



Irish Medicines Board Impact on Laboratory Practice

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New Role

- Competent Authority for *in-vitro* diagnostic medical devices on 29 June 2001
- Competent Authority for general medical devices and active implantable medical devices on 01 October 2001



Structure of Medical Devices Department





Supporting Structure

- Committee for Medical Devices and Diagnostics
 - ◆ Requires amendment to IMB Act 1995 to give it legislative basis as an Advisory Committee of the IMB
- Sub-committees of the Advisory Committee for specific projects.
- Panel of Experts



Legislation governing Medical Devices

- Active Implantable Medical Devices
90/385/EEC
- Medical Devices Directive 93/42/EEC
- *In-vitro* Diagnostic Medical devices
Directive 98/79/EEC
- Medical Devices incorporating stable
derivatives of human plasma or human
blood Directive 2000/70/EEC



Irish Legislation for IVD's

- S.I. No. 304 of 2001 European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001
- Effective date 29 June 2001
- Transition phase until 07 December 2003. An additional period of two years is allowed for devices to be put into service



Competent Authority

- The body who acts on behalf of the government of a Member State to ensure that the requirements of the Medical Devices Directives are carried out in that particular Member State.
- The primary role of the CA is to ensure that all medical devices sold on the Irish market meet the Essential Requirements of the Directives and in doing so, do not compromise the health and safety of patients, users and where appropriate, any other persons



Notified Body

- Certification organisation which the Competent Authority has designated to carry out conformity assessment procedures
- One designated in Ireland for IVD, AIMD and MD Directive i.e. NSAI



CE Mark

- Devices meeting the Essential Requirements of the Directives will be entitled to carry the “CE Marking” which indicates conformance with the appropriate Directive. Once devices are CE Marked they can be freely marketed anywhere in the EEA without further control



Notified Body for IVD Directive

- One Notified Body appointed 31 July 02
- Annex III, Annex IV, Annex VII
- IVD's from medium and high risk category
 - i.e. List A - Virology products
 - List B - Diseases
 - Self test kit - Glucose monitoring



How IMB undertakes role of CA for IVD's

- Maintenance of a register of IVD's
- Establishment and administration of a vigilance system, including recalls
- Examination and approval of applications for performance evaluation
- Designation and monitoring of Notified Bodies in Ireland



How IMB undertakes role of CA for IVD's, cont'd

- Arbitration in disputes between manufactures and the Notified body
- Maintenance of surveillance systems
- Enforcement of legislation, where necessary
- Participation in international activities including EU, MRA, GHTF



Impact on Laboratory Diagnostics

- After December 2003, only CE marked *in-vitro* diagnostic reagents, reagent kits, calibrator control material, instrument, apparatus, etc, can be placed on the market
- All manufacturers under the IVD Directive must report incidents and near incidents to the IMB if they occur in Ireland
- Users can report issues of concern to the IMB but they should also report to the manufacturer



Impact on Laboratory Diagnostics

- Recall activities in Ireland must be reported by manufacturers to the IMB
- Handling of vigilance and recall in the laboratory setting should be integrated built into the quality system
- Liaison with IMB
- DATH's working group.



Obligations on All Parties

- Mandatory obligation of the manufacturer to report vigilance / recalls and it should be built into their quality system
- User reporting is not mandatory in Irish law but is encouraged
- Competent Authority must investigate and may inform the Commission and Member States if action is required



Timescale for Reporting

Manufacturer's should report as soon as possible

- An incident should be reported within 10 days
- Near incident 30 days

Time runs from when the manufacturer has been informed of the incident



Vigilance for IVD's

Incidents which need to be reported:

- Those which led to a death
- Those which led to a serious deterioration in the state of health of a patient, user or other person
- Those which might have led to death or serious deterioration in health



Vigilance for IVD's, cont'd

Incidents which are exempt from reporting:

- Deficiency of a new device found by the user prior to its use
- Service life or shelf life
- Negligible likelihood of impact on test result
- Expected and foreseeable side effects
- User error in use of device which was specified by manufacturer



How Users Should Report

User Report Form DSF-4-01-01/4 should be submitted to the IMB

- ◆ A report should not be delayed due to incomplete information
- ◆ The report is accepted by phone, fax, email but must be followed up in writing. All user reports are verified before acceptance
- ◆ The manufacturer must be informed in conjunction with IMB



Minimum Information Required for User Report

- Identifiable reporter i.e. manufacturer
- Name of the device
- Incident date, description and outcome
- Distributor of the device on the Irish market and where possible the EU market
- Manufacturer's details if available



Process at the IMB

- Report received
- Verification by telephone, fax, email, etc
- Manufacturer contacted for comment
- User report not generally passed over to manufacturer
- If deemed valid, initial report requested and received from manufacturer



Process at the IMB, cont'd

- Review by IMB
- Final Report
- Accepted
- User informed of outcome



Recall of an IVD

Definition:

- Standard EN 46001/2 paragraph 3.15 when there is a risk of death or serious deterioration to the state of health, the return of a medical device to the supplier, its modification by the supplier at the site of installation, its exchange, or its destruction, in accordance with the instructions contained in an Advisory Note
- Article 18 of Directive 98/79/EEC



Determining the Need for a Recall

The manufacturer assesses the following:

- The hazard arising from the device shortcoming
- The probability of a hazard occurring or implication of result of IVD test
- Whether the risk outweighs any possible hazard caused by the recall due to its temporary or permanent removal from use



Manufacturer's Obligations

- Prepare a Notice to provide information and / or advise on what actions should be taken in the use modification, disposal or return of a IVD
- Advisory Notices should be issued when implementing recalls but it is not mandatory
- Where possible the IMB should be including in the drafting of such a notice
- Carry out full reconciliation of stock in the market place



Recall Activities in a Hospital Laboratory

- Receipt of Recall Notice and Advisory Notice
- Review and determine impact
- Follow suggested action by removing product from service
- Quarantine until returned to manufacturer
- Destroy, if requested



IMB Involvement with EU

- Experts meeting
 - ◆ IVD medical devices
 - ◆ General medical devices and active implantable medical devices
- Working groups
 - ◆ Vigilance
 - ◆ Eudamed
 - ◆ IVD Borderline issues
 - ◆ Common Technical Specifications for IVD's



Interested Parties for IVD's

- IVD Manufacturers
- IMDA, EDMA
- Government Departments e.g. DOH&C, Foreign Affairs, Trade & Enterprise
- NSAI
- EU Commission and Member States



National Medical Device Information

- Legislation – Statutory Instruments
- Guidelines - IMB and EU MED.DEV
- Application Forms
- Advisory Notices
- Safety Notices



Obtaining Relevant Information

- By IMB website www.imb.ie
- By Medical Devices Information Packs
- By telephone, email with IMB at medicaldevices@imb.ie
- Useful websites e.g. MDA, EU Commission, FDA
 - ◆ All links can be found at www.imb.ie



The Future

- Implementation of the IVD Legislation by 07 December 2003
- Communication with the IVD sector which includes hospital laboratories as the end user of the device
- On-line reporting for users in relation to serious vigilance issues
- Pro-active Medical Devices Department