IRISH MEDICINES BOARD

news LETTER

MEDICAL DEVICES

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Letter from the Editor

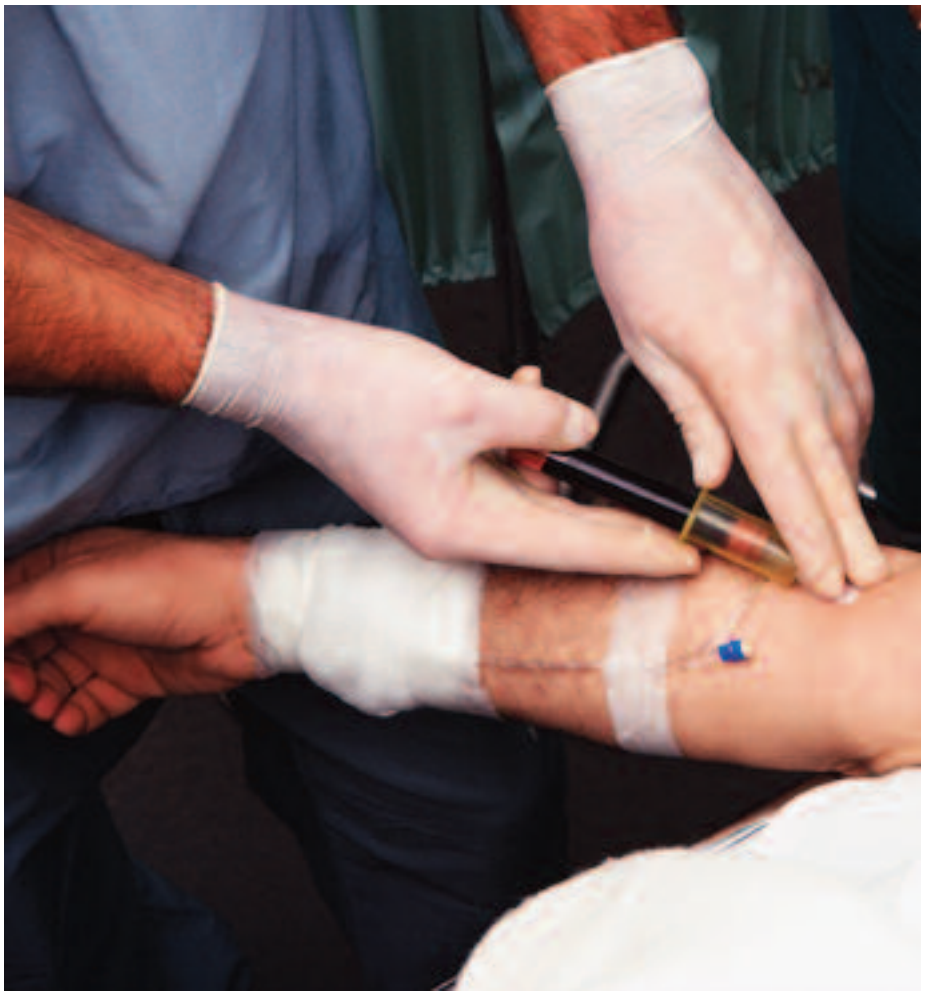
Welcome to the third and final edition of the medical devices newsletter for 2008

This year has been eventful at both a European and national level.

In Europe we have seen a number of new proposals and publications from the Commission. Namely, the proposal for the recast of the medical device directive in May and the publication of a new legal framework for the modernisation of the New Approach in July. In this edition we have an article addressing how this publication will impact the regulation of medical devices.

The activities of the Medical Devices Department during 2007 are summarised in this Newsletter, further details may be found in the IMB Annual Report. In this edition we have articles on the distribution of medical devices and Radio Frequency Identification Device (RFID) technology and the potential for electromagnetic interference with medical devices.

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



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RFID technology and the potential for electromagnetic interference with electrical medical devices

The use of Radio Frequency Identification Device (RFID) technology in healthcare is receiving increasing attention, due to the potential benefits the technology confers for patient safety and asset traceability.

