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# Letter from the Editor

*Welcome to the first edition of the medical devices newsletter for 2014.*

In this edition, we are pleased to include an article from Prof. Brian Caulfield, Lead Investigator at the Applied Research for Connected Health (ARCH) Centre at University College Dublin, describing the exciting new digital model for delivery of healthcare known as Connected Health. The article describes both the advantages and challenges associated with implementing and building a connected health system.

In this issue, we have an article on the new format on the IMB medical device safety notice launched in April 2014. The article outlines the purpose of the safety notice and the role of the IMB in communicating important information to users, regarding the safe use of their medical device. The new safety notice sees the introduction of a traffic light system to prioritise communications to stakeholders.

We highlight the recent medical device brochure which outlines important information for retailers of medical devices and their role in ensuring medical devices for sale in Irish stores are safe and comply with relevant laws. Advice for retailers is provided on record keeping, incidents and outlines key information retailers should look for when sourcing devices.

Also included is this edition is an update on the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published opinions and future mandates, the IMB 2014 Post Market Surveillance Audit Plan and the ongoing Voluntary Joint Assessments of Notified Bodies. Additionally, we have included updates on the recent European working groups meetings namely, Notified Body Operations Group, International Medical Devices Regulators Forum, Medical Device Expert Group, MDEG Vigilance, Compliance and Enforcement Group and *In-vitro* Diagnostics Technical Group.

As always, the IMB welcomes feedback on the content of our newsletter and encourages readers to submit suggestions for articles that would be of interest by contacting us at medicaldevices@imb.ie.

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## Upcoming Events

### IMB MEDICAL DEVICES INFORMATION DAY

The IMB will be holding a medical devices information day on Thursday 23rd October 2014. This event will take place in the Crowne Plaza Hotel, Santry.

The agenda for the day is currently being finalized. The agenda and registration forms will be available on the IMB website **www.imb.ie** over the coming months.

# Connected Health – What's it all about?

PROF. BRIAN CAULFIELD, LEAD INVESTIGATOR AT THE APPLIED RESEARCH FOR CONNECTED HEALTH (ARCH) CENTRE AT UCD AND DEAN OF PHYSIOTHERAPY AT UCD.

*Don't look now, but we are in the middle of a revolution. The mode in which we engage with digital technology to measure numerous aspects of our interaction with the world around us is changing.*

The vanguard of this movement is best exemplified by the recent massive growth in the market for personal fitness and wellness sensing devices and mobile apps such as Fitbit and Runkeeper. It is likely that the majority of people reading this article already own either an exercise monitoring device and/or mobile application. The market for these devices, non-existent just a few years ago, was estimated at US$300m in 2013 and is forecast to rise exponentially over the coming years, with expectations for sales of almost US$500m devices in 2017.[1] This rapidly growing market is the thin end of a consumer led movement to leverage digital technology supports to monitor and quantify indices of health and fitness. It uses the associated data to enhance performance, regardless of where a person sits on the spectrum of health, and it is setting the pace for the formal healthcare sector.

It is no secret that the healthcare system is in dire need of repair. An ageing population, associated rising incidence of chronic disease, and spiralling healthcare inflation are causing us to reimagine the way in which we manage health and social care. We are being forced to find new processes that deliver proactive and efficient care across the lifespan by means of engaging people in their own care and moving the focus of care into the home and community. Rapidly expanding technological capabilities offer great opportunity to deliver this new model for healthcare.

The use of information and communications technology in healthcare has been called many things ranging from e- to wireless- to digital-health but all of these terms imply a technology focus and recent experience has shown us that when we focus on technology we do not achieve true innovation at a care level. A more all-encompassing term that has been advanced in recent years to describe this field is that of Connected Health. Connected Health comprises any series of **devices, services or interventions** that are **designed around an individual's needs** in such a way that they are engaged in **self management** and can receive care in the most **proactive** and efficient manner possible, preferably outside the acute care environment. The term implies that all stakeholders in the process are 'connected' by means of **timely sharing and presentation of accurate and pertinent information** regarding status and the need for care.[2]


Though it offers a wonderful opportunity for society, delivering Connected Health is far from easy. To date significant financial investment and research activity has failed to bring about widespread technology-enabled transformation in care models in any major markets. The evidence base required to convince payors and policy makers to engage in the necessary fundamental process innovation is not yet available and we still have significant challenges to address in this field. There are multiple layers, and stakeholders, in the process; the data layer, the care layer, the change layer, and the sustainability layer.

