IRISH MEDICINES BOARD

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IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2 TEL: 01 676 4971 FAX: 01 676 7836 EMAIL: MEDICALDEVICES@IMB.IE

Letter from the Editor

Welcome to our Special Edition of the Medical Devices Newsletter, focusing on the proposals for new Regulations on medical devices.

In September 2012, the European Commission adopted proposals to introduce two Regulations to strengthen the European Union's medical devices regulatory system and to standardise the application of rules throughout the European Union. The proposed medical device Regulation will replace the current directives on medical devices and active implantable medical devices (Directives 93/42/EEC and 90/385/EEC respectively) and the proposed *in vitro* diagnostic Regulation will replace the *in vitro* diagnostic medical device directive (Directive 98/79/EC).

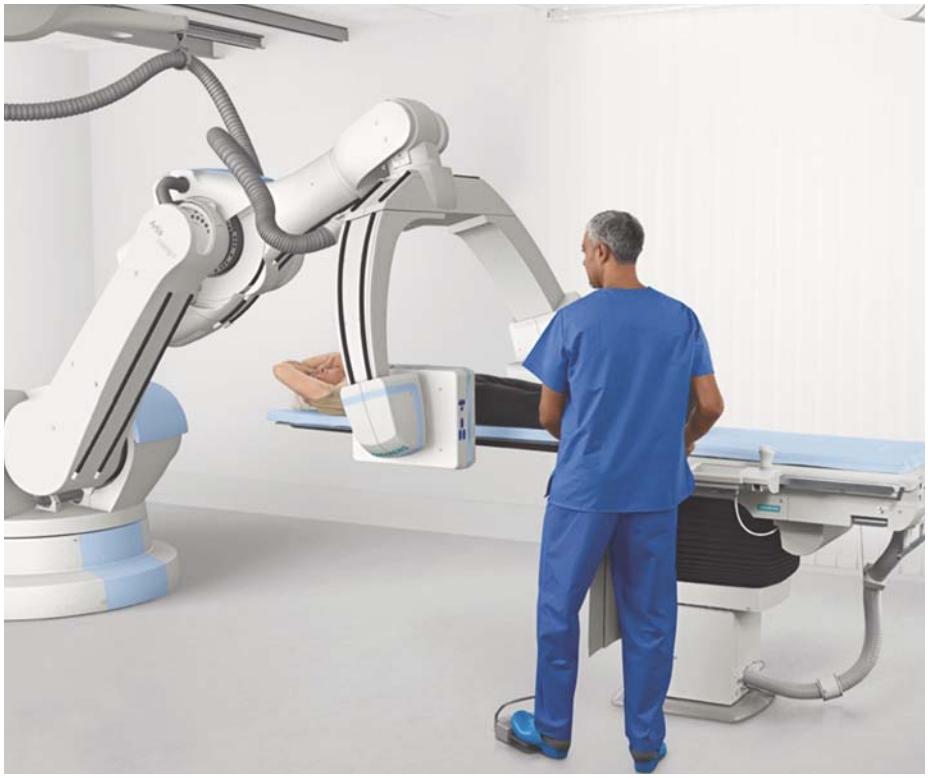
These two proposals will now be subject to discussion by the European Parliament and the Council and subject to the legislative process described overleaf.

It is anticipated that these proposed regulations, when agreed, will form the basis for the regulatory framework for medical devices for at least the next decade.

For further details please refer to the proposed Regulations at the following link: **http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm**.

We hope that you find our synopsis useful and informative. If you have any comments on the Commission's proposed Regulations please feel free to send them to the IMB at **medicaldevices@imb.ie**

The Irish Medicines Board would like to take this opportunity to bid you best wishes for the festive season and good fortune for 2013.



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European Legislative Procedure

There are three main institutions involved in European legislation: the European Parliament, the Council of the European Union and the European Commission.

This article seeks to clarify the roles these institutions and how proposed legislation is decided in Europe.

