IRISH MEDICINES BOARD

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# news LETTER

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## Letter from the Editor

*Welcome to the first edition of the medical devices newsletter for 2006.*

We would like to wish our readers a very happy and prosperous New Year. 2006 promises to be an interesting year for medical devices with one of the main activities being the review of the Medical Device Directive 93/42/EEC at the European Council and Parliament. The opportunity is also being taken with this review to amend the Directive 90/385/EEC on active implantable medical devices to align it with the other two framework Directives on medical devices.

In this edition of the newsletter we raise the issue of point of care testing which is taking place more and more in the Irish healthcare setting. This article has been written by an expert who has been involved in the clinical governance of point of care testing in the Mid-Western Health Board and should provide some useful information for those involved in the area.

We are also focusing on custom-made medical devices and the type of auditing being undertaken by the IMB as part of its proactive programme of work. This article serves to provide information on how proactive audits are carried out and what is expected of the manufacturer if such an audit is requested.

As always readers are encouraged to provide feedback particularly in relation to articles that may be of interest by contacting us at medicaldevices@imb.ie.

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# Breast Implants – Information for Women Considering Breast Implants

On the 16th November 2005, the Tánaiste and Minister for Health & Children, Mary Harney TD launched the publication "Breast Implants – Information for Women Considering Breast Implants". The booklet was produced on behalf of the Department of Health & Children by a subcommittee of the Advisory Committee for Medical Devices at the Irish Medicines Board. This was written in response to the need to provide information for women considering breast implant surgery being identified by the European Parliament and the European Commission.

The booklet is comprehensive and covers topics including;

- Reasons for having a breast implant.
- Are breast implants the only option?
- Types of implants.
- Role of the General Practitioner.
- The operation.
- Short-term effects of surgery.
- Long term risks of breast implantation.
- Choice of Surgeon and issues to discuss with him/her.
- Consent.


*Ann O'Connor, Medical Devices Director, IMB; Mary Murray, Clinical Nurse Specialist, St. Vincent's Hospital; Mary Harney, Tanaiste & Minister for Health & Children; Wilf Higgins, Advisory Committee for Medical Devices & IMB Board Member; Margaret O'Donnell, Consultant Plastic Surgeon; Pat O'Mahony, CEO, IMB.*

This publication was one of a number of community and national measures identified by the European Parliament and the European Commission in relation to breast implants. Specific measures include the design control of the breast implant which was achieved by the reclassification of breast implants as class III medical devices in S.I. No. 358 of 2003, European Communities (Medical Devices) (Reclassification of Breast Implants) (Amendment) Regulations, 2003. Other measures include rules on advertising for breast implants, assessment of the need for national registers for breast implantation, and mechanisms for the long term follow up of women with breast implants.

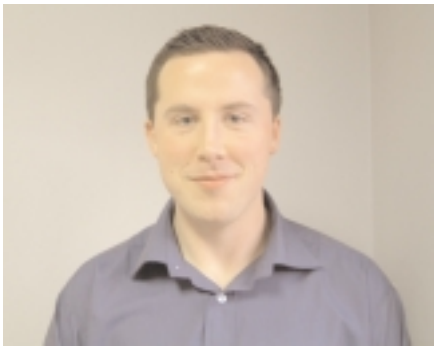
*Wilfrid J Higgins*
*Chairman, Advisory Committee for Medical Devices & IMB Board Member*

## Staff Update Staff Update Staff Update Staff Update Staff Update Staff Update Staff Update Staff Update

The Medical Devices Department is delighted to announce that Ms. Angela Mulhall and Dr. Patrick Buckley joined the medical devices team in January 2006. They have both been appointed into the role of Technical Officer primarily to support the vigilance function of the Medical Devices Department.

*Angela Mulhall*, after completing a BEng in Electrical and Electronic Engineering in 1993, subsequently joined the medical devices industry in 1996. She has worked with medical devices ranging from muscle stimulators to breast implants to surgical packs. Throughout her career she has been involved with all aspects of quality systems, setting up user friendly tracking systems to analyse defective products, compiling technical files and submitting medical device applications for CE marking. Angela will be working with vigilance issues regarding general medical devices and active implantable medical devices.

