IRISH MEDICINES BOARD

news LETTER

MEDICAL DEVICES

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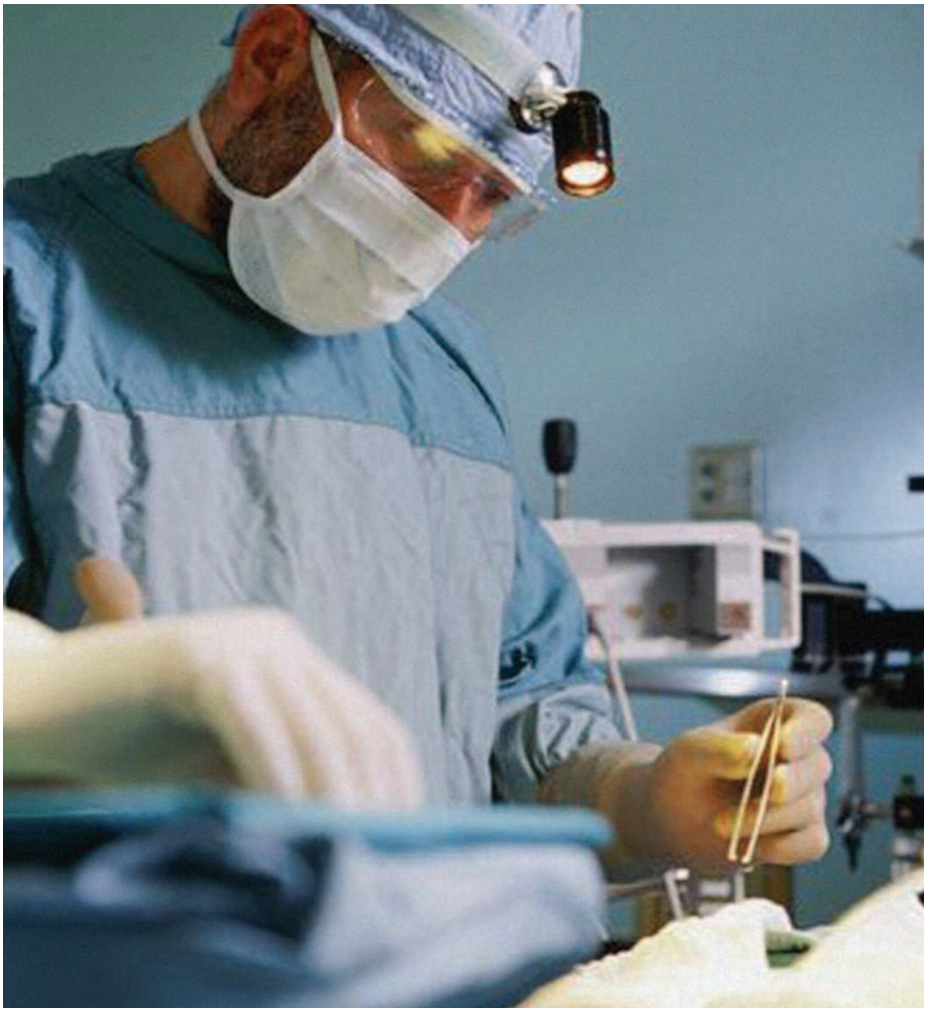
Letter from the Editor

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

In this edition of the newsletter we provide an update of the major changes impacting the regulation of medical devices as a result of Directive 2007/47/EC which must be applied from 21st March 2010; major changes include those relating to clinical data evaluation and conformity assessments conducted by notified bodies.The timing of notified body certificate issuance to the new requirements of 2007/47/EC is also discussed. We also feature an article on the Field Safety Notices (FSN) issued by medical device manufacturers which, from the 1st of August, will be placed on the IMB website. Updates on all European meetings attended by the IMB are 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**.



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2007/47/EC – Major Changes Impacting Medical Device Regulation

The Directive 2007/47/EC which was published in September 2007 and amends the Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC) and the Biocides Directive (98/8/EC), comes into effect from 21st March 2010.

