IRISH MEDICINES BOARD

news LETTER

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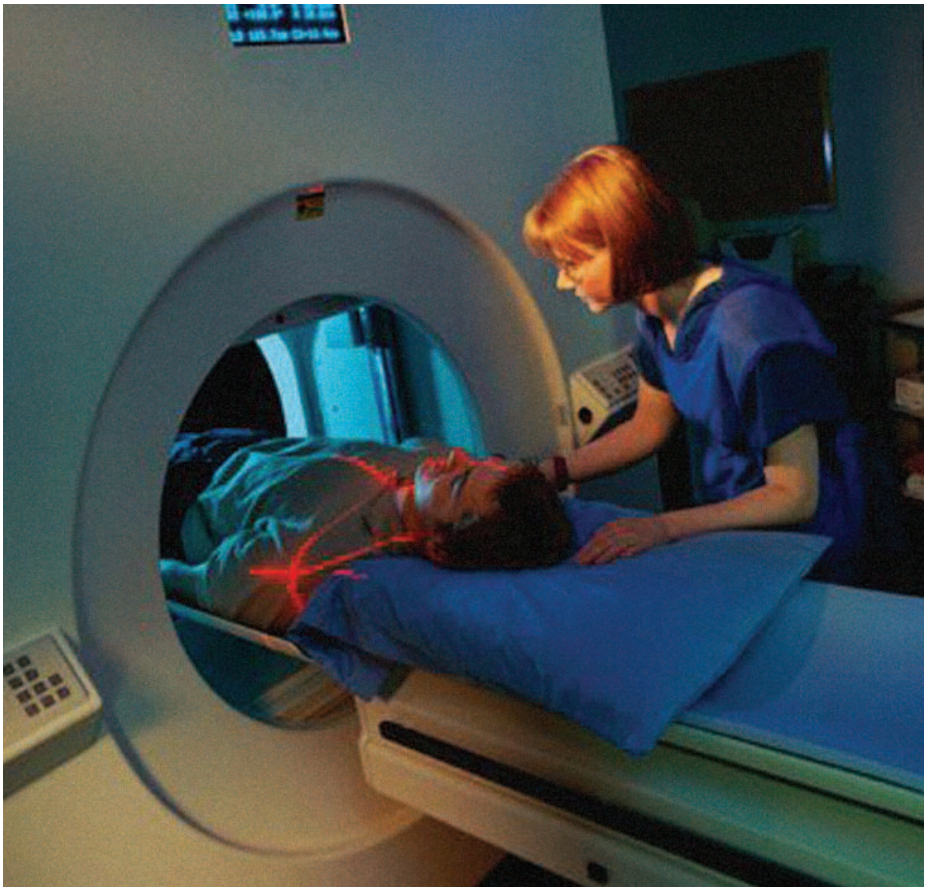
Letter from the Editor

Welcome to the third and final edition of the medical devices newsletter for 2009

2009 has been an eventful year at both a European and national level. This year saw the launch of the Irish Medicines Board's new structure for safety, licensing and registration of human medicines and medical devices.

In this edition we feature an article on the impact of Directive 93/42/EEC as amended by 2007/47/EC on Class I Medical Devices. We also provide an overview of the '*Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care*' which have recently been published. These guidelines extend the principles outlined in the Point of Care Testing Guidelines for hospitals published by the IMB in 2007. Updates on European meetings attended by the IMB are also provided and a number of upcoming events are highlighted.

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. Finally, we would like to wish all our readers a very happy and peaceful Christmas.



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Class I Medical Devices – Impact of Directive 93/42/EEC as amended by 2007/47/EC

Manufacturers or the Authorised Representatives of Class I medical devices are required to follow the procedure referred to in Article 11.5 and Annex VII of Directive 93/42/EEC, meet the applicable Essential Requirements of Annex I and draw up an EC Declaration of Conformity prior to placing their devices on the market.

Directive 2007/47/EC, which comes into force on the 21st March 2010, amends Directive 93/42/EEC on medical devices. A number of these changes have an impact on Class I medical devices; most notably, the technical documentation required for conformity assessment under Annex VII.