The DATA layer is the one that is receiving most airplay at present, with a large interest in the opportunity that big data analytics can offer in enabling Connected Health models. Data is the fuel for the healthcare process, yet we must extract knowledge from it before we can derive its inherent value. The data challenge begins with the process of efficient capturing of relevant data from a variety of sources and devices across the spectrum from unobtrusive wearable sensors to detailed investigations performed in a clinical environment. The old model of episodic data access is no more with mobile sensing platforms now offering capability to access data on a 24/7 basis if necessary. Following capture, other elements in the data layer include technologies for aggregation, communication, storage, processing, analytics and knowledge

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## Connected Health – What's it all about?

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extraction, as well as access models and sharing of that knowledge amongst stakeholders. Also important in the data layer are issues such as privacy, ownership, access rights, and security.

The CARE layer is concerned with understanding how we can leverage the knowledge that is created from data to drive the development of integrated care strategies that are proactive, based on the principle of prevention and early intervention through user engagement and self management. Critical to development in this area is involvement of end users (both healthcare professionals and patients alike) in the process of care model innovation rather than innovation informed by technological capability alone. Globally, the transition towards large scale implementation of data driven connected care models is limited and we are finding it hard to move beyond multiple parallel pilot deployments that are not sufficiently standardised or integrated in approach to enable pooling of resultant datasets to provide evidence regarding clinical or economic efficacy.

The CHANGE layer in Connected Health has not received significant attention until quite recently. It pertains to understanding how we can leverage technology supports to positively influence personal behaviour with regard to health and lifestyle, how this relates to issues such as health literacy, and how we can change work practices of those responsible for delivery of care. Also critical to the change agenda is how organisations can adapt to new care models and how policy can influence the process of transition. Finally, the SUSTAINABILITY layer is what will ultimately decide whether we transition to a new connected care world. It deals with the issues of payment models, evaluation of cost savings, insurance and reimbursement models, and new collaborative business models for connected health.

So, there are many exciting opportunities offered by the digital and data revolutions that are going on around us. The pathway towards a new integrated and connected care model that is promised is not a simple one but there are some very exciting national initiatives in this area and Ireland is playing a central role in the global effort to make connected care a reality.

For more information on Connected Health research at UCD please visit www.connectedhealthireland.com


1 ON World, Mobile Sensing Health & Wellness. 2013. http://onworld.com/mobilesensing/health/

2 Caulfield B & Donnelly S. Quarterly Journal of Medicine 2013 Aug; 106(8): 703-7. doi: 10.1093/qjmed/hct114


# IMB Launches New Safety Notice

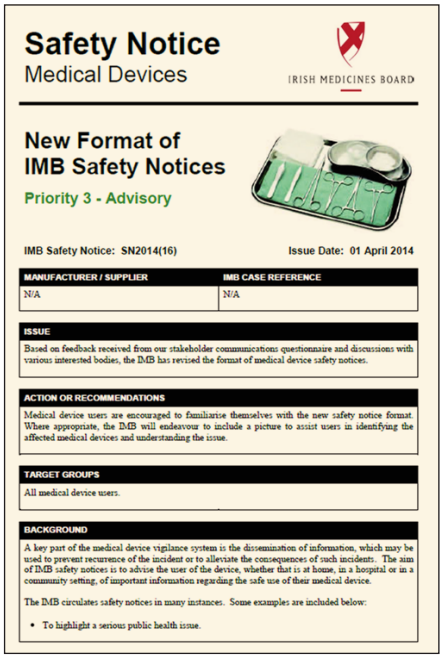
*Based on feedback received from our stakeholder communications questionnaire completed in 2013 and discussions with various interested bodies, the IMB has revised the format of medical device safety notices.*

The first safety notice in the new format was issued on the 1st April 2014.

A key part of the medical device vigilance system is the dissemination of information, which may be used to prevent recurrence of the incident or to alleviate the consequences of such incidents. The aim of IMB safety notices is to advise the user of the device, whether that is at home, in a hospital or in a community setting, of important information regarding the safe use of their medical device.