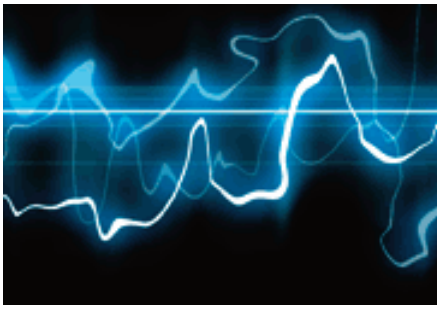
RFID advocates believe that one day everybody will have a radiofrequency identification tag implanted under their skin that details their medical history and can be accessed and updated by healthcare professionals. This application is several years away but the use of RFID technology in healthcare is continually expanding to improve patient safety and deliver improved quality of service.

Current applications of RFID technology in healthcare include

- Tagging of pharmaceutical products to improve supply chain visibility and prevent the distribution of counterfeit drugs.
- RFID tags with temperature sensors to monitor and record the storage temperature of blood bags thus allowing confirmation that the blood has been correctly stored prior to infusion.
- Patient wristbands containing RFID tags that interface with hospital information systems, allowing administrative tasks like admissions, transfers and discharges to be automated
- Asset tracking solutions to improve equipment availability for critical procedures and theft prevention.
- Replacement of conventional identification wristbands on newborn babies with RFID-enabled models to increase safety and security.

WHAT IS RFID?

RFID is an automatic identification and data capture methodology that uses radio waves to transmit information and identify objects. Each object that needs to be identified has an RFID tag attached or embedded in it which can be used to identify and trace devices and to store data. RFID readers wirelessly communicate with the tags to identify the item connected to the tag and may read or write additional data to the tag. It is similar in application to bar code technology but uses radio frequency (RF), instead of optical-based readers, to identify the item being



tracked. Data collected from tags and readers is then passed through communication interfaces (cable or wireless) to host computer systems for processing.

The two essential elements of an RFID system are the RFID tag and the RFID reader.

RFID tags (sometimes referred to as transponders) are small electronic devices that are attached or embedded into the objects requiring identification. The tags generally contain an integrated circuit / chip containing an antenna that can send and receive radio waves. RFID tags can be categorised based on their power source:

- *Passive RFID Tags* do not contain a battery or internal power source. When placed in the electromagnetic field generated by a reader, the tag is powered up and communicates with the reader for verification and exchange of data.
- *Active RFID Tags* have a battery which is used to power the chip's circuitry. This allows the tag to broadcast over larger distances and support additional features over passive tags. However, these tags are generally bulkier and more expensive relative to passive systems.

RFID readers wirelessly communicate with tags. Readers that communicate with passive tags generally require a greater power output compared to active tag systems. There are two types of reader: read only and read / write which can write new information back to a tag that has been equipped with a read / write memory. Readers are becoming increasingly sophisticated to allow integration into IT networks.

RFID operating frequencies can be organized into four main frequency bands: - Low frequency (LF), High frequency (HF), Ultra-high frequency (UHF) and Microwave.

The choice of frequency is dependent on the nature of the RFID application and the read environment. Generally :

- As a tag's operating frequency increases, more data can be transferred.
- Systems that operate in the UHF and microwave frequencies have a longer operating range than LF & HF systems.
- As the frequency increases, the ability to penetrate metals or liquids is reduced.

ADVANTAGES OF RFID OVER OTHER IDENTIFICATION TECHNOLOGIES

RFID is increasingly being considered for identification applications due to its advantages compared with conventional technologies e.g. bar coding:

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- Communication can occur without a direct line of sight, whereas identification technologies such as barcodes must be placed in front of a laser scanner or vision system for the information to be read. As a result, the tag no longer has to be visible on the object thus minimising the need to manually reposition objects for scanning.
- Information can be collected automatically from the tagged object. This can be automatically performed as the tagged object passes by a reader.
- Multiple RFID tags can be read simultaneously, as all tags within the range of the reader can be read instantaneously.
- Unlike printed codes, additional data can be written to the tag.
- RFID tags have the ability to store a larger amount of information than traditional identification technologies such as bar-coding.

IMPACT OF RFID TECHNOLOGY ON MEDICAL DEVICES

Electromagnetic Compatibility (EMC) between RFID systems and electrical medical devices is a critical consideration for the implementation of RFID technologies in a healthcare environment. Electromagnetic Compatibility is defined as the ability of a device to function properly and without introducing excessive electromagnetic energy that may interfere with other devices.