The changes to the technical documentation required for Class I medical devices under point 3 of Annex VII are summarised below:

1. the general description of the product, including any variants planned must now include details of the intended use(s) of the device(s);
2. devices placed on the market in a sterile condition must now include, in addition to the description of the methods used the sterilisation validation report;
3. the solutions adopted as referred to in Annex I, Chapter I, Section 2;
4. the pre-clinical evaluation;
5. the clinical evaluation in accordance with Annex X.

Pre-clinical evaluation referred to in point 4 above may, for example, be composed of experimental data including results of design calculations, mechanical/electrical bench testing, modelling, biocompatibility testing and any performance tests carried out in animal models. The type of pre-clinical evaluation chosen by the manufacturer, while considering the risk and characteristics of the device, must be sufficient to fulfil the requirements of the Directive. Any relevant harmonised standards may be used to demonstrate conformity.

Class I devices are now required to undergo a clinical evaluation in accordance with Annex X of the Directive. Annex X itself has undergone an extensive revision under 2007/47/EC. Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data is referred to as clinical evaluation. There are three routes by which the clinical evaluation requirement may be met:

1. a critical evaluation of the relevant scientific literature relating to the safety, performance, design characteristics and intended purpose of the device;
2. a critical evaluation of the results of a clinical investigation;
3. a critical evaluation of a combination of data generated from 1 and 2.

Generally, in the case of Class I medical devices, a full clinical investigation may not be necessary, provided that there is sufficient data from equivalent devices (following option 1 above) to complete a clinical evaluation and demonstrate conformity to the Essential Requirements. In this case equivalence must be demonstrated between the device under assessment and the device(s) against which it is being compared. Such devices must be equivalent with regard to intended purpose, physical, design, biological and technical characteristics. The data provided from equivalent device(s) must also be sufficient to fully demonstrate compliance with each relevant Essential Requirement. If it is considered that clinical data is not required to demonstrate conformity this must be adequately justified and based on the output of the risk management process (Annex X, 1.1d). In these circumstances reliance on performance evaluation, bench testing and pre-clinical evaluation alone must be duly substantiated.

In addition, the manufacturer is now required, under Annex VII(4) referring to Annex X, to actively update the clinical evaluation documentation with data generated from post-market surveillance. If, however, a specific post market clinical follow-up is not deemed necessary, it must be duly justified and documented by the manufacturer.

Under Annex VII(5) Class I devices which are sterile and/or have a measuring function now have the option to be assessed under Annex II, full quality assurance conformity assessment, as well as Annexes IV, V or VI.

In relation to registration of Class I medical devices; under Article 20 of 93/42/EEC as amended by 2007/47/EC, information relating to the registration of persons responsible for placing devices on the market in accordance with Article 14 shall no longer be treated as confidential. As such, from the 21st March 2010, the fee charged for searches of the human and veterinary medicine databases will be extended to the medical device database.

Medical devices placed on the market or put into service after the 21st March 2010 must be in conformity with the new requirements of the revised directive. Before the 21st March 2010, manufacturers are not obliged to comply with the new requirements introduced by Directive 2007/47/EC, but they may do so on a voluntary basis. Medical devices which have been lawfully placed on the market or put into service prior to the 21st March 2010 can continue to be marketed and used after that date and are subject to the general market surveillance provisions. If manufacturers place products on the market or put products into service which comply with the new requirements prior to the 21st March 2010, they should document that their Declaration of Conformity states compliance with Directive 93/42/EEC as amended by Directive 2007/47/EC. Declarations of Conformity issued as of the 21st March 2010 are automatically deemed to refer to the relevant directive in its revised version. As of that date, manufacturers must be in a position to provide proof of compliance with all requirements of the revised directives which are applicable to their respective product.

