IRISH MEDICINES BOARD

MEDICAL DEVICES
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Letter from the Editor

Welcome to the final edition of the medical devices newsletter of 2006.

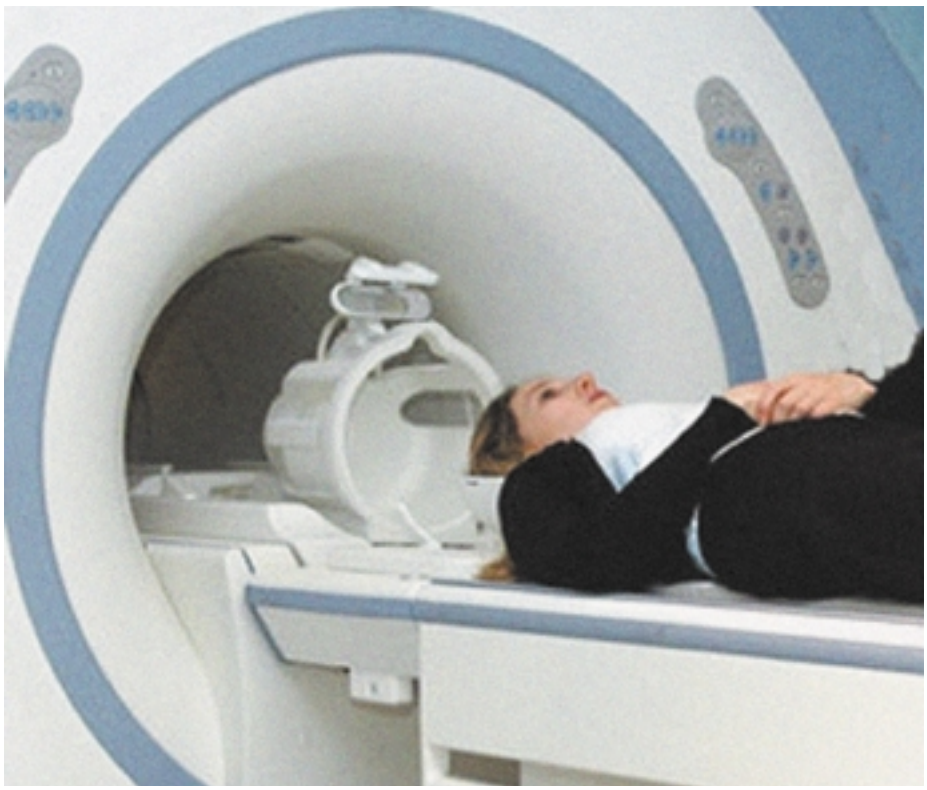
In this edition we provide information in relation to the state of play surrounding the discussions on the proposed amendments to the Medical Device Directive 93/42/EEC that are taking place at the EU Council and at Parliament level. Progress has been made during the Austrian and Finish presidencies but more work remains to be done during the incoming presidency of Germany.

We also bring to the attention of our readers a very useful report in relation to 'Medical Devices Competitiveness and Impact on Public Expenditure', which was published by the European Commission. This report provides information on the input of medical devices to health systems in Europe and on the importance of it as an industry in Europe.

We are also pleased to have an article in relation to the Vigilance Committee in Beaumont Hospital, which was appointed in 2003. This Committee took an active part in the Dublin Area Teaching Hospitals pilot regarding a model for a hospital vigilance committee / system. This article outlines the progress made and the benefits obtained from the model / system.

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

Finally, as this is the last newsletter for 2006, we would like to wish our readers a happy and peaceful Christmas.



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Medical Device Directive – The European Perspective

What is the current state of play at European level with regard to legislation for medical devices?

We currently have three working Council Directives dealing with medical devices, 93/42/EEC on medical devices, 93/385/EEC on active implantable medical devices and 98/79/EC on in-vitro *diagnostic medical devices.*

Much has changed even within such a short period. The developments in the industry have been rapid, particularly in combination medical devices and tissue cell based medical devices. Clinical trials have grown in number and type. The number of products that can be defined as falling between cosmetic and medical categories has likewise increased. The range of custom-made devices has grown. Issues in relation to vigilance and enforcement are always under review. It seemed logical that these issues needed to be addressed and while that was being done there could be a consolidation of the Directives to make them more relevant and clearer in focus. Since the1990s experts from the various Member States have been meeting regularly through the Medical Device Expert Group (MDEG) forum and the bi-annual Competent Authority meetings interpreting the older Directives while flagging the need for a newer review at Council level. We have also seen in the same period a number of new Member States joining the EU and particularly in the case of Eastern Europe bringing very different experiences of medicines and devices in general.