To date, there have been limited incident reports relating to electromagnetic interference (EMI) of medical devices from RFID sources. However the results of a recent study [1] indicated that RFID devices have the potential to disrupt the operation of electrical medical devices resulting in potentially serious incidents. In this study, the susceptibility of forty one separate devices such as defibrillators, infusion pumps, ventilators and pacemaker programmers to electromagnetic interference from RFID systems were tested using a 868 MHz passive systems, a 125 kHz active systems and a 125Khz active tag at a distance of 200cm from the medical device. 123 tests were performed which found that radio frequency identification induced 34 incidents of electromagnetic interference. Of these incidents, 22 were classed as hazardous examples of which include the shutdown and restart of mechanical ventilators and the shutdown of syringe pumps.

Given the critical operations performed by medical electrical equipment, it is imperative that the introduction of RFID systems into healthcare facilities is carefully managed to minimise the risk of EMI to devices. Practices to minimise EMI of devices include:

- Purchase, installation, service and management of equipment to be coordinated to ensure EMC.
- Follow good EMC design and installation practices.
- On-site testing to estimate the minimum distance that should be maintained between potential sources of electromagnetic interference and specific medical devices.
- Radio frequency transmitters should have the lowest possible output power to reliably accomplish the intended purpose.
- When servicing/maintaining medical devices, care needs to be taken to ensure EMI protection remains in place and in good condition.
- Follow the manufacturer's recommendations.

REFERENCES

1. Remko van der Togt *et al.* (2008). Electromagnetic Interference From Radio Frequency Identification Inducing Potentially Hazardous Incidents in Critical Care Medical Equipment. *Journal of the American Medical Association*. **299**(24):2884-2890.

Medical Devices and the Distributor

INTRODUCTION

The term "medical device" covers a wide range of products which distributors may deal with on a daily basis. Currently there are in the region of 500,000 different medical devices that may legally be placed on the Irish market. In addition, Ireland is home to 13 of the world's top 25 medical device companies and this sector is rapidly increasing its Research and Development activities. As the industry is developing, products are becoming more complex and distributors should be aware of the medical devices legislation and its implications, as they have an important role to play in the supply chain of these products from manufacturer to end user. This article looks at the impact of medical devices legislation on distributors and their role in handling of these healthcare products.

MEDICAL DEVICE PRODUCTS

A wide range of products, other than medicines, are classified as medical devices and are used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap. The range of products includes contact lenses, bandages, heart valves, hospital beds, resuscitators, radiotherapy machines, surgical instruments, syringes, wheelchairs, walking frames and orthopaedic shoes - many thousands of items used each day by healthcare providers and patients. The term "medical device" also covers *in-vitro* diagnostic test kits, reagents, calibrators and related software *etc*. Examples include blood glucose testing kits, pregnancy test kits and other self-testing kits, etc.

LEGISLATION

Medical devices placed on the market in Ireland must meet the requirements of the national medical devices regulations: S.I. No. 252 of 1994, S.I. No. 253 of 1994 and S.I. No. 304 of 2001 for medical devices, active implantable medical devices and *in-vitro* diagnostics respectively. The legal responsibility for placing compliant medical devices on the market rests with the manufacturer or their designated authorised representative. In many EU Member States, distributors of medical devices are governed by national distributor legislation. In Ireland, there is currently no legislation specifically addressing the distribution of medical devices. Discussions are ongoing with the Department of Health & Children in relation to development of national legislation. In the interim, the IMB is developing guidance for distributors regarding medical devices. It is also worth noting that harmonised legal control over distributors at an EU level will be enhanced with the changes to the New Approach legislation discussed elsewhere in this newsletter.

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CE MARKING

Medical devices meeting the "Essential Requirements" of the legislation are entitled to bear the "CE marking", which indicates conformance with the appropriate legislation. Once medical devices are CE-marked, they can be freely marketed anywhere in the EEA. Before affixing the CE marking to a medical device, a manufacturer must go through one or more conformity assessment procedures to confirm that the design and / or production are compliant with the essential requirements of the appropriate legislation. The stringency of these procedures depends on the risk classification of the product concerned and the applicable legislation.