Regulatory Update

MEDICAL DEVICE EXPERT GROUP ON BORDERLINE AND CLASSIFICATION

The last meeting of the Borderline and Classification group took place in September. Several specific classification cases were discussed, a number of which are now included in the most recent version of the Manual on Borderline and Classification, version 1.5, which was published on the Commission's website during November. A sub-group of the working group is to be established to discuss the definition and classification of software; both standalone and that used in conjunction with medical devices. The group will comprise a small number of National Competent Authorities, industry representatives and the European Commission; the group is to be chaired by Sweden and a number of Member States including Ireland have agreed to participate in the discussion. The first meeting is scheduled for early December. An update on the ongoing revision to MEDDEV 2.4/1 on classification of medical devices was also presented. The next meeting of the Borderline and Classification Working Group is scheduled for early 2010.

COMPLIANCE AND ENFORCEMENT WORKING GROUP (COEN)

The COEN meeting was held in October. Updates were provided on specific market surveillance projects and specific cases of concern for Member States. Further discussion was held on the impact of the new approach legislation, draft guidance on the use of legal tools for market surveillance, updates to the guidance notes for manufacturers of class I medical devices and to the guidance note for manufacturers of custom-made medical devices.

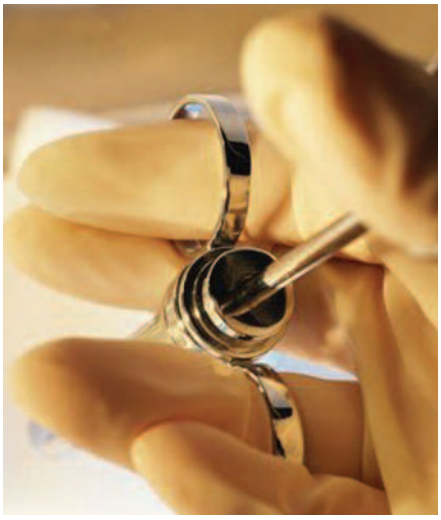
MEDICAL DEVICE VIGILANCE EXPERT GROUP

A meeting of the Medical Device Vigilance Expert Group was held in October. Discussion at the meeting included the recast of the medical devices directive, the implementation of the vigilance enquiry form, the implementation of MEDDEV 2.12-1 rev 5, Eudamed, GHTF Study group 2 and the NCAR exchange process. The meeting was held over two days, the first day was attended by regulators only and the second day included representatives from other stakeholders.

Also in October a further meeting of the EU Ad-Hoc task force that has been set up to investigate the possible improvement of the EU regulatory frame-work concerning vigilance, was held in Brussels. The discussion focused on the identification of proposals for the recast.

EUDAMED WORKING GROUP

A meeting of the EUDAMED Working Group took place in October. The main topic under discussion was the development and implementation of the new version of the European Database on Medical Devices, EUDAMED 2. The EUDAMED system acts as a central repository for information exchange between National Competent Authorities and the Commission. Information on the registration of manufacturers, authorized representatives and devices; certificates issued, modified, supplemented, suspended, withdrawn or refused; and incidents/near incidents reported through the vigilance National Competent Authority Reporting system may be captured by the system. The European Commission recently redeveloped the system improving both the user interface and functionality. A new clinical investigation module has also been implemented allowing Competent Authorities to upload information relating to ongoing clinical investigations as well as any decisions taken in relation to these investigations. The European Commission is currently running a number of EUDAMED 2 training courses for Competent Authorities. EUDAMED 2 went live in mid-November. A written Committee procedure, under Article 7, on the Commission Decision on the European Databank on Medical Devices (Eudamed) was passed at the end of October. This Decision Directive allows for the establishment of the EUDAMED databank for the purposes of maintaining data relating to registration, incidents, certificates and clinical investigation of medical devices. Member states are to apply this Decision from 1st May 2011.



The European Commission also gave an update on the ongoing translations of the GMDN coding system into the official languages of the European Union. The next meeting of the EUDAMED Working Group is scheduled for mid-April 2010.

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IVD TECHNICAL GROUP MEETING

A meeting of the IVD Technical Group (IVDTG) took place in September. An update was provided on the market surveillance operation for blood glucose meters. The documentation review has been completed by all three participating countries (UK, IE and FR). A meeting of representatives from each of the three member states was held in October to review the findings. A report of the findings will be presented at the next IVDTG meeting in February, 2010 and to the COEN group.