It is against this background that the EU Commission initiated a public consultation process in May 2005. The most significant proposals received, related to the need for greater transparency in identifying products, conformity assessment, clarification of clinical evaluation requirements, post market surveillance compliance of custom-made devices and alignment of Directive 90/385/EEC with the later Directives. Following this consultation the Commission launched its proposed revision of the Directives. As part of this process a Council Working Party was set up to examine and improve the existing Medical

Devices Directives and a Council Working Party on Advanced Therapies was established. The Commission also proposed a review of the New Approach Directive (covering a number of Directives dealing with consumer safety and enterprise development), aimed at a more harmonized approach to dealing with legislation. A key development in this process was the development of the comitology procedure which gives greater involvement to the European Parliament in committee work.

The Council Working Party on Medical Devices has combined a wide range of technical, legal and administrative experts who generally travel from their respective countries for the meetings. The Member State that holds the presidency chairs the meeting and the European Commission and Council secretariat

are also represented at the meetings. The Working Party had its first meeting under the Austrian Presidency in January 2006 and these meetings have continued through the Finnish Presidency to date. Among the areas that have been examined are the definitions of a medical device, the classification rules, the safety of borderline products, the level and time scale of certification required with products, reprocessing of medical devices, reporting systems, the safety of clinical trials and dealing with combination therapies.

The Council Working Party on Medical Devices cannot be viewed in isolation. There is also the Council Working Party on Advanced Therapies and a number of other Directives including the Machinery Directive and the Cosmetic Directive, which need to be considered. The participants of the Medical Devices Working Party are aiming to provide clarity with respect to the borderline with other Directives while at the same time ensuring as far as possible that products don't fail to be regulated.

The proposed changes to the Medical Device Directive are part of a co-decision procedure involving input from both the European Council and European Parliament. The European Parliament has tabled a large number of amendments to the proposal with a strong focus on reprocessing of medical devices and the use of toxic substances within the devices. These amendments are being examined at the EU Council Working Party. The aim is to achieve a compromise but not at the expense of compromising safety or creating legal ambiguity.

The Irish delegation from the Department of Health and Children works very closely with the Irish Medicines Board (IMB) and there is a

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common approach taken on the issues. With such a large medical device industry, we are very much aware of how crucial decisions at Working Party level are for the industry here.

At this stage, we are coming to the end of the Finnish Presidency. Germany takes over the presidency in January 2007. There have been considerable draft text changes made to the original Directives and consensus, where possible, achieved on a number of issues. Over the entire year 2006 there have been up to eighty working papers produced and fifteen meetings held. The definition of a medical device has been re-examined with a greater emphasis on the 'medical purpose' of the product. The whole process of clinical evaluation has been strengthened, particularly improving technical documentation and the prevention of 'shopping around' by manufacturers looking for easier portals into the European market. A greater level of Member States communicating between each other on the outcome of clinical investigation review has been proposed. Similarly there is a proposal for more stringent adverse event reporting during clinical investigations of products. A number of Member States were concerned about the retention of technical documentation by manufacturers and the issue of timescales for keeping such documents has been reviewed. Other areas where there has been good progress include he definition of a medical device as 'single use', legislating for custom made devices, assessment of design dossiers and improvements in transparency, particularly for the consumer / patient.

The issue of combination therapies, particularly devices with viable cells, has been debated both at this EU Council Working Party and the EU Council Working Party for Advanced Therapies. The correct regulatory framework for such products, we feel, is probably the single most crucial issue that has been faced by the Working Parties. There is considerable debate on whether such products should be dealt with through a medicines or a medical device framework. The products themselves are new and innovative and often involve a medical device structure containing viable cells. Much of the debate has centred around whether such viable cells can be viewed as ancillary to the device or whether the principal mode of action should decide the correct regulation. There is no doubt that the two Working Parties are committed to ensuring these products are safe before going on the market place. The key question is which framework offers the best safe option.

Finland is aiming for a first reading of the amended text in European Parliament. This is an ambitious target and there are outstanding key areas still being addressed. Whatever the timescales, the Council Working Party are anxious to get it right. This is not about creating unnecessary bureaucracy or red tape. Indeed the European Commission has indicated that they view less red tape leading to better economic growth. At the end of the day if we achieve enhanced public safety along with clear signposts for the industry to help them get their products on to the market, it will be a job well done.