Since its publication all medical device stakeholders: medical device manufacturers, notified bodies, competent authorities and the European Commission have been working to ensure a smooth transition to the new requirements of 2007/47/EC.

The main changes, outlined below, include those relating to clinical data evaluation, notified body assessments, and the development of medical device communication systems and procedures. 2007/47/EC also confers increased capacity on the European Commission to adapt non-essential elements of the Directive via a regulatory/comitology procedure rather than necessitating a formal revision of the entire legal text. These areas include classification, notified body management, vigilance and clinical evaluation.

CLINICAL EVALUATION

One of the most significant changes in 2007/47/EC relates to clinical data and its evaluation. Clinical data is specifically defined and the Directive now explicitly states that in order to demonstrate conformity to the Essential Requirements, a clinical evaluation is required. This is applicable to all classes of medical devices unless the exclusion of clinical data can be appropriately justified.

The use of existing clinical literature to support an 'equivalent' device has been elaborated. The data must relate to the safety, performance, design characteristics and intended purpose of the device and must adequately demonstrate compliance to each relevant Essential Requirement. The use of existing clinical data for implantable/class III medical devices is appropriate only if adequately justified.

The clinical evaluation of a medical device must become an evolving document and be actively updated with data gathered from post-market surveillance and clinical follow up. Failure to not conduct post-market evaluation must be duly justified.

The Clinical Evaluation & Investigation (CIE) working group is currently revising available guidance on clinical evaluation and post-market clinical follow-up.

CONFORMITY ASSESSMENT

Another of the most significant changes in 2007/47/EC relates to changes to conformity assessment by the full quality assurance system outlined in Annex II. A notified body must conduct an assessment of technical and design documentation for devices falling in class IIa and class IIb on a representative sampling basis. The Directive defines generic device group and device sub-category which are applicable to the sampling size chosen for IIb and IIa respectively. The depth and extent of this review should reflect the classification of the device, the novelty of the intended treatment, the degree of intervention, the novelty of the technology or materials, and the complexity of the design and/or technology. In addition, class I devices with a sterile or measuring function can now demonstrate conformity using Annex II.

The Notified Body Operations Group is developing guidance in relation to representative sampling and the review of associated technical documentation.

In addition, demonstration of conformity to the Essential Requirements also requires that a manufacturer provides evidence relating to the monitoring and control that they have over third parties such as suppliers or subcontractors.

EUDAMED

Provisions for the EU medical device database system, EUDAMED, has been further elaborated in 2007/47/EC to include data on registration of class I medical devices, their manufacturers and authorised representatives; Notified Body certificates issued, modified, suspended or withdrawn; vigilance information; and information relating to clinical investigations of medical devices. The EUDAMED working group and the various medical device working groups impacted by these changes are developing standard data formats, datasets and any necessary implement-

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ing measures. It is hoped that all these elements of EUDAMED will now be fully implemented

MEDICAL DEVICE CERTIFICATES

The responsibilities of a Notified Body with regard to withdrawal and suspension of certificates and communication of such activities to the Competent Authorities are further defined in the revision to the Directive.

It is envisaged that all certificate information will be uploaded to the EUDAMED database system. The enhanced transparency allowed for in the revision also means that this certificate information will be non-confidential.

All certificates issued by a notified body, including those per Annex VI, have a maximum validity of 5 years, although a shorter period of validity is at the discretion of the Notified Body.