An update was also provided on the progress of the new adoption of the Common Technical Specifications (CTS); Decision 2009/108/EC amending Decision 2002/364/EC. Due to an administrative error, the draft Commission Decision which later became Commission Decision 2009/108/EC was not transmitted to the European Parliament for its right of scrutiny. In order to remedy the procedural mistake, the content of Commission Decision 2009/108/EC will be re-adopted in a new Commission Decision. The currently adopted CTS (2009/108/EC) remains valid and it is hoped that the new adoption, will be in place by the end of 2009.

The CTS and guideline for vCJD were also reviewed and discussed. It was emphasised at the meeting that the CTS is intended for blood screening assays only, however to avoid self-certification, all vCJD tests will be listed in Annex II List A. As such, only blood screening assays will have to comply with the CTS.

However, if other applications of these tests are proposed e.g. confirmatory, diagnostic they shall be assessed with similar rigour to screening tests and the performance of these tests shall be specifically adapted to the intended use.

In the context of the revision of the IVD Directive, a small ad-hoc group has identified the technical points to be addressed (for example in house tests, genetic testing, classification rules etc). The technical group consists of representatives from Member States, the European Diagnostic Manufacturers Association (EDMA) and European Commission (EC) services. A draft document was presented for comment at the meeting.

CLINICAL INVESTIGATION & EVALUATION WORKING GROUP

The Clinical Investigation & Evaluation working group meeting took place in September. The key items discussed included the revision of the MEDDEV document on clinical evaluation (MEDDEV 2.7/1) which is being updated in line with the revised medical devices directive and with the Global Harmonisation Task Force (GHTF) document on clinical evaluation. The clinical module of the EUDAMED database, which will centrally store information on clinical investigations of medical devices, has been finalised and is subject to adoption by a comitology procedure before the end of 2010. An update was provided on the pilot programme for reporting of adverse events which occur during clinical investigations which is being undertaken by a number of selected Member States and device manufactures.

COMMITTEE FOR ADVANCED THERAPIES (CAT)

The CAT at the European Medicines Agency (EMEA) is currently developing a guidance document relating to advanced therapy medicinal products (ATMP) containing chondrocytes. In relation to combination ATMPs (i.e. a medical device combined with an ATMP), a meeting was held at the end of November between members of the CAT, the EMEA and representatives from both the NB-MED group and the Notified Body Operations Group (NBOG). The objective of this meeting was to discuss how the CAT will interact with medical device notified bodies in relation to their assessment of medical device components in combination ATMPs.

NOTIFIED BODY OPERATIONS GROUP (NBOG)

The final meeting for 2009 of the Notified Body Operations Group (NBOG) took place in November. Further work was done on draft guidance for Notified Bodies on auditing suppliers to medical device manufacturers. In addition, an advanced draft of the guidance for notified bodies on audit report content was presented. This document is aligned with the GHTF document on regulatory audit reports. This document is now to be sent to the notified body representative groups for comment. It is hoped that both documents will be finalised and published soon. The final draft of the revised MEDDEV on clinical evaluation was tabled for information. This document now includes a section outlining the role of the notified body and a checklist for notified bodies when conducting assessments of clinical evaluations. In addition, a checklist for Member States when reviewing a notified body's ability to assess clinical evaluation data is under preparation.

An update was provided on the ongoing programme for peer review of Member States during notified body surveillance audit activities. In addition, the group discussed the proposed future recast of the medical devices directives with regard to the process for notified body designation. Finally, the potential impact of the recast of the IVD Directive on notified bodies was also discussed.