The IMB circulates safety notices in many instances. Some examples are included below:

- To highlight a serious public health issue.
- To draw attention to field safety corrective actions which, following an IMB risk assessment, are deemed to be related to medium or high risk safety issues.
- To highlight an issue that has already been communicated by a manufacturer via a field safety notice but where the manufacturer has indicated to the IMB that they have experienced difficulty reaching all customers or obtaining feedback from all customers.
- To highlight an issue when either the device manufacturer or distributor to the Irish market no longer exists. For example, where the manufacturer has gone into liquidation or where the manufacturer is not known e.g. counterfeit devices.
- To communicate concerning trends identified by the IMB in relation to particular product families.
- To communicate safety concerns identified by the IMB in monitoring vigilance issues e.g. equipment management issues and traceability issues.



**Safety Notice**
Medical Devices
IRISH MEDICINES BOARD

**New Format of IMB Safety Notices**
Priority 3 - Advisory

IMB Safety Notice: SN2014(16) Issue Date: 01 April 2014

| MANUFACTURER / SUPPLIER | IMB CASE REFERENCE |
|---|---|
| N/A | N/A |

**ISSUE**
Based on feedback received from our stakeholder communications questionnaire and discussions with various interested bodies, the IMB has revised the format of medical device safety notices.

**ACTION OR RECOMMENDATIONS**
Medical device users are encouraged to familiarise themselves with the new safety notice format. Where appropriate, the IMB will endeavour to include a picture to assist users in identifying the affected medical devices and understanding the issue.

**TARGET GROUPS**
All medical device users.

**BACKGROUND**
A key part of the medical device vigilance system is the dissemination of information, which may be used to prevent recurrence of the incident or to alleviate the consequences of such incidents. The aim of IMB safety notices is to advise the user of the device, whether that is at home, in a hospital or in a community setting, of important information regarding the safe use of their medical device.

The IMB circulates safety notices in many instances. Some examples are included below:

- To highlight a serious public health issue.

Due to the varying nature of these safety notices, the IMB intends to prioritise these communications. A traffic light system of red, amber and green will be used to aid in dissemination of safety information.

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## IMB Launches New Safety Notice

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The proposed system is risk based and is outlined in a table below:

| Priority | Category | Examples |
|---|---|---|
| Priority 1 | For Immediate Action | • Urgent product removal<br>• Urgent information |
| Priority 2 | Warning | • Action required<br>• Caution in use |
| Priority 3 | Advisory | • Traceability issue<br>• Generic information regarding medical devices |

All safety notices will be assigned a priority number (1-3) and will be categorised as outlined in the table. The examples included in the third column of the table are not an exhaustive list.

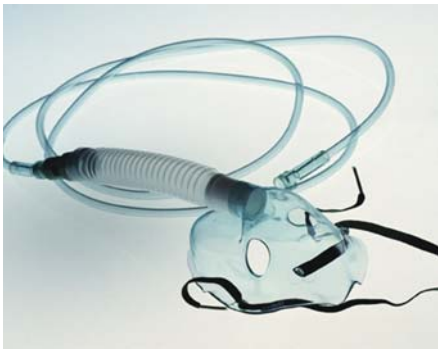
For the coming months the new format safety notices will continue to be placed on the IMB website under the 'Advisory' notice type. The priority will be indicated on the safety notice heading. The IMB website will be updated in the coming months.

The new format will also provide information on the target audience, the background to the issue and details of the recommended actions.

In practice, IMB safety notices are

only issued for a small percentage of the overall field safety notices distributed in Ireland. The recipient of the safety communication should ensure that the communication reaches the most appropriate personnel within their organisation. The recipient should also ensure that the issue outlined in the notice is considered, the risks assessed and the appropriate / recommended actions are completed.

In some instances, the recipient of



the notice may not be the most appropriate person to deal with the issue, therefore a well defined, effective mechanism for managing the communications is necessary. Some organisations, hospitals and the community care setting have found that it is very beneficial to have one designated medical device vigilance contact, a local medical device vigilance team that meet to assess the issues that arise, local medical device vigilance procedures and a database to support the management of such communications. Such structures and defined responsibilities and processes help to ensure that the communications are dealt with in a timely manner.

Another key element of the vigilance system is user reporting. The IMB currently operates a voluntary system whereby a user, healthcare professional or any other person who identifies a medical device safety issue can report it to the IMB. The IMB strongly encourages healthcare professionals and members of the public who have encountered a safety issue with a medical device that they have used to report this to the IMB.