ENHANCED COOPERATION

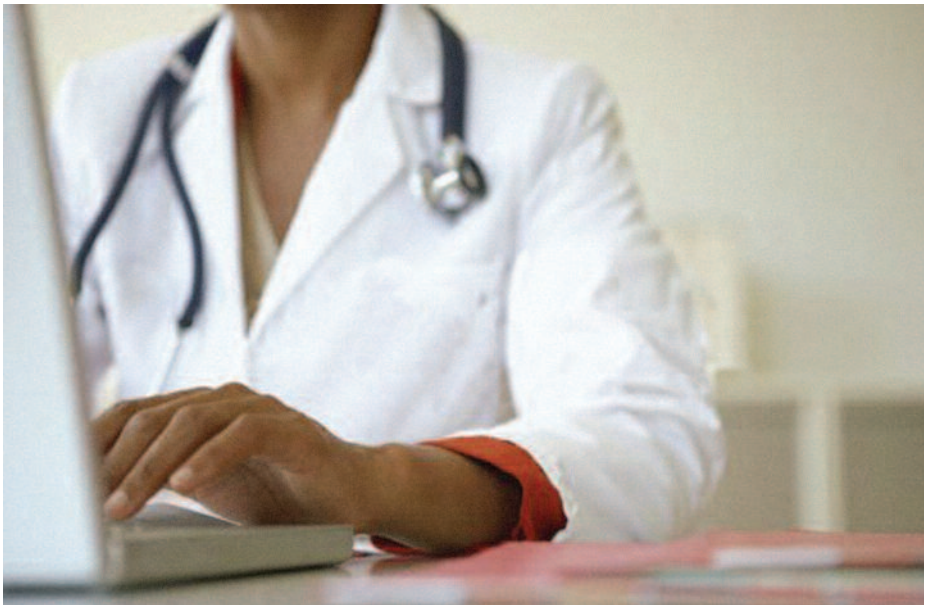
The addition of Article 20a in 2007/47/EC allows for enhanced cooperation between Member States and exchange of information to ensure the appropriate application of the Directive. The area of market surveillance is specifically referenced in this section on cooperation. Provision is also made for participation in international initiatives on cooperation such as the Global Harmonisation Task Force.

HEALTH PROTECTION MEASURES

Further powers are conferred upon the Member States to take action at a national level to withdraw, restrict or subject medical devices to marketing requirements to ensure the protection of public health and safety. The EC, based on the actions and reasons of the MS, will consider whether a larger European action is required. When necessary these measures can be adopted through the regulatory/comitology procedures. Such changes have also been made with respect to the safeguard clause described in Article 8.

SOFTWARE

Software has been added as one of the entities in the definition of a medical device. Software is a medical device in its own right when specifically intended



by the manufacturer to be used for a medical purpose. Typically, software used for general purposes in a healthcare setting is not a medical device. An Essential Requirement has been added to ensure that software, which is considered as a medical device, is appropriately validated according to the state of the art taking into account the development lifecycle, risk management, validation and verification.

The Software Task Force is to be reinitiated with the aim of providing further guidance on software when used in, or when constituting, a medical device.

REPROCESSING

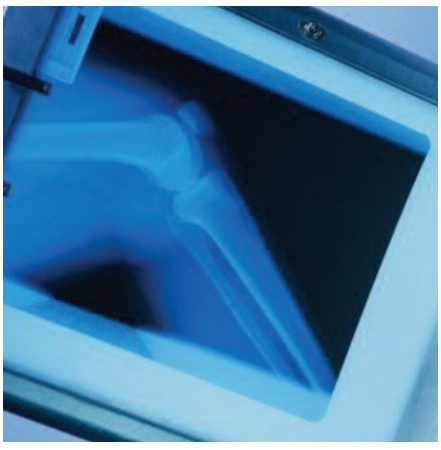
In order to protect patients against any risks arising from reprocessing of medical devices, 2007/47/EC adds a definition of single use as a device intended to be used once only for a single patient. Further text has been added with an aim to harmonise the labelling of single use devices and requires that information is provided on the characteristics and technical aspects which could be affected if the device were to be reused. The European Commission (EC) has also committed to report to the European Parliament on reprocessing of medical devices by September 2010 and propose any additional measures which may be necessary to protect public health. The EC is already seeking information from Member States on issues relating to reprocessing.

CLASSIFICATION

Several changes have been made to Annex IX where the classification rules are outlined. In particular, the definition of the central circulatory system has been revised to include the descending aorta to the level of the aortic bifurcation. This will mean that several devices used in the abdominal aorta and at the bifurcation will be classified as class III rather than class IIb. In addition, continuous use of a medical device has been defined.