THE ROLE OF THE DISTRIBUTOR

The distributor plays an important role in the distribution and management of medical devices to end users and should to be aware of a number of key points relating to medical device as follows:

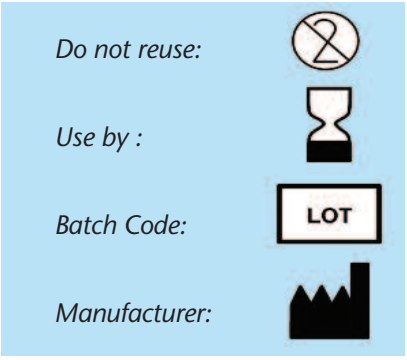
(1) Any medical device sold by a distributor must bear the CE marking.
(2) Distributors should purchase medical devices from reputable sources.
(3) Distributors buying medical devices from a non European-based manufacturer should ensure that there is an authorised representative within the European Community for the products.
(4) Distributors should ensure that devices they handle are stored in the appropriate conditions at all times, including during transportation, and that contamination from other products is avoided.
(5) Devices or device packaging which has been damaged during transport or storage should not be distributed / supplied to the market.
(6) Appropriate records must be kept relating to the receipt and supply of medical devices, including records of the customers to which particular batches of product (or individually identified products) were sent. This information is especially important in the case of a recall or other field safety corrective action by the manufacturer.
(7) If a distributor is notified of a recall of a medical device, they should ensure the specific recall instruction is followed immediately, such as notifying all affected end users, returning fax-backs to the manufacturer and, where instructed, removing, quarantining and returning affected product.
(8) If a distributor becomes aware of an incident with a medical device, they should promptly advise the manufacturer, as the legal responsibility for follow-up of an incident lies with the manufacturer of the medical device.
(9) A distributor who is assembling system and procedure packs (e.g. theatre packs) becomes a manufacturer under the medical devices legislation. They must comply with the requirements of the legislation e.g. registration with the IMB and the preparation of a legal declaration.
(10) Distributors suspecting counterfeit medical devices should notify the IMB and provide as much information as possible. Where possible samples should be provided to the IMB.
(11) The distributor may also wish to advise the IMB if they have serious concerns relating to medical devices. A user report form is available on the medical devices section of the IMB website. An online system for reporting of incidents is also available.

LABELLING OF MEDICAL DEVICES

All medical devices must be labelled in accordance with the requirements of the legislation. The following are examples of the requirements that must be on a medical device label:

(1) Name and address of the manufacturer
(2) For devices imported from outside the European Community the name and address of the legal Authorised Representative for the manufacturer
(3) The details necessary for the user to be able to identify the device and the contents of the packaging
(4) The CE mark (this should be accompanied by a four digit number if a notified body has been involved in the conformity assessment)
(5) The date of manufacture and the expiry date if applicable
(6) The batch code, preceded by the word "lot", or the serial number
(7) The word "sterile" if the device is a sterile product
(8) Any special storage and handling instructions
(9) Where appropriate an indication that the device is for single use.
(10) Any warnings and/or precautions to take
(11) Where applicable, the method of sterilisation.

Where appropriate, the above information may take the form of symbols. This is of particular relevance where the medical device is small and there is insufficient space on the label for all the information. Examples of common symbols for medical devices are shown below:



Staff Update

The Medical Devices Department is delighted to announce that Ms. Sharon Carty has joined the medical devices team in recent months. Sharon takes up the position of administrator for the class I / IIa product unit within the Post-market Evaluation Section

New Legal Framework for modernisation of the New Approach

The medical device directives are part of a series of different pieces of legislation relating to diverse industry sectors within the Community, referred to as 'New Approach' legislation.

On 23rd June 2008, Member States adopted a New Legal Framework for Modernisation of the New Approach for marketing of products in Europe. It is hoped that with these changes, trade barriers will be reduced for small and medium enterprises, while maintaining and enhancing the safety of products placed on the market.

This package of legislation consists of two regulations[1, 3] and one decision[2] which will impact on a wide range of industrial sectors, including some which do not currently fall under EU legislation. The question is how will these new legal texts impact the medical device industry?

(1) REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93.