Safety notices will be published on the IMB website (www.imb.ie) and will continue to be circulated, at the time of publication, to healthcare professionals

who have subscribed to the IMB mailing list. The IMB will also circulate, via email, a listing of IMB safety notices at the end of each calendar month.

The IMB will no longer circulate UK Medicines and Healthcare Products Regulatory Agency.

MHRA medical device alerts (MDAs). Medical device users can continue to receive MDAs by registering with the MHRA website.

Medical device users are encouraged to familiarize themselves with the new safety notice format. Where appropriate, the IMB will endeavour to include a picture to assist users in identifying the affected medical devices and understanding the issue.

## Selling Medical Devices in Ireland – A Guide for Retailers

The IMB has published, *Selling Medical Devices in Ireland;* an information leaflet for retailers informing them of the important role they play in ensuring that medical devices for sale in Irish stores are safe and comply with relevant laws. The leaflet includes information on what is a medical device and what records to keep in relation to medical devices. It includes advice on what to do when a customer contacts a retailer about an issue or incident related to the use of a device.

The leaflet also helps to clearly outline the key information retailers should look out for when sourcing medical devices. This includes:

- That the text on the label is in English.
- That the device has a CE mark on the label, packaging and/or the device itself. As well as the CE mark, some devices must also show a four digit number to confirm that they meet important safety requirements.


These include devices that measure something e.g. a thermometer and those that are supplied in a sterile state e.g. bandages and plasers.

- A European address on a CE marked device. This is a legal requirement.
- That the expiry date, where this is relevant to the product, has not passed.
- That stock is bought from a manufacturer, an authorised dealer or from a reputable supplier.
- The presence of elaborate or unexpected claims about a medical device. Retailers should be wary in these cases as it is unlikely such claims are true.

This leaflet *Selling Medical Devices in Ireland* is available to download on the IMB website www.imb.ie. Printed versions can be ordered from brochures@imb.ie.

## Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) – Opinion Update

*The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is one of three scientific committees hosted by the European Commission. The SCENIHR remit is to provide opinions on emerging or newly-identified health and environmental risks on various issues which represent a significant risk to consumer safety or public health.*

Since the last IMB Newsletter article on SCENIHR in April 2013 several opinions have been published.

- In May 2014, SCENIHR published its preliminary opinion on 'The safety of Metal-on-Metal joint replacements with a particular focus on hip implants' dated 24th February 2014.
- In May 2014 SCENIHR published its final opinion on Poly Implant Prothèse (PIP) Breast Implants (2013 update).
- The safety of the use of bisphenol A in medical devices. SCENIHR adopted this opinion by written procedure on 27th January 2014.
- Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. SCENIHR approved this opinion at the 4th plenary meeting of 12th December 2013.

Preliminary SCENIHR opinions are expected shortly on the following on the following topics

- The safety of dental amalgam and alternative dental restoration materials for patients and users
- The safety of medical devices containing DEHP (di (2-ethylhexyl) phthalate) plasticized PVC on groups possibly at risk
- Health effects of nanomaterials used in Medical Devices.

The SCENIHR have recently been mandated by the Commission to provide an opinion on the safety of surgical meshes used in urogynecological surgery. This opinion is due January 2015. All the SCENIHR opinions and opinion mandates can be found at http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm

# IMB Post Market Surveillance Audit Plan for 2014

This post-market surveillance activity forms part of the review of manufacturer's compliance to the European Directives and related Irish legislation by the IMB. It is the responsibility of the IMB to ensure that manufacturers placing medical devices on the Irish market are in compliance with the medical devices legislation. One of the ways that the IMB has met this obligation is by conducting post market surveillance audits of Irish medical device manufacturers. The aim of the audit is to ensure that the medical device manufacturer is complying with the essential requirements and schedules of the medical device legislation and related statutory instruments.

Post market surveillance audits can be initiated from a number of sources:

- IMB post market surveillance / compliance plan
- Concerns raised in relation to specific medical device vigilance issues
- Changes in legislation
- Complaints received about CE marked products
- Post-market surveillance sampling across a specific technology / sector


- Receipt of information from internal / external sources
- Requests from other competent authorities
- IMB register of medical devices
- Any other source that may arise from time to time

As well as reactive surveillance, the IMB also executes a proactive post market surveillance plan each year. This plan is a risk based approach taking into consideration issues which have been identified during the course of the previous year.

