisation application.
c. Spinhalers - } refillable	MDR	
d. Diskhalers - } refillable	MDR	
e. Other empty or re-fillable inhalers	MDR	
12. Powered nebulisers		
a. Device	MDR	May be sold with medication and their performance/drug delivery will be assessed by a drug regulatory authority as part of the medicines Marketing Authorisation application.
b. Medication	MA	
13. Insulin injection		
a. Disposable pen injectors integral with insulin cartridge	MA	
b. Re-usable insulin pens	MDR	

c. Sterile single-use syringes (empty)	MDR	
d. Insulin	MA	
14. Blood bags		
a. Sterile empty	MDR	
b. Sterile with anticoagulant	MDR	
c. Platelet additive solutions	MDR	
15. Dialysis products		
a. Equipment	MDR	
b. Peritoneal solution including CAPDs	MA	
c. Haemodialysis solution	MDR	
d. Haemofiltration solution	MA	
e. Solutions for on-line haemodiafiltration	MA	
16. Anaesthetic and other medical gases and oxygen cylinders		
a. Pipeline/manifolds/AGSS	NHSE*	*UK position is that they are not covered by the MDR. NHS Estates & Facilities have responsibility within the Department of Health for fixed installations
b. Bulk supply gas including cylinder	MA	
c. Oxygen concentrators	MDR	
d. Ozone generators	MDR	
17. Monoclonal antibodies		
a. In vitro diagnostics	*	* These are regulated under the In Vitro Diagnostic Medical Device Directive 98/79/EC
b. Immunotoxins	MA	
18. Human tissues		
a. Dura grafts	MA	
b. Skin fibroblasts	*	*These products are not covered by the Medical Devices Regulations 2002.
c. Bone	*	Contact MHRA Medicines Borderline Section in the first instance
19. Dental products		
a. Pit and fissure sealants	MDR	
b. Root canal sealers: medicated/non-medicated	MDR	
c. Root canal dressings (e.g. polyantibiotic pastes, antiseptics)	MA	
d. Pulp capping material	MDR/MA	If used for drug delivery then product covered by MA.
e. Dry socket preparation	MDR/MA	If used for drug delivery then product covered by MA.
f. In vivo diagnostics, e.g. disclosing tablets	MA	

g. Haemostatic agents and astringents	MA/MDR	Depends on product mode of action, see EC guidance.
h. Aluminium sulphate / salts astringents	MDR	
i. Retraction cords: medicated /non-medicated	MDR	
j. Fluoride preparations: e.g. tablets, gels, varnishes	MA/MDR	Depends on primary mode of action and the claims being made for the product.
k. Hard tissue scaffolds	MDR	
l. Desensitising agents: physical/pharmacological	MDR/MA	Depends on mode of action
m. Periodontal dressings: medicated/non medicated	MDR	
n. Periodontal antibacterials: e.g. gels, ointments, fibres	MA	
o. Varnishes: protective/drugs delivery	MDR/MA	Depends on primary mode of action and the claims being made for the product.
p. Toothache preparations	MA	
q. Artificial saliva	MDR	
r. Mouth ulcer preparations: medicated/non-medicated	MA/MDR	
s. Antibacterial mouthwashes/ gels	MA	Depends on primary purpose, some may be cosmetics if no medical claims made – verify with MHRA medicines.
20. Contraception products		
a. IUDs without action	MDR	
b. Diaphragms	MDR	
c. Condoms with/out spermicide	MDR	
d. IUDs with hormone action	MA	
e. Spermicidal preparations e.g. creams pessaries, sponge film	MA	Where primary purpose is a drug delivery system
21. Impregnated devices		
a. Antithrombotic coatings gelatin/heparin/protein	MDR	Unless primary purpose is to treat infection
b. Bacteriological coatings chlorhexidine/benzalkonium chloride/silver/salts/ antibiotics	MDR	
22. Disinfectants		These products overlap with the regulations covering biocidal products. Only products intended for a 'medical' purpose will be covered by the medicines or medical device regulations.
a. Topical disinfectants	MA	
b. Alcohol only wipes / swabs	MDR	
c. Wipes/swabs with medicinal substance (chlorhexidine, cetrimide, iodine etc)	MA	
d. Disinfectants specifically intended for disinfecting	MDR	

medical devices		
23. Plasma volume expanders	MA	
24. In vivo diagnostic agents		
a. X-ray contrast media including MRI	MA	
b. Barium meal	MA	
c. other in vivo imaging agents	MA	
d. labelled urea for H pylor test	MA	
e. gases for lung function tests	MA	
25. Transdermal patches		
a. Disposable with medicament	MA	
b. Iontophoresis device (non disposable/reusable)	MDR	
26. Irrigation solutions (including those used in the eye)	MDR/MA	For mechanical rinsing purposes but if solution contains a pharmacologically active substance then the product is likely to be covered by MA. Note: Eye washes for emergency purposes are usually considered to be medical devices.
27. 'Activated' medicinal products		
a. Medicinal product	MA	
b. Activating device e.g. laser	MDR	
28. Administration products		These products are covered by MDR even though they may be supplied in the same pack as the medicine unless they form the closure of the container (e.g. bottle cap/dropper assembly)
a. Medicine spoons	MDR	
b. Droppers	MDR	
c. Oral syringes	MDR	
d. Eye baths	MDR	
29. IVF media	MDR	Will generally be regarded as Class III medical devices on the basis of European Consensus. For details see the manual of decisions [6].
30. Agents for transport, nutrition and storage of organs intended for transplantation	MDR	Will generally be regarded as Class III medical devices on the basis of European Consensus. For details see the manual of decisions [6].
31. Artificial skin systems	MDR	Products that do not contain material of human origin, will be covered by the MDR but products that do contain material of human origin are not covered by the MDR. Note that the regulations on advanced therapy medicinal products may apply to such products.
32. Viscoelastic gels for joint lubrication	MA/MDR	Depends on mode of action