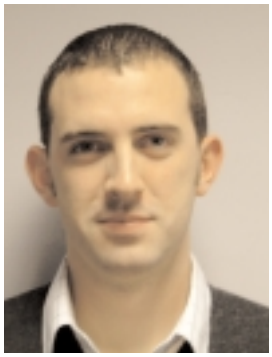
SEAN HOWLETT
Department of Health and Children

Staff Update

The Medical Devices Department is delighted to announce that Ms. Orla Goggin and Mr. Paul Scannell joined the medical devices team in September 2006 and November 2006 respectively.

Orla graduated from UCD in 2003 with a B.E. in Electronic Engineering. During her final year, Orla worked on developing an aid for the diagnosis of carpal tunnel syndrome. She continued her studies at TCD and completed the M.Sc in Bio-engineering in 2004. Her thesis involved the development of a user interface for tibial stress fracture prediction. Prior to joining the IMB, Orla gained industry experience with a major multinational manufacturer of orthopaedic implants, where she spent eighteen months on a graduate development programme supervising production and participating in maintenance, quality and engineering projects. Orla has been appointed into the role of Technical Officer primarily to support the compliance and auditing function of the Medical Devices Department

Paul graduated from mechanical engineering, Trinity College, Dublin in 2002. He continued his studies at the Trinity Centre for Bioengineering and completed a PhD in 2006. The subject of his thesis was the development of mechanoregulation algorithms to predict peri-prosthetic bone adaptations following a total hip replacement. Paul will be working with vigilance issues regarding general medical devices and active implantable medical devices.



The Beaumont Hospital Vigilance Committee

The Vigilance Committee in Beaumont Hospital was appointed at the end of 2003, and had its first meeting as a committee in early March 2004. In addition to medical device alerts, hospital incidents involving medical devices are also referred to this committee. The membership of the committee follows the recommendations of the IMB vigilance pilot document and meets every two months. The committee membership is, as follows:

Chair
Ms. Margaret Swords, Deputy CEO

Vigilance Officer
Dr. Josette Galligan, Senior Physicist / Clinical Engineer
Mr. Alan Boyle, Supplies Manager
Mr. Paul Gregory, Supplies
Ms. Suzanne Dempsey, Divisional Nurse Manager
Dr. Lesley Malone, Chief Physicist
Ms. Stephanie O'Gara, Health & Safety Co-ordinator
Ms. Marion McCarthy, Insurance / Claims Coordinator
Mr. Peter Jacob, Chief Pharmacist
Mr. Pauric Reilly, Pathology Manager
Dr. Paul Brennan, Vice-Chair Medical Executive
Mr. Paul Nadine, Technical Services Manager

All medical device alerts and hospital incident reports are sent to myself as the hospital's Vigilance Officer for medical devices, as the point of contact for the hospital, and in my absence to the Co-Vigilance Officers. Our Co-Vigilance Officers are Alan Boyle and Paul Gregory, chosen as they are often my first point of call when determining whether we have a certain medical device or not, and if so, where. All medical device alerts received are logged on a simple spreadsheet database, with the date received, whether the alert is for information purposes or action, the make and model of device, and whether it is in use in the hospital. If the alert is for information purposes only, it is sent to the appropriate managers, who are then responsible for passing on the information to the relevant staff in their area. We try as much as possible to have one point of contact to ensure that nobody is left out, such as the nursing representative on the committee for all alerts relevant to

nursing, particularly when there is quite a lot of movement of staff. If an action is called for, the alert is sent with a close-out form to be signed by the designated action person. In general all medical device alerts are dealt with as they are received, unless they require more discussion at the committee meeting. The date the alerts are sent out, the action person, and close-out date are also recorded for quick reference purposes on the database. All medical device alerts are accessible on the hospital intranet, as are the minutes of the committee meetings. At the committee meetings we work through new and outstanding alerts systematically until they are completely signed off, either through a close out form or in the minutes.

Hospital incidents involving medical devices are either a device issue or a procedural issue. We ask that all devices involved in an incident are kept in isolation with a non-serviceable tag, and with all the accessories and disposables that were used with it. The asset number or serial number of the device, as well as its make and model, should also have been recorded on the incident form. When they have been cleared by a member of the Medical Physics and Clinical Engineering Department and in some cases Health and Safety, they can then be collected by the supplier. In some cases, such as that of a disposable device or set, they may be collected immediately by the supplier. The committee is then kept informed of the progress and the results of the manufacturers investigation. If it is clearly a medical device fault, then this is reported to the Irish Medicines Board Medical Devices Department in the form of an adverse incident report. Procedural issues are either referred back to the relevant area, or hospital committee, with recommendations from the Vigilance Committee.