*Dr. Patrick Buckley* completed a BSc in Biochemistry and Molecular Biology in 2000. In 2005, Patrick completed a PhD in Experimental Pathology at the Department of Genetics and Pathology, Rudbeck Laboratory, Uppsala University, Sweden. His work focused on the extensive development and application of microarray technologies for the



analysis of constitutional and disease associated clinical samples both in research and diagnostic settings. Before joining the IMB, he also gained experience in the area of pharmacovigilance with a global contract research organisation. Patrick will be primarily working with vigilance issues regarding *in-vitro* diagnostic medical devices and also in other IVD related issues as required.

# Regulatory Update

The first reading at the European Council of the draft proposals in relation to the amendments to 93/42/EEC concerning medical devices and 90/385/EEC concerning active implantable medical devices took place in January 2006. This followed a detailed consultation by the EU Commission with stakeholders and also an impact assessment by the EU Commission of the proposed amendments. The most important areas where improvement is being planned is in relation to conformity assessment, clarification of the clinical evaluation requirements for medical devices, post market surveillance and provision of legal certainty with more binding rules. Specifically the Directive will be amended to correct anomalies and remove incoherence in relation to the classification of medical devices, modification of the Directive to clarify the tasks of Notified Bodies under the quality assurance modules particularly in relation to Annex II module, significant modification of Annex X concerning clinical data and its evaluation and also the possibility to centralise data on clinical investigations in the European databank. Also being proposed is an explicit requirement for a post market vigilance system reporting to Competent Authorities for custom-made medical device manufacturers, inclusion of medical devices that incorporate tissue of human origin with ancillary action to that of the medical device, modification of the Directive to allow certain information to be categorised as 'not confidential' i.e. relaxation of article 20 on confidentiality to allow certain information be made public. This is further expanded by the introduction of a new article 20a on 'Co-operation', which aims to provide a legal basis for better co-ordination and communication of national authorities in relation to market surveillance activities.

With regard to 90/385/EEC, this legislation is to be updated to align it with the other framework Directives on medical devices i.e. 93/42/EEC concerning medical devices and 98/79/EEC on *in-vitro* diagnostic medical devices. Updates being proposed include changes to definitions in line with other medical device legislation, addition of the requirement in relation to the European databank for medical devices, provisions in relation to authorised representatives, provisions on blood and plasma as well as health protection measures.

A further series of meetings of the European Council are scheduled to take place under the Austrian presidency. While this review is taking place there is also a separate discussion running in parallel with regard to the review of the New and Global Approach legislation under which the Medical Devices Directives fall. This may have significant impact on the medical device legislation over the coming years. Some of the key proposals being considered here are the legal basis for accreditation and for market surveillance systems. Currently the Commission have issued a paper on this subject which attempts to bring together the results of discussions and consultation on all preparatory documents drawn up for the revision of the New Approach. It is envisaged that a formal Commission proposal will be available by the end of 2006. This topic is under the responsibility of the Department of Trade and Enterprise in Ireland.

The revision to the MED.DEV on vigilance reporting is continuing under the leadership of Germany. It is envisaged that this work will be brought to a conclusion in the latter half of 2006 with the aim of submitting the final text to the Medical Devices Expert Group (MDEG) meeting at the end of 2006. Further detail on the proposals can be found in the last medical devices newsletter of November 2005.

A high level meeting of Senior Officials from EU Member States with the EU Commission was held in Brussels in January 2006. The focus of the meeting was to outline the status of the revisions to the medical devices legislation, proposals in relation to New and Global Approach legislation and a review of the level and type of meetings that should be held in 2006 in relation to medical devices. The aim was to ensure better co-ordination by Member States and the Commission and strengthening the focus and efficiency of working groups in Europe. Also considered was the need to improve the use of the European databank by Competent Authorities and how the global medical device nomenclature should be used particularly in context of the language requirements in the EU.

## The Irish Medicines Board signs Confidentiality Agreement with the Food and Drug Administration

*Shown above is Mr. Pat O'Mahony, Chief Executive of the Irish Medicines Board (IMB) and Dr. Murray Lumpkin of the Food and Drug Administration (FDA) at the recent signing of a confidentiality agreement between the IMB and the FDA. The agreement provides for a formal system of sharing information between the two organisations in a timely manner to further enable the common goal of protecting public health. FDA has similar agreements in place with the European Commission / EMEA and Competent Authorities in a number of other countries.*

# Proactive Auditing of Custom-Made Medical Device Manufacturers – Prosthetics, Orthoses and Seating

*The manufacture of custom-made orthotics and prosthetics falls under the scope of the EU Directive 93/42/EEC concerning medical devices and its related Irish legislation S.I. No. 252 of 1994, European Communities (Medical Devices) Regulations, 1994.*

It is important to understand the term 'custom-made'.