EUROPEAN PARLIAMENT

The European Parliament is one of two bodies that, together, provide the European Union's legislative function in passing European laws. Members of the European Parliament (MEPs) are directly elected by the citizens themselves. The number of seats allocated to a Member State is dependent on the population size of the Member State.

COUNCIL OF MINISTERS OF THE EUROPEAN UNION

The Council of Ministers, also called the Council of the European Union or simply Council, is the second of the two European Union legislative bodies.

Unlike the European Parliament, whose members are elected by the people, the Council is made up of 27 ministers, one from each of the European Union's Member States, who represent their government's viewpoints. The size of a Member State's population determines the number of votes that each Member State's minister wields. The Council operates a qualified majority system which sets out criteria which must be met for each decision e.g. Member States voting in favour must represent a certain proportion of the European population.

The Council is the main decision-making body of the European Union, along with the European Parliament, it passes laws. Generally, neither the Council nor the European Parliament proposes new legislation; this is a function of the European Commission

EUROPEAN COMMISSION

The European Commission represents and upholds the interests of Europe as a whole. It drafts proposals for new European laws, such as the proposed Regulations on medical devices, and manages the day-to-day business of implementing European policies and spending European Union funds.

The European Commission oversees and implements European policies by:

- proposing new laws to Parliament and the Council;
- managing budgets and allocating funding;
- enforcing European law (together with the Court of Justice);
- representing Europe internationally.

ORDINARY LEGISLATIVE PROCEDURE

The legislative process in Europe is a co-decision between the Parliament and the Council. Both the European Parliament and the Council are attributed the same weight by the ordinary legislative procedure.

A proposal is sent to both the Parliament and the Council by the European Commission and is then normally subject to two phases of discussions. If after the second reading, the Council and Parliament cannot agree, the proposal is brought before a Conciliation Committee. The Conciliation Committee is made up of an equal representation of both Council and Parliament representatives together with representatives of the Commission. Upon agreement, the text is sent to Parliament and the Council for a third reading to allow for its adoption as a legislative text. However, Parliament can still reject the proposed law by a majority of the votes cast. This process is discussed in greater detail below.

OUTLINE OF THE PROCEDURE

The Commission makes a draft legislative proposal which is presented to the European Parliament and the Council. This proposal is also made available to the parliaments of

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European Legislative Procedure

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Member States. Within eight weeks, a Member State's parliament may present an opinion on whether the proposed legislation complies with the principle of subsidiarity i.e. is it more effective to take action at a national, regional or local level rather than at a European level. If the principle of subsidiarity has been met the European Parliament prepares to adopt the proposal through the mechanism described below.

First Reading

There is no set time limit for the first reading during which the European Parliament adopts its position by simple majority. This position may, however, contain a number of amendments to the original proposal.

Where a position is adopted without any amendments by the Parliament, and the Council accept the original proposal, the Council adopt the act by a qualified majority, which is signed by the Presidents of the European Parliament and Council and published in the Official Journal.

In the case where Parliament has made amendments with which the Council agrees, the act is adopted by the Council by qualified majority and then signed and published. However, should the Council disagree with, or reject, some or all of the amendments it adopts its position by a qualified majority. The act is then forwarded to Parliament for its second reading together with a full explanation of its reasoning in adopting its position.

Second Reading

Unlike the first reading a time limit of 3 months exists for second readings by the Parliament. This time limit may be extended to 4 months. During this time the Parliament must examine the Council's position and either approve, reject or make amendment to it.

Where it is decided to approve or take no decision on the Council's position, the act is deemed as adopted, signed and published. A decision, by absolute majority, to reject the Council's position definitively closes the procedure. Parliament may also decide, by an absolute majority, to propose amendments to the Council's position; this is then submitted to the Council and the Commission with the former having 3 months in which to act. If approved by the Council, the act is deemed adopted, signed and published. If the Council rejects some or all of the amendments proposed by the Parliament the Conciliation procedure is launched within a 6 week deadline.

