MEDICAL DEVICES AGENCY

DIRECTIVES BULLETIN

BULLETIN No. 17
May 1995

MEDICAL DEVICES AND
MEDICINAL PRODUCTS

INTRODUCTION

This information bulletin is the 17th in a series. It sets out, in broad terms, the distinction between medical devices and medicinal products and outlines the regulatory controls likely to apply in future.

This document aims to present the Department of Health's current views on the interpretation of the Medical Devices Regulations where enquiries from medical device manufacturers and others have shown that there is uncertainty.

This bulletin is intended as general guidance and should not be regarded as an authoritative statement of the law nor as having any legal consequence. It follows that manufacturers and others should not rely on the 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.

The Department of Health does not accept liability for any errors, omissions or misleading or other statements in the bulletin whether negligent or otherwise. An authoritative statement could be given only by the courts

BACKGROUND

As a general rule a product covered by this bulletin is regulated either by the Active Implantable Medical Devices Regulations SI 1992 No 3146 or the Medical Devices Regulations SI 1994 No 3017 or by the Medicinal Products Directive 65/65/EEC. A product will normally only be subject to the requirements of one of these Directives.

The Medical Devices Directive, as implemented in the UK by the Medical Devices Regulations (SI 1994 No 3017), brings within its scope many of the products currently subject to Orders under Section 104 of the Medicines Act 1968 and some pharmaceutical products currently controlled under Directive 65/65/EEC. The Regulations also have implications for the regulatory control of products that incorporate or are used to administer medicinal products and medicinal substances.

MEDICAL DEVICE OR MEDICINAL PRODUCT?

In order to decide which of these Directives applies, one should consider:

- *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 may also be considered to be a medicinal product.

Medical Devices may be assisted in their function by pharmacological, immunological or metabolic means. Where such means are primary with respect to the principal purpose of a product, it is a medicinal product.

A list has been prepared as an Annex to this bulletin which provides guidance as to whether the products listed are likely to be the responsibility of the Medical Devices Agency or the Medicines Control Agency. The list thereby indicates the legislation which is likely to apply to such products.

WHICH PRODUCTS WILL BE TRANSFERRING FROM MEDICINES CONTROL TO DEVICE CONTROL?

The Medical Devices (Consequential Amendments - Medicines) Regulations 1994 (SI 1994 No 3119) will remove a range of products from medicines control in the UK when they are first marketed under devices control, at whatever point in time this occurs during the transitional period provided for in the Medical Devices Regulations.

The main groups of products affected are:

- *wound dressings*
- *some dental products*
- *absorbable surgical materials - including sutures and bone cements*
- *intra-uterine contraceptive devices*
- *contact lens care products*

Whenever during the transitional period the manufacturer decides to market his product under the Medical Devices Regulations, he must ensure that any marketing authorisations issued under the Medicines Act in respect of that product have been withdrawn/have lapsed when he first places the product on the market with a CE marking.

WHAT ABOUT THOSE DEVICES THAT INCORPORATE OR ADMINISTER A DRUG?

Devices that incorporate or are used to administer a drug are covered in Regulation 2(1) of SI 1994 No 3017. As indicated above, the intended principal function of the product, and the method by which this action is achieved, determines the legislation relevant to the product.

There are three types of device which are used to administer or incorporate a medicinal product:

- ***Devices which are used to administer medicinal products (eg a syringe marketed empty).*** *The device is covered by the relevant Medical Devices Regulations.*

- ***Devices for administration of medicinal products such that the device and the medicinal product form a single integral product designed to be used exclusively in the given combination and which is not re-usable (eg a syringe marketed pre-filled).*** *Directive 65/65/EEC applies to the product as a whole. In addition, the relevant essential requirements in Annex I of Directive 93/42/EEC apply with respect to safety and performance related features of the device (eg a syringe forming part of such a product).*

- ***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 (eg a heparin coated catheter).*** *SI 1994 No 3017 applies to the product as a whole. In addition, the*

safety, quality and usefulness of the medicinal substance must be verified by analogy with the methods in Directive 75/318/EEC (SI 1994 No 3144) 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, and the notified body carrying out relevant conformity assessment procedures in respect of such a device must consult a drug regulatory authority established under Directive 65/65/EEC on those aspects of the device mentioned in the preceding sentence.

