

**Report  
On The Functioning Of  
The Medical Devices Directive  
(93/42/EC of 14 June 1993)**

**Medical Devices Experts Group**

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Correction 1 - July 3, 2002

This correction specifies (page 17) that Portugal holds the chair of MSOG.

## Summary

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The Directives on medical devices, adopted respectively in 1990, 1993 and 1998, constitute for the first time a coherent and comprehensive legal framework for medical devices in the Community Member States. Although national law implementing the Directives is recent, Commission, Member States and stakeholders have agreed to review the functioning of the regulatory framework, in order to improve the regulatory framework and its implementation where possible. A number of meetings was held throughout 2001 and 2002, and various submissions were received from Member States, industry and Notified Bodies. This report presents a consensus view, reflecting the outcome of these discussions. The report is mainly concerned with the Medical Devices Directive 93/42/EC. However, as the Directives concerning active implantable and in-vitro diagnostic medical devices are part of the wider regulatory framework for medical devices, they are referenced in a few specific sections of the report.

The impact of medical devices on health care and health policy seems largely unknown outside the sphere of health care professionals. Similarly, the impact of medical devices on national health budgets may surprise by its steady increase over years: in some countries it exceeds that of the pharmaceutical sector.

Medical devices are fundamentally different from the pharmaceutical sector. This is reflected in the legal frameworks applicable to both sectors. The system put in place by the EU has gained worldwide recognition and has provided a source of inspiration for the work of the Global Harmonisation Task Force (GHTF). Various regulatory changes carried through worldwide reflect the EU experience.

The report identifies issues and concerns as well as suggestions and ongoing actions. The overall conclusion from the report is that the Medical Devices Directive provides in itself an appropriate legal framework with a view to safety aspects and technological evolution. However, areas were identified where there is room for improvement in implementation, to be achieved by all parties involved: national authorities, Notified Bodies, Commission and industry. The most critical area where improvements should be made concerns conformity assessment. Action required relates to a number of issues, including designation and monitoring of Notified Bodies, reclassification of devices, conformity assessment by Notified Bodies, proper implementation of provisions on clinical data, and on quality assurance. Failure to act on one of these elements in the field of conformity assessment will not produce the required improvements. Inversely, it is also understood that major issues identified with the implementation of the directives will be solved by a combined action on these elements. Improvement should be achieved by better implementation, more clarification of existing provisions and better co-ordination mechanisms between authorities on a number of aspects. A number of issues where the Directive would require modifications in order to improve the regulatory framework have been identified.

The report reflects the outcome of discussion in the Medical Devices Expert Group, which includes the Commission services, national authorities, representatives from notified bodies, European standards organisations and industry. At this stage it does not commit the Commission or Member States.

On the basis of this report the Commission intends to present the Council and the European Parliament the policy conclusions to be drawn from the present report.

## 0 - Introduction

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The Directives on medical devices, adopted respectively in 1990, 1994 and 1998, constitute for the first time a coherent and complete legal framework for medical devices in the Community Member States. This system is based on the New Approach towards technical harmonization, and aims to set the highest levels of safety, to provide access to the Community market, and to promote innovation.

Although national law implementing the Directives is recent, Commission, Member States and stakeholders have agreed to review the functioning of the regulatory framework, in order to improve the regulatory framework and its implementation where possible. More precisely, this review process is based on three elements:

1. The 1993 medical devices directive itself requests <sup>1</sup> the Commission to submit a report to the Council, no later than five years from the date of implementation of the Directive, concerning
  - (i) information on incidents occurring following placing of devices on the market
  - (ii) clinical investigation carried out in accordance with the procedure set out in Annex VIII of the Directive and
  - (iii) design examination and EC type examination of medical devices that incorporate as an integral part a substance which, is used separately, may be considered to be a medicinal product as defined in Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device .
2. The Commission is in the process of an overall review of the New Approach. A consultation process is going on, and a consultation document has been posted for public comment on the web. Elements of the review of the functioning of the medical devices directive will be fed into the overall review of the New Approach. Similarly, some issues identified in the overall review are reflected in the present report, or may have an impact on solving issues raised.
3. Finally, various member states have suggested that the review process should be extended to cover not only the reports referred to in article 11§4 , but all elements of the directive that have given rise to concern or where improvements can be made. These requests should be seen in the light of the public debate in various Member States that has taken place mainly on long-term implants, such as breast implants and hips.

The Medical Devices Expert Group, which includes the Commission services, national authorities, representatives from notified bodies, European standards organisations and industry, devoted a number of meetings to this review throughout 2001 and 2002. The present report reflects the outcome of these discussions. At this stage, it does not commit the Commission or Member States.

Against a general background on the medical devices sector and the Community regulatory framework, it sets out the various issues and concerns raised in the course of the review process, and formulates actions to improve the regulatory framework or its implementation.

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<sup>1</sup> - Article 11§4

# 1. Medical Devices and their impact on public health.

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A large and evolving sector...

Medical devices cover a wide range of products. Figures have been advanced of over 10,000 different families of medical device types; given variations in the features of each of these device families, over 400,000 different medical devices could be on the market.

Medical technologies and devices are vital, integral components of patient care and have an impact on the living of citizens in a very concrete way. They make contributions to a large number of health care areas. (box next page). Examples of medical technology contributing to the health care in key health priorities identified by Commission, European Parliament and Member States for reduction and improvement for patient health in Europe (cardio-vascular diseases, interventional cardiology, stroke management, cancer, delivery systems, wound care, musculo-skeletal disorders, etc.) are given in Annex 1.