Conciliation & Third Reading

Representatives of the 27 Member States and an equal amount of members of the European Parliament form the conciliation committee. Over a 6 week period, up to a maximum of 8 weeks, the committee aim to find a compromised position on a joint text. If a joint text cannot be agreed upon within this timeframe, the act is deemed not to have been adopted and the procedure is terminated. Where a joint text is approved by the committee, it is presented to both the Council and Parliament for their approval over a 6 week period which is extensible to 8 weeks. After both institutions approve the text, it is signed and published.

By Wilf Higgins, Chairman of the Irish Medicines Board's Advisory Committee for Medical Devices

Vigilance & Market Surveillance

As outlined in the explanatory memorandum to the proposed regulations, the Commission considers that "a well functioning vigilance system is the 'backbone' of a robust regulatory framework in this sector because complications with medical devices that are designed to be implanted or to operate for many years or even decades might come to light only after a certain period of time". Chapter VII of both proposed Regulations specifically deals with vigilance and market surveillance.

The key proposals in these areas are discussed below.

VIGILANCE

Chapter VII Section 1 Vigilance: Articles 61 to 66 of the proposed medical device Regulation (Article 59 to 64 of the proposed IVD Regulation) deal with the medical device vigilance system. The key changes proposed include the introduction of an EU portal and development of the coordinating Competent Authority (CA) role with emphasis on 'work- and expertise-sharing to avoid inefficient duplication'. A number of concepts from the Vigilance MEDDEV 2.12-1 'Guidelines on a medical device vigilance system' are included in the proposed regulations.

The proposals introduce specific timelines for reporting of Field Safety Corrective Actions (FSCAs). A proposal of 15 days has been included in Article 61 of the proposed medical device Regulation (Article 59 of the proposed IVD regulation) for both serious incidents and FSCAs. Please note that Article of the proposed medical device Regulation (Article 64 of the proposed IVD Regulation) has included the option of using implementing acts to introduce reporting timelines. The concept of periodic summary reporting, already in the Vigilance MEDDEV, has been introduced into the proposed Regulations. Reporting of FSCAs undertaken in third countries in relation to a device also placed on the EU market has also been introduced.

The electronic system for vigilance reporting is introduced in Article 62 of the proposed medical device Regulation (Article 60 of the proposed IVD Regulation). The system is aimed at collating and processing reports from manufacturers on serious incidents and FSCAs, periodic summary reporting and trend reports for example. Database access shall be granted at an appropriate level to the Commission, Member States and notified bodies (NBs). Health care professionals and members of the public will also be given opportunity to access some vigilance information on this system. The central database will electronically transmit vigilance reports to the relevant CAs based on criteria such as where the incident took place and where the FSCA is being undertaken *etc*.

Under Article 63 of the proposed medical device Regulation (Article 61 of the proposed IVD Regulation), there is a requirement for the CA to carry out a risk assessment with regard to reported serious incidents or FSCAs. There is also a requirement for the coordinating medical device CA to liaise with medicinal product and tissue and cells CAs in the case of combined products.

The role of the coordinating CA, which is contained in the Vigilance MEDDEV 2.12-1, is introduced into the proposed Regulations. The proposals outline when a Member State should assume the role of the coordinating CA and the tasks involved. The concept of trend reporting, also in the Vigilance MEDDEV 2.12-1, is outlined in Article 64 of the proposed medical device Regulation (Article 62 of the proposed IVD Regulation). The requirement for manufacturers to ensure their technical documentation is updated with information on incidents, FSCAs *etc* in also included in the proposals.

The proposals indicate that implementing acts may be used in relation to reporting, harmonisation of reporting forms, timelines and other items.

The coordinating CA should liaise with the NB which issued the certificate for a particular medical device regarding the impact of serious incidents on the certification. Manufacturers are required to make updated documentation available to the NB to assess the impact of vigilance data on the conformity assessment and the certificate issued.