*'Custom-made' means, in relation to a device—*

*(a) that it is manufactured specifically in accordance with a written prescription of a registered medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and*
*(b) that it is intended to be used only for a particular named patient;*

*but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the registered medical practitioner or professional user;*

Examples of custom-made prosthetics are partial foot and hand prosthetics, conventional (non-modular) prosthetic limbs that are patient specific and prescribed prosthetic sockets.

Examples of custom-made orthotics are patient specific splints and patient specific footwear.

Seating can be custom-made, for example, certain padding, supports and restraints can also be custom-made.

Manufacturers of custom-made medical and dental devices must be registered with the Irish Medicines Board (IMB).

As part of the IMB's proactive compliance strategy for custom-made medical devices the Medical Devices Department will be carrying out audits on manufacturers of custom-made seating, orthotics and prosthetics throughout 2006. The scope of the audits is verification of compliance with the Directive 93/42/EEC for medical devices and related Statutory Instrument S.I. No. 252 of 1994. Our aim is to assist the manufacturers of these devices to understand and become compliant with the legislation. The following outlines how the audit process will work.

Surveillance is carried out dependant on what the IMB deems appropriate e.g. targeted audits in relation to a specific category of custom-made medical

device. If you are to be audited, the initial contact will normally be made by telephone. During this conversation some enquiries will be made regarding the exact nature of devices that are manufactured at your premises and as to the scale of the manufacture and the number of employees involved, etc. The audit usually is scheduled 3 to 4 weeks after the initial contact is made by the IMB. The Auditor sends a letter detailing the audit plan. Confirmation that the dates are suitable is requested in this letter.

The audit plan normally consists of a review of the following items:

- Registration
- Risk Assessment
- Design
- Materials
- Manufacturing / Facilities
- Training
- Cleanliness / Cross Infection Controls
- Labelling / Packaging
- Statement of Conformity
- Device Performance

All documentation pertaining to the manufacture of custom-made medical devices should be kept available for five years. Normally the Auditor will request to examine samples of this documentation for the purpose of verification with the legislation. Good and complete records are paramount. Much of the audit will consist of documentation review and in order to assist in the audit process any documents related to the above from the past five years should be at hand.

The audit begins with an opening meeting during which the process is explained and the company or department representative outlines the work carried out, and any plans for the future. The manufacturer also has the opportunity to ask any questions they might have in relation to the audit.

The audit is then carried out working through the topics listed in the plan and any other issues that might arise. Each of the topics will be reviewed by examination of relevant documentation and examination of materials and facilities where appropriate.

Following the audit, the Auditor will draw up a list of non-compliances. These non-compliances are classed as major, minor or observations. A major non-compliance requires a corrective action to be completed within four weeks, and evidence of this to be furnished to the IMB. Examples of major non-compliances are:

- Not being registered with the IMB
- Not having a Statement Concerning Devices for Special Purposes
- Risk of cross-infection
- Use of unsafe materials in the manufacturing process

A minor non-compliance requires a corrective action within an agreed timeframe, and again evidence of this must be furnished to the IMB. Examples of minor non-compliances are:

- Minor deviations from operating procedures
- Minor incongruence in documentation
- Statement or label missing one element

An observation does not require evidence of a corrective action but is rather intended as a guide for best practice. The manufacturer is asked to verify their understanding of an observation.

At the close out meeting the non-compliances will be discussed and timeframes agreed upon.

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# Clinical Governance of Point-of-Care Testing: The Role of the Point-of-Care Testing Committee

*With the advances in diagnostic technology and the healthcare services the use of in-vitro diagnostic devices for providing results at or near the patient side is becoming commonplace in our hospitals.*

It is important that there is a comprehensive organisation-wide policy for the implementation and management of point of care IVDs in the hospital environment, with the inclusion of all relevant personnel to ensure the safe and effective use of point of care IVDs for diagnostic use. The implementation of such a policy would be overseen by a Point of Care Committee, which should include representation from all relevant areas in the hospital. In this issue of the newsletter we have invited Dr. Ned Barrett, Consultant Biochemist at the Mid-Western Hospital in Limerick to provide an overview of their experience in the implementation and management of point of care testing for the mid-western region and the importance of the Point of Care Committee in this process.