## Medical Devices Directives define Medical devices as

“ any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;”

The medical devices sector is in constant evolution. Particularly in the health care sector, society and citizens directly benefit from technological progress, probably more than in any other sector. At the same time, the speed of change and the degree of sophistication obtained also create challenges: does the regulatory framework provide sufficient guarantees for progress and safety, can care providers handle the potential offered by medical technology, is the degree of sophistication in itself a source of concern, is sufficient training provided?

Originally a technology associated with mechanical engineering, technological developments in the medical device sector have shifted boundaries. Tissue- engineering entering the two traditional sectors of healthcare, blurring traditionally clear borderlines pharmaceuticals and medical devices. Information and telecommunication technologies have added new dimensions to medical devices, introducing at the same time enormous benefits and complexity. The increased complexity of devices will put extra burdens on users and on national health care systems who have responsibility for training qualified staff to handle medical technology.

The ageing of population will affect the medical devices sector, as does the perception of health citizens have today. Quality of life and subjective well-being are considered as legitimate concerns.

In vitro diagnostic devices offer a powerful tool for the screening and monitoring of the population on particular diseases. IVDs are a small part of public health expenditure, but they can have an enormous impact on citizens health and national health policies.

Events that occurred in recent years in Member States, such as breast implants, dialysers, disinfectants, have highlighted the political sensitivity of the sector. Even if the zero-risk with medical devices does not exist, the public expects the highest safety standards and a no-failure rate. In case of difficulties in health care, it will immediately challenge government and the regulatory system in place, more than in any other sector. The debate on breast implants also suggests that any regulatory framework, how well designed for a sector as a whole, will be put into discussion if specific issues can not be dealt with in a convincing way.

### **Contribution to health care**

- ◆ **Prevention:** protecting against disease by preventing or reducing the risk of its occurrence or reoccurrence, or limiting its security, e.g., vaccine-delivery devices, prophylactic devices, and sterilisers.
- ◆ **Screening:** detecting a disease or abnormality, or risk factor associated with these in asymptomatic populations, e.g., mammography for breast cancer, prostate-specific antigen testing for prostate cancer, and colorectal cancer screening devices and tests.
- ◆ **Diagnosis:** identifying the cause and nature or extent of disease, e.g., CT for head injuries, angiography for atherosclerosis, and glucose monitoring tests for diabetes.
- ◆ **Treatment:** restoring maintaining, or improving health, including cure of acute disease, care of chronic conditions, palliation to relieve or alleviate when cure is not possible, or avoidance of deterioration, e.g., drug delivery systems, prosthetic joints radiation therapy for cancer, bioartificial organs and laparoscopy for minimally invasive surgery.
- ◆ **Rehabilitation:** restoring, maintaining or improving an impaired person's ability to function, e.g., ambulatory aids, incontinence and ostomy aids, sensory aids, and assistive devices for speech impairment
- ◆ **Improvement of Quality of Life:** enabling patients to lead a fuller and more comfortable life, often outside the hospital environment and often returning to full time employment, for example by means of ambulatory infusion pumps and monitoring equipment.
- ◆ **Reducing the cost of Healthcare:** by reducing the length of hospital stay; shortening surgical and diagnostic procedures; and improving the outcome of treatment.

Outlook for Medical Technology Innovation - Will Patients get the care they need?",  
Report 1: The State of the Industry,  
The Lewin Group for HIMA, 2000, page 12

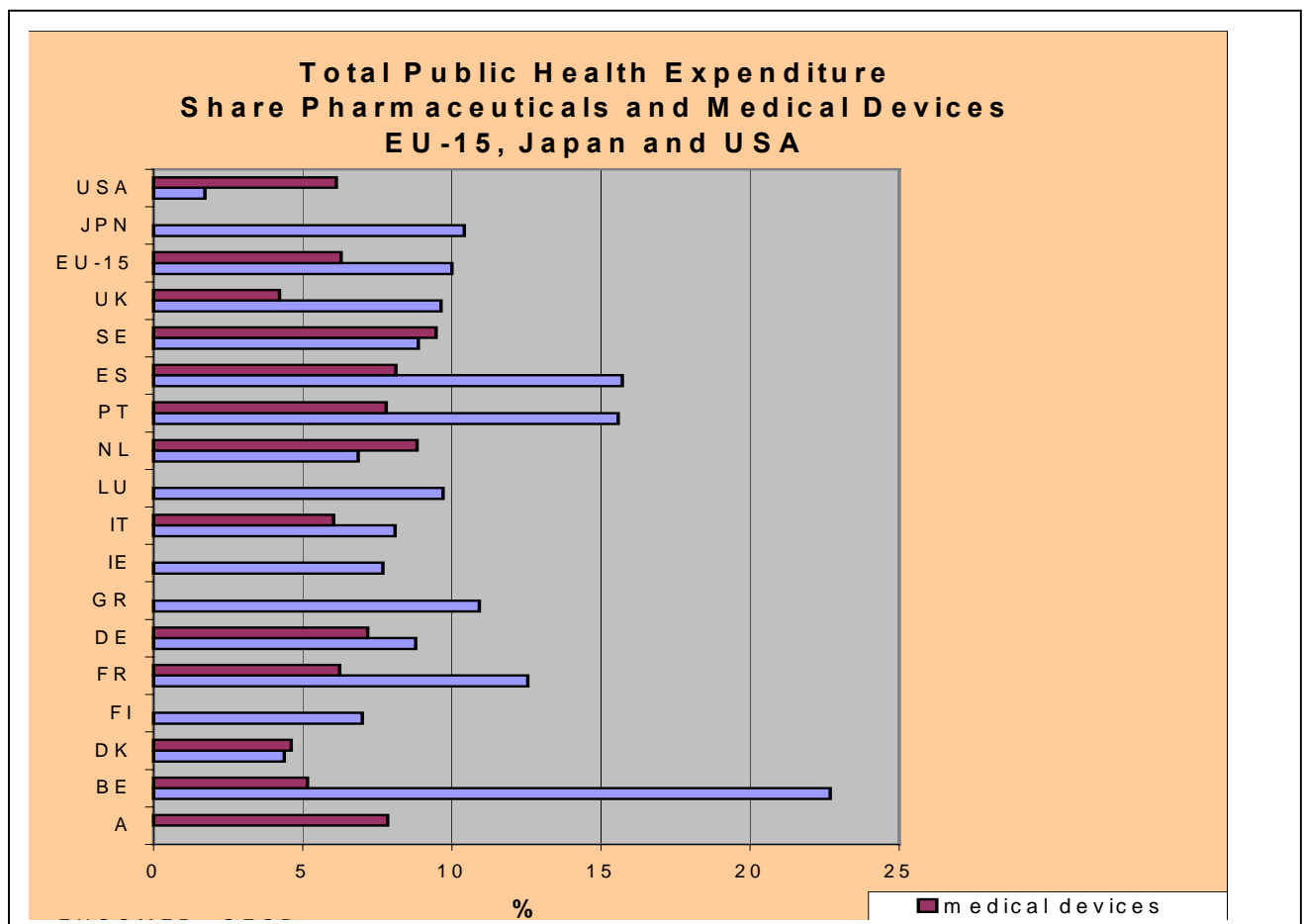
Also the 'future patient' has an impact on the sector. The perception of where the balance of responsibility lies for health and health care between the state or provider and patient is