MARKET SURVEILLANCE

Chapter VII Section 2 Market Surveillance: Articles 67 to 75 of the proposed medical device Regulation (Article 65 to 73 of the proposed IVD Regulation) concern the area of market

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surveillance. Market surveillance tools are included in the current Directives and many of the concepts are similar in the proposed Regulations. For ease of reference, the market surveillance Articles have been collated into one chapter and the proposed legislative requirement for CAs to carry out market surveillance highlights the focus on this area.

The main objectives are to reinforce the obligations of CAs, provide legal tools and ensure effective coordination of market surveillance activities.

Many of the concepts of the New Approach Regulation (EC) No 765/2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products, have been brought into the proposed medical devices and IVD Regulations. For example, CAs shall perform appropriate checks on the characteristics and performance of devices and Member States shall periodically review and assess the functioning of their surveillance activities.

A centralised electronic system for market surveillance is also proposed. Article 70, 72 and 74 of the proposed medical device Regulation (Article 68, 70 and 72 of the proposed IVD Regulation) provide the mechanism for dealing, respectively, with: non compliant devices which present a risk to health and safety, compliant devices which present a risk to health and safety and preventative health protection measures. This may relate to a device, a group of devices or a specific category.

Other noteworthy items in the proposed Regulations also intended to enhance vigilance and market surveillance include:

- A unique device identification system to enhance post-market safety of medical devices, help reduce counterfeiting and ensure better traceability throughout the supply chain;
- Clearer responsibilities for economic operators *i.e.* manufacturers, authorised representatives, importers and distributors.

Clinical Evaluations and Investigations

The following article discusses the implications of the proposed medical device Regulation on medical device clinical evaluations and investigations.

The Commission's proposal for a Regulation has specific requirements for clinical evaluation and investigation of medical devices; which build on those already in place in Medical Device Directive 93/42/EEC.

Chapter VI lays out the key obligations manufactures are to undertake in terms of clinical evaluation when demonstrating the safety and performance of their devices. Annex XIII outlines how a manufacturer should conduct a clinical evaluation and defines the post-market clinical follow-up responsibilities. Annex XIV describes the general requirements and documentation required when conducting a clinical investigation.

In addition, a number of definitions relating specifically to clinical evaluation and investigation are included in Chapter I Article 2.33 - 2.41. Most notably, the concept of a sponsor has been defined; this can be the manufacturer, their authorised representative or another organisation or institution, such as a Contract Research Organisation (CRO), conducting clinical investigations on behalf of the manufacturer.

CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

Under Article 49 of Chapter VI, manufactures are required to conduct a clinical evaluation in accordance with Annex XIII. Three options remain available when conducting a clinical evaluation: (1) a critical evaluation of available scientific literature where equivalency can be demonstrated, (2) a critical evaluation of clinical investigations conducted or (3) a combination of (1) and (2). However, further emphasis has been placed on the need for clinical data to be derived from clinical investigations, particularly in the case of implantable devices and devices falling within Class III. For such devices, it is proposed that, under Annex XIII A.5, demonstration of intended purpose, technical and biological equivalency is no longer a sufficient justification for not performing a clinical investigation to generate clinical data. In other cases, where such equivalency can be demonstrated, the clinical data relating to the equivalent device may be deemed relevant.

A post-market clinical follow-up plan should form part of the post-market surveillance plan unless it is deemed unnecessary and can be duly justified. However, where a post-market clinical follow-up of a CE marked device, used within its intended purpose, would submit subjects to additional invasive or burdensome procedures the sponsor must notify the concerned Member State at least 30 days prior to its commencement. Such follow-ups are referred to as post-market clinical follow-up investigations and require notification and adverse event reporting to national authorities.

CLINICAL INVESTIGATION

Chapter VI, Articles 50 to 60, and Annex XIV of the proposed Regulation contain provisions for clinical investigations. The proposals are restricted to only cover clinical investigations carried out for regulatory purposes i.e. for obtaining or confirming regulatory approval for market access. Non-

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Clinical Evaluations and Investigations

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commercial clinical investigations that do not pursue a regulatory purpose are not covered by this Regulation.