Several corrections were made to the existing classification rules to correct various anomalies. Devices used for storing x-ray images have been classified as class IIa medical devices and devices used for disinfecting invasive medical devices are in class IIb.

The mechanisms for classifying medical devices have been further elaborated in 2007/47/EC. The revised text adds further provisions relating to legal adap-



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tation of the existing classification rules or deviation from these classification rules for specific devices if deemed necessary. In addition, specific text has been included to allow for delineation of medical devices from other healthcare products in borderline cases. These provisions involve a regulatory/comitology decision making procedure and can be initiated upon a 'duly substantiated' request from a Member State.

CUSTOM MADE MEDICAL DEVICES

Manufacturers of custom made medical devices must have provisions in place to gather data from market experience with the device. This includes reporting of adverse incidents to competent authorities and gathering of post-market clinical follow up data.

AUTHORISED REPRESENTATIVE

A manufacturer must nominate a single authorised representative if they do not have a registered place of business within the EU. This single representative should at least be applied to all devices within the same model. The authorised representative role is now specifically included in terms of obligations regarding vigilance, registration, clinical investigations, CE marking, document retention etc. The address details of the authorised representative must also be included along with that of the manufacturer's on the labelling for the device.

E-LABELLING

The revised Directive also allows the information provided with a device by a manufacturer to be provided by means

CE

other than paper copy e.g. electronically, if it is deemed appropriate. The e-labelling of in-vitro diagnostics is already common place. A medical device working group is currently developing guidance on the types of general medical and active implantable medical devices which may be suitable for e-labelling.

DOCUMENT RETENTION

For implantable medical devices, documents must be retained by the manufacturer or authorised representative for a period of fifteen years from the date of the last manufactured product.

DESIGN FOR PATIENT SAFETY

The revision to the Directive makes further provision for devices to be designed specifically with patient safety in mind e.g. ergonomic design. The revision recognises the level of training and knowledge of the user within the Essential Requirements by consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of the intended user.

It also requires that the manufacturer place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body.

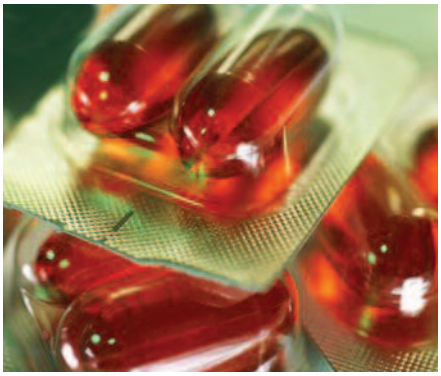
DRUG-DEVICE COMBINATION CONSULTATIONS

The revision to the Directive seeks to clarify the procedure, requirements and timelines where a notified body assessing a drug-device combination (medicinal substance or stable human blood derivative), seeks the opinion of a medicines competent authority or the EMEA on the quality and safety of the medicinal substance when used in the context of the drug-device combination. The notified body must verify the usefulness of the substance incorporated in the device with regard to the intended purpose. The competent authority (or EMEA) is obliged to provide an opinion within 210 days. Further post-market requirements e.g. safety information and changes to the drug or device are also provided for.

This procedure has also been included in the active implantable medical device directive which means that such combinations will now require opinion from a competent authority or the EMEA on the medicinal substance or human blood derivative component.

PHTHALATES

Medical devices containing phthalates must be labelled as such in order that exposure is minimised for patients at risk e.g. children, pregnant women. Manufacturers are obliged to avoid the use of substances which pose risks to patients unless no alternative is available. In these instances, manufacturers are encouraged to develop alternative substances with lower risks.



How Directive 2007/47/EC affects Notified Body Conformity Assessments and Certificates

CONFORMITY ASSESSMENTS

From 21st March 2010, medical device manufacturers must ensure that medical devices they place on the market comply with the requirements of 2007/47/EC and make a Declaration of Conformity to that effect. The conformity assessment activities of Notified Bodies have been amended by Directive 2007/47/EC by the introduction of several changes, namely:

1. Review by Notified Bodies of technical documentation for class IIa and class IIb devices on the basis of representative sampling.
2. The Notified Body must assess the appropriateness of the manufacturer's controls over third parties in cases where a manufacturer has subcontracted the design, manufacture, final inspection or testing of a medical device to another party.
3. A Notified Body must consult a national pharmaceutical competent authority or the EMEA "before taking a decision" regarding the evaluation of an active implantable medical device (AIMD) which incorporates a medicinal substance with ancillary action to the one of the device. This provision already applies to general medical devices.

