IMPLEMENTATION OF THE MEDICAL DEVICES DIRECTIVES OF THE EUROPEAN COMMUNITY:

Guidance to Local Research Ethics Committees from the Department of Health

A series of three Medical Device Directives, regulating the safety and marketing of medical devices throughout the European Community, started to come into effect from the beginning of 1993. These Directives will eventually replace existing national systems in each Member State and will benefit both the manufacturer, by creating harmonisation of controls within a single system, and purchasers and users by providing reassurance that devices marketed anywhere throughout the European Community will meet common standards of performance and safety.

The first of these Directives, the Active Implantable Medical Devices Directive (**AIMDD**), encompasses all implantable powered devices within its scope, e.g. pacemakers and implantable defibrillators, and came into force on 1 January 1993. The Medical Devices Directive (**MDD**) covers most other medical devices and will come into effect, subject to the Parliamentary process, in January 1995. The In Vitro Diagnostic Medical Devices Directive (**IVDDD**) will cover any equipment or reagent intended to be used in-vitro for the examination of substances derived from the human body. This Directive is currently being drafted by the Commission and is not expected to come into force until 1996 at the earliest.

Under the provisions of these Directives, no device may be sold freely on the market in the EC without a CE (Communauté Européan) marking apart from two specific exceptions where devices are either custom-made or are undergoing clinical investigation. With the exception of Class I (low-risk) devices, in order to obtain this marking, the manufacturer must go through a conformity assessment procedure in order to confirm that the device in question complies with the relevant Essential Requirements. These are designed to ensure that a device:

(i) does not compromise the clinical condition or safety of the patient;

(ii) presents minimum risk to device users or, where appropriate, to any third party; and

(iii) achieves its intended purpose as designated by the manufacturer.

In order to demonstrate these features satisfactorily, clinical data may be required, particularly with the higher risk devices. This data may be obtained from previous clinical experience with the device, or may be a compilation of scientific literature relating to the device or a similar device. If this clinical data is, however, not available, e.g. in the circumstances of a new device being produced, evidence from a specifically designed clinical investigation may be required in order to demonstrate performance and/or determine any undesirable side effects. Under the provisions of the **AIMDD** and **MDD**, all such clinical investigations must be notified to the Competent Authority (the body set up in each Member State to enforce the regulations of the Directives - in the case of the UK, the Secretary of State for Health acting through the Department of Health's Medical Devices Directorate) of the Member State(s) in which the investigation(s) is(are) being performed, and the required

documentation submitted, the details of which are laid out in the Directives. Under the terms of the MDD, part of the required documentation must be a copy of the opinion of the relevant LREC(s).

The Competent Authority then has 60 days in which to make an assessment of the documentation and inform the applicant of any objections, aided by a number of assessors, expert in a wide range of subjects relating either to clinical research or aspects of the device itself. If within this period no objections are raised, the clinical investigation may then proceed. The only grounds on which the Competent Authority may raise objections under the terms of the Directive are in a situation where the investigation is felt to prejudice either public health or public safety. Whilst this has the effect of preventing a proposed clinical investigation proceeding, it is envisaged that such grounds will arise mainly in respect of technical and material problems relating to the particular device. In no case will the Competent Authority give authorization for a clinical investigation to proceed locally in circumstances where an unfavourable LREC opinion has been received. In the case of a proposed multicentre trial, where one or more LRECs have raised ethical objections, the Competent Authority will only consider the application in terms of the centres where a favourable LREC opinion has been delivered.

All clinical trials of CE marked devices will not require notification to the Competent Authority unless such a device is being proposed for a use other than that intended under its existing authorization.

The relevant sections of the Directives that lay out the provisions relating to clinical investigation of devices are:

AIMDD: Article 10, Annex VI, Annex VII;

MDD: Article 15, Annex VIII, Annex X.

If you have any queries or require further information concerning these requirements, please contact:

Dr S M Ludgate
Senior Medical Officer
Medical Devices Directorate
Room 110
14 Russell Square
LONDON WC1B 5EP

These notes were distributed to Local Research Ethics Committees by the Department of Health in December, 1993.