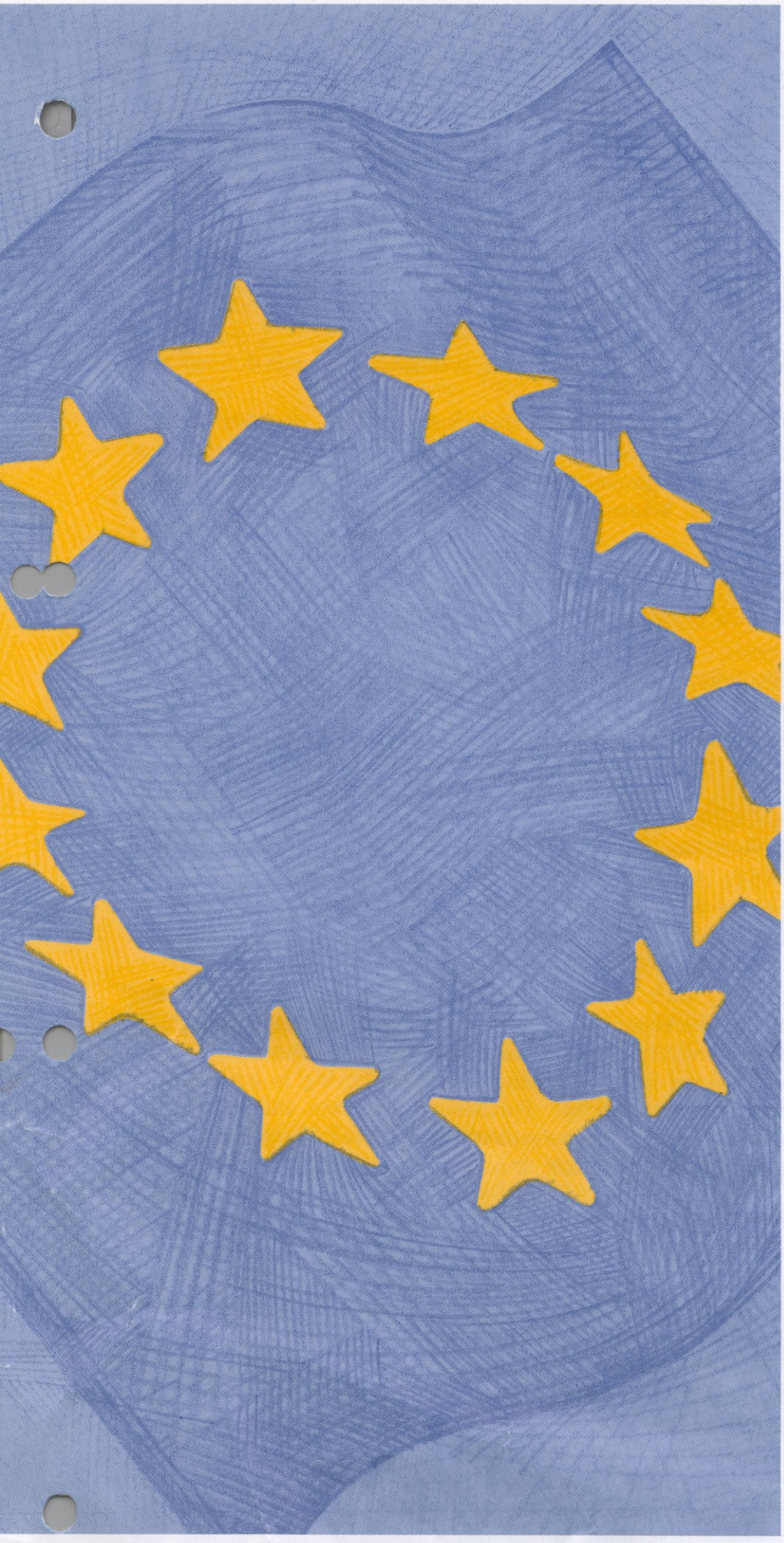

DEPARTMENT OF HEALTH

MEDICAL DEVICES DIRECTORATE

DIRECTIVES BULLETIN

INFORMATION ABOUT THE EC MEDICAL DEVICES DIRECTIVES

Bulletin number 8

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DEPARTMENT OF HEALTH

Introduction

A series of three Directives regulating the safety and marketing of medical devices throughout the European Community started to come into effect from 1 January 1993. This bulletin sets out in broad terms:-

- why we need the Directives
- how patients and users are expected to benefit
- the devices covered by each Directive
- the timetable for their implementation in the UK
- some of the key points in the Directives

What is a medical device?

For the purpose of the Directives, a medical device is defined as:-

"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 on human beings for the purpose of:

-diagnosis, prevention, monitoring, treatment or alleviation of disease,

-diagnosis, monitoring, treatment, or 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."

Why do we need the Directives?