These new evaluation requirements must be implemented by Notified Bodies from 21st March 2010 when issuing or renewing certificates under Directive 93/42/EC or 90/385/EEC.

To ensure that manufacturers have the correct certification as of 21st March 2010 it is advised to request a conformity assessment be carried out in line with the relevant amended directive prior to this date; particularly in the case of manufacturers of:

- New types of medical devices,
- Devices whose classification has been changed due to the revised classification rules
- Devices that undergo changes which require assessment by a notified body.

These certificates shall still refer to the parent Directive, i.e. 93/42/EEC or 90/385/EEC. However, the design-dossier examination report, type-testing report or audit report should document that the Notified Body carried out the conformity assessment in accordance with the amended directive i.e. 2007/47/EC.

In all other cases these new assessment requirements shall be phased in during Notified Body periodic surveillance audits.

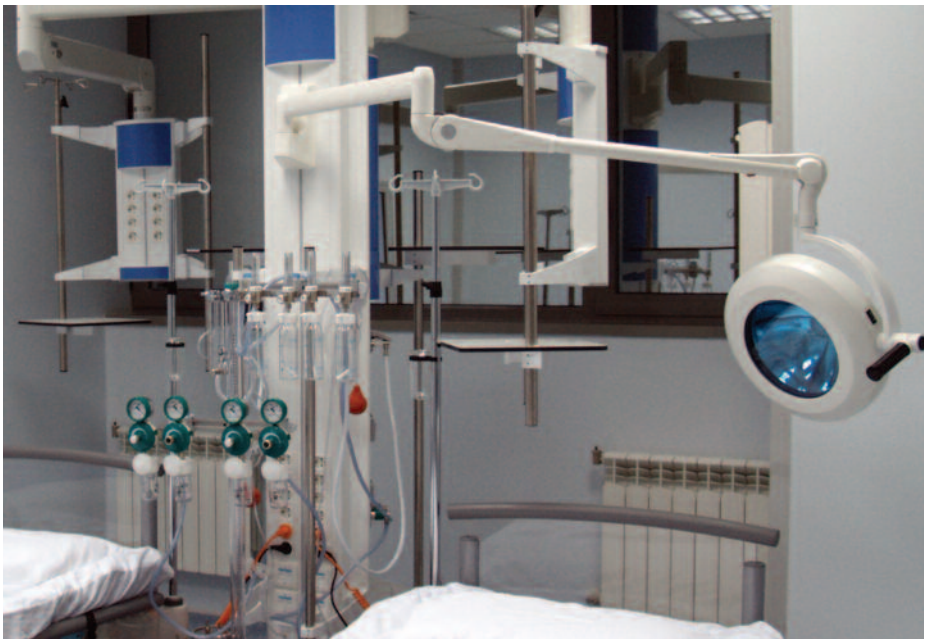
CERTIFICATES ISSUED PRIOR TO THE IMPLEMENTATION OF DIRECTIVE 2007/47/EC

Currently certificates issued in accordance with Annexes V and VI of Directive 93/42/EEC and Annex 5 of Directive 90/285/EEC do not have to include a period of validity of the certificate. As of 21st March 2010 Directive 2007/47/EC amends Article 11(11) of Directive 93/42/EEC and Article 9(8) of 90/285/EEC such that certificates issued in accordance with these Annexes are now limited to a validity of a maximum of 5 years.

Products which are placed on the market or put into service prior to 21st March 2010 with a certificate with unlimited validity can remain on the market. However, in order that further devices can be placed on the market after 21st March 2010 the manufacturer must seek re-certification by a Notified Body for a limited validity certificate. The concept of 'placing on the market' or 'putting into service' applies to individual devices rather than types of devices.