TRANSITIONAL ARRANGEMENTS

SI 1994 No 3017 provides for a transitional period from 1 January 1995 to 13 June 1998. During this period, in the UK, manufacturers may choose to follow either the national rules in force on 31 December 1994 such as product licensing under the Medicines Act, or the provisions of the Medical Devices Regulations. The change in status of products "transferred" from medicines control to control under the Medical Devices Regulations will mean that, once CE marked, such products, as with all other medical devices, can generally be sold freely anywhere in the European Economic Area. It should be noted that the transitional period referred to does not apply to clinical investigations carried out under the Medical Devices Regulations. Proposed clinical investigations carried out under these Regulations must be notified to the Medical Devices Agency from 1 January 1995. The Agency may be contacted at the address below for guidance about, and application forms for, clinical investigation approval.

FURTHER INFORMATION

Further information on medical devices generally and copies of the earlier bulletins in our series on the Medical Devices Directives, can be obtained from:-

Miss R Hickson
Department of Health
Medical Devices Agency
14 Russell Square
LONDON WC1B 5EP

Telephone (0171) 972 8090 and (0171) 972 8300
Fax (0171) 972 8112.

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

Mrs E A Baker
Department of Health
Medicines Control Agency
Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ

Telephone (0171) 273 0467
Fax (0171) 273 0323

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DRUG DEVICE DEMARCATION

Further information and interpretation will become available in an EC guidance document (to be published in due course)

DEVICE		CONTROL NOW	FUTURE CONTROL	COMMENT
1.	Contact Lens Care Products			
a.	Disinfecting solutions	MA	MDR	
b.	Cleaning solutions	MA	MDR	
c.	Rinsing solutions	MA	MDR	
d.	Hydrating solutions	MA	MDR	
e.	Wetting agents	MA	MDR	
f.	Comfort drops	MA	MDR/MA	Considered to be accessories to medical devices when used with contact lenses. However they are medicinal products if therapeutic claims are made.
2.	Other Ophthalmics			
a.	Artificial tears	MA	MA	
b.	Fluorescein ocular strips	MA	MA	
c.	Injectable fluorescein	MA	MA	
d.	Rose Bengal	MA	MA	
e.	Solution for preserving corneal material prior to transplant	None	None	Under discussion at Commission.
f.	Ocular endotamponades	MDR	MDR	
g.	Viscoelastic/viscosurgical products	MA	MDR	
3.	Surgical Dressings			
a.	Non-medicated	MDR	MDR	Class depends on manufacturer's claim. Some products under review.
b.	Medicated	MA	MDR	
4.	Sutures and Ligatures			
a.	Absorbable	MA	MDR	
b.	Non-absorbable	MDR	MDR	
5.	Resorbable bone plates/polylactic/polyglycolic acid	MA	MDR	
6.	Hard tissue scaffolds			
a.	Hydroxyapatite with/out collagen	MA	MDR	
b.	Calcium phosphate with/out collagen	MA	MDR	
c.	Bioglas	MA	MDR	
d.	Coral	MA	MDR	
7.	Soft tissue fillers			
a.	Collagen	MA	MDR	
b.	Silicone elastomer dispensions, eg Bio/uroplastique	MA	MDR	
8.	Bone cements			
a.	Polymethylmethacrylate with/out antibiotic	MA	MDR	

NOTE MA = Medicines Act 1968, Medicines for Human Use Regulations 1994 (SI 1994 No 3144) and Directive 65/65/EEC
MDR = Medical Devices Regulations 1994 (SI 1994 No 3017) and Directive 93/42/EEC