At present, each Member State in the Community controls the safety and marketing of its medical devices in different ways. The Directives will benefit manufacturers by harmonising these controls within a single system, instead of having to comply with 12 different sets of rules. Purchasers and users will also be re-assured that devices manufactured in the UK or anywhere in the Community meet common standards of performance and safety.

Replacement of existing national controls

Adoption of the Directives will mean that the UK's voluntary system of manufacturer registration and product approval for controlling certain medical devices used by the NHS, will eventually be replaced by a more comprehensive statutory system, covering <u>all</u> devices used in the UK.

Benefits for patients and users

At the same time the Directives will also benefit patients and users, by setting out **essential requirements** which make it clear that devices must not compromise the health or safety of the patient, user or any other person and that any risks associated with the device are still compatible with patient health and protection. Any side effects must be acceptable when weighed against the intended performance. Devices meeting these requirements will be entitled to carry the "CE" marking.

The Directives

The Active Implantable Medical Devices Directive

Scope

This first Directive covers all powered implants or partial implants that are left in the human body. Heart pacemakers are the most common example of powered implants. About 10,000 such devices are implanted in the human body in the UK every year.

Timetable

The Directive was adopted by the European Council on 20 June 1990. The UK regulations needed to implement it were laid before Parliament on 11 December 1992 and came into effect on 1 January 1993. A copy of the Active Implantable Medical Devices Regulations 1992 can be obtained from HMSO quoting SI 1992 No 3146.

The Medical Devices Directive

Scope

The second Directive planned by the European Commission, will cover most other medical devices, ranging from, for example, first-aid bandages, tongue depressors, through to hip prosthesis.

Timetable

A Common Position on the Directive was reached at the Council of Ministers' Internal Market Council on 8 February 1993. The Directive will take effect on 1 January 1995.

The In Vitro Diagnostic Medical Devices Directive

Scope

This last Directive will cover any medical device, reagent, reagent product, kit, instrument, apparatus or system which is intended to be used in-vitro for the examination of substances derived from the human body. Some examples of in-vitro diagnostic devices are blood grouping reagents, pregnancy test and Hepatitis B test kits.

Timetable

The Commission is now drafting this Directive and a formal proposal is expected later this tear. It will be 1996 at least before this Directive takes effect in the UK.

Key points in the Directives

CE marking

CE

The CE marking that appears on the medical device or on its packaging **means that the device satisfies the requirements essential for it to be fit for its intended purpose.** From January 1993, the CE marking will probably start to appear on a relatively small number of high technology products, such as heart pacemakers. Eventually all devices (except custom-made and devices intended for clinical investigations) whether used in private or public hospitals and nursing homes, or sold in retail outlets, will have to carry the CE marking.

Classification

The Medical Devices Directive will include a classification system whereby the level of regulatory control applied to devices is proportional to the degree of risk inherent in the device. The strictest controls will therefore only apply to the limited number of high risk products.

The Competent Authority

The Competent Authority is the body set up to carry out the requirements of the Directives in each Member State. In the UK, the Competent Authority is the Secretary of State for Health acting through the Department of Health's Medical Devices Directorate. The Competent Authority's main role will be to ensure compliance with the Regulations, evaluate adverse incident reports received from manufacturers and users, and carry out a pre-clinical assessment of devices intended for clinical investigation.

Notified Bodies

The Competent Authority is also responsible for approving the independent certification organisations that will check and prove that medium and high risk medical devices meet the essential requirements and thus enable manufacturers to apply the CE marking to their products. A Notified Body is the name given to the organisation that will carry out these checks.

Clinical investigations

The Directives will require that for all devices intended for clinical investigation in the EC, there must be a formal assessment of the risks such investigations might pose to the health and safety of patients. From 1 January 1993, manufacturers of **active implants** must inform the Competent Authority if they intend to start a clinical investigation, at least 60 days before it is due to begin. The investigation can start after the 60 day period unless the Competent Authority notifies the manufacturer of a decision to the contrary on grounds of public health. All proposals for clinical investigations must still be referred to the Local Research Ethics Committee but this should usually be done before an application is made to the Competent Authority.

National Reporting and Investigation Centre (NATRIC)

At present, the Department of Health operates a voluntary system (known as NATRIC) based on user reporting covering all device-related adverse incidents and this will continue under the new system.

Adverse incident reporting (Vigilance)

However, arrangements for reporting adverse incidents will also change when the UK regulations take effect. Manufacturers will be required by law to report **serious** incidents to the Competent Authority; information about these will be collected and evaluated centrally and, where necessary, made available to other Member States. The overall aim of the new system will be to improve the safety of patients, users and others by seeking to prevent the same type of serious incident recurring elsewhere in the Community.

Further information

Other bulletins in this series go into more detail on each of the Directives and areas of specific interest such as the CE marking, Clinical Investigations and Adverse Incident Reporting (Vigilance). Further information about the Medical Devices Directives and the Department of Health's responsibilities, can be obtained from:-

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