Point of Care Testing in Primary and Community Care – A Co-Operative Movement

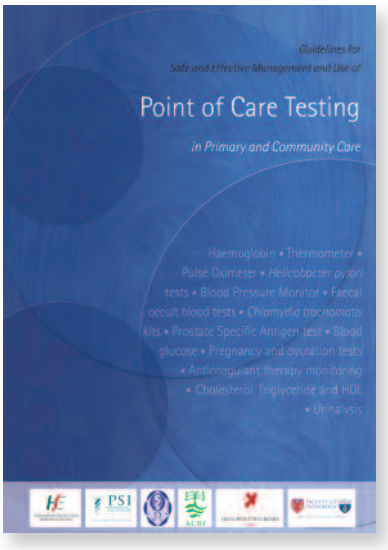
The Irish Medicines Board in association with the Pharmaceutical Society of Ireland (PSI), the Health Service Executive (HSE), the Faculty of Pathology (RCPI), the Association of Clinical Biochemists in Ireland (ACBI) and the Academy of Medical Laboratory Science (AMLS) has produced 'Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care'. These guidelines extend the principles outlined in the Point of Care testing guidelines published by the IMB in 2007, from hospital to community settings. These guidelines are also supported by the Health Information and Quality Authority (HIQA)

Point of care testing (POCT) involves the performance of a test in the immediate vicinity to a patient to provide a rapid result outside the conventional laboratory environment. Recent advances in diagnostic technology and the delivery of healthcare services has resulted in an increase in the demand for and provision of POCT in Primary and Community Care environments. GP surgeries, community pharmacies, community clinics, health centres, industrial medical centres and anticoagulation clinics all represent Primary and Community Care locations. While the concept of POCT in Primary and Community Care is not new, the complexity and variety of tests and instruments available and in use has evolved significantly.

The capacity to provide a rapid test result which can be acted upon directly permits increased clinical effectiveness and improved outcome for patients. However this is only true if the result delivered is accurate and reliable.

There are three different aspects to POCT; Diagnosis, Monitoring and Screening. Where POCT is being used primarily for screening purposes as is usually the case in a pharmacy setting, then a robust system of patient consent, follow-up and referral should be put in place. POCT is not a replacement for conventional laboratory testing but rather a supplement to it. Point of Care (POC) test results which are used for diagnosis or critical patient management decisions, or which give unexpected results should be confirmed by hospital laboratories to ensure accurate diagnosis and to facilitate correct patient management decisions.

The majority of tests used for POCT (for example pregnancy tests and blood glucose meters) fulfil the definition of an *in-vitro* diagnostic medical device (IVD). IVDs are regulated by the *in-vitro* diagnostic medical devices directive 98/79/EC and related Irish Regulations. The IVD Directive has been mandatory since December 2003 and has been implemented in Ireland via the Statutory Instrument S.I. No. 304 of 2001, European Communities (*in-vitro* diagnostic medical devices) Regulations, 2001.



Other commonly used POCT devices such as blood pressure monitors, pulse oximeters and thermometers are regarded as general medical devices (GMDs). General medical devices are regulated by the medical devices directive 93/42/EEC and related Irish Regulations. The medical devices directive (93/42/EEC) has been mandatory since June 1998 and has been implemented in Ireland via the Statutory Instrument S.I. No. 252 of 1994, European Communities (Medical Devices) Regulations, 1994.

There is a wide variety of tests available and in use for POCT in Primary and Community Care, examples of which are outlined in Table 1. These include test kits operated alone or with an instrument which can provide either a qualitative or quantitative result.

Table 1: Examples of POC tests used in Primary and Community Care settings (not an exhaustive list)

Medical Device	Medical Device category
Blood glucose (includes self-testing devices)	IVD
Urinalysis (with or without a reader)	IVD
Cholesterol, Triglyceride and HDL	IVD
Anticoagulant therapy monitoring (includes self-testing devices)	IVD
Pregnancy and ovulation tests (includes self-testing devices)	IVD
Prostate Specific Antigen test	IVD
Haemoglobin	IVD
Chlamydia trachomatis kits	IVD
Faecal occult blood tests	IVD
Helicobacter pylori tests	IVD
Blood Pressure Monitor	GMD*
Pulse Oximeter	GMD*
Thermometer	GMD*

** GMDs (general medical devices) differ greatly from IVDs in relation to their mode of action, quality control procedures and quality assurance structures. Advice relating to these devices should be sought from a source with relevant expertise such as the manufacturer or their authorised representative.*

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KEY RECOMMENDATIONS

The following list summarises the key recommendations in these guidelines, which are necessary for the safe use and management of POCT in Primary and Community Care.