Certificates issued prior to 21st March 2010 maintain their validity. In the case where there are changes to an approved design of a device of approved quality management system a new certificate is necessary. Additionally, should a medical device fall into a different classification as a result of the changes to Annex IX of Directive 93/42/EEC a new certificate in accordance with the appropriate conformity assessment is required for devices placed on the market or put into service as of 21st March 2010.

The European Commission has published an interpretative document on the Implementation of Directive 2007/47/EEC. It may be downloaded from the European Commission website, http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/interpretative_documents_en.htm



Field Safety Notices on the IMB website

From 1st of August, 2009 the IMB will place all field safety notices (FSN's) received through the European medical device vigilance system on the IMB website (www.imb.ie). The IMB's aim is to provide a database of all FSN's distributed by the manufacturers of medical devices that can be accessed by all medical device users. A pilot project was started on the 1st July 2009 and only FSN's received by the IMB from this date will be available on the website.

As per the guidance given in Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12-1 rev 5, a manufacturer must inform all customers and/or users of any field safety corrective action that affects the medical devices they have been supplied with. The guidance document recommends that manufacturers do this through the distribution of a FSN. Examples of actions that require notification include product recall, field modification or a training update. The IMB, as competent authority for the Irish market, must also be informed of all field safety corrective actions that may affect the Irish market, as per guidance in MEDDEV 2.12-1 rev 5.

Only users and customers directly affected by a field safety corrective action receive a FSN from the manufacturer, the authorised representative or distributor of the device. The IMB website will display all FSN's distributed by manufacturers as they are received by the IMB, whether they are related to devices on the Irish market or not. The introduction of this database does not impact or change the notification procedure used by manufacturers; users will still receive FSN's that affect them from the manufacturer, their representatives or their distributors.

The FSN's will be located under 'Field Safety Notices' in the publication section of the IMB website. If users or customers have any questions relating to the contents of the FSN they should contact the manufacturer or their authorised representative using the contact details in the FSN document.

Upcoming Events

BEAI Annual Scientific Meeting 2009

The annual scientific meeting of the Biomedical Engineering Association of Ireland will take place in the Tullamore Court Hotel, Tullamore, Co. Offaly on September 26th 2009. The meeting is being held in association with Engineers Ireland. If you are interested in attending the conference, further information may be found at www.beai.org or by contacting Noel Murphy by email at noel.murphy@hse.ie.

IVD Information Day 2009

The IMB *In-vitro* Diagnostic (IVD) Device Information Day will be held on 06 November 2009. The meeting is intended primarily for IVD manufacturers. Keynote speakers will include representatives from the EU Commission, Industry and representatives from other medical device Competent Authorities. Topics for discussion include 'The impact of international issues on future IVD developments' and 'IVD Legislation – Current and Future Developments'. Particular attention will be given to the Vigilance System for IVDs and examples of issues identified during audits of IVD manufacturers conducted by the IMB in 2009.

Venue Details:

The IVD Information Day will be held in the Camden Court Hotel, Camden Street, Dublin 2.

A preliminary agenda is now available and further details can be obtained from the IMB website at www.imb.ie.

Regulatory Update

COMPETENT AUTHORITY MEETING

The 24th meeting of Competent Authorities for Medical Devices took place on July 2-3 2009 under the Swedish EU presidency. It was an informal meeting of regulatory authorities from European Economic Area-EEA countries (EU Member States, Iceland, Liechtenstein and Norway) competent for medical devices and delegates from the sector for medical devices of the European Commission. The main goal of the meeting was to exchange views on current and future European legislation and its national implementation in order to ensure and maintain the safety and quality of medical devices. The main issues that were on the agenda and discussed were:

- Transposition and implementation of the revised Medical Devices Directive 2007/47/EC
- Borderline and classification issues regarding medical information systems.
- The need for exchange of views with other sectors having a regulatory structure analogous to the medical devices sector.
- Implications on the devices sector of the adopted European "Goods package".
- Working groups of the EC and international matters

The European Council also presented the work of the Ad Hoc Committee on Counterfeiting of Medical Products and similar crimes involving threats to public health.

