Safeguarding public health

MHRA

BULLETIN No. 17

MEDICAL DEVICES AND MEDICINAL PRODUCTS

Amended April 2006

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INTRODUCTION

This information bulletin 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 bulletin specifically relates to the differentiation between medical devices and medicinal products.

REGULATIONS

There are 3 main Directives covering medical devices:

- Medical Devices Directive 93/42/EEC
- In Vitro Diagnostic Medical Device Directive 98/79/EC
- Active Implantable Medical device 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.
These directives are transposed into UK law by Statutory Instrument 2002 No 618, the Medical Devices Regulations 2002 and SI 1697 the Medical Devices (amendment) regulations 2003 (referred to as MDR from now on)
Medicinal products are regulated under the Medicines Act 1968 and the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (SI 1994 No 3144) and amending regulations (SI 2005 No 2759). These are the principal provisions, which transposed into UK law European legislation on medicinal products (Directive 2001/83/EC, amending Directive 2004/27/EC and Regulation (EC) 726/2004).

BACKGROUND - Historical note

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 30th October 2005, some further products falling within the following categories will generally now be regulated as medical devices. However, each application is determined on a case-by-case basis:

- *Artificial Tears*

- *Non-medicated dermatological products*
- *Zinc Oxide Products (without pharmacological action): (e.g. in bandages & non-medicated dermatological creams)*
- *Aluminium sulphate /salts, Astringents (dental use)*

The MDR have now been in place for over 10 years. However there may still be areas where the regulatory classification is unclear, particularly where products incorporate or are used to administer a medicinal product.

DEFINITIONS:

Products making medical claims, as a general rule, will be regulated either by the Medical Devices Regulations or by medicines legislation,
The revised definition of a medicine is:

I. *Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
II. *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 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 the Directive shall apply.
The definition of a medical device is:
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software 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

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; a substance administered for diagnostic purposes, 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 Annex to this bulletin provides a list of products with guidance as to the legislation likely to apply to such products.

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 which incorporate or are used to administer a medicinal product:

1. *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.

2. *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 re-fillable*:

For example a syringe marketed pre-filled. 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 apply with respect to safety and performance related features of the device (e.g. a syringe forming part of such a product).

3. *Devices incorporating, as an integral part, a substance, which, if used separately, may be considered to be a medicinal product and which is such that 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 concerning the testing of proprietary medicinal products. Under the classification rules set out in the Medical Devices Directive (see Bulletin Number 10), such a device would fall into class III under rule 13. 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 EMEA where appropriate on the medicinal aspects of the device.

In MHRA's opinion 'integral' means a single component product (eg such as coated or incorporated within) rather than a pack containing the two components (i.e. a drug and a device).

FURTHER INFORMATION - Publications and Guidance

The European Commission has also published guidance on the demarcation between medical devices and medicinal products in their MEDDEV 2.1/3. This is available, without charge, from the Commission website at http://europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm. *This document has not, however, been updated since the recent legislative amendments were made.*

Printed copies of the Medical Device Directives:

- Medical Devices Directive 93/42/EEC and supplements 2000/70/EC and 2001/104/EC
- In Vitro Diagnostic Medical Device Directive 98/79/EC
- Active Implantable Medical Device Directive 90/385/EC

and the Medicinal Products Directives 2001/83/EC & 2004/27/EC are available to purchase from:

Stationery Office Books
Publications Centre
51 Nine Elms Lane
London SW8 5DR
Tel 020 7873 8372
Fax 020 7873 8247

Copies of the Medical Device Directives are also available from the European Commission website at:

www.europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist.html
Copies of the UK medical devices regulations are available from

www.legislation.hmso.gov.uk/si/si2002/20020618.htm
and

http://www.opsi.gov.uk/si/si2003/20031697.htm

Copies of Guidance Note 8 'A Guide To What is A Medicinal Product' are available from the MHRA website http://www.mhra.gov.uk. (This document is currently being revised.)
Copies of guidance documents and other bulletins in our series can be obtained from our website http://www.mhra.gov.uk or by leaving a message on 020 7084 3203 (24 hour answer phone).