changing. The 'responsible patient' will have new responsibilities and rights. Patients now increasingly have the means to monitor, diagnose and treat themselves, which on the other hand raises issues for national health policies in areas as monitoring of blood pressure or self-testing on AIDS or genetic testing. Patients express increasingly a demand for information on health matters. The regulatory system should be able to demonstrate a certain transparency in the provision of information on medical devices including their regulatory compliance or non-compliance

**With a high impact on public expenditure....**

Recent information relating to public expenditure on health and medical devices is available mainly from the OECD <sup>2</sup> and a study carried out by Eucomed <sup>3</sup>. Mention can be made of a study



for the European Commission <sup>4</sup> that dates from 1996, but data go back to the early nineties. The OECD study covers only partly medical devices. Figures presented by industry - which are set off against the OECD figures - are quite detailed in relation to medical devices.

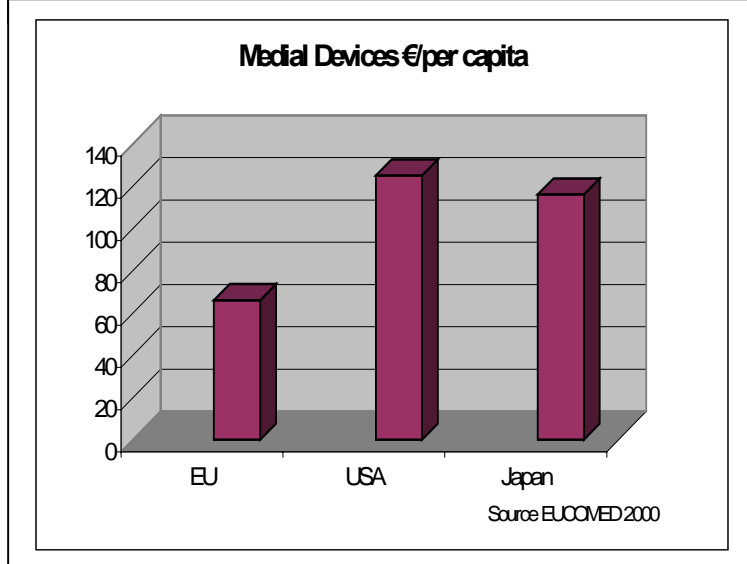
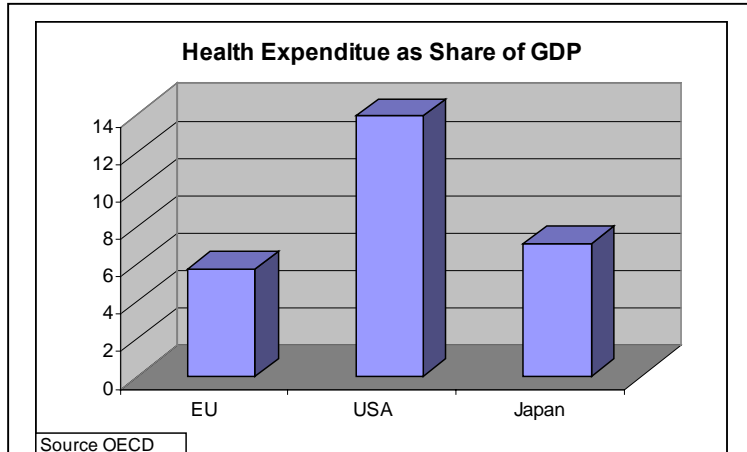
The combination of the information made available by OECD and industry suggests that the impact is quite significant, although different from one country to the other.

