

## Letter from the Editor

Welcome to the second edition of the medical device newsletter for 2010.

In this edition we cover a few of the topics which are ensuring that 2010 will be another busy year for medical devices at the Irish Medicines Board (IMB). This edition serves to further highlight some of the changes which occurred as a result of the revision to the Medical Device Directives which came into force in March 2010 and also to draw attention to planned future pieces of legislation and regulatory developments which will have significant implications for medical devices.

Further to revised guidance documents published on manufacturing of class I and of custom made medical devices, we include an article on the key changes that the revision to the Directive has had on this area. In particular, requirements for custom made manufacturers to have a vigilance system in place and also changes in relation to availability of the custom-made 'statement concerning devices for special purposes'.

The European guidance document on medical device classification (MEDDEV 2.4/1) has undergone significant revision to align the document with the provisions of the

revised Directive. The major changes are covered in one of the articles included in this edition.

One article covers the publication of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report in April 2010 on 'Safety of reprocessed medical devices marketed for single use'. The report was requested by the European Commission to further inform its imminent report to the European Parliament and Council on this topic. The Commission's report may include further regulatory proposals for device reprocessing.

In addition to the European regulatory updates provided, particular attention is drawn to the public consultation which is currently underway on the proposed recast of the *In-Vitro* Diagnostics (IVD) Directive, 98/79/EC. The related article outlines the key proposals made by the Commission in their consultation document. These include proposals relating to classification and conformity assessment of IVDs, proposed changes to the scope of the Directive and poses questions in relation to clinical evidence for IVDs.

## CONTENTS

### Editorial

Changes to the Medical Devices Legislation that Impact Custom-made Medical Device Manufacturers

New Approach and the IMB Post Market Surveillance Plan

SCENIHR's Report on the Safety of Reprocessing Single-Use Medical Devices

### Regulatory Update

Changes to MEDDEV 2.4/1 on the Classification of Medical Devices

European Commission Public Consultation on the Revision of the *In Vitro* Diagnostic Medical Devices Directive (98/79/EC)





## Changes to the Medical Devices Legislation that Impact Custom-made Medical Device Manufacturers

*The recent revision of the Medical Device Directive effects the requirements for manufacturers of custom-made medical devices in particular to have a specific post-market surveillance/vigilance system in place and also makes changes in relation to provision of the custom-made 'statement'.*

Medical devices are regulated in Ireland according to S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994, which transposed the Medical Devices Directive, 93/42/EEC, into Irish law. Irish-based manufacturers of custom-made medical devices, medical devices specifically made for a particular named patient, must meet the requirements of S.I. No. 252 of 1994, hereafter referred to as the "Regulations".

The Medical Devices Directive was amended by Directive 2007/47/EC which came into force in March 2010. This amendment was subsequently transposed into Irish law by way of S.I. No. 110 of 2009 which introduced a number of changes to the Regulations. The aim of these amendments is to strengthen the regulation of medical devices and to further safeguard public health.

Active Implantable Medical Devices are regulated in Ireland by S.I. No. 253 of 1994, which transposes the Active Implantable Medical Devices Directive, 90/385/EEC into Irish law. 2007/47/EC also amended this Directive which is reflected by S.I. 109 of 2009.

A number of general changes were introduced to the Regulations that have an impact on the manufacturing of custom-made medical devices. These changes have been summarised below;

- The definition of a custom-made medical device was modified in the Active Implantable Medical Device Directive to exactly reflect the current definition provided in the general Medical Device Directive.
- A greater emphasis has been placed on clinical data.
- The Essential Requirements were amended to introduce the concept of designing a medical device for patient safety, to reduce the risk of user error.
- An Instructions for Use (IFU) supplied with a medical device must include the date of issue or the latest revision of the IFU.