Chapter II of this regulation stipulates the accreditation of conformity assessment bodies e.g. Notified Bodies for medical devices. The aim of this regulation is to enhance the confidence in, and quality of, products through further harmonisation of conformity assessment bodies across the EU.

The Regulation states that the accreditation of Notified Bodies be conducted by nationally appointed accreditation bodies, unless the Member State can provide documented evidence that accreditation is not required for the verification of the competence of the conformity assessment body. In this instance, the Member State must be able to demonstrate that existing measures are sufficient. The Regulation lays out the responsibilities of a national accreditation body whereby a conformity assessment body will be issued an accreditation certificate verifying competence for specific assessment activities.

The activities and performance of national accreditation bodies will be monitored by a single organisation at European level in much the same way as designating authorities are monitored by peer review by the Notified Body Operations Group (NBOG). The European body monitoring accreditation is to be known as the European co-operation for Accreditation (EA).

It should be noted that, with respect to notified bodies for medical devices, accreditation is not a replacement for the designation and surveillance role of a competent authority/designating authority, such as the IMB. Rather, accreditation is an additional measure taken to help ensure harmonisation of Notified Bodies for medical devices across the European Union.

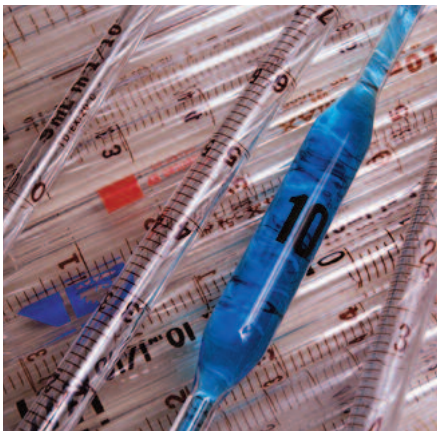
Chapter III deals with market surveillance and control of products entering the community market.

Products such as medical devices fall within the scope of Articles 16 to 26 of this Regulation.

This Regulation allows for additional measures for medical device market surveillance such as:

- new requirements for increased co-operation and communications between Member States and the Commission;
- the extension of market surveillance activities to all economic operators (such as importers and distributors);
- a requirement for Member States to alert users of hazards relating to devices.

In the case of market surveillance, if an industry sector has existing provisions in legislation, the principle of "*lex specialis*" shall apply, i.e. if the provision in the medical devices legislation are stronger and are considered to provide a higher level of market surveillance then these shall apply or *vice versa*.



This Regulation was published on 14th August 2008 in the Official Journal of the European Union and came into force on 3rd September 2008. The Regulation will apply from 1st January 2010.

(2) DECISION No. 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

This Decision provides a common legal framework in the form of a "toolbox" of measures for use. Definitions and general obligations for economic operators (manufacturers, authorised representatives, importers, and distributors) are outlined. Rules and procedures for areas such as CE marking, market surveillance, conformity assessments and market place safety are also presented. The provisions of this Decision can be used immediately. In time, these measures can then, if required, be incorporated into future revisions of the relevant legislation i.e. medical devices directives.

This Decision was published on 14th August 2008 in the Official Journal of the European Union. The provisions of the Decision can be used immediately but to be operational they need to be fed into existing Directives when they are revised.

(3) REGULATION (EC) No. 764/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

This regulation is based on the principle of mutual recognition to ensure the free movement of goods within the European market. However, this Regulation shall not apply to products which are already subject to mutual recognition, such as medical devices.

The impact of these new pieces of legislation on the regulation of medical devices needs to be fully considered at a European level, involving all relevant European medical device working groups.

Medical Device Department 2007 Statistics

2007 was a busy and productive year for the Medical Devices Department. During 2007 the Medical Devices Department underwent a significant restructuring and business process reengineering program. Monitoring of safety issues on the market place continued to be a key day-to-day activity.

Significant activity took place in the areas of vigilance, compliance, classification and a number of complex clinical investigations were reviewed.

VIGILANCE

A total of 840 vigilance reports were received and assessed in 2007, which represented a decrease on the number of reports received in 2006 as seen in Figure 1. This decrease was due to multiple factors including the continued low numbers of Competent Authority reports being circulated by other Member States.