<sup>2</sup> - Reference to be added

<sup>3</sup> - EUcomed: "European Medical Technologies and Devices Industry Profile 2000". The study can be obtained from Eucomed, Brussels.

<sup>4</sup> - "The global competitiveness of the European Medical Devices Industry" prepared by L.E.K Partnership

Data gathered at national level seem to confirm these findings. For instance, according to a German study <sup>5</sup>, one third (100 billion DM) of the German statutory health insurance system's total expenditure (300 billion DM) is spent in the hospital sector. 70 % of these costs flow into human resources. 50 % of the rest (15 billion DM) are for medical devices in hospitals.



### Distinct from Pharmaceuticals.

The medical devices and pharmaceutical products present similarities as both are used, broadly speaking, for a number of similar functions: diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, or control of conception.

However, there are substantive differences, which mainly lay in the way of action: in contrast to pharmaceuticals, medical devices do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means; traditionally, medical devices are based on engineering technology. Therefore, the risks involved and the potential impact on the body are

of a different nature. This difference has a number of consequences, in particular on the regulatory environment and the life-cycle of products.

In contrast to pharmaceutical products, medical device regulation is based on the New Approach. Regulatory requirements relate to a number of safety risks for patient and user, and to the performance claimed by the manufacturer. Placing on the market or putting into service of medical devices is not subject to a formal authorisation, as is the case with pharmaceutical products. However various conformity assessment procedures are defined involving, except for low risk medical devices, third party certification. These procedures are to be implemented on the basis of classes of medical devices, these classes being defined in relation to the nature of risks involved. An important role exists for voluntary European standards.

<sup>5</sup> - "Trends in the German hospital market"; study carried out for BVMed by Roland Berger & Partners GmbH, Munich/Germany.

The life-cycle of medical devices is relatively short. Devices are subject of a continuous review based on feedback from health professionals and from the market. For instance, since their introduction on the market, pacemakers are said to be in their 10<sup>th</sup> generation.

Recent technologies, including the use of animal tissues, tissue engineering and the use of pharmaceuticals in medical devices reduce in specific aspects the differences between pharmaceuticals and medical devices, and suggest that the model of the New Approach has to be adapted.

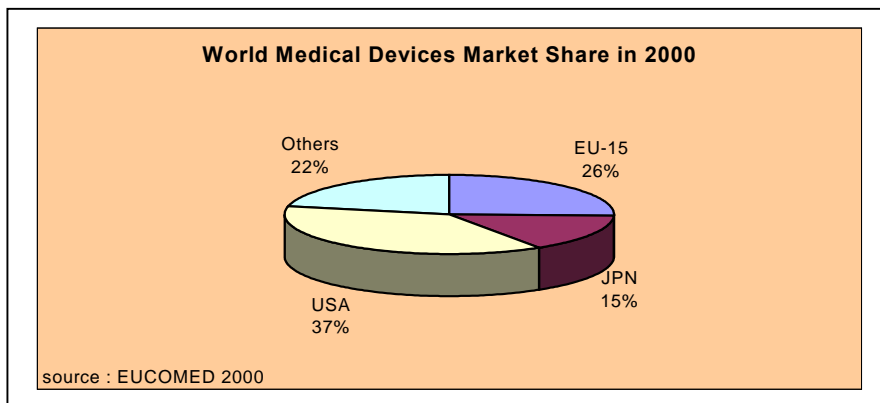
A table setting out in schematic form the differences between the two sectors is attached in Annex 2 .

## 2. The sector dynamics and economics <sup>6</sup>

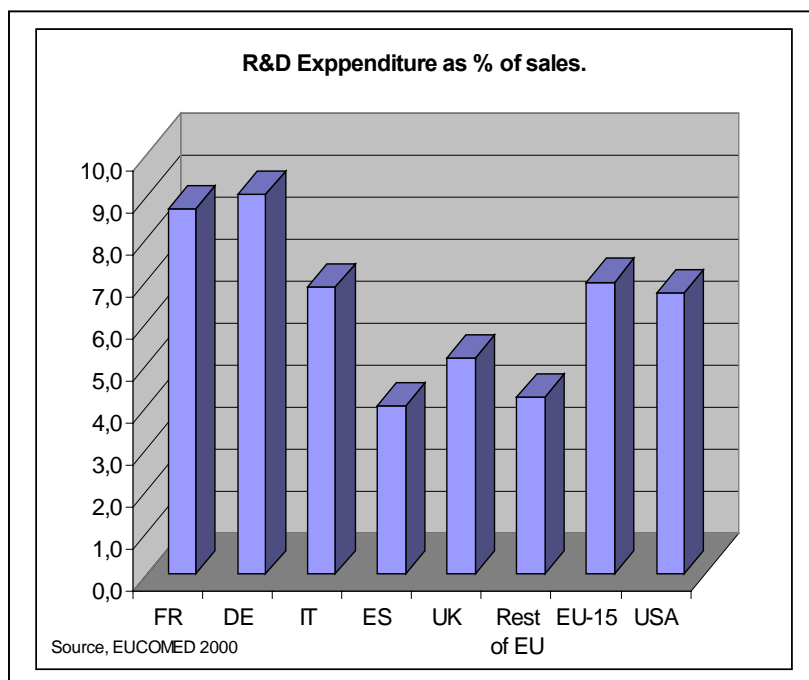
In its contribution to the review process, European industry reports that the European Market is valued at 41 billion EURO and is the second largest market in the world for medical device technology, preceded by US and followed by Japan.