Prior to a sponsor making a first application to conduct a clinical investigation, they must acquire an identification number from the electronic registration system proposed i.e. EUDAMED. The sponsor must then register their clinical investigation on this registration system and provide certain information including contact details, a description of the device and the purpose of the investigation. This information will be made publically available through the electronic registration system. Certain data may be kept confidential where necessary e.g. protection of personal or commercially sensitive data.

Following receipt of the unique identification number and registration of the study, a sponsor may submit an application to the Member State(s) concerned accompanied by the documentation required as per Annex XIV. This documentation consists of the application form, investigators brochure, clinical investigation plan and other details including ethics committee opinion (when available), proof of insurance, informed consent and data protection arrangements. Full details of the content for these documents can be found in Chapter 2 of Annex XIV.

The proposed timelines for the approval process have also been significantly amended in the Commission's proposals under Article 51. Upon receipt of an application, a Member State must respond to the sponsor within 6 days and advise whether the investigation falls within the scope of the Regulation and whether the application is

complete. If valid, and subject to the Regulation, the sponsor is notified of a complete application and validation date.

The approval process allowing for a clinical investigation to commence is influenced by both the classification and type of device concerned. Clinical investigations involving Class III medical devices and implantable or long-term invasive Class IIa and IIb medical devices require Member State approval prior to their commencement. For all other investigational devices, a clinical investigation may commence 35 days after a Member State validates an application provided it considers that the rights, safety and well-being of the subjects are protected and a refusal, based on public health, patient safety or public policy, has not been issued.

The assessment of applications conducted by Member States is also touched upon by the Regulation, which states that the assessment must be undertaken by a reasonable number of persons with the necessary qualifications and experience. Additionally, the opinion of at least one person from a non-scientific background must also be taken into consideration as shall the view of at least one patient.

Sponsors of multi-Member State clinical investigations may submit a single application to an electronic registration system which is then communicated to all Member States concerned. The sponsor may also nominate a coordinating Member State. However, should the nominated Member State be unable to fulfil this role, they must agree with another Member State that they take on the coordinating role.

The role of the coordinating Member State is to assess the documentation submitted in support the investigation as outlined in Chapter 2 of Annex XIV. Documentation relating to local ethics committee opinion, proof of insurance and informed consent shall be assessed by each individual Member State concerned, as shall documentation relating to the principal and coordinating investigators and investigation sites. The coordinating Member State has responsibility for compiling the results of the coordinated assessment when deciding on the sponsor's application. However, each Member State retains the right for deciding whether the clinical investigation may be conducted on its territory.

Any substantial modifications made

to a clinical investigation must be notified to the concerned Member States and accompanied by the relevant updated documentation. After 30 days of this notification, a sponsor may implement the modifications unless it has been refused by a Member State.

Article 59 details the recording and reporting criteria for events which occur during a clinical investigation. Sponsors are obliged to report, without delay, the following:

a) a serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;

b) device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

c) new findings in relation to any event referred to in points (a) to (b).

Additionally, any of the above events occurring in a third country which is partaking in the same clinical investigation must also be reported. Member States shall harmonise their assessment of such events under the direction of the coordinating Member State.

A temporary interruption of an investigation must be notified to the Member States within 15 days of the interruption. Similarly, once an investigation has ended the sponsor must also notify Member States within 15 days together with a justification in the case of an early termination. Additionally, a sponsor must submit a report which summarises the results of the clinical investigation within one year of it ending.

Notified Bodies

One of the main objectives in the new proposed medical device Regulation is the uniform control of notified bodies designation and monitoring by the Member States. In particular, the proposed Regulations look to harmonise the approach and implementation of the designation requirements across Member States through the involvement of "joint assessment teams".