Class IIb general medical devices and general category *in-vitro* diagnostic medical devices (IVDs) represented the largest number of reports received, at 243 and 159 respectively. An increase in the number of reports relating to Class I devices was also noted.

Single use, non-active implantable and electro-mechanical medical devices represented the most common reports received per product family as highlighted in Figure 2. As shown in Figure 3 the largest number of IVD reports related to clinical biochemistry and haematology devices devices.

During 2007, the IMB received 333 Field Safety Corrective Actions relating to medical devices that directly impacted the Irish Market. These resulted in a combination of 224 product removals, 119 Field Safety Notices, 59 software upgrades and 29 hardware modifications. The implementation of corrective actions was closely monitored by the Medical Devices Department.

NOTIFIED BODIES

The IMB conducted three surveillance audits on the Irish notified body, the National Standards Authority of Ireland (NSAI), during 2007. Of these, two took place at NSAI's offices in Ireland and the third at NSAI's office in the United States of America.

During one of these audits of NSAI,

Figure 1: *Number of Vigilance Reports Received between 2000 and 2007*

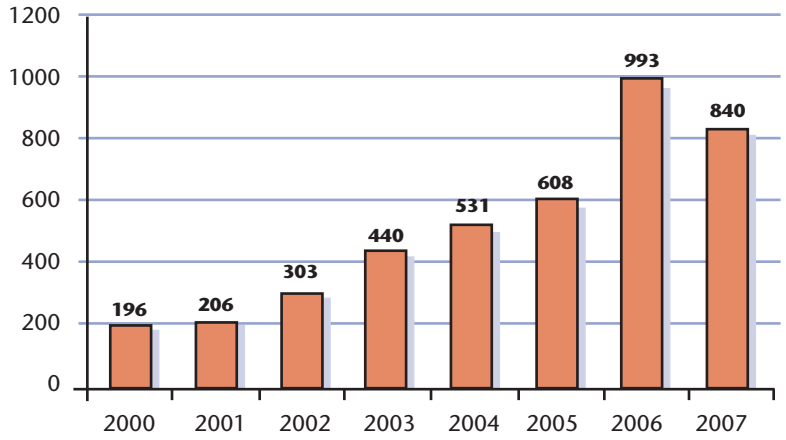


Figure 2: *Family Groups of Devices Implicated in Vigilance Reports in 2007 – General Medical Devices and Active Implantable Medical Devices*

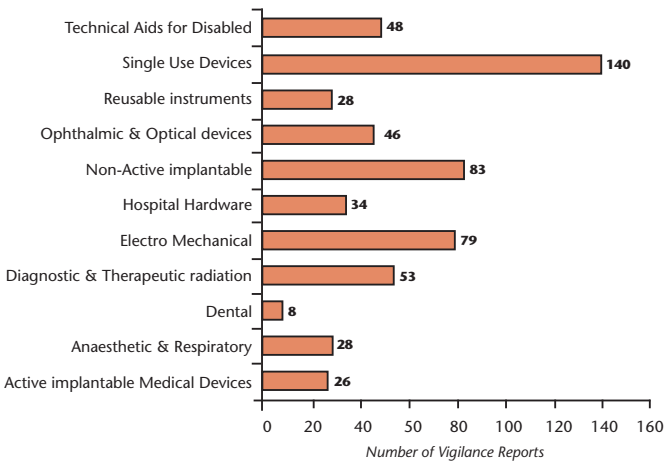
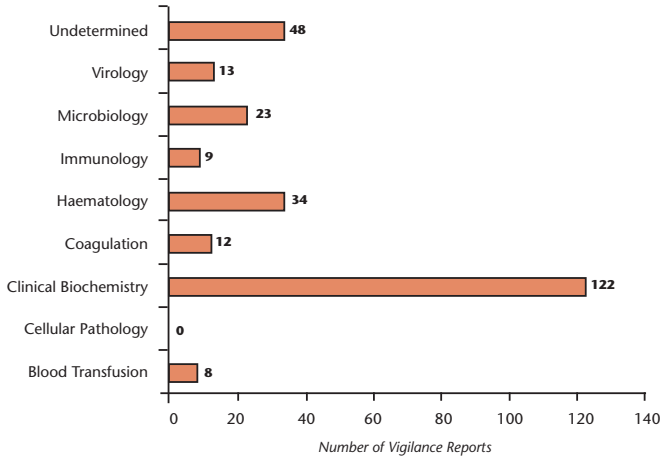


Figure 3: *Family Groups of Devices Implicated in Vigilance Reports in 2007 – In-vitro Diagnostic Medical Devices*



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the IMB's performance was reviewed by colleagues from the Danish Medicines Agency. This peer review system established by the European Notified Body Operations Group (NBOG) is a useful tool to help ensure a harmonised approach to notified body audits.