The EU market currently accounts for 25.6% of the world-wide sales of medical devices. This compares to an estimated 31% share in 1993. The reduction in overall market share is due partly to rapid expansion of medical technology sales in other markets; partly to

market consolidation resulting in better distribution channels, and partly because of reducing prices of many devices. However, the decrease in world market share is also due to significantly lower European expenditure on healthcare (5,7% of GDP in EU compared to 13,9% in USA and 7,1% in Japan).



The L.E.K. study <sup>7</sup> shows that the position of European medical device manufacturing in Europe in 1993 was strong with 76% of the EU Market served by EU manufacturing <sup>8</sup>. The Commission intends to launch a study that which will complete and update the L.E.K. study.



The European Medical Device Industry employs more than 300,000 people and comprises more than 7000 individual business entities, 70% of which are small or medium size enterprises.

More particularly as regards IVDs, the sector employs about 30,000 people in the EEA in 1998; 10% of these are in Research & Development. EDMA, the European IVD industry federation, estimates that sales in 1998 were 5,700 million Euro. The IVD industry has suffered significant loss of employment in the last decade (perhaps up to 10,000

employees in Europe) due mainly to consolidation. The top five companies in the industry now

<sup>6</sup> - Information supplied by the EUCOMED and EDMA trade associations

<sup>7</sup> - L.E.K. Partnership May 1996, "The Global Competitiveness of the European Medical Devices Industry", Executive Summary, page 4, figure 3.

<sup>8</sup> - See EUCOMED European Medical Technologies and Devices Industry Profile 2000, pages 33-34.

represent 60% of the market and the indications are that this consolidation will continue. The driver of this consolidation is falling margins resulting from the continuing cost containment squeeze in the public health sector. Investment in R&D in the EEA has fallen from about 11% in 1992 to about 7% in 1998.

The corresponding figure for US R&D investment in 1998 is about 15%, employment about 56,000 and the market is about 8,000 million Euro. These estimates are less reliable than those for the EEA. According to EDMA, the US market is more buoyant simply because the US is spending about 30 Euro per capita per year on IVDs compared with 15 Euro in EEA and 22 Euro in Japan.

Although the GDP has been steadily increasing in the 1990's and health expenditure has expanded slightly faster than GDP, expenditure on IVD products has been almost static. Industry is concerned that cost containment in Europe has hit laboratory medicine hard. According to EDMA, spending on IVDs and in vitro testing in Europe is now so low that it will have long term effects on the costs of treatment. EDMA fears that the absence of a sufficiently strong policy on diagnosis now means that treatment in the future will be much more expensive.

Country	Market Size 2000 billion	% of World Market 2000	Health Expenditure % GDP	Medical Devices per capita	Growth Rate 2000
<b>EU</b>	41*	25.6%	5.7%*	66	5.5%
<b>USA</b>	60*	41.5%	13.9%*	125	7%
<b>Japan</b>	24.5*	15%	7.1%*	116	4%
<b>Rest of World</b>	34.5*	18%	-	-	15%
<b>World</b>	160*	100%	-	-	6%

Source EUCOMED and ADVAMED (formerly HIMA) 2000, [World Bank 2000 World Development Indicators](#) (Market size figures indicated exclude In-vitro Diagnostic devices (IVDs) which are up to 17% of the overall market value)

### 3. Legal framework

#### Three main directives

The medical devices sector is covered by three Directives, covering a wide scope of products (see annex 3).

The first Directive was adopted in 1990; it deals with active implantable medical devices<sup>9</sup>. The second Directive, adopted in 1993, deals with medical devices in general.<sup>10</sup> The third Directive, adopted in 1998, deals with in vitro diagnostic medical devices.<sup>11</sup>

The 1998 Directive on In Vitro Diagnostics Medical Devices (hereafter the **IVDD**) brought a number of modifications to the 1994 Directive on Medical Devices (hereafter **MDD**), in particular regarding the creation of a European Data Base for Medical Devices and the introduction of a mechanism allowing Member States to take action based on the precautionary principle.

No changes were brought to the 1990 Directive on Active Implantable Medical Devices (hereafter **AIMDD**).

#### Tissues

Special provision is made in the Directives to exclude from their scope transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin. Also excluded are transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

The Commission proposal for the IVDD also contained a section on the use of non viable human tissues in medical devices. Whilst progress in the Council was possible on the IVD devices, the Council was reluctant to proceed on tissues as proposed by the Commission. The Council therefore only adopted the Commission proposal in so far it related to IVD devices.

In a later stage, discussions in the Council suggested that it would be advisable to restrict the Commission's proposal on the use of non-viable human tissues to devices containing derivatives of human blood and human plasma. Devices incorporating other derivatives of human tissues should be the subject of a special directive.

The Directive modifying the MDD in relation to medical devices incorporating containing derivatives of human blood and human plasma was adopted in December 2000.<sup>12</sup>

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<sup>9</sup> - Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices L 189 20 July 1990

<sup>10</sup> - Council Directive of 93/42/EEC of 14 June 1993 concerning medical devices L 169 12 July 1993

<sup>11</sup> - Council Directive of 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices L 331 7 December 1998

<sup>12</sup> - Directive 2000/70CE of 16 December 2000, OJEC L 313 of 13.12.2000 as last amended by Directive 2001/104/EC.

Work on a proposal for the use of other derivatives of human tissues has been overtaken by developments on tissue engineering in general. Work is currently undertaken in the Commission to come forward with specific proposals on tissue engineering.