- In the technical documentation (documentation, that must be kept available for inspection by the IMB, allowing an understanding of the design, manufacture and performances of the device), the manufacturer must now include the name and address(es) of the manufacturing site(s).
- The technical documentation must be kept for at least 5 years after the last product has been manufactured. In the case of implantable custom-made medical devices, the documentation must be kept for 15 years.
- The information relating to the registration with the IMB of manufacturers responsible for placing devices on the market shall no longer be treated as confidential. Note: The IMB registration system and process is currently under review, which will include how the changes to confidentiality of the data on the register will be implemented by the IMB.

The two main changes to the Regulations that directly impact custom-made medical device manufacturers relate to the Custom-made Statement Concerning Devices for Special Purposes, and post market surveillance. These changes are explained below.

### Custom-made Statement Concerning Devices for Special Purposes

The manufacturer of a custom-made medical device must draw up the



statement referred to in Schedule 8 of the Regulations. The legislative amendments have resulted in the following change / addition to the statement

- The patient may be identified on the statement by name, acronym or numerical code,
- and the statement must now include the name and address of the manufacturer.

Custom-made medical devices are classed into one of four classes (classes I, IIa, IIb or III) dependent upon the risk the device poses to the patient, and in accordance with the classification rules outlined in the Regulations. It should be noted that it is a requirement that the custom-made statement must be made available to the particular patient for whom the device has been manufactured, for class IIa, IIb and III custom-made medical devices. The device manufacturer must ensure that the statement is supplied with the custom-made medical device so that it may be made available to the patient on request.

### Registration

Manufacturers of custom-made active implantable medical devices based in Ireland are now also required to register with the Irish Medicines Board, providing details of their place of business and of the devices manufactured. Manufacturers based outside of the European Union can appoint a single authorised representative within a European Member State for this purpose.

### Post Market Surveillance

Manufacturers of custom-made medical devices must have provisions in place to review and document data from market experience with the devices they manufacture. Manufacturers may already have a complaints-handling system in place, however, in

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order to comply with a the revised Regulations, this system must be extended to cover the reporting of any vigilance incidents to the Irish Medicines Board (IMB) and to implement any corrective actions that may be deemed necessary.

The system must include an obligation for the manufacturer to notify the IMB of the following incidents, immediately on learning of them, and the relevant corrective actions:

- (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his or her state of health;
- (ii) any technical or medical reason connected with the characteristics



or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

Additional guidance on vigilance reporting for medical devices, the *IMB*

*Guide to the Vigilance System for Medical Devices* is available on the publications section of the IMB website.

In addition to the above requirements, there are further changes to the Regulations that may impact manufacturers of custom-made medical devices. It is recommended to review S.I. 110 of 2009 and, in particular, Schedules 1 and 8, to determine if any of the amendments have had an effect on processes, systems or documentation. The *IMB Guide for Custom-Made Medical Device Manufacturers*, is also available on the publications section of the IMB website.

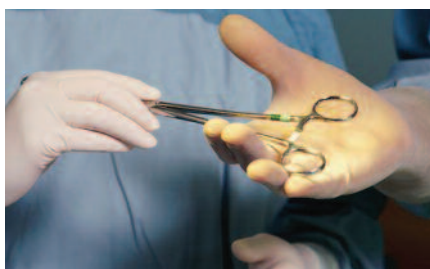
It should also be noted that as part of the IMB's post market surveillance programme, audits of custom-made medical device manufacturers are conducted each year. The aim of these audits is to ensure that the medical device manufacturer is complying with the 'Essential Requirements' and schedules of the Regulations.

## New Approach and the IMB Post Market Surveillance Plan

Medical devices legislation is an example of 'New Approach' legislation which covers many products placed on the market, ranging from medical devices to machinery, lifts and toys. The New Approach is an integral part of the free trade of goods within the European Community. The safety of many different types of products has been regulated through such EU-harmonised legislation since the mid 1980s. The recent revision to the New Approach arose out of the European Commission's concern regarding inconsistencies in both the level of activity of market surveillance and competence of notified bodies in Member States across the various sectors. The intention of the revision to the New Approach was also to provide clarification across the sectors regarding definitions and on the obligations of the various economic operators.