33. Parenteral fluids (diluent)		
a. Water for injection	MA	
b. Saline	MA	
34 Head lice products	MA/MDR	Such products will either be medical devices or medicinal products, depending upon their mode of action.
35. Corn plasters		Note that products containing salicylic acid will be considered as Class III medical devices under rule 13 due to the analgesic properties of salicylic acid. Products containing other acids (e.g. trichloroacetic, nitric) for the treatment of corns are considered as IIa devices.
a. Containing salicylic acid	MDR	
b. Containing other acids	MDR	
36. Pre-filled, single use, syringes specifically intended for mechanical flushing of ports and catheters (saline / heparin etc)	MDR	These are accepted as medical devices provided that they are specifically intended for the mechanical flushing of medical devices such as ports and catheters, even when the flush may result in the fluid entering the body. Such products must be clearly contraindicated for direct systemic administration. Classification will depend upon the ingredients contained in the flushing solution. Pre-filled syringes for systemic administration are always regulated as medicinal products.
37. Other products		
a. Weight loss tablets	MA/MDR/ Food supplement	Depends on mode of action and claims made. Products that act pharmacologically or metabolically and claim to suppress appetite, burn fat, speed up metabolism or treat obesity are likely to be regarded as medicinal products. Fat absorption and bulking agents are likely to be regulated as medical devices if making a medical claim (e.g. treatment rather than just a slimming product). Products not regulated as devices or medicinal products are likely to be regulated as food supplements, provided no medicinal claims are made.
b. Active coal / carbon solutions for treatment of acute poisoning	MA	By consensus of EU Member States such products are considered to be medicinal products.
c. Products for the regulation of vaginal flora containing lactobacillus	MA	
d. Leeches and maggots	MA	Considered to be medicinal products when there is a clear intended medical purpose.
e. Products for the treatment of addiction to nicotine	MA/MDR	Most products intended to treat the addiction to nicotine will be considered to be medicinal products

6 References, guidance and contacts

1 Medical devices are regulated by three main directives:

- Medical Devices Directive 93/42/EEC
- In Vitro Diagnostic Medical Devices Directive 98/79/EC
- Active Implantable Medical Devices Directive 90/385/EC

Directive 93/42/EEC has been supplemented by Directives 2000/70/EC and 2001/104/EC covering devices that incorporate as an integral part stable blood derivatives. There are also several amending Directives, including 2007/47/EC.

European directives on medical devices are available on: http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/index_en.htm

2 The directives are transposed into UK law by: the Medical Devices Regulations 2002 Statutory Instrument 2002 No 618, the Medical Devices Regulations 2002 SI 1697, the Medical Devices (amendment) Regulations 2003 and the Medical Devices (amendment) Regulations 2008 SI 2936.

3 Human Medicines Regulations 2012 (SI 2012/1916).

This transposed into UK law the European legislation on medicinal products - Directive 2001/83/EC relating to medicinal products for human use, amended by Directive 2004/27/EC and Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

European pharmaceutical legislation medicinal products for human use is available on: <http://ec.europa.eu/health/documents/eudralex/vol-1/>

UK regulations are available on: <http://www.legislation.gov.uk/>

Guidance from the European Commission

4 MEDDEV 2.4/1 Classification of medical devices.

<http://ec.europa.eu/DocsRoom/documents/10337/attachments/1/translations/en/renditions/native>

5 MEDDEV 2.1/4 Interface with other directives - Medical devices/directive 89/336/EEC relating to electromagnetic compatibility and directive 89/686/EEC relating to personal protective equipment.

<http://ec.europa.eu/DocsRoom/documents/10281/attachments/1/translations/en/renditions/native>

6 Information on specific borderline cases 'Manual on borderline and classification in the Community Regulatory framework for medical devices' from the Medical Devices Expert Group on Borderline and Classification: (referred to as the 'manual of decisions'):

<http://ec.europa.eu/DocsRoom/documents/12867/attachments/1/translations/en/renditions/native>

MEDDEV 2.1/3 Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative

<http://ec.europa.eu/DocsRoom/documents/10328/attachments/1/translations/en/renditions/native>

Enquiries

For detailed or specific enquires on medical device demarcation:

Tel: 020 3080 7386 Email: devices.regulatory@mhra.gsi.gov.uk

Information on medicinal product aspects contact:

Mrs E A Baker Tel: 020 3080 6467 Email: elizabeth.baker@mhra.gsi.gov.uk