## Main features of regulatory framework

The directives concerning medical devices are based on the principles of the **New Approach**<sup>13</sup>.

Under this approach, the Directives define the **essential requirements** that devices have to meet when they are put on the market or put into service. Requirements relate to issues such as risk assessment and risk management, chemical, physical and biological properties, infection and microbiological contamination, construction and environmental properties, protection against radiation, etc.

In order to allow technological progress to be taken into consideration in the design and manufacturing of medical devices, the directives do not specify technological solutions to be adopted by manufacturers.

Products can only be placed on the market or put into service, if they were subject of a **risk assessment, a risk management process and a risk/benefit analysis**.

Devices can only be placed on the market provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

According to the directives, the solutions adopted by the manufacturer for the design and construction of devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles:

- eliminate or reduce risks as far as possible
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

In order to facilitate compliance with the essential requirements, the Directives foresee recourse to **harmonized European standards**. Where the reference of these standards have been published in the OJEC, compliance with such standards will provide a presumption of conformity with the relevant essential requirements. Whilst the essential requirements are obligatory, the standards remain voluntary.

Furthermore, the Directives contain a number of **conformity assessment procedures**, which depend on the type of products and type of risks involved. Except for low risk devices, these

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<sup>13</sup> - Council Resolution of 7 May 1985 on a New Approach to Technical Harmonisation and Standards, OJ 1985 N° C 135/1, 4.6.85

procedures always involve independent bodies, so-called Notified Bodies, designated and monitored by national authorities. In a number of cases, authorities act themselves as Notified Bodies.

Devices that meet the essential requirements and have undergone the appropriate conformity assessment procedures will be **CE marked**. The CE denotes a formal statement by the manufacturer of compliance with the Directives' requirements.

Part of the overall concept of the New Approach are mechanisms open to public authorities to take corrective action. Under the "**safeguard clause**", they can take action with regard to products that constitute a danger for health. Under the procedure of "**formal objection**" to **harmonized standards**, they can challenge harmonized standards: if the objection is upheld by the Commission, after consultation of the Member States, the standard will cease to provide a presumption of conformity with essential requirements.

However, the Directives on medical devices contain a number of provisions that reflect the **specific nature of medical devices** for public health compared to other products covered by New Approach legislation:

- post market surveillance and vigilance procedures
- procedures for systems and procedure packs
- registration of persons responsible for placing devices on the market
- Clinical investigation
- Creation of a European database
- Reclassification of medical devices
- Precautionary principle

Finally, as regards In Vitro Diagnostic Medical Devices, the possibility is foreseen for the adoption of **Common Technical Specifications (CTS)**. CTS establish appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials. They find their origin in a practice in some Member States whereby for selected devices (mainly used for the evaluation of blood supply and of organ donation) such specifications were adopted by public authorities.



#### 4. Implementation of the Directive.

The AIMDD, MDD and IVDMDD have been implemented in all Member States.

In order to ensure a coherent implementation of the Directives, Commission, national authorities and stakeholders have created a number of instruments and working groups, in addition to the – formal – Committee created by the Directives.

1. The main platform for discussion on implementation issues is the **MDEG, the Medical Devices Experts Group**. MDEG is chaired by the Commission. Participants are the national competent authorities (including applicant countries) representatives of industry, European standards bodies and of Notified Bodies. Users - the medical profession - participate on an occasional basis. Although meetings are open to other stakeholders, such as patient organizations, participation has been low, mainly because of the absence of representative European organisations. MDEG deals with issues relating to the MDD, the AIMDD and the IVDD. However, recently the need has been identified to dedicate specific MDEG meetings to implementation of the IVDD.

MDEG has set up a number of **specific Working Groups** that report to MDEG. The currently active WGs relate to :

- vigilance,
- Mutual Recognition Agreements and the Global Harmonisation Task Force,
- BSE/TSE,
- the European Database for Medical Devices (EUDAMED) and the Global Medical Devices Nomenclature (GMDN),
- Common Technical Specifications for IVDs and
- clinical evaluation (chaired currently by France).

As the need arises, specific groups are created, for instance on the use of PVC and Latex.

MDEG can adopt **guidelines, “MedDevs”**, that reflect the consensus view of authorities and stakeholders on issues of interpretation or implementation. MedDevs are published on the Commission’s website. They relate to issues such as classification of medical devices, interface with other directives – medical devices/medicinal products, designation and monitoring of Notified Bodies within the framework of EC Directives on medical devices, vigilance etc.

2. The Directives create a number of implementation tasks for national authorities. In order to co-ordinate national action, and to create transparency in the exercise of national competencies, two Working Groups have been created composed of representatives of national administrations, dealing respectively with
  - Notified Bodies (the **Notified Bodies Operations Group, NBOG**, chaired by the United Kingdom) and
  - Market Surveillance (the **Market Surveillance Operations Group, MSOG**, chaired by Portugal).

Both Groups meet hosted by the Commission. Output of their work is presented in the MDEG.

3. Notified Bodies meet on a regular basis in the framework of the **Coordination of Notified Bodies Medical Devices (NB-MED)**. The aim is to co-ordinate in the assessment of technical issues. Typically the group meets 3 times per year. Every Notified Body concerned with medical devices can send delegate(s) to this group. The **NB-MED** lays down its conclusions in **recommendations and consensus statements**. A list of subjects covered by consensus statements and recommendations is included at Annex 4.
4. Scientific advice on particular issues is obtained from the **Scientific Committee on Medicinal Products and Medical Devices**, created by Commission Decision N° 97/579/EC of 23 July 1997 <sup>14</sup>. The list of the Committee's **Opinions** adopted so far is available on the website of the Commission <sup>15</sup>

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<sup>14</sup> - (Official Journal N° L 237 of 28.8.97).