It is envisaged that these "joint assessment teams" will comprise assessors from other Member States and assessors representing the European Commission. These activities will be overseen by the Medical Device Coordination Group (MDCG) covered elsewhere in this edition. In this way, it is expected that the varying interpretations and implementation of the requirements will be reduced and all notified bodies have the necessary competence to carry out the pre-market assessment of medical devices.

The requirements for notified bodies are detailed in Chapter IV of the proposed Regulation.

In Article 28, the requirement for the national authority responsible for notified bodies is outlined. They are to be impartial, objective and independent; to have a sufficient number of competent personnel; to communicate procedures, decisions on and changes to designation to the Commission and to be regularly peer-reviewed.

Article 29, Article 31 and Annex VI detail the specific requirements relating to notified bodies, with additional detailed requirements for notified body personnel knowledge and experience, and the minimum quality and process documentation. Subsidiaries and subcontracting of notified body tasks is outlined in Article 30, with the requirement for the notified body to verify that the subcontractor meets the requirements in Annex VI.

The major change to the designation procedure is detailed in Article 32. On receipt of an application for designation, the national authority responsible draws up a preliminary assessment report and sends the report to the EU Commission which transmits this to the MDCG. It is here that a joint assessment team composed of at least 2 experts, one of whom leads on behalf of the Commission, is established and subsequently works with the national authority to conduct the assessment for designation as a notified body. The assessment report drawn up by the national authority is reviewed by the MDCG which then issues a recommendation which must be taken into account by the national authority when making its designation decision. Many aspects of the steps are given timelines within the procedure.

Article 33 outlines how Member States notify the Commission and other Member States of the notified bodies they have designated including the scope for which the notified body is designated, the conformity assessment procedures and the types of devices that the body is designated as competent to assess.

The subsequent notification procedure and the documentation required to accompany the notification from the national authority is described. It mentions that there may be necessity to further define the NANDO codes and types of devices for the scope expressions. There is also now a forum to raise objections to a notification within a stipulated timeframe. This objection will be reviewed at the MDCG and potentially by the Commission in the case of divergent opinions.

Specific requirements for national authorities for monitoring of notified bodies are outlined in Article 35 to specify that there must be an on-site assessment of the notified body every year and also a three year full review of designation. The national authority must report on its oversight and monitoring activities to the Commission and other Members States on an annual basis. A summary report of these activities will also be made publicly available.

Article 36 outlines in more details the procedure for changes to the details of a notified body's designation, e.g. scope to assess new device type. In addition it is proposed that notified bodies may also be suspended for a maximum of one year and this suspension may be renewed once. In cases where a notified body has been suspended or indeed there has been any change to a notification, the national authority must review whether manufacturer's CE certificates have been impacted.

The Commission also proposes that it will investigate all concerns regarding a notified body brought to its attention and of its own accord. The proposal outlines the potential for the Commission to change the notified body's designation status.

IIt is envisaged that the new regulations governing notified bodies for medical devices will greatly enhance harmonisation and ultimately further safeguard device effectiveness and patient safety.

Increased Coordination and Transparency

COORDINATION & MANAGEMENT

Effective and consistent implementation throughout Europe of the requirements of the medical device Regulations is necessary to ensure the system operates effectively, fairly and provides appropriate protection to public health. Effective coordination and management of the regulatory system are critical to achieving consistent implementation by every Member State.

The Commission has outlined in Chapter VIII of the proposals for Regulations that a central expert committee, namely the Medical Device Coordination Group (MDCG), will be established with experts in the field of medical devices nominated by the Member States. This group will be chaired by the Commission and it will establish subgroups in relevant areas, when neces-

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Increased Coordination and Transparency

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sary. It will also act as a forum for dialogue with stakeholders including healthcare professionals, notified bodies and the medical device industry.

The proposed tasks of the MDCG detailed in Article 80 will include contribution to the oversight and assessment of notified bodies for medical devices; contribution to oversight of the assessment of selected specific high risk/novel medical devices; development of guidance in specific areas; provide support for coordination of activities for clinical investigations, vigilance and market surveillance, to develop harmonised administrative practices and to provide support to the Commission.