Work on the revision to the New Approach began in 2003 and resulted in the publication of the "Goods Package" in June 2008. The Goods Package consists of two Regulations and a Decision:

- Regulation No. 765/2008 outlines the provisions on market surveillance and accreditation.
- Regulation No. 764/2008 serves to



strengthen the principle of mutual recognition.

- Decision No. 768/2008 aims to develop further harmonization of legislation over the coming years.

Since May 2009, the IMB has participated in the Market Surveillance Forum, an inter-departmental group led by the Department of Enterprise, Trade and Innovation (DETI) and established to consider the impact of the revision to the New Approach legislation. The purpose of the market surveillance forum is to share knowledge and experience between bodies that have responsibilities under New Approach legislation and to assist various agencies affected in preparing for the change to the legislation.

The DETI provides a secretariat role to the forum and communicates

guidance from relevant European Senior Officials' Group meetings. They have also coordinated the submission of the National Sector-specific Market Surveillance Programme for 2010-11 to the European Commission in early January 2010. This submission is a requirement under Regulation 765/2008. A public narrative document was prepared by each agency to outline their activities in the area of market surveillance. These activities include;

- implementation of the requirements of the legislation in relation to post market surveillance for medical devices,
- device-specific post market surveillance projects involving specific product families,
- post market surveillance audits of manufacturing sites in Ireland and
- audits of the Irish Notified Body, NSAI.

The document also outlines areas of horizontal cooperation and methods of information exchange employed by the IMB to communicate with stakeholders.

A copy of the public narrative document is available on the DETI website: (<http://www.deti.ie/enterprise/standards/productsafety.htm>).



## SCENIHR's Report on the Safety of Reprocessing Single-Use Medical Devices

The Medical Device Directive (MDD, 93/42/EEC) distinguishes between single use medical devices (SUDs) and reusable medical devices. In April 2010, the Scientific Committee on Emerging and Newly Identified Health Risks published a report requested by the European Commission entitled 'The Safety of Reprocessed Medical Devices Marketed for Single-Use'.

The medical device manufacturer placing the device on the market or putting it into service determines a device's suitability for reprocessing dependent on many factors including device design, materials, intended purpose, risk, success and repeatability of reprocessing protocols.

For medical devices intended for reuse, the manufacturer must provide detailed information about the validated processes established and data specified for cleaning, disinfection, packaging, sterilisation, where appropriate, and any restriction on the number of times a device is reprocessed and reused.

SUDs are intended and designed by the manufacturer to be used only once for a single patient and so no information is provided by the manufacturer in relation to their reprocessing. The recent revision of the MDD by (2007/47/EC) does require, however, that manufacturers of SUDs provide information on the known characteristics and technical factors that could pose a risk if the device were to be reused.

In order to ensure reprocessing of SUDs does not have an effect on patient safety the revision of the MDD has provided further clarification on SUDs. The European Commission (EC) committed to analyse the issue of reprocessing of SUDs to determine if specific additional legislative measures were required. To this end, the EC circulated a questionnaire to Member States in 2008 in relation to reprocessing and requested an analysis of the topic by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

On 15th April 2010, the SCENIHR, which is an independent Scientific Committee, provided the Commission with a scientific report entitled *The*



*Safety of Reprocessed Medical Devices Marketed for Single-Use.* The SCENIHR report is focused on possible risks, health implications, potential effects on materials and device performance and quality control aspects of reuse of SUDs. It does not examine economic, environmental, ethical or legal aspects of reprocessing. The report seeks to address the specific questions:

1. Whether the use of reprocessed SUDs constitutes a hazard for human health causing *e.g.* infection/cross contamination and/or injury?
2. Characterisation of any risk to human health identified?
3. The particular conditions or uses under which the reprocessing of SUDs poses a risk *e.g.* intended use, reprocessing method used, functionality, raw material, handling, design.

The SCENIHR report identified various hazards associated with reprocessing of SUDs, including the potential for infection due to inappropriately reprocessed devices, potential toxicity from chemical residues of reprocessing and alteration in performance of the device. The report recognises, however, that

specific quantification of these risks is not possible due to a lack of data on clinical outcomes for patients treated with reprocessed SUDs.