<sup>15</sup> - [http://europa.eu.int/comm/food/fs/sc/scmp/index\\_en.html](http://europa.eu.int/comm/food/fs/sc/scmp/index_en.html)

## 5. Impact at an international level.

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The Medical Devices Directives have had an impact at an international level in several ways.

### Global Harmonization Task Force

The Directives on medical devices have been a model for the activities of the GHTF. Various documents issued by GHTF aimed at regulatory convergence were directly inspired by the Community model. This is true in particular for the approach based on Essential Principles, contained in a GHTF document that reflects almost literally Annex I on essential requirements of MDD 93/42/EC. Other examples are the GHTF documents on labelling, the role of standards, vigilance, quality systems audit, etc.

The outcome of GHTF is now looked at very carefully by an increasing number of regulatory authorities. At the last GHTF Conference, Singapore 2002, more than 30 countries were represented.

#### GHTF

The Global Harmonization Task Force (GHTF) is a platform for representatives from national medical device regulatory authorities and the regulated industry from three geographical areas: Europe, Asia-Pacific and North America.

The objective of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade.

The GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

### Australia

The new Australian medical devices legislation (in force as from 5 October 2002) is aligned on the principles of GHTF and therefore de facto it will achieve harmonisation with the MDD and AIMDD. The draft legislation is currently proceeding through the required process for its adoption. The requirements regarding clinical studies are expected to be very close to the EU requirements. The current Post Marketing Surveillance scheme will most likely be replaced with the European Vigilance system.

### Canada

The current Canadian legislation for the control of medical devices - Medical devices regulations July 1998 - was subject to comment during its development in the context of the Global Harmonisation Task Force. This was especially relevant in an European context in that the legislation uses some of the elements of the MDD including definitions, essential requirements, risk classification and graduated approach to conformity assessment. The legislation makes some elements mandatory which are not in the EU systems, ie compliance with standards.

## **USA**

The USA has taken up the concept developed in the EU of using 3rd parties for conformity assessment. The FDA Modernisation Act (FDAMA) of 1997 was created under pressure of the Congress a so-called Third Party Review Program. The purpose was to improve the efficiency and timeliness of the pre-market 510(k) process by which applies to the majority of devices marketed in America. Under the Program, FDA has accredited third parties who have to submit their review, recommendation, and the 510(k) to FDA who has by law 30 days to issue a final determination.

## **Japan**

The Japanese authorities have recently, (February 2002), announced that they will be part of a trial for the usage of a GHTF document on the format of technical documentation ' Summary technical documentation' STEDs. The format will be accepted as the basis for approval for new and improved medical devices during a 1 year trial period. The STED is based on the essential principles of safety and performance which are in turn based on EU essential requirements.

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## **6. Overall assessment of the functioning of the Medical Devices Directives**

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Discussions on the functioning of the Medical devices Directives lasted for more than a year. Discussions led to a number of conclusions shared by all stakeholder

It is acknowledged that the Directives have created a comprehensive and uniform regulatory framework for medical devices, repealing incomplete and divergent national rules and bringing about a significant improvement in the regulatory system in Europe. On the whole, the approach on conformity assessment procedure, based on the grading of risks, has proven right, as does the transfer of responsibilities to competent bodies acting under

### **Summary of main conclusions.**

1. The medical Devices Directives provide in themselves an appropriate legal framework with a view to safety aspects and technological evolution. However, there is room for improvement in implementation, to be achieved by all parties involved: national authorities, Notified Bodies, Commission and industry;
2. The most critical area where improvements should be made concerns conformity assessment. Action required relates to a number of issues, including designation and monitoring of Notified Bodies, reclassification of devices, conformity assessment by Notified Bodies, proper implementation of provisions on clinical data, on quality assurance and Post Market Surveillance.
3. Failure to act on one of these elements in the field of conformity assessment will not produce the required improvements. Inversely, it is also understood that major issues identified with the implementation of the directives will be solved by a combined action on these elements.
4. As the regulatory framework in itself is deemed appropriate, improvement should be achieved by better implementation, more clarification of existing provisions and better co-ordination mechanisms between authorities on a number of aspects.
5. There are however a number of issues where the Directives would require modifications in order to improve the regulatory framework.

the authority of national authorities in respect of verification and certification. Market monitoring by the authorities and the vigilance system in particular are basically appropriate instruments for reacting to problems with products that come to light during the marketing and application phases. Furthermore, specific mechanisms have been introduced allowing intervention by authorities in the interest of public health, such as the health protection measures on the basis of the precautionary principle.

Though the Directive must be judged positively on the whole, mention should be made of a number of problems, weak points and areas where improvements can be made. These concern both the rules themselves and their proper application.

Furthermore, if the current regulatory approach is suited to most types of product, its application to other some categories must continue to be verified on a case-by-case basis. For instance, for products of biological origin (such as products made of human tissue), the approach can be questionable - biological safety aspects as well as ethical questions and political implications may call for regulation according to other principles.

Ahead of the formal implementation of the conclusions of this Report, national authorities and Commission services have already started action. Various Working Groups have been created to deal with specific issues, such the Clinical Evaluation Task Force, the Notified Bodies Operations Group and the Market Surveillance Group.