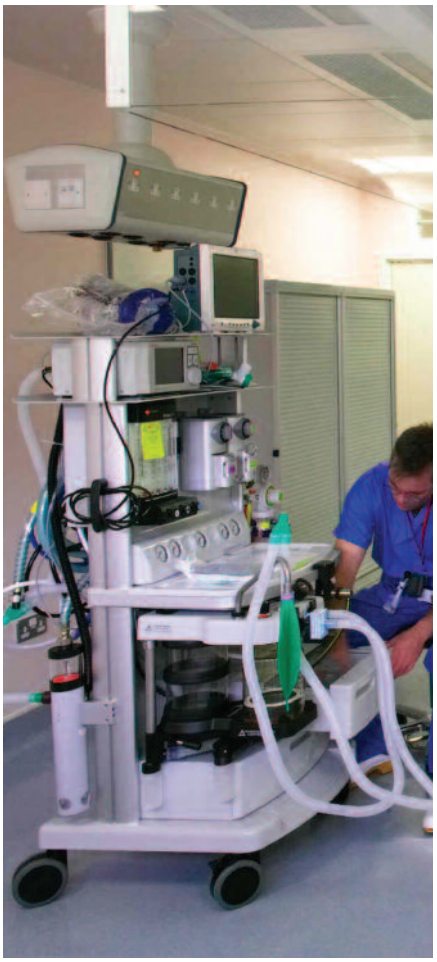
NBOG

A meeting of the Notified Body Operations Group took place in June. The NBOG Best Practice Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis (NBOG BPG 2009-4) was finalised and was subsequently published in July. Other topics for discussion included the revision of designation scope definitions, to role of the NB in assessment of clinical evaluation data and NB assessment of suppliers and subcontractors. A progress report was given on the scheme for competent authorities to be peer reviewed whilst undertaking a NB surveillance audit.

The NBOG meeting was followed by two-day training course/workshop for auditors from competent authorities to exchange ideas on NB management and surveillance audit.

CLASSIFICATION AND BORDERLINE

The classification and borderline working group was held in May. Borderline cases discussed by the group included osmotic laxatives, products containing simethicone and products containing *Lactobacilli*. These products are to be discussed again at subsequent meetings. The Manual on Classification and Borderline was updated to reflect consensus positions reached by the group. In addition the revised MEDDEV 2.1/3 on borderline products was finalised and subsequently published in June. An advanced draft of the classification MEDDEV to reflect changes arising from 2007/47/EC was tabled at the meeting for further discussion at subsequent meetings.



CAT

The Committee for Advanced Therapies (CAT) at the EMEA during recent meetings discussed procedures and mechanisms required for interaction with medical device notified bodies during evaluation of combination advanced therapy medicinal products. A document on the procedure for consultation of a NB will be released by EMEA for comment later this year.

EUDAMED

A meeting of the EUDAMED Working Group took place in April. Discussions were held on the draft EUDAMED Guide and Data Forms which explains and describes the data content as foreseen in the Medical Device Directives. The European Commission demonstrated the new functionalities proposed for EUDAMED2 and presented the current EUDAMED statistics of use. In light of the recast of the Medical Devices Directive discussion were held on the future application and use of EUDAMED.

MEDICAL DEVICE VIGILANCE EXPERT GROUP

A meeting of the Medical Device Vigilance Expert Group was held in May. Discussion at the meeting included the implementation of the vigilance enquiry form, the implementation MEDDEV 2.12-1 rev 5, EUDAMED, GHTF Study group 2 and the NCAR exchange process. Ireland presented 3 papers at this meeting.