Point-of-care testing (POCT) has been variously described over the past thirty years; however, it is generally accepted to be the performance of an analytical test by a healthcare professional for a patient outside of the conventional laboratory setting. The College of American Pathologists has defined POCT as *"analytical patient testing activities provided within the institution, but performed outside the physical facilities of the clinical laboratories. It does not require permanent dedicated space, but instead includes kits and instruments, which are either hand carried or transported to the vicinity of the patient for immediate testing at that site"*. It includes both quantitative and qualitative tests on various body fluids such as blood, urine, stools and saliva. Point-of-care testing devices include urinalysis test strips used with or without a reader, blood glucose meters, blood gas analysers, co-oximeters, electrolyte analysers, devices for measuring markers of myocardial damage or of heart failure, coagulation meters, pregnancy test devices with or without readers, HbA1c meters, strips or devices for the detection of drugs of abuse in urine, devices used in emergency departments for the detection of alcohol and many others.

POCT activity has grown dramatically in recent years. Analytical, technological and communication developments have enabled point-of-care testing to provide test results almost immediately for patient management. These developments enable POCT devices to be managed centrally and allow for information exchange between POCT devices and laboratory information systems. Point-of-care testing now has the potential to increase clinical effectiveness and contribute to improved outcomes for patients.

Adverse incidents were reported in several countries in the early years of using point-of-care testing in the management of Type 1 diabetes in hospitals. Sadly, some of these incidents resulted in fatalities. In many countries the professional bodies involved in laboratory medicine have published national guidelines on the practice and management of point-of-care testing. These guidelines emphasise the importance of clinical laboratory involvement in ensuring the quality and reliability of point-of-care testing. The leadership and co-ordination roles of the clinical laboratory are crucial to the success and safety of POCT. In recent years, national regulatory bodies such as the UK's MHRA and the US's FDA have provided comprehensive guidelines, evaluation reports and other documents to guide healthcare bodies in ensuring the proper clinical governance of point-of-care testing in their organisations. The standards set by accreditation bodies for clinical laboratories are gradually extending to point-of-care testing. Our patients do not expect lower standards for point-of-care testing in our wards, clinics and emergency departments.

In December 2002, the then Mid-Western Health Board established a committee (the POCT Committee) to co-ordinate and to set standards for point-of-care testing in the Board's hospitals. Following the reform of health service structures and since the establishment of the Health Service Executive (HSE), the Committee is responsible for these functions within the acute hospital services network for the mid-west region. This is one of eight such hospital networks within the country. The POCT Committee reports to the Network Manager.

The membership of the POCT Committee is multidisciplinary and includes representatives of consultant staff, laboratory consultants, laboratory management, nursing management, diabetes and neonatal nurse specialists, nursing practice development, clinical engineering, and the hospital general manager. A consultant physician with a special interest in diabetes chairs the Committee. At least six meetings are held each year. Meetings are well-attended and last about one hour. An annual report is published at the end of each year.

The POCT Committee's first task was to draft a Point-of Care Testing Policy for the service. The Policy has been adopted and published. It sets out the prerequisites for the safe and effective point-of-care testing and provides a secure framework for the quality assurance of point-of-care testing in the network's acute hospitals. Only POCT devices approved by the Committee may be used within these hospitals and this requirement applies to all POCT devices whether they have been

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## Proactive Auditing of Custom-Made Medical Device Manufacturers

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Following an audit, evidence that the appropriate actions have been taken should be sent to the Auditor within the agreed timeframe. Where satisfactory responses have not been received and / or where breaches of the regulations have taken place, further action may be taken which can in certain circumstances involve the use of the enforcement power by the IMB as outlined in the legislation.

Anyone with any queries regarding compliance with the legislation, registration or pending audits, etc should not hesitate to contact the Medical Devices Department of the Irish Medicines Board on 01-6764971, or alternatively email medicaldevices@imb.ie.