The role of Vigilance Officer takes up on average two hours a week of my time, though at the start this was considerably more as I spent a lot of time explaining the process to individuals while trying to get close-out forms signed off. Early on I was invited to speak at the senior nursing executive weekly meeting, which clarified a lot of issues and where the point of contact for nursing was agreed. Similar information sessions with the main groups in the hospital could therefore also be valuable in explaining the vigilance system and getting staff on-board. We also used our hospital's weekly staff newsletter to post a brief explanation of the medical device vigilance process. We will be reviewing the possibility of rotating the post of Vigilance Officer within the committee, as there are currently no additional resources provided for with this post. The work of the Vigilance Officer also requires approximately two hours a week of clerical support, which in our case is currently borne by my department's secretary.

Though medical device alerts regarding major faults and recalls have always been correctly addressed prior to the introduction of the vigilance system for medical devices, the process was not documented. In some cases there was repetition of work, particularly if more than one alert was posted for the same device and issue from each agency, such as one each from the FDA, the MHRA, and the manufacturer. This vigilance system for medical devices ensures that the process of receiving and addressing medical device alerts is documented, focused to the relevant people, and is a closed loop. There is now also a closed loop system for the hospital incident forms, with staff getting feedback and actions documented. The fact that more and more staff are regarding the Vigilance Committee as a resource, and not just more paperwork, is a good indication of its success and of its value.

DR. JOSETTE GALLIGAN
Senior Physicist / Clinical Engineer
Vigilance Officer for Beaumont Hospital

Medical Devices Competitiveness and Impact on Public Health Expenditure

The recently published report on *Medical Devices Competitiveness and Impact on Public Health Expenditure* prepared by Competitiveness, Markets and Regulation, Rome (CERM) and the University of Florence for the Medical Devices Sector of DG Enterprise provides an analytical overview of the state of the European Union medical device industry with regard to the following aspects:

(a) The impact of innovation in medical devices on health costs and expenditure;
(b) The innovativeness of the European medical device industry;
(c) The competitiveness of the European medical device industry as compared to that of the United States and Japan.

This report is broken down into the following chapters:

1. Introduction and Structure of the Study
2. The Medical Device Marketplace at Macro Level
3. The Medical Technology – Health Expenditure Link: Theory and Empirical Evidence
4. Economic Evaluation of Medical Devices: Some Case Studies
5. Competitiveness, Productivity and Industry Structure
6. R&D Innovation
7. Statistical Shortcomings for the Sector: Analysis and Proposals
8. Policy Recommendations

MEDICAL DEVICE INDUSTRY

The report found that the worldwide medical device market in 2003 was valued at over €184 billion. The US constitutes the largest world market for medical devices, representing a world share of 38-43%. The European market, at 30-34% of the world share, is the second largest market; here the two main national markets, namely Germany and France, account for half of its size.

Regarding medical devices input into the health systems in Europe, 6.2% of total health expenditure goes on medical devices. This percentage is higher for new Member States (7.6%) than for the EU-15 aggregate (5.4%). As compared to Europe, the share of medical devices over total health expenditure is lower both in the US and in Japan (about 5.1%).

Medical devices are also an important part of the European manufacturing sector. The industry contributes to 1.3% of total EU-25 manufacturing employment and has shown a dynamic performance also during the recent years of economic slowdown. In 2001 and 2002 medical device production in the EU-25 recorded strong growth rates (12.5% in 2001 and 7.8% in 2002), well above the average of the manufacturing sector (1.8% and 0.3%). However, the report states that European industry is lagging behind the US, both in terms of competitiveness and innovativeness.

Interesting differences emerge from the analysis of the industry structure. The European industry is characterised by a larger share of small firms than compared to the US and Japan. The medical device industry is extremely diversified and European countries turn out to be net exporters of technologies related to implantable devices, therapeutic equipment and supplies. When comparing R&D of the European and US firms, the US has a leading position in terms of patent and publication counts.

The report also discusses innovation in medical technology and devices and noted that it appears correlated to the trend of improved health outcomes recorded for most countries in the world where patients are able to live longer, be healthier, and where they can be productive for longer over their lifespan.