In addition, one observed audit of a NSAI auditor was undertaken by the IMB.

CERTIFICATES OF FREE SALE

In 2007, 432 Certificates of Free Sale for medical devices were issued, which represented a 24% increase over 2006 figures.

REGISTRATIONS

There were 261 new notifications/ amendments to the register for medical devices in 2007. A total of 139 *in vitro* diagnostic medical devices and 122 general medical devices were registered. The number of new device manufacturers / organisations registered was 32.

CLINICAL INVESTIGATIONS

During 2007, 3 new clinical investigation applications for general medical devices and amendments to 4 previous clinical investigation applications were received under S.I. No. 252 of 1994. One application for use of a device on compassionate grounds was also received.

CLASSIFICATIONS

50 classification queries were received in 2007. 54% of the queries originated from other Competent Authorities and 20% originated from other external stakeholders. A number of these queries require further discussion at the European Medical Devices Expert Group (MDEG) Classification/Borderline Working Group.

POST MARKET SURVEILLANCE ACTIVITIES

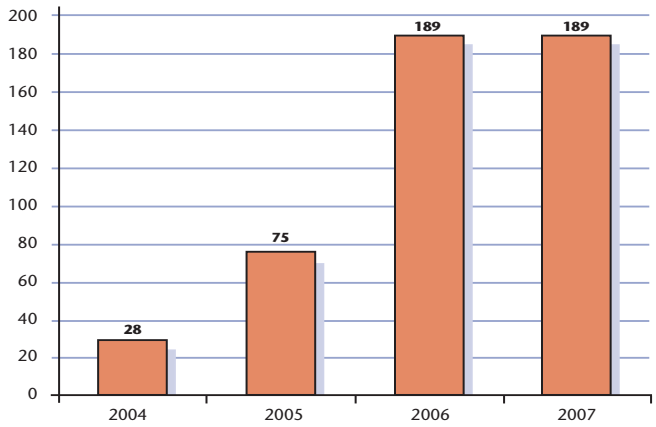
During 2007 there were 189 compliance cases opened, which equalled the figure for 2006 as seen in Figure 4. The majority of compliance cases (65%) related to the withdrawal or suspension of CE certificates by notified bodies throughout Europe for a variety of medical devices. Missing or incorrectly affixed CE marking accounted for another 6% of cases. Other problems identified and investigated as part of compliance cases in 2007 included labelling, classification and registration issues. Requests for assistance from other European Competent Authorities accounted for another 4% of cases.

The proactive compliance activities relating to procedure packs and continuous positive airway pressure machines (CPAP) were concluded in 2007. One of the proposals arising from these projects was to develop legislation around regulation of distributors of medical devices. Discussions are ongoing with the Department of Health and Children in relation to development of national legislation.

The second phase of the proactive compliance activity relating to procedure packs focused on medical device systems during 2007. A review of the IMB register was completed to identify systems manufacturers and a number of compliance visits were conducted in 2007. It is expected that this activity will be completed during 2008.

In 2007, four post market surveillance audits were carried out. Two manufacturers were audited following issues arising from the market-place, while the remaining two audits were proactive post market surveillance audits. The program of custom-made device audits continued in 2007 and a total of twenty audits took place.

Figure 4: *Number of Compliance Cases Opened during 2004 to 2007*



Regulatory Update

EUDAMED WORKING GROUP MEETING

A meeting of EUDAMED working group relating to the EU medical device database system took place during October in Brussels. Discussions centred on analysis of the current system and on the development of an improved and updated version, EUDAMED II. It was stated that future access to the EUDAMED application will be through the EU Commission's Enterprise Portal. An update on the translation of the Global Medical Device Nomenclature (GMDN) codes into the official languages of European Union was given. The translations are ongoing and are expected to be completed by 2010.