SCENIHR reports that these potential risks are greater when reprocessed SUDs are used in invasive medical procedures.

In addition, the report identifies that reprocessing of SUDs may cause difficulty in maintaining device traceability and ensuring that appropriate information is provided to the user of the device.

The report highlights that some SUDs may be amenable

to reprocessing but concludes that 'In order to identify and reduce potential hazards associated with reprocessing of a specific single-use medical device, the whole reprocessing cycle starting with the collection of these SUDs after (first) use until the final sterilization and delivery step, including its functional performance, needs to be evaluated and validated'

It is critical to recognise that the manufacturer of a SUD is no longer legally responsible for the device if it is reprocessed. Rather, the legal responsibility is assumed by the party that places the reprocessed SUD on the market or puts the reprocessed SUD into service.

A copy of the SCENIHR report may be downloaded from the European Commission's website at the following web address;

[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_027.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf)

Additional information on reprocessing of medical devices is also available on the EC's website.

The EC is due to submit its analysis of reprocessing of SUDs to the European Parliament and Council in September 2010. This report may include specific recommendations as to whether specific additional legislation is required on the topic of reprocessing.



## Regulatory Update

### Compliance and Enforcement Working Group (COEN)

A meeting of the COEN Working Group was held in Brussels during May. Updates were provided by a number of Member States on specific market surveillance projects and various issues of mutual interest. Discussion continued on the impact of the revision to new approach legislation, and the progress of a number of guidance documents being developed by the group was presented. The Commission also updated the group on the transfer of medical devices from DG Enterprise to DG Sanco, which is progressing well. The next meeting of the COEN group will be held in October 2010.

### Unique Device Identification Working Group

The Unique Device Identification (UDI) Working Group met in June. The discussions concentrated on the possibilities and practicalities of establishing a European UDI System and also the current work of the GHTF *ad hoc* working group on UDI. The aim of this meeting was to tackle the issues and questions raised at the March Competent Authority meeting in Madrid in relation to UDIs. It was agreed that the main goal of a UDI system is to improve patient safety by enhancing the identification of devices in case of adverse events and facilitating traceability of devices in the event of a field safety corrective action. The UDI database was also discussed. The next meeting of the group is scheduled for October.

### MDEG

The Medical Device Expert Group (MDEG) met in June. During the plenary session, updates on legislation currently undergoing revision, including Directive 2003/32/EC on medical devices utilising tissues of animal origin and amendment of Annex II List A of Directive 98/79/EC to include vCJD assays, were provided by the European Commission (EC). The current draft of the proposed legislation on the provision of electronic Instructions For Use for certain types of medical devices was discussed. The EC provided an



update on the status of the proposals to recast the medical devices legislation, indicating that they may table proposals for discussion before the end of 2011. The EC also indicated that the public consultation on the proposed recast of the *In Vitro* Diagnostics Directive would commence in July. Documents endorsed by the MDEG included the revised MEDDEV on classification and revised guidance documents for Class I and custom-made medical device manufacturers.

### Clinical Investigation & Evaluation Working Group

The Clinical Investigation & Evaluation (CIE) Working Group met during June. The primary work item related to the template format and associated guidance on serious adverse event reporting during clinical investigations. Following the meeting, a revised document is to be circulated to the group for final agreement. The other key discussion topic was on which clinical aspects of the Directive or other clinical proposals should be considered as part of the ongoing recast of the medical devices legislation.

### Notified Body Operations Group

The Notified Body Operations Group (NBOG) met in July. The discussions focussed on which elements of the Designating Authorities handbook and related guidance should be con-

sidered for revision. An update was provided on the review of notified body designation scopes in line with the new scope definitions published by NBOG during 2009. Discussion and experience was exchanged on the peer review programme. This programme is designed to harmonise and standardise the audit/surveillance of a notified body by their national authority. The IMB participated again in this programme during 2010, being peer reviewed during an audit of the Irish notified body by a colleague from the German Designating Authority.