The Commission has proposed that it will continue to provide technical, scientific and logistic support to the medical devices framework rather than any one central agency such as the European Medicines Agency (EMA). The Commission will be supported by institutions such as the Joint Research Centre (JRC), the MDCG and its existing scientific committees.

TRANSPARENCY & TRACEABILITY

One of the major short comings identified in the Commission's analysis of the existing medical device framework was a lack of transparency and available information on medical devices on the European market. Chapter III of the proposals seek to ensure identification of economic operators and traceability of medical devices throughout the supply chain. Every manufacturer and authorised representative must register their details and those of the devices they are placing on the European market on a central database (a re-developed EUDAMED) and each economic operator must be able to identify who supplied them with a device and to whom they supplied a device. Manufacturers will be required to affix each device with a Unique Device Identification (UDI) code as outlined in Article 24. This UDI code will be consistent with internationally recognised formats so that devices can be full traceable across Europe. Healthcare institutions will need to establish systems and have the necessary hardware to utilise UDI. UDI will be implemented in stages proportionate to the risk class of the device.

The European database (EUDAMED) will be further developed as described in Article 27 to serve as a central information system for the medical devices network and will afford the necessary transparency with varying levels of open access to the public, healthcare professionals, notified bodies, medical device manufacturers and national authorities. The database will comprise of six modules: registration of devices, European UDI, certificates issued by notified bodies, clinical investigations, vigilance and market surveillance.

The proposals require that more and clearer standardised information is available in the instructions for use and patient information for medical devices and more standardised format for associated documentation for authorities. In addition, manufacturers of high risk medical devices will be required to publish a summary of safety and clinical performance that must be written clearly so that it is clear to the intended user of the device.

It is envisaged that the publicly available information on EUDAMED will include information on medical devices on the European market, medical device manufacturers and their authorised representatives, summary of safety and clinical performance for high risk devices, information on certificates issued by notified bodies, information on clinical investigations and information on field safety notices issued by manufacturers.

SPECIFIC ASPECTS OF THE PROPOSAL FOR AN *IN-VITRO* DIAGNOSTIC MEDICAL DEVICE REGULATION

The proposal for a Regulation on *in-vitro* diagnostic medical devices shares many common horizontal elements with the medical device proposal. The most significant change within the proposed IVD Regulation is the proposal for a rules

based risk based classification system for IVDs replacing the existing positive listing system which is detailed in Chapter V and Annex VII. This new system, which is predominately aligned with globally agreed models, proposes four risk classes A, B, C and D (lowest to highest risk) for IVDs. The assignment to one of these risk classes will be based on 7 classification rules. The conformity assessment route available for an IVD is proportionate to the risk class and the new proposal envisages notified body assessment for IVDs in risk classes B to D. This will undoubtedly mean that more and more IVDs will be subject to notified body assessment in the future.

The proposed IVD Regulation also defines (Article 2) and places some specific requirements (Annex VIII) around 'companion diagnostics' which are used to determine how responsive a patient will be to a particular medicinal product or therapeutic regimen and to try to establish whether they are at increased risk of particular side effects.

The proposed IVD Regulation changes the requirements in Article 4.5 for IVD tests manufactured within healthcare institutions. These products are currently exempted from the existing legislation, however the new proposal is that IVDs in risk classes A to C will continue to be exempted provided that the healthcare institution is accredited to a recognised laboratory standard or equivalent. IVDs in risk class D will be subject to the full provisions of the legislation (with a number of provisions not applicable).

Another key element of the IVD proposals is the re-enforcement of clinical evidence (Chapter VI) requirements for IVDs to include data to demonstrate scientific validity, analytical performance and clinical performance. There will also be specific requirements for certain types of clinical studies involving *in-vitro* diagnostic devices.

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IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2
tel: +353 1 6764971 fax: +353 1 6767836 email: medicaldevices@imb.ie: http://www.imb.ie