MEDICAL DEVICES AGENCY
DIRECTIVES BULLETIN

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ACTIVITIES OF HEALTHCARE ESTABLISHMENTS (IN-HOUSE MANUFACTURE) IN THE UK.

FOREWORD

This bulletin is the 18th in the series and represents MDA's current view on the questions relating to "in-house" manufacture. It should not be regarded as an authoritative statement of the law nor as having any legal consequence. An authoritative statement could be given only by the courts. It follows that those affected should not rely on this document but should reach their own decisions 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.

INTRODUCTION

Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices and Directive 93/42/EEC concerning medical devices are now in force. They have been implemented in the United Kingdom by the Active Implantable Medical Devices Regulations 1992 (SI 1992 No 3146) and the Medical Devices Regulations 1994 (SI 1994 No 3017). Bulletin No 8 gives general information on the Directives for medical devices.

This bulletin provides guidance on the extent to which the MDA considers that the manufacture of medical devices by healthcare establishments is covered by the implementing Regulations. The term "healthcare establishment" includes for the purposes of this bulletin, a NHS hospital, private hospital, general practice, clinic, rehabilitation centre, occupational therapy centre and any similar establishment which is responsible for the care of patients.

This bulletin deals specifically with the 1993 Directive on medical devices and the 1994 Regulations which implement it. However, MDA believes that the views expressed in this bulletin would, in principle, apply equally to active implantable medical devices, in which case reference should be made to the corresponding 1992 Regulations.

MANUFACTURER

The Regulations for medical devices define the manufacturer as "the person [natural or legal] who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name regardless of whether these operations are carried out by that person himself or on his behalf by a third party" Any obligation of a manufacturer under these Regulations extends to a person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.

The obligations imposed on persons other than manufacturers do not extend to a person who assembles or adapts devices already on the market to their intended purpose for an individual patient. In practical terms this means that a surgeon who assembles an orthopaedic

implant, a dentist who fits a dental appliance, a nurse who makes a plaster cast, a technician who assembles an anaesthesia system, a surgeon who uses a laser for a purpose other than that stated by the manufacturer of the laser, etc are **NOT** regarded as manufacturers of medical devices.

PLACING ON THE MARKET

Placing on the market means "the first making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market". A Commission guide to new approach Directives explains that "making available" means the transfer of the product by way of transfer of ownership or the passing of the product to the final consumer or user in a commercial transaction, for payment or free of charge regardless of the legal instrument on which the transfer is based (sale, loan, hire, leasing, gift, or any other type of commercial or legal instrument).

DEVICES REMAINING WITHIN A HEALTHCARE ESTABLISHMENT

A draft guide being developed by a Commission working group recognises that devices made by a healthcare establishment and remaining within that establishment for use only by (or under the direction of) staff of that establishment are a special case. Likewise, MDA considers that this local activity carried out by healthcare establishments does **NOT** result in a device being placed on the market or put into service so the Regulations do not apply.

DEVICES TRANSFERRED TO OTHER HEALTHCARE ESTABLISHMENTS

If a healthcare establishment manufactures a device and that device is transferred to another body (eg another establishment under a different management), then that device is regarded as being placed on the market under the name of the manufacturing establishment and the Regulations will apply. It makes no difference whether the device is supplied for payment or free of charge, or whether the quantity of devices is small or large.

This also applies to those establishments marketing products covered by regulation 11, namely, assembly of systems or procedure packs (including sterile packs). [Simple resterilisation of devices (eg surgical instruments) with no change in ownership of the devices and without incorporation into new procedure packs is **NOT** regarded as coming within the scope of the Regulations.]

DEVICES TRANSFERRED TO PATIENTS

Falling between the two situations above is the case where a device is made by a healthcare establishment and is given or attached to a patient under its care (even if that paitent has been referred from another healthcare establishment) who subsequently carries it away. For example, a hospital may produce a sterile pack internally for its own use (ie "in-house" procedure pack and excluded from the Regulations) and a patient may leave the accident and emergency department with a sterile dressing from that pack. MDA regards this normal hospital activity as internal to that hospital and thus excluded

from the Regulations. Furthermore, MDA believes that similar normal activities carried out by other healthcare establishments such as disablement services departments, occupational therapists, general practitioners, etc are also outside the scope of the Regulations. Other examples would be a general practitioner fabricating an arm sling from bandage, rubber tubing and polyurethane foam; a physiotherapist making a splint or support.

On the other hand when healthcare establishments manufacture devices with the intention of marketing them as opposed to treating patients, MDA would regard such manufacture as being covered by the Regulations.

CLINICAL INVESTIGATIONS

Under regulation 16, before a manufacturer makes a device available for clinical investigation he must give notice to the Secretary of State. The device may then be made available only if the Secretary of State does not prohibit the investigation from going ahead. There is **no** transitional period in the UK for this regulation so it applies from 1st January 1995.

MDA does **NOT** consider that a healthcare establishment, intending to make a device manufacturerd within that establishment available for clinical investigation with patients being treated in the same establishment or by the same body or legal entity, needs to give notice of the investigation to the Secretary of State under regulation 16.

DECISIONS AS TO WHETHER AN ACTIVITY IS COVERED BY THE REGULATIONS

Healthcare establishments should review their manufacturing activities and decide whether or not they are covered by the Regulations. If any body has any doubt about whether any of their activities are covered they should seek their own legal advice. If any activity is identified, all relevant obligations must be identified and complied with but the transitional period until **13th June 1998** should be taken into account.

OTHER OBLIGATIONS

Even if healthcare establishments decide their activities are not subject to the Regulations on medical devices, they need to be aware of their responsibilities under general consumer protection legislation and to ensure the safety of patients and users alike.

FURTHER INFORMATION

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