MEDICAL DEVICES AGENCY

DIRECTIVES BULLETIN

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SALE AND SUPPLY OF IN VITRO DIAGNOSTIC MEDICAL DEVICES

INTRODUCTION

This information bulletin is the 12th in a series and outlines the current controls in the UK for the sale and supply of in vitro diagnostic medical devices (IVDs) and introduces the main elements of the proposed In Vitro Diagnostic Medical Devices Directive.

WHAT IS AN IVD?

Currently there is no statutory definition of an IVD. The following definition is taken from the Directive 93/42/EEC of 14 June 1993 concerning medical devices, published in the Official Journal of the European Communities on 12 July 1993, (Number L 169/1).

> *'..."device used for in vitro diagnosis" means any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of samples derived from the human body with a view to providing information on the physiological state, state of health or disease, or congenital abnormality thereof;...'.*

The regulations which will implement the medical devices Directive in the UK will come into force on 1 January 1995 and will contain a definition of "used for in vitro diagnosis" based on the above definition. The medical devices Directive does not apply to IVDs. Accordingly, the regulations implementing the Directive will not apply to IVDs.

SUPPLY OF IVDs: CURRENT CONTROLS

At present there is no legislation dealing specifically with all aspects of the safety of IVDs.

The Department of Health's Manufacturer Registration Scheme does not cover IVDs and there is no requirement that IVDs be evaluated by the Department before being marketed in the UK.

VOLUNTARY EVALUATION PROGRAMME FOR IVDs

However, the Department's Medical Devices Agency operates a voluntary evaluation programme for certain IVDs, with the object of providing unbiased performance and safety information to would-be purchasers. Details of this programme are available from Mr Paul Garden, Room 204, Medical Devices Agency, 14 Russell Square, London WC1B 5EP, telephone 0171-972-8147.

However, there are some legal requirements which apply to certain IVDs.

THE HEALTH AND SAFETY AT WORK ACT 1974

The Health and Safety at Work Act 1974 imposes a general duty on any person who designs, manufactures, imports or supplies any article for use at work (which includes IVDs) to make sure that the article is safe and without risks to health as far as is reasonably practicable. The Act includes a requirement for appropriate testing and examination and the provision of adequate information about the use of the article.

THE GENERAL PRODUCT SAFETY REGULATIONS 1994

The General Product Safety Regulations 1994 impose safety requirements in relation to any consumer product for which there are no specific provisions in rules of EC law governing all aspects of the safety of the product. At present there is no EC law governing all aspects of the safety of IVDs which are consumer products. Accordingly, until such time as the regulations which will implement the proposed IVD Directive come into

force, the General Product Safety Regulations apply to IVDs. Under the latter regulations, such IVDs may not be placed on the market unless they are safe products. The regulations also impose on producers a requirement to provide information to consumers. Requirements are also imposed on distributors.

THE HIV TESTING KITS AND SERVICES REGULATIONS 1992

These regulations make it illegal to sell or supply an HIV testing kit, unless it is accompanied by a notice which indicates that the kit must not be sold or supplied to a member of the public, and which includes appropriate warnings about the interpretation of results.

IVDs THAT CONTAIN RADIOACTIVE SUBSTANCES

In the case of IVDs which contain radioactive substances there is a need to comply with the requirements of The Radioactive Substances (Carriage by Road) (Great Britain) Regulations 1974 and any other relevant legislation. Advice on specific legal requirements should be obtained from Health and Safety Executive, Baynards House, 1 Chepstow Place, London W2 4TF, telephone 0171-229-3456 or from the local area office of the Health and Safety Executive.

PROPOSED IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVD) DIRECTIVE

The proposed IVD Directive is currently at the planning stage. The latest indication of the European Commission's intentions is contained in the Commission's draft working document "Draft Proposal for a Council Directive on In Vitro Diagnostic Medical Devices", dated April 1993(III/D/4181/93-EN). Adoption of the IVD Directive by the Council of Ministers is not expected before the beginning of 1997. Thereafter, UK legislation to implement the IVD Directive will be required.

STRUCTURE OF THE PROPOSED DIRECTIVE

Detailed negotiations on the terms of the proposed Directive have not yet started. It is possible that the Directive in its final form may differ significantly from the proposals in the Commission draft working document mentioned above. However, at the moment, it seems likely that the Directive will follow a format similar to that of the active implantable medical devices Directive and medical devices Directive. It seems likely to consist of a number of Articles dealing with definitions, scope, free movement, standards, reporting of adverse incidents, vigilance, notified bodies and so on. There will probably be Annexes to the Directive containing detailed information on the Essential Requirements, conformity assessment procedures and classification criteria.

CLASSIFICATION CRITERIA

It seems likely that the IVD Directive will incorporate a classification system that is similar to the system in the medical devices Directive whereby the level of control applied to devices is proportional to the degree of risk inherent in the device. However, classification is likely to be by reference to the degree of reliance to be placed on the results obtained, whether an incorrect result could be hazardous to the patient or to a third party and whether the conduct of a conformity assessment, where a notified body is involved, can be expected to improve the performance of an IVD. Devices covered by this Directive seem likely to be grouped into three classes:

- ***IVDs for self testing**: These devices are intended by the manufacturer to be used by people who are not specially trained in clinical laboratory techniques. This category of device includes those intended for self testing in the home environment. In addition to preparing a Declaration of Conformity, as for low risk IVDs, the manufacturer will probably have to apply to a notified body for an assessment of the design. Alternatively it seems likely that the manufacturer may be able to follow the conformity route for high risk IVDs.*

- ***Annex 2 IVDs**: The strictest controls are likely to apply to: reagents and reagent products for blood grouping; reagent and reagent products for the detection of HIV, HBV and HCV infections in blood, for diagnosis, blood transfusion and/or preparation of blood derivatives. A notified body will probably carry out, at the manufacturer's choice, either an audit of the full quality assurance system or type testing plus some form of production audit or sample examination.*

- ***IVDs that are not intended for self testing and are not included in Annex 2**: The manufacturer will probably have to declare conformity with the provisions of the Directive, including compliance of the product with all relevant Essential Requirements. This would mean that the manufacturer would be legally obliged to meet those requirements and would have to prepare technical documentation in support of the Declaration of Conformity.*

Further information about the role of notified bodies can be found in Directives Bulletin Number 6.

ESSENTIAL REQUIREMENTS

The Essential Requirements of the proposed Directive are likely to be similar to those in the medical devices Directive. There will probably be an additional requirement that devices must achieve the specified performances particularly in terms of analytical sensitivity, specificity, accuracy, repeatability, reproducibility and limits of detection stated by the manufacturer.

AVAILABILITY OF DOCUMENTS CITED ABOVE

Copies of Acts and Regulations are available from HMSO Publications Centre, PO Box 276, London SW8 5DT, telephone 0171-873-9090, fax 0171-873-8200 or from HMSO Bookshops in London, Birmingham, Bristol, Manchester, Belfast and Edinburgh.

FURTHER INFORMATION

Further information about the EC Directives concerning medical devices including a copy of the draft IVD Directive and copies of the earlier bulletins in our series about these Directives, can be obtained from:-

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