### EMA-CAT-NB Coordination Group

The EMA-CAT-NB Coordination Group met at the European Medicines Agency (EMA) in London during June. This group forms an interface between the EMA, members of the Committee for Advanced Therapies (CAT) and medical device experts from NB-MED and NBOG. The group's objective is to define procedures and related guidance on the interaction with notified bodies during assessment of combined Advanced Therapy Medicinal Products (ATMP). The first document 'Procedural advice on the consultation of notified bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007' was published on the EMA website during July for public consultation. The IMB are acting as chair of this group.

### Medical Device Vigilance Expert Group

A meeting of the Medical Device Vigilance Expert Group was held in June. The one day meeting was largely composed of regulator-only sessions, with the remaining 20% of the meeting comprising joint regulator-stakeholder sessions. Discussion at the meeting included the recast of the medical devices directive, the implementation of MEDDEV 2.12-1 rev 6, the Coordinating Competent Authority, the XML Electronic report form, EUDAMED, GHTF Study group 2 and the NCAR exchange process.

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### Medical Device Expert Group on Borderline and Classification

The last meeting of the Borderline and Classification working group took place in May. Several specific classification cases were discussed, a number of which are now included in the most recent version of the Manual on Borderline and Classification, version 1.7, which is available for download from the Commission's website. The manual now contains positions on ethyl chloride spray for local anaesthesia, substances for chemical peeling and pathogen inactivation systems for platelets.

The revisions and comments on MEDDEV 2.4/1 were discussed and finalised. MEDDEV 2.4/1 rev. 9 was published in June and is available for download from the Commission's website. Further details on the key changes can be found in the "Major Changes to MEDDEV 2.4/1 on the Classification of Medical Devices" article of this newsletter. The next meeting of the group is scheduled for September 2010.

### EUDAMED Working Group

The last meeting of the EUDAMED working group took place in April. The main topics discussed included the publication of the EUDAMED Decision (see below), the transfer of the responsibility for medical devices within the Commission from DG ENTR to DG SANCO and the introduction of the new IT team who will be administrating the new EUDAMED 2 system. Updates were also given on the progress of the implementation of EUDAMED II and on the translation of the GMDN nomenclature into the official languages of the EU. The next meeting of the group is scheduled for October 2010.

On the 19th of April, the European Commission adopted a Decision obliging EU Member States to use a European Databank for Medical Devices (EUDAMED) as of 1st May 2011. EUDAMED is a secure web-based portal for rapid information exchange between national authorities and is already used on a voluntary basis by a number of EU countries. The EUDAMED database will contain details on device registrations, certificates, incidents and clinical investigations. The Decision was published in the Official Journal and may be downloaded from the following website:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:102:0045:0048:EN:PDF>

## Major Changes to MEDDEV 2.4/1 on the Classification of Medical Devices

The most recent revision of the MEDDEV on classification, 2.4/1, was published by the Commission in June of this year following extensive consultation with the various interested parties at the Borderline and Classification Medical Device Expert Group. The last version of this document, which comprised two parts, has now been consolidated into one document. Aside from this aesthetic change, there have been several major changes to the content of the document which will be discussed in this article.

The key changes in the document include text on the derogations from the classification rules that reclassified breast implants and hip, knee and shoulder joint replacements. The requirements relating to devices containing human blood derivatives and devices manufactured using tissues of animal origin have also been included. Additionally, the MEDDEV takes account of the changes arising from Directive 2007/47/EC, which further amends Directive 93/42/EEC and became applicable from 21st March 2010.

Part 1 of the previous revision of the MEDDEV is covered by Section 1 to 4.1 in this latest revision 9. There are several textual amendments and new additions, which are summarised as follows;

Section 3.1 on basic definitions has had several additions and now

includes explanatory text for intended purpose, reusable surgical instrument, critical anatomical locations and procedure packs. For instance, in relation to anatomical locations, the aortic arch, descending aorta and the aortic bifurcation are now included within the definition of the central circulatory system.

