DEPARTMENT OF HEALTH

MEDICAL DEVICES DIRECTORATE

DIRECTIVES BULLETIN

PRE-CLINICAL ASSESSMENT PROCEDURES

THE PRODUCT REGISTRATION SCHEME

DEPARTMENT OF HEALTH

Introduction

This information bulletin is the fifth in a series and sets out:-

- the aim of pre-clinical assessment of clinical investigations, as laid down in the Directives
- how the new arrangements will operate
- details of the voluntary product registration scheme for active implantable medical devices

PRE-CLINICAL ASSESSMENT:

The **AIMD Directive** requires that all powered implantable medical devices intended for clinical investigation in the EC meet the essential requirements of the Directive, apart from those aspects at which the investigation is aimed. This means that there must be a formal assessment of the risks which clinical investigations might pose to the health and safety of patients.

The Active Implantable Medical Devices (AIMD) Directive

The manufacturer must inform the Competent Authority of the EC country where the investigation will take place of his intention to undertake a clinical investigation at least 60 days before it is due to begin. After the 60 day period, the investigation can start, unless the Competent Authority has notified the manufacturer of a decision to the contrary, based on considerations of public health.

The Competent Authority

The Department of Health's Medical Devices Directorate is the Competent Authority for the UK and has responsibility for implementing the **AIMD Directive** in the UK.

Previous UK position

All proposals for clinical investigations of medical devices before 1 January 1993 were referred to the Local Research Ethics Committee (LREC) for approval before the investigation began.

Start of new arrangements

The new arrangements for clinical investigations involving active implantable devices began on 1 January 1993. The transitional period referred to in the Directive does not apply to clinical investigations.

The new arrangements

(1) All proposals for clinical investigations must continue to be referred to the LREC. This should happen before an application is made to the Competent Authority. The responsibilities of LRECs will remain unchanged.

(2) An application must be made to the Competent Authority, at least 60 days before the investigation is due to begin. The Directive requires that manufacturers provide data on the device and the intended investigation to the Competent Authority.

(3) The 60 day period will begin on the day the Competent Authority receives the application.

(4) The Competent Authority may request additional information from the manufacturer where this is required by the Directive. Because the 60 day period does not stop while this information is awaited, the application may be rejected on the grounds that there is insufficient time for proper assessment if the manufacturer does not provide the information requested within 14 days without good reason.

(5) The Competent Authority will assess the application against the requirements of the Directive by evaluating the data provided, using external expert assessors where appropriate.

(6) If the Competent Authority does not notify the manufacturer of an objection by the end of the 60 day period, the clinical investigation can begin providing it has LREC approval.

(7) Where an objection is raised to an application during the 60 day period, the manufacturer will be advised of the reason.

Will there be an appeals procedure?

There will be no appeals procedure. If a manufacturer disagrees with the Competent Authority's decision he should advise the Competent Authority in writing. If the matter is not resolved he may seek a Judicial Review.

Confidentiality

All data provided by the manufacturer will be held in confidence by the Competent Authority and, where appropriate, by the external assessors.

Where external assessors are employed, their contract with the Competent Authority will include clauses on confidentiality and a requirement to declare any conflict of interest. External assessors are not allowed to retain any documents relating to the application.

Guidelines

The UK Competent Authority has produced:-

(1) A clinical investigation package for manufacturers.
(2) An explanatory leaflet for expert assessors.

Copies are available from the address at the end of this bulletin.

Other medical devices Directives

It is expected that clinical investigation requirements will also be included under the proposed **Medical Devices** and **In Vitro Diagnostic Medical Devices Directives.**

The PRODUCT REGISTRATION SCHEME:

For a number of years the Medical Devices Directorate has maintained a voluntary register for cardiac pulse generators marketed in the UK.

Background

The scheme :

(1) has had the wide support of manufacturers,

(2) has been found to be very useful to the Medical Devices Directorate,

(3) has assisted communications with manufacturers at times when product recalls have been necessary.

Registration

The product register is <u>not a requirement</u> of the **AIMD Directive**, but a voluntary system used by the UK Competent Authority in its communication with industry.

Devices concerned

The existing scheme is being extended to cover all active implantable medical devices. This will include devices designed to be used in conjunction with active implantable medical devices but supplied separately, for example permanent implantable leads and programmers.

Use of the Register

The register will add to the data held by the Competent Authority and will be shared with the Medical Devices Directorate's specialist professional and technical sections.

Information requested

The information sought from manufacturers for inclusion in the register is similar to the information manufacturers are required to provide with their devices if they are to comply with the Directives' and standards' requirements. No confidential information is required.

How to register

A standard form to cover all kinds of active implantable medical devices will be used.

Pre-clinical assessment application forms and further information

Pre-clinical assessment application forms are available from Room 614A of the following address or on the telephone/fax numbers quoted. Further information and copies of the clinical investigation package for manufacturers, the explanatory leaflet for expert assessors and the product registration form may be obtained from:-

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