A small sub-group meeting of the Clinical Evaluation Task Force (CETF) also took place relating to the development of the clinical module of EUDAMED. Such a system would allow for exchange of information on clinical investigations notified, particularly in circumstances when Member States have raised an objection to an investigation or an investigation has been withdrawn, suspended or terminated.

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IVD TECHNICAL GROUP MEETING

A working group comprised of Commission services, Member States representatives and Industry experts met in Brussels during October to discuss the most appropriate way to address the issue of Common Technical Specifications (CTS) for variant Creutzfeldt-Jakob Disease (vCJD) assays.

Whilst recognising that CTS are necessary, the group felt that it would be premature to establish detailed requirements at this time. Substantial scientific progress is awaited and needed in this area, and fixing detailed requirements in the CTS at this time would create a constant need for updating.

Therefore, it is proposed to keep the CTS relatively general and to develop a guidance document reflecting the state of knowledge today, thereby allowing for easier updates. The content of the guidance document can then be moved into the CTS once scientific knowledge in this area has become more established.

MDEG VIGILANCE WORKING GROUP

A Medical Device Expert Group (MDEG) Vigilance meeting was held in September. At the meeting, manufacturer representatives provided feedback on implementation of the revised MEDDEV by Competent Authorities throughout Europe. An update was given on the XML form, which manufacturer's can use to report incidents to Competent Authorities. A pilot using this XML form will take place over six months, beginning January 2009. An update was also provided in relation to the ongoing projects of GHTF Study Group 2.

E-LABELLING

The second meeting of the e-labelling ad-hoc group took place in early November in Brussels. The group was established to examine the issues involved in implementing alternative forms of labelling and electronic Instructions For Use (IFU) for general medical devices. The discussion focused on developing a draft proposal detailing the key considerations for e-labelling of general medical devices. The types of general medical devices that may be suitable for e-labelling were considered e.g. implantable medical devices, devices operated from computer networks, the risk management approach required and implementation issues.

CLINICAL EVALUATION TASK FORCE

The Clinical Evaluation Task Force (CETF) met during September. The group, having completed its original terms of reference, is to become a permanent EU working group with new terms of reference. It is likely this new group will be called the Clinical Investigation and Evaluation Working Group. Issues discussed at the meeting included the final draft guidance on clinical investigations of coronary stents, reporting mechanisms for serious adverse events occurring during clinical investigations and the development of the clinical module of the EU medical device database (EUDAMED) for exchange of information between Competent Authorities on clinical investigations.

CLASSIFICATION & BORDERLINE WORKING GROUP

The MDEG Classification & Borderline working group met during September. The key topic on the agenda was the revision of the guidance borderline MEDDEV 2.3/1 on demarcation between the medical devices directives and others such as the medicinal products directive. This MEDDEV provides guidance on classification of products which occupy the borderline between different regulatory regimens e.g. medical devices and medicines. The Manual on Classification & Borderline which contains consensus classifications positions reach by the group was updated after the meeting and is available for download from the EC website.

COMPLIANCE AND ENFORCEMENT WORKING GROUP

The EU Compliance and Enforcement working group (COEN) met in September. The meeting was attended by twenty Member States where items discussed included the work programme of COEN for 2009, draft guidance on the use of legal tools for market surveillance. Review of protocols for specific co-ordinated market surveillance projects and specific cases of concern for Member States. The impact of the New Approach legislation will be discussed further in January in relation to its impact on the work programme of COEN.

Upcoming Events:

The Electro Technical Council of Ireland in conjunction with the Biomedical Engineering Association of Ireland, & IMSTA are hosting a one day conference on Medical Equipment Quality Management. See below for more detail:

MEDICAL EQUIPMENT QUALITY MANAGEMENT

Your Responsibilities and Opportunities Explained
(Can you Risk not knowing!)

One-Day Conference – Thursday 26th March, 2009, 09.00 – 16.30.
Post Graduate Centre, Trinity College, St James's Hospital, Dublin.

Organised by the Electro Technical Council of Ireland in conjunction with the Biomedical Engineering Association of Ireland, & IMSTA.

For further details please email peter.grainger@hse.ie.

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