Section 3.2 refers to standalone software which, whilst in some circumstances may be considered to be an active medical device, has not been covered by this revision. The issue of qualification and classification of standalone software is currently being discussed by a sub-group of the Borderline and Classification Medical Device Expert Group with the aim of publishing a guidance document on the topic in the near future.

Section 3.3 now advises manufacturers to take account of additional Directives which may affect the classification of particular devices, namely: Directive 2003/12/EC on the reclassification of breast implants, Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements and Directive 2003/32/EC with respect to medical devices manufactured utilising tissues of animal origin.

Section 3.5 relates to handling of inter-

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pretational problems and has been expanded to include reference to the consensus positions contained within the Manual on Borderline and Classification and MEDDEV 2.1/3 rev. 3 regarding medical device/medicinal product combinations & borderline.

Part 2 of the last version of the MEDDEV is now covered in section 4.2 of version 9. Several amendments have been made to reflect the changes to the classification rules in Annex IX of 93/42/EEC, arising from Directive 2007/47/EC and the additional directives on breast implants, orthopaedic joint replacements and devices incorporating tissues of animal origin. Several examples of devices for the various rules have also been either removed, clarified or added. The major changes are highlighted below.

Note 2 of **Rule 2**, referring to solutions intended for preservation of organs during storage and transport not being medical devices, has been removed as this topic is now covered in the Manual.

**Rule 4** now contains an explanatory note on the concept of injured skin, which can occur either due to pathological factors (e.g. diabetic ulcers) or external factors (e.g. burns).

The text of **Rule 5** has been amended to reflect that of the revised Directive. A urinary catheter is now given as an example of a device which may be either a transient, short term or long term use device and may be classed as



Class I, IIa or IIb accordingly. Short term corrective lenses are now given as an example of Class IIa devices, with long term corrective contact lenses classed as Class IIb.

The second indent of **Rule 6** has been amended to include the term 'control a defect of the heart or of the central circulatory system', and the examples have been expanded to include related cardiovascular catheter introducers and distal protection devices. All surgically invasive devices intended for transient use intended specifically for use in direct contact with the central nervous system and associated examples have now been included.

Again, the second indent of **Rule 7** has been amended to include the term control a defect of the heart or of the central circulatory system with the addition of ablation catheters as Class III devices.

**Rule 8** has been extensively amended due to the derogation from the rule by Directive 2003/12/EC on breast implants which are Class III devices

and Directive 2005/50/EC on hip, knee and shoulder joint replacement systems and system components which are also Class III devices. Prosthetic joint replacements which are not covered by 2005/50/EC continue to be considered Class IIb devices under Rule 8. Internal closure devices, including vascular closure devices providing they are for use in the peripheral vascular system, are also Class IIb devices. The list of examples given as Class III devices due to their being in direct contact with the central circulatory or nervous system has been expanded.

**Rule 13** has been amended to include a section classifying devices incorporating, as an integral part, human blood derivatives as Class III devices.

Devices specifically used to disinfect invasive devices are now considered to be Class IIb devices under **Rule 15**; as such, washer-disinfectors for endoscopes and disinfectants for the fluid pathways of haemodialysis equipment are no longer classed as Class IIa devices.

The term 'non-active' is no longer included in **Rule 16**, which now just refers to devices specifically intended for recording of X-ray diagnostic images.

Revision 9 of the classification MEDDEV is available to download at the following address:

[http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index\\_en.htm](http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm)

## European Commission Public Consultation on the Revision of the In Vitro Diagnostic Medical Devices Directive (98/79/EC)

The European Commission has launched a public consultation on the technical aspects of the planned revision of Directive 98/79/EC on *In Vitro* Diagnostic (IVD) medical devices.

Under the consultation process the views of the public and interested parties are sought in relation to the future legislative proposal which will address issues such as classification of IVDs, conformity assessment procedures, scope of IVD types subject to the requirements of the IVD Directive and clinical evidence for IVDs.