1. Where POCT services are provided, a system for clinical and managerial governance of the service should be established including a person designated as responsible and accountable for the service.
2. It is advisable that providers of POCT are aware of other laboratory services in their locality which can provide specialist advice and expertise if required and be cognisant of utilising them as appropriate. It is recommended to consult the Guidelines for Safe and Effective Management and Use of Point of Care Testing which recommends communication between the hospital and Primary and Community Care sectors.
3. Only trained and fully competent staff should perform POCT.
4. Standard operating procedures should be developed and implemented for all aspects of the POCT service, including the performance of the POC test, record keeping, interpretation of results, patient referral criteria, quality assurance, patient and staff safety and health.
5. Quality assurance is key to assuring the accuracy and reliability of a POCT service and quality control testing should be performed for POC tests in accordance with manufacturer's instructions. It is further recommended that POCT providers should participate in External Quality Assurance (EQA) schemes, where available.
6. Patient results should only be interpreted and reviewed by appropriately trained personnel.
7. All patient and quality control results should be recorded appropriately either via paper or electronic format in accordance with defined procedures and the Data Protection Act.
8. Appropriate referral criteria should be in place to ensure that confirmatory testing is performed and patients are referred for further medical attention as necessary.
9. All adverse incidents that occur with POCT devices must be reported to the manufacturer and/or the Irish Medicines Board (IMB) using the appropriate form located on the IMB website (www.imb.ie) and/or the appropriate professional regulatory body, if necessary.
10. POCT should be reviewed and monitored on an ongoing basis and a test should be withdrawn or suspended in the event of a safety related issue e.g. a recall.
11. POCT devices should be CE marked as this is an indication that the device meets the requirements of the relevant legislation.
12. It is the responsibility of the service provider to ensure that appropriate occupational health advice is provided to staff performing POCT.
13. Records should be kept of staff who have been trained in carrying out and/or interpreting test results.

It is recommended that these guidelines be adopted by those responsible for POCT in Primary and Community Care settings in Ireland to ensure that POCT is performed in a well structured and controlled manner to minimise the risk to public health and to ensure patient safety. These guidelines will be reviewed and updated in light of further developments in the area of POCT.

The implementation of these guidelines should facilitate a well-managed and properly governed system for the provision of POCT services in Primary and Community Care settings, which in turn will deliver considerable benefits to the Irish health service and to patients. These guidelines are available online at **www.imb.ie**. A hard copy version is also available – please contact **medicaldevices@imb.ie**

Upcoming Events

PRINCIPLES OF EUROPEAN MEDICAL TECHNOLOGY REGULATORY AFFAIRS

A three-day course and module 1 of M.Sc. Medical Technology Regulatory Affairs will be held from the 1st to 3rd March 2010, in the Clayton Hotel, Galway, Ireland. The aim is to develop a clear understanding of the regulatory path for placing and maintaining medical technology on the market in the European Union and associated territories.

For more information, please contact TOPRA by email: **mscadmin@topra.org** or telephone: +44 (0) 207 510 2560. Further information is available from: www.topra.org/mtra1.ie

IVD INFORMATION DAY

The IVD Information Day, which was due to be held on 6th November 2009, has been postponed until Q1 2010. The event will be advertised on the IMB website **www.imb.ie** in due course.

Staff Update

The Irish Medicines Board is delighted to announce that Patrick Murphy and Aoife Higgins have joined the Medical Devices Vigilance and Compliance section of the Human Products Safety Monitoring Department of the IMB.

Aoife Higgins takes up the position of Vigilance and Compliance Administrator for the Medical Devices Vigilance and Compliance section.

Patrick Murphy takes up the position of Scientific Officer for general medical devices. Patrick's academic qualifications include a degree in Engineering (Mechanical and Manufacturing) and a M.Sc. in Bioengineering, both from University of Dublin, Trinity College. Prior to joining the IMB, Patrick worked as an R&D Design Assurance engineer in a medical device company.

Orla Keane has recently been promoted to the position of Product Manager – Class I / IIa products in the Medical Devices Vigilance and Compliance section.