SHARE OF DEVICE BY CLASS

The report reviewed the share of devices by class produced by each country classified according to their level of risk. The proportion of class I (low risk devices) is greater than 80%, constituting the main medical device industry focus in Poland, the Czech Republic, Iceland and Switzerland. Austria and Ireland are the European countries with the largest share of products classified into class III, the class with higher-risk devices requiring clinical trials. The result for Ireland is interesting and is associated with a large ownership of US-based corporations of Irish manufacturers. Nowadays the report tells us that almost 50% of the Irish manufacturing employment is in foreign-owned firms (61% of them being US firms), as compared to an average for the other European countries (EU-15) of 19%. Medical and optical equipment are among the sectors where foreign industry predominates.

POLICY RECOMMENDATIONS

The report makes a number of key policy recommendations, which are:

1. Member States and the European Commission should clearly state the key policy objectives and address the policy options in their full complexity and trade-offs

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Regulatory Update

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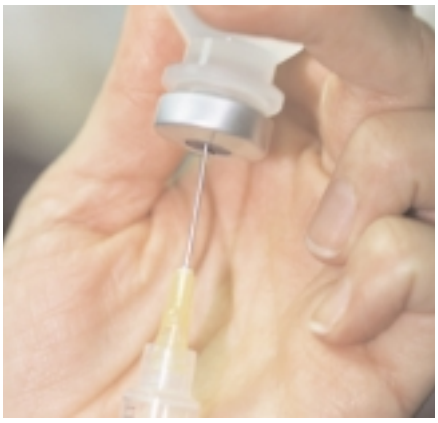
2. Member States should enhance their coordination to define concerted policies in order to send consistent signals to the market, reduce uncertainty, orient R&D and innovation toward cost-reducing or affordable technologies
3. Members States should enhance the use of evidence-based medicine and Health Technology Assessment (HTA) analysis as an input to: (a) their coverage policies; (b) their policies aimed at incentivating and strengthening research, development, and innovation in medical devices
4. The Commission should reinvigorate the process of coordination and harmonisation of national Health Technology Assessment processes and experiences
5. Member States should diversify the financial structure of medical expenditure as a means to ease the policy trade-offs and to achieve financial and social sustainability
6. Member States and the European Commission should promote and establish a coherent statistical framework for the analysis of the competitiveness and innovativeness of the medical device sector in Europe

The complete report can be accessed at the following website: http://ec.europa.eu/enterprise/medical_devices/c_f_f/md_final_report.pdf.

Two meetings of the EUDAMED Working Group were held recently in September and in November respectively. At the first meeting, the European Commission gave a presentation on the status of EUDAMED to-date and provided an update into what has been done concerning EUDAMED in the last two years. After an analysis of the EUDAMED database, the Commission's Informatics Unit presented a possible future development of the access structure of the system. The working group members commented about the procedure and the technical aspects.

The translation issue of the GMDN coding system was also discussed. Availability of national translations and possibilities for implementing these translations in the GMDN web database were also considered. The GMDN Agency gave a presentation on the structure and usability of their website (the link for the website is www.gmdnagency.com). This website provides the link for manufacturers and Member States to register to allow them to become a member and have access to the GMDN and frequent code updates.

At the second meeting, the Commission informed that the implementing measure in EUDAMED cannot be adopted until the GMDN has been translated into the Community languages. However, the Commission again confirmed that if a Member State, such as Ireland, uploads registration data from their National database into EUDAMED, then manufacturers and authorised representatives who have registered their *in-vitro* diagnostic medical devices with such Member States have fulfilled their obligations under Article 10 (6) of the *In-vitro* Diagnostic Medical Devices Directive and, therefore, are



not required to provide a notification of the placing on the market of their devices to each Member State concerned by the placing on the market.

A meeting of the E-labelling Working Group took place in October. The draft MED.DEV on E-labelling of *in-vitro* diagnostic medical devices was considered. It was agreed that the text proposed was acceptable with some minor changes. The draft MED.DEV will now be sent to the Medical Devices Expert Group (MDEG) meeting in December 2006 for consideration. E-labelling guidance in relation to general or active implantable medical devices will not be considered until the legal basis for E-labelling of such devices is clarified in the proposed amendments to the relevant legislations currently under discussion at EU Council and EU Parliament.

The proposed changes to MED.DEV 2.12-1 rev 4 April 2001 on the medical device vigilance system are at an advanced stage. The Vigilance Working Group aims to bring the proposals to final conclusion at its meeting in December. It is envisaged that the proposed text will be discussed at the MDEG in December 2006.

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