MEDICAL DEVICES AGENCY

DIRECTIVES BULLETIN

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INFORMATION ABOUT THE PACKAGING AND PACKAGING WASTE DIRECTIVE

INTRODUCTION

This information bulletin is the 16th in a series and explains how new European legislation on packaging and packaging waste will affect all of us, and in particular manufacturers of medical devices.

BACKGROUND

The need to protect the environment has been of increasing concern over recent years. Reflecting this concern, a programme of legislation to reduce the amount and environmental impact of waste is being developed in the European Union. A Framework Directive was passed in 1991 which emphasises the need to reduce overall levels of waste, and following on from this, the European Commission has defined certain types of waste as priority areas for waste reduction. Among these "Priority Waste Streams" is packaging and packaging waste, and a "Packaging and Packaging Waste Directive" was adopted in December 1994.

All packaging used for medical devices will be subject to the new Directive.

OBJECTIVES OF THE DIRECTIVE

The Packaging and Packaging Waste Directive is intended to:

- ensure the functioning of the Single Market
- reduce the impact of packaging on the environment, including the amount of packaging waste going to landfill.

SCOPE

The Directive will apply to **anybody** who produces or has contact with packaging or packaging waste. This will include industry (eg: manufacturers and suppliers of medical devices), commercial interests (eg: wholesalers and retailers), service users (eg: hospitals and community healthcare), and householders.

DEFINITIONS

"Packaging" can be either:

(1) Primary packaging for a single sales unit to the final user (eg: the wrapping round a bandage), or

(2) Secondary packaging around a group of products, which can be removed without affecting the characteristics of the product, or

(3) Tertiary packaging which facilitates handling and transportation of the product (does not include containerised transport)

"Reuse" means that packaging must be capable of being used for a number of trips or rotations in normal use, and capable of recovery once it is no longer reused.

"Recovery" means that packaging waste must be capable of being either recycled or composted, or can be incinerated with energy recovery.

TIMESCALE FOR IMPLEMENTATION

The Packaging and Packaging Waste Directive came into force on 31 December 1994. UK Regulations to implement it will have to come into effect by June 1996, but full compliance with the essential requirements will not be compulsory until December 1997.

ESSENTIAL REQUIREMENTS

The Directive lays down certain requirements with which packaging materials will have to conform. **From January 1998 only packaging which meets the requirements can be placed on the market.** Compliance will be necessary with harmonised standards, which will cover the manufacture and composition of packaging. CEN, the European standards making body, is working to define these standards and the UK industry contribution is being coordinated via BSI.

SAFETY

The Directive will not affect existing safety requirements. So, for instance, the Directive does not require manufacturers to use recycled waste in producing packaging for sterile medical devices, in so far as it is consistent with health and safety. In the same way, it is accepted that some packaging from medical devices may have become contaminated and therefore not suitable for recycling, although it could be recovered by incineration with energy recovery.

A standing committee established under the Directive will have a remit to consider any difficulties encountered in applying the Directive to certain identified areas, including primary packaging for medical devices. The detailed procedure for this is to be determined.

TARGETS

The Directive requires that within 5 years of National implementation (ie: by mid 2001) an overall total of between 50% and 65% of all packaging waste produced in each Member State must actually be recovered. Within this target, between 25% and 45% must be recycled, and at least 15% of each type of packaging material (plastic, paper, etc) must be recycled. Individual Member States may set higher targets, provided this does not restrict trade within the Union. There are additional targets for the maximum concentrations of heavy metals such as lead, cadmium, mercury and hexavalent chromium, and these may influence the manufacturer's choice of printing methods.

Each Member State will be required, as part of an overall environmental policy, to set up systems to enable these targets to be met, and to encourage industry and others to reduce the overall quantities of waste produced. They are also required to publicise the targets to the general public and others, and within two years of the date the Directive is implemented to ensure that consumers and others have the necessary information to enable them to contribute fully to the reuse, return and recycling of packaging.

It will be for each Member State to determine how the targets will be met, and by which sectors of industry. The UK will be implementing the recovery requirements of the Directive by means of Regulations under the Environment Bill, which contains enabling

powers to impose an obligation on industry. This Bill has just completed its passage through the Lords and will go to the Commons shortly. There will be consultation on the contents of the packaging Regulations and the targets later this year.

INFORMATION SYSTEMS

In order to show performance against these targets, Member States will have to provide the European Commission with information about the quantities and types of waste being produced, and the proportions reused or recovered. There will be further discussion between the Commission and Member States on the harmonised form of the data reports to be required. This is likely to mean industry and users having to provide information to Government.

MARKING AND IDENTIFICATION SYSTEMS

The Directive provides for the establishment of a marking system, to facilitate appropriate disposal. The European Council has until the start of 1997 to decide on a suitable marking system. UK industry will be consulted on the scope and basis of a marking system.

TRANSITIONAL PERIODS

The Directive allows a three year transitional period from the date of its adoption (ie: to late 1997) before compliance with the essential requirements will become compulsory.

Packaging manufactured before the Directive was adopted may, provided it is in conformity with existing national laws, continue to be placed on the market for up to five years.

FURTHER INFORMATION

Further information about the medical devices Directives, and copies of the other bulletins in the series can be obtained from:-

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For other general information on environmental issues, contact the Department of Environment Enquiry Office on:

0171-276 0900