FURTHER INFORMATION - MHRA contact details

For detailed or specific enquires on Medical Device Demarcation please contact the Medical Devices section of MHRA:
Telephone: 020 7084 3386
Fax: 020 7084 3112

E-mail: era@mhra.gsi.gov.uk
Or write to:

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Further information on medicinal product aspects can be obtained from:
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DISCLAIMER

This document presents the Medicines & Healthcare products Regulatory Agency (MHRA)'s current views on the interpretation of the Medical Devices Regulations and the Medicines Act as they relate to drug/device demarcation issues. It is intended as general guidance and should not be regarded as an authoritative statement of the law nor as having any legal consequence. Manufacturers and others should therefore not rely solely on this bulletin, 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.
MHRA does not accept liability for any errors, omissions, misleading or other statements in the bulletin whether negligent or otherwise.

ANNEX 1

DRUG DEVICE DEMARCATION

In the table below MDR indicates Medical Device Regulations and MA the medicines legislation

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	Comfort Drops: 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. Drops indicated for relief from purely environmental factors are not considered to be either.
2. Other Ophthalmics		
a. Artificial tears (unmedicated)	MDR	Considered to be medical devices if therapeutic claims are made. Products indicated for relief from purely environmental factors are not considered to be devices. Medicated drops are considered to be medicinal products.
b Artificial tears (medicated)	MA	
c. Fluorescein ocular strips	MA	
d. Injectable fluorescein	MA	
e. Rose Bengal	MA	
f. Solution for preserving corneal material prior to transplant	see comment	Current Commission guidance suggests that such products should be considered to be medicinal products, but are not normally currently regulated as devices or medicines in the UK.
g. Ocular endotamponades	MDR	
h. Viscoelastic/viscosurgical products	MDR	May become medicines if additional claims are made

PRODUCT	APPLIABLE REGULATION	COMMENT
3. Surgical Dressings a. Non-medicated b. Medicated c. bandages containing Zinc Oxide without pharmacological action	 MDR MDR/MA MDR	 Depends on manufacturer's claim
4. Non-medicated dermatological Creams	MDR	Including those containing zinc oxide (without pharmacological action)
5. Sutures and Ligatures a. Absorbable b. Non-absorbable c. Biological Sealants	 MDR MDR MA/MDR	 Depends on mode of action.
6. Resorbable bone plates/polylactic/polyglycolic acid	MDR	
7. Hard tissue scaffolds a. Hydroxyapatite with/out collagen b. Calcium phosphate with/out collagen c. Bioglas d. Coral e. Cartilage repair systems	 MDR MDR MDR MDR MA/MDR	 Tissue scaffolds containing bioactive materials are likely to be medicinal products Depends on mode of action
8. Soft tissue fillers a. Collagen (non human) b. Silicone elastomer dispensions, eg Bio/uroplastique	 MDR MDR	 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 the forthcoming regulations on advanced therapy products may also apply to such products. Consult with MHRA

PRODUCT	APPLICABLE REGULATION	COMMENT
9. Bone cements a. Polymethylmethacrylate with/out antibiotic	MDR	
10. Joint Replacements coated with a. Hydroxyapatite/calcium phosphate b. Bone growth factor (Beta BGF) c. Genetically engineered BGF	MDR MDR MDR	Coatings of human origin are not covered by the MDR (b) and (c) used alone are controlled by MA
11. Inhalation products a. Prefilled Metered dose inhalers b. Chamber spacers for use with metered dose inhalers c. Spinhalers - } refillable d. Diskhalers - } refillable e. Other empty or re-fillable inhalers	MA MDR MDR MDR 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.
12. Powered Nebulisers a. Device b. Medication	MDR MA	As above
13. Insulin injection a. Disposable Pen injectors integral with insulin cartridge b. Re-usable insulin pens c. Sterile Single use syringes (empty) d. Insulin	MA MDR MDR MA	
14. Blood Bags a. Sterile empty b. Sterile with anticoagulant c. Platelet additive solutions	MDR MDR MDR	