The 2014 plan will incorporate elements of the following classes of medical devices:

- *In-vitro* diagnostic medical devices
- Class III medical devices
- Procedure packs

Notification of proactive surveillance audits is typically issued to the manufacturer four to six weeks in advance of the scheduled dates. Notified body re-designation and observed assessments are also included within the IMB's 2014 audit schedule along with participation in the European joint assessments of notified bodies for class III medical devices.

For further information in relation to audits please refer to IA-G0009-1 Guide for Medical Device Manufacturers on Auditing by the Irish Medicines Board to the Medical Device Relations (IA-G0009-1). For further information on fees please refer to Guide to Fees and the Fee Application Form for Human Products 2014.

All above documents are available from www.imb.ie

# Voluntary Joint Assessments Update

*One of the objectives of the joint plan for immediate actions, communicated in February 2012 by the European Commissioner for Health and Consumers, is to ensure that only well-functioning, properly resourced and appropriately staffed notified bodies (NBs) are authorised to conduct conformity assessments in the field of medical devices.*

A specific action foreseen in the joint plan was the conduct of voluntary joint assessments of NBs responsible for 'class III' (high risk) medical devices, whereby the national designating authorities would be assisted by Commission representatives in the conduct of their surveillance, designation and re-designation assessments of their NBs. The objective of these joint assessments was to identify and document, where appropriate, opportunities for improvement in the designating authority's performance of such assessments.

Joint assessments commenced in 2013 on a purely *voluntary* basis – with the consent of both the designating authorities and NBs concerned. The performance of each designating authority was assessed to the criteria laid down in the relevant European legislation on medical devices and related Commission guidelines. The joint assessment team comprised of Commission experts, national experts and, where necessary, interpreters selected by the Commission's interpretation service.

To date, over 20 voluntary joint assessments have taken place. The interim report of the first joint assessments carried out in ten countries between January and July 2013 can be found at www.nbog.eu. It is expected that a final report will be published in the near future.

The voluntary joint assessment process has been proven to be a useful instrument to gain a global view on the performance of both designating authorities and NBs in the medical devices sector. It is expected that the experience gained will facilitate the implementation of the new joint assessments required by Commission implementing regulation (EU) No 920/2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.

# Regulatory Updates

## NOTIFIED BODY OPERATIONS GROUP

An Notified Body Operations Group (NBOG) meeting was held on the 8th November 2013.

Key items discussed at NBOG included:

- Joint assessment of designating authorities voluntary scheme 2013.
- Discussion & questions relating to the implementation of the Regulation on Notified Bodies (920/2013) and the Recommendation for Notified Bodies (2013/473/EU)
- Discussion on ongoing reviews of guidance documents relating to design changes and quality system changes; change of notified body; renewal of certificates and DA handbook checklists and forms.

A further Notified Body Operations Group (NBOG) meeting was held on the 19th -20th February 2014. Key items discussed at NBOG included:

- Further planning for the mandatory joint assessment scheme for notified bodies under 920/2013 with particular focus on the selection and scheduling of resources and on creating standard documents of the process.
- A discussion was had on various topics arising from the implementation Regulation and Recommendation including unannounced inspections.
- Own brand labelers and the transfer of certificates from one notified body to another were also subject to discussion.
- An updated draft guidance on design changes and quality system changes was presented.

## INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

The IMB have been nominated by the European Commission to the IMDRF Management Committee and will continue to actively participle to develope, enhance and harmonise regulatory systems.

The International Medical Device Regulators Forum (IMDRF) Management Committee met in Brussels for three days from 11th -15th November. The IMDRF is comprised of representatives from medical device regulatory authorities from Australia, Brazil, Canada, China, EU, Japan, Russia, the USA and observers from the World Health Organisation (WHO). Its objective is to harmonise regulatory systems as much as possible.

Key work items ongoing at the IMDRF include work items including the:

- review of the national competent authorities report (NCAR) exchange program
- roadmap for implementation of unique device identification system
- Medical device single audit program
- List of recognised standards
- Regulated product submission; and
- Software as a medical device

The three day meeting included an open 'stakeholder' session on 'Innovation for safety' included representatives from patient groups, healthcare professional, the medical device industry, notified bodies and the clinical research community.

The IMDRF Management Committee met again in San Francisco, USA from 25th to 27th March 2014.