DEVICE		CONTROL NOW	FUTURE CONTROL	COMMENT
9.	Joint Replacements coated with			
a.	Hydroxyapatite/calcium phosphate	MDR	MDR	
b.	Bone growth factor (Beta BGF)	MDR	MDR	(b) and (c) used alone are controlled
c.	Genetically engineered BGF	MDR	MDR	by MA.
10.	Inhalation devices			
a.	Metered dose inhalers	MA	MA	
b.	Chamber spacers for use with metered dose inhalers	MDR	MDR	Device Class I but (b) (c), (d) & (e) may be sold with medication and
c.	Spinhalers	MDR	MDR	their performance/drug delivery will
d.	Diskhalers	MDR	MDR	be assessed by MCA.
e.	Other empty inhalers (non powered)	MDR	MDR	
11.	Powered nebulisers			
a.	Device	MDR	MDR	
b.	Medicament	MA	MA	
12.	Insulin Injection			
a.	Pen injectors integral with insulin cartridge (disposable)	MA	MA	
b.	Re-usable insulin pens	MDR	MDR	
c.	Sterile Single Use syringes (empty)	MDR	MDR	
d.	Insulin	MA	MA	
13.	Blood Bags			
a.	Sterile empty	MDR	MDR	
b.	Sterile with anticoagulant	MA	MDR	
c.	Sterile with anticoagulant & empty satellite bags	MA	MDR	
14.	Dialysis devices			
a.	Device	MDR	MDR	
b.	Peritoneal solution including CAPDs	MA	MA	
c.	Haemodialysis solution	None	MDR	
d.	Haemofiltration solution	MA	MA	
15.	Anaesthetic gases and oxygen cylinders			
a.	Pipeline/manifolds/AGSS	*	*	* Under discussion at Commissi
b.	Bulk supply	NHSE	NHSE	NHS Estates have responsibility within DH for fixed installations
c.	Gas including cylinder	MA	MA	
16.	Monoclonal antibodies			
a.	In-vitro diagnostics	MDR	MDR	Future IVD Directive
b.	Immunotoxins	MA	MA	
17.	Human tissues			
a.	Dura grafts	MA	*	}
b.	Skin fibroblasts	None	*	} * Under Departmental review
c.	Bone	None	*	}

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18.	Dental Products			
a.	Pit and Fissure Sealants	MA	MDR	
b.	Root Canal Sealers: Medicated/Non-medicated	MA	MDR	
c.	Root canal dressings (eg polyantibiotic pastes, antiseptics)	MA	MA	
d.	Pulp capping material	MA	MDR/MA }	If used for drug delivery then
e.	Dry Socket Preparation	MA	MDR/MA }	product is covered by MA
f.	In-vivo diagnostics, eg disclosing tablets	MA	MA	
g.	Haemostatic Agents and Astringents	MA	MA/MDR	Refer to forthcoming EC guidance
h.	Retraction Cords: medicated/Non-medicated	MA	MDR	
i.	Fluoride Preparations: eg Tablets, Gels, Varnishes,	MA	MA	
j.	Hard Tissue Scaffolds	MA	MDR	
k.	Desensitising Agents: Physical/Pharmacological	MA	MDR/MA	
l.	Periodontal Dressings: Medicated/Non-Medicated	MA	MDR	
m.	Periodontal Antibacterials: eg Gels, Ointments, Fibres	MA	MA	
n.	Varnishes: Protective/Drug Delivery	MA	MDR/MA	
o.	Toothache Preparations	MA	MA	
p.	Artificial Saliva	MA	MA	
q.	Mouth Ulcer Preparations: Medicated/Non-Medicated	MA	MA/MDR	
r.	Antibacterial Mouthwashes/Gels	MA	MA	
19.	Contraception Products			
a.	IUDs with/out chemical action	MA	MDR	
b.	Diaphragms	MDR	MDR	
c.	Condoms with/out spermicide	MDR	MDR	
d.	IUDs with hormone action	MA	MA	Where primary purpose is a drug delivery system
e.	Spermicidal preparations eg creams, pessaries, sponge, film	MA	MA	
20.	Impregnated Devices			
a.	Antithrombotic coatings gelatin/heparin/protein	MDR	MDR	
b.	Bacteriological coatings chlorhexidine/benzalkonium chloride/silver salts/antibiotics	MDR	MDR	
21.	Disinfectants			
a.	Topical Disinfectants	MA	MA	Relationship/overlaps with the proposed Biocidal Products Directive currently under review
b.	Disinfectants specifically for Medical Devices	MDR	MDR	
22.	Other Biodegradable Implants	MA	MDR	
23.	Plasma volume expanders	MA	MA	
24.	X-ray Contrast Media including MRI	MA	MA	
25.	Transdermal patches			
a.	Disposable with medicament	MA	MA	
b.	Iontophoresis Device (non disposable/re-usable)	MDR	MDR	
26.	Irrigation solutions including those used in the eye	MA	MDR	For mechanical rinsing purposes but if solution contains a pharmacologically active substance then the product is covered by MA

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DEVICE		CONTROL NOW	FUTURE CONTROL	COMMENT
27.	`Activated' Medicinal Products			
a.	Medicinal Product	MA	MA	
b.	`Activating' device eg laser	MDR	MDR	

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