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purchased, leased, used on loan or received as a gift from a pharmaceutical company or a patient organisation. A register of point-of-care devices is maintained by the Clinical Engineering Department. The POCT Committee has responsibility for ensuring that point-of-care testing within the network's acute hospitals is suitable for its intended use, is adequately supported and is only undertaken by appropriately trained staff. The Committee also has responsibility for ensuring that point-of-care testing satisfies the requirements of legislation, EU Directives, laboratory and hospital accreditation and meets the HSE's requirements in relation to protecting data, patient confidentiality and risk management. The committee is obliged to inform the Network Manager of unsatisfactory, flawed, inappropriate, or poor quality POCT practices and to request that these practices be stopped or modified so as to ensure compliance with the Network's POCT Policy.

All proposals for new point-of-care testing must be submitted to the POCT Committee for approval. Proposals are evaluated under several headings. These include clinical need, clinical responsibility and accountability, evidence that what is proposed will be adequately funded, maintained and supported, suitability of the device for the applications proposed, adequacy of user training, adequacy of quality assurance procedures and record keeping and compliance with safety, data protection and infection control requirements.

Training in the use of point-of-care devices is usually provided by the manufacturer or supplier and only in exceptional circumstances by the relevant laboratory specialty. The POCT Policy states that only members of staff whose training and competence has been established and recorded are permitted to carry out point-of-care testing. This requirement is easily enforced in the case of devices that require operator PID numbers and that are linked through the hospital network and controlled and monitored centrally. The maintenance of training records for point-of-care testing and the administration of user PID numbers in our busy acute hospital setting is time consuming and is carried out by secretarial support for the Committee. Operational software for some POCT systems such as glucose maintain comprehensive records of operator competencies and generate lists of staff members requiring retraining. Such systems readily identify staff prone to test errors and those with poor quality records and facilitate the scheduling of retraining of those so identified.

Certain themes are common to all training programmes for POCT devices. These include the basic principles of the measurement process, the demonstration of the correct use of the device, an understanding of the consequences of the improper use of the device, instruction on the safe collection of the sample for testing, training in calibration and appropriate quality control techniques. Training is not complete until the trainee performs a number of analyses that satisfy the trainer of the trainee's competence.

Quality assurance is an integral component of point-of-care testing. It includes all the actions taken to ensure that the results are reliable and that the patient has been correctly identified. It also encompasses the recording of the result, the correct interpretation and the taking of appropriate action. Internal quality control procedures enable users to decide whether patient results are reliable before they are released and acted on. External quality assessment is used to establish the degree of comparability between sites for the same test and is retrospective.

The Committee has reviewed existing arrangements with POCT suppliers to ensure conformance with best practice. Point-of-care testing contracts have substantial costs associated with them and must be concluded in accordance with the HSE's procurement and materials management guidelines. Such contracts should establish an agreed and structured system for the provision of point-of-care testing equipment. It is important that POCT contracts are consistent with all elements of the POCT Policy and must encompass supply, installation, training, maintenance, support and audit.

An external auditor inspects all glucose meters monthly. The inspection assesses compliance with the standards of practice across a range of headings. The audit findings are discussed with the nurse manager for the ward or unit and whatever remedial action needs to be undertaken is agreed. The POCT Committee reviews overall performance trends identified by the audit exercises. Urine analysis meters are audited twice annually.

The POCT Committee has approved the installation of urinalysis readers in all wards as a means of reducing operator-dependent error associated with manual timing and visual reading of colour change on the urine dip-stick. The Committee is piloting the use of similar readers for point-of-care pregnancy tests.

Our POCT Committee is strongly of the view that the clinical governance of point-of-care testing requires resources. Input is needed from number of hospital departments and disciplines such as the laboratory, nursing, medical, clinical engineering, information and communication technology, contracts and supplies, clinical risk management, infection control, nursing practice development, and hospital administration. Staff resources are required for training, administration of user competencies, system monitoring, audit and co-ordination of external quality assessment. The limit on health service staff numbers is likely to influence how POCT Committees undertake and prioritise their responsibilities. However, a well-managed and properly governed system of point-of-care testing will deliver considerable healthcare benefits and is value for investment and should be adequately resourced.

In summary, the Point-of-Care Testing Committee is crucial to the clinical governance of point-of-care testing. It identifies the need for such testing in the various acute hospital settings. The Committee comprehensively evaluates all proposals for point-of-care testing. The Committee's Policy on Point-of-Care Testing, which has been approved and adopted by the region's Acute Hospital Network, ensures that such testing is performed in a safe reliable way and that it improves clinical effectiveness and benefits the patient.

Written by:
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