EU AD-HOC TASK FORCE (VIGILANCE)

In May the second meeting of the EU Ad-Hoc task force was held in Brussels. This group has been set up to investigate the possibility of improving the EU regulatory framework concerning vigilance. A representative from the IMB attended

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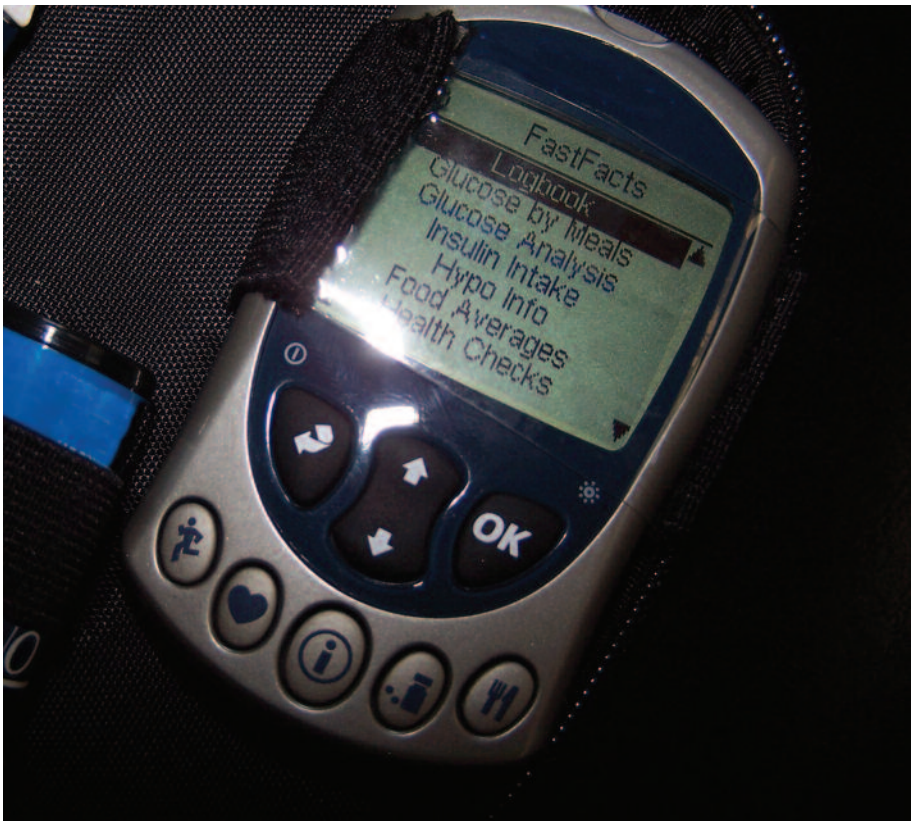
the meeting. The discussion focused on Article 10 of the Directive. Items for the recast were also identified.

COMPLIANCE AND ENFORCEMENT WORKING GROUP (COEN)

The COEN meeting was held in May 2009. 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. Updates were also provided on specific market surveillance projects and specific cases of concern for Member States. Member States were asked to comment on a future perspectives document.

BLOOD GLUCOSE METER (BGM) PROJECT

The trilateral Post Market Surveillance Operation involving an assessment of the "user manual" for the blood glucose meter and the "instructions for use" for the associated reagents (strips or electrodes) is ongoing. The assessment will include issues relating to maltose interference and units of measurement. The Irish, UK and French Competent Authorities are involved in this co-ordinated action. The associated documentation has been received and is under review. It is hoped that the findings from this project will be available later this year.



VCJD

The common technical specifications (CTS) and Guidance document were finalised at a meeting of the small subgroup on 27th April 09. The CTS and Guidance document were a major challenge to draft given the number of unknowns and the paucity of samples. The group is grateful to the many experts involved for providing invaluable feedback. It is envisaged that the CTS will be updated as scientific knowledge develops in this area.

AOB/For Information

IMB Medical Device Newsletters

To date, the IMB have been circulating hard copies of the medical device newsletters by post. It is proposed that from 2010, the newsletter will be circulated by email only. This newsletter will also be available to download from our website at www.imb.ie.

If you would like to continue receiving copies of the newsletter by email, please send your contact details along with your email address to medicaldevices@imb.ie or you can register for medical device updates on the IMB website at http://www.imb.ie/subscribe.aspx.

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