PRODUCT	APPLICABLE REGULATION	COMMENT
15. Dialysis Products a. Equipment b. Peritoneal solution including CAPDs c. Haemodialysis solution d. Haemofiltration solution e. Solutions for on-line haemodiafiltration	 MDR MA MDR MA MA	
16. Anaesthetic and other medical gases and oxygen cylinders a) Pipeline/manifolds/AGSS b) Bulk supply Gas including cylinder c) Oxygen concentrators d) Ozone generators	 NHSE* MA MDR MDR	*UK position is that they are not covered by the MDR. NHS Estates have responsibility within DH for fixed installations
17. Monoclonal antibodies a. In-vitro diagnostics b. Immunotoxins	 See comment MA	These are regulated under the in vitro Diagnostic Medical Device Directive 98/79/EC which came into force from June 2000.
18. Human tissues a. Dura grafts b. Skin fibroblasts c. Bone	 MA * *	*These products are not covered by the Medical Devices Regulations 2002. Contact MHRA Medicines Borderline Section in the first instance
19. Dental Products a. Pit and Fissure Sealants b. Root Canal Sealers: Medicated/Non-medicated c. Root canal dressings (e.g. polyantibiotic pastes, antiseptics) d. Pulp capping material e. Dry Socket Preparation f. In-vivo diagnostics, e.g. disclosing tablets g. Haemostatic Agents and Astringents h. Aluminium sulphate / salts astringents	 MDR MDR MA MDR/MA} MDR/MA} MA MA/MDR MDR	 If used for drug delivery then product covered by MA. Depends on product mode of action, see EC guidance.

PRODUCT	APPLICABLE REGULATION	COMMENT
i. Retraction Cords: Medicated /Non-medicated	MDR	
j. Fluoride Preparations: e.g. Tablets, gels, varnishes	MA	
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	
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 eg creams pessaries, sponge film	MA	Where primary purpose is a drug delivery system
21. Impregnated Devices		
a. Antithrombotic coatings gelatin/heparin/protein	MDR	
b. Bacteriological coatings chlorhexidine/benzalkonium chloride/silver/salts/ antibiotics	MDR	Unless primary purpose is to treat infection
22. Disinfectants		
a. Topical Disinfectants	MA	*These products overlap with the Biocidal Products Regulations 2001. Products intended to be used on patients will come within the medicines legislation. Those for use on medical devices will come within the medical devices legislation.
b. Alcohol prep pads / swabs	MA	
c. Wipes/swabs with medicinal substance	MA	
d. Disinfectants specifically intended for disinfecting Medical Devices	MDR*	

PRODUCT	APPLICABLE REGULATION	COMMENT
23. Plasma volume expanders	MA	
24. In-vivo Diagnostic Agents a. X-ray contrast Media including MRI b. Barium meal c. other in-vivo imaging agents d. labelled urea for H pylor test e. gases for lung function tests	 MA MA MA MA MA	
25. Transdermal patches a. Disposable with medicament b. Iontophoresis Device (non disposable/reusable)	 MA 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 considered to be medical devices, however eye washes intended for use to alleviate eye irritation resulting from environmental factors such as smoke, dust etc are not considered to be medical devices.
27. `Activated' Medicinal Products a. Medicinal Product b. Activating device e.g. laser	 MA MDR	
28. Administration Products a. Medicine Spoons b. Droppers c. Oral syringes d. Eye baths	 MDR MDR MDR MDR	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 (eg bottle cap/dropper assembly)

PRODUCT	APPLICABLE REGULATION	COMMENT
29. Agents for transport nutrition and storage of organs intended for transplantation		Commission guidance suggests that such products should be considered to be medicinal products; however in the UK these are not considered to be medicinal products and are not regulated as medical devices.
30. Artificial Skin systems	MDR	Products, which do not contain material of human origin, will be covered by the Medical Devices Regulations. Otherwise consult with MHRA. Note that the forthcoming regulations on advanced therapy products may also apply to such products. Consult with MHRA .
31. Viscoelastic gels for joint lubrication	MA/MDR	Depends on mode of action
32. Parenteral Fluids (Diluents) a. Water for injection b. Saline	 MA MA	
33 Head Lice Products	MA/MDR	Such products will either be medical devices or medicinal products, depending upon their mode of action. Full Guidance on these products is available as an Annex to Medicines Guidance Note 8 'A guide to what is a medicinal product'.
34. 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 (eg 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.

PRODUCT	APPLICABLE REGULATION	COMMENT
b. Active coal / carbon solutions for treatment of acute poisoning	MA	
c. products for the regulation of vaginal flora containing lactobacillus	MA	By consensus of EU Member States such products are considered to be medicinal products.
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

Note: Please refer to MHRA Medicines Guidance Note 8 'a guide to what is a medicinal product' for additional information.