Key work items ongoing at the IMDRF include work items including the:

- Medical Device Single Audit Program
- National Competent Authority Report
- Recognized Standards
- Regulated Product Submission
- Software as a Medical Device
- Unique Device Identification

The meeting included an open Stakeholder Forum and stakeholder interactive workshops that included the Medical Device Single Audit Program, Software as a Medical Device and WHO Global Initiatives. On the final day of the meeting, the IMDRF management committee discussed feedback from the open Stakeholder Forum and workshops and made decisions regarding the current and proposed Work Items.

## MDEG VIGILANCE

A meeting of the Medical Device Expert Group on Vigilance was held in Brussels on 17th and 18th December 2013. Several proposed revisions to and enhancements of the current guidelines on the vigilance system took up a significant part of the agenda, where trend reporting, ISO 19218-1/2 and SNOMED coding standards and device specific vigilance reporting guidance were discussed in detail.

The format of the MEDDEV document itself was also discussed. Revision controls for the guidance document, the forms and the xml schema were agreed.

A device specific guidance document for ablation catheters was reviewed by the group and was referred to plenary session to obtain other stakeholders comments.

The exchange of information amongst member states was also discussed in much detail. These discussions included a review of the NCAR (EU and IMDRF) exchange process. This is an area where the IMB continues to be very proactive.

An update on the current developments of the vigilance aspect of Eudamed was provided.

The need for more coordination amongst member states was highlighted by industry representative and it was noted that a taskforce to look at this area has been identified and would commence their work in early 2014.

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## Regulatory Updates

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The IMB is to chair this group. An update on current work items in the IMDRF program was given with the review of the NCAR exchange being one of the main topics.

### MEDICAL DEVICE EXPERT GROUP

The Medical Device Expert group met over two days on the 15th and 16th January 2014. The key focus of the meeting was to provide updates to the competent authorities on the implementation of the joint plan for immediate actions. A detailed overview and discussion was held on the voluntary joint assessment of notified bodies, progress to date and typical findings. In addition, the mandatory scheme starting 2014 for notified bodies was overviewed. Updates were provided on the coordination of vigilance issues with monthly teleconferences and a discussion was held on the experience to date and types of cases discussed at these teleconferences. The Commission also outlined their plans to formally report on the implementation of the plan in April 2014 which will include an outline of proposed next steps and actions for Member State authorities and the Commission to take.

The Commission updated on the work items of the vigilance working group and provided specific updates on the taskforce on metal on metal hip implants. The SCENIHR preliminary report on metal on metal hip implants is anticipated to be published in February / March 2014. (Post meeting note: the SCENIHR opinion on MOM was published 13th March 2014).

During the plenary session, multiple stakeholders attended including patient groups, healthcare professional associations, notified body associations and the industry. Updates were provided on the joint plan, joint assessments and each of the different medical device working groups.

### COMPLIANCE AND ENFORCEMENT GROUP

The Compliance and Enforcement Group (COEN) met in early February 2014. Key items discussed at COEN included:

- The standard 60601-1 and presumption of conformity.
- The limits for phthalates in medical devices were discussed.
- A checklist for auditing of cleaning and re-sterilisation of re-usable sterile medical devices will be piloted by a number of Member States.

### *IN VITRO* DIAGNOSTICS TECHNICAL GROUP

A meeting of the IVD Technical Group was held on 18th March. At this meeting the priority areas in relation to the future IVD legislation were identified as classification rules, reference laboratories, companion diagnostics, interventional clinical performance studies and common technical specifications (CTS).

A number of proposed amendments to Decision 2002/364/EC on common technical specifications for *in vitro* diagnostic medical devices were also presented for discussion and consultation.

In addition, an update on activities in the framework of the IMDRF was provided. The current work items include the national competent authority report (NCAR) exchange program, unique device identification (UDI), medical device single audit program (MDSAP), software as a medical device (SaMD), regulated products submission (RPS) and recognised standards.

### IMB MEDICAL DEVICE NEWSLETTERS ELECTRONIC CIRCULATION ONLY FROM 2014

*To date, the IMB have been circulating hard copies of the medical device newsletters by post and electronic copies by email. From this edition onwards, the newsletter will be circulated by email only.*

*This newsletter is also be available to download from the IMB 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 vigilance@imb.ie or you can register for medical device updates on the IMB website at www.imb.ie/subscribe.aspx.*

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