### Classification of IVDs:

Currently the classification system for IVDs is based on perceived risk. There are four IVD categories including General Category, Annex II List B, Annex II List A and devices for self-testing (non Annex II). However, the inclusion of a device within Annex II requires specific legislation. The proposal in the public consultation is to adopt the model of the Global Harmonization Task Force (GHTF) and implement it for IVDs. The GHTF operates a rules-based classifica-

tion of IVDs which are laid down in the guidance document GHTF/SG1/N045: 2008, entitled "Principles of *In Vitro* Diagnostic (IVD) Medical Devices Classification", adopted on 19th February 2008.

### Conformity assessment procedures:

Conformity assessment is the process of review that takes place by the manufacturer and/or the Notified Body in

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**European Commission Public Consultation on the Revision of the In Vitro Diagnostic Medical Devices Directive (98/79/EC)**

order to ensure that safe and compliant product is placed on the European market. On satisfactory completion of conformity assessment, the manufacturer is entitled to affix the CE mark on their medical device. In the context of a possible adoption of a risk-based classification system according to the GHTF model, the European Commission is requesting feedback on the need to amend the current conformity assessment procedures for IVDs. The GHTF guidance document GHTF/SG1/N046: 2008 entitled "Principles of Conformity Assessment for *In Vitro* Diagnostic (IVD) Medical Devices", adopted on 31st July 2008, sets out the elements of conformity assessment applicable to the different classes of IVDs according to the GHTF model.



**Scope of IVD types subject to the requirements of the IVD Directive:**

Currently, under Article 1(5) of Directive 98/79/EC, IVDs that are manufactured and used within the same health institution for diagnostic purposes are excluded from the scope of the IVD legislation, irrespective of whether they are used for testing samples within that institution or from another legal entity *i.e.* from a GP practice or another hospital. If a laboratory manufactures an in-house assay and then transfers it to another hospital laboratory within a different legal entity, for diagnostic use, it is considered to fall within the scope



of the legislation. Under the consultation process the European Commission is seeking feedback on the need to review this exemption in particular to ensure a high safety standard for "in-house tests" and to prevent unfair competition between CE marked IVDs and "in-house tests", recognising that for certain diseases, only "in-house tests" may be available. It is therefore necessary to determine if there is a need to clarify or limit the scope of this exemption and/or to submit some "in-house tests" to certain requirements of Directive 98/79/EC.

Feedback is also requested on the need to clarify the scope of Directive 98/79/EC in relation to genetic tests, diagnostic services and Point-Of-Care / near-patient IVDs.

**Clinical Evidence for IVDs:**

The "Essential Requirements" of Directive 98/79/EC foresee requirements regarding the performances of IVDs. In particular, the demonstration of performance should include, where appropriate, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference and limits of detection stated by the manufacturer. These requirements are a mix of analytical and clinical requirements. The European Commission is seeking feedback on the need to further clarify the requirements regarding clinical evidence for IVDs and the need to extend the requirements regarding the demonstration of clinical validity

and clinical utility of the device in Directive 98/79/EC.

The Public Consultation is available on the European Commission website and may be accessed from the IMB website at the following link:- <http://www.imb.ie/EN/Consultation/s/Consultation/European-Commission-Public-Consultation-on-the-revision-of-the-Invitro-Diagnostic-Medical-Devices-Directive-9879EC.aspx?page=1&year=0&categoryid=>

Any comments on the public consultation should be submitted by mail, fax or email to;

European Commission Health and Consumers Directorate-General (DG SANCO)  
Unit SANCO B2,  
Cosmetics and Medical Devices  
B-1049 Brussels - Belgium,  
Fax: 00 32 (0) 2 296 64 67,  
Email: SANCO-IVD-REVISION@ec.europa.eu.

Respondents may also provide a copy of their feedback to the IMB ([medicaldevices@imb.ie](mailto:medicaldevices@imb.ie)) and the IMB will consider this feedback in our own response to the European Commission.

The consultation process is open for submissions until the 15th September 2010.