However, as it was voiced recently, *"it is not enough to produce better guidance, clarify rules and tighten the requirements upon manufacturers. What is needed above all is for national authorities across Europe, and the European Commission itself, to devote sufficient human and other resources to this important area. It is clear that this is not the case now. There is a real risk that unsafe medical devices could be placed on the market. They could remain on the market until they have compromised, perhaps fatally, the health and safety of patient or user. That is unacceptable"*.<sup>16</sup>

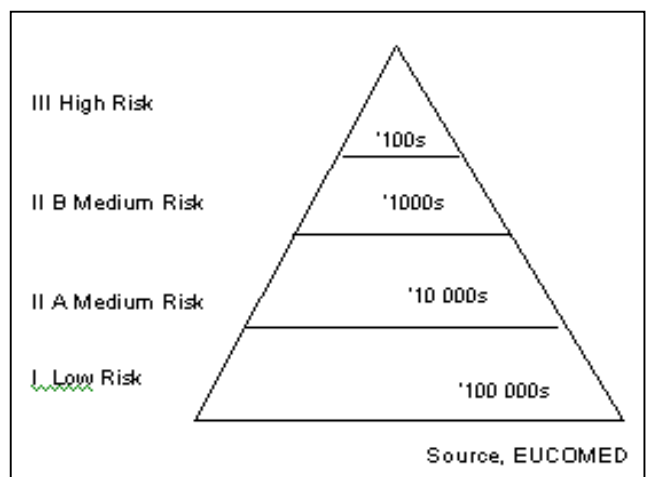
## 7. Issues, concerns and actions.

In the sections below, this report indicates particular issues dealt with, describes the regulatory system, presents the difficulties identified and formulates proposals to handle them. Implementation of these proposals will require in a number of cases a verification of various reference documents that exist, such as the text of Directives, international and European standards, Meddevs, Notified Body consensus statements, third country experience, GHTF documents. Implementation is not part of this Report.

Approximate number of products in each class

### 7.1 Classification of medical devices

Medical devices are classified on the basis of a decision tree into 4 classes (I, IIA, IIB, III). Classes determine the conformity assessment procedures available for a particular device. The decision tree is based on a number of Rules, which build on the concept of a risk-based approach related to the duration of use, invasiveness and hazards associated with the medical devices. In addition there are special rules for specific type of devices, for example those utilising animal tissues or blood bags or incorporating a medicinal product. Class III devices present the highest risks and are



<sup>16</sup> - Lord Hunt, Parliamentary Under-Secretary of Health, (UK) in the MDA 2001 Annual Meeting: protecting patients - raising standards. September 20<sup>th</sup>, 2001.

subject to the most stringent conformity assessment rules.

In order to ensure a coherent interpretation of the Classification Rules, the MDEG has elaborated a guidance document<sup>17</sup> to aid in the classification of medical devices.

The Directive has foreseen the possibility to adapt the rules in the light of technical progress and information that has become available under the vigilance procedures (article 9). In addition, where the outcome of the classification under the Classification Rules is unsatisfactory with regard to resulting conformity assessment procedures, Member States can submit substantiated requests to the Commission in order to obtain for individual medical devices and groups of medical devices, a re-classification decision (article 13).

As regards classification three major issues have been identified: the necessity for upgrading (or downgrading) of certain medical devices in order to ensure the most appropriate conformity assessment, certain anomalies in the outcome of the classification of particular devices, and some incoherence in the classification rules.

### 7.1.1 Up (down) grading of medical devices; anomalies

The debate on breast implants has raised the question whether long term implants should not be classified as Class III devices instead of Class IIB devices. The practical difference concerns the conformity assessment procedure in case the manufacturers opts for the "quality approach" instead of the "product approach"<sup>18</sup>. If a device belongs to Class III, the Notified Body has to carry out a specific design examination, leading to a EC design examination Whilst there has always been a strong consensus of all Member States Commission that there was a case for placing breast implants into Class III, differences of opinion existed as to the question whether this should be best achieved by a modification of and the Classification Rules, i.e. a modification of the Directive, or by a decision based on article 13.

Eventually, MDEG took the view that the mechanisms foreseen by the Directive should be used before modification of the Directive should be considered, the more as the Classification Rules have proven to work well to the point that they have been internationally accepted in the GHTF.

In the course of the debates, Member States have indicated a number of products where reclassification decisions should be considered. This relates not only to upgrades from IIA or IIB to III (e.g. intraocular lenses, breast implants, stents, hip implants, ventricular assist devices (VADs), portable medical infusion pumps) but also from class IIA to IIB (e.g. disinfectants), or from class I to class IIA (e.g. nursing beds, wheelchairs and patient lifters).

Breast implants are Class IIB devices. In order to ensure that under the Quality Assurance Scheme Notified Bodies carry out a design dossier examination leading to an EC design-examination certificate, it has been decided to proceed, on the basis of article 13, to a reclassification into Class III.

Commission Communication 15 November 2001

Whilst in most cases reclassification concerns an upgrading, Member States have also indicated that there may be cases for down-grading. Down-grading can be achieved similarly by using the mechanism foreseen in article 13.

<sup>17</sup> - Guideline for the classification of medical devices Meddev 2.4/1 Rev 8 07-2001

<sup>18</sup> - See hereafter.

Discussions have also revealed that in some cases implementation of the Classification Rules can lead to **anomalies**.

For instance, while single use surgical instruments require conformity assessment involving a Notified Body, reusable non-sterile instruments are classified as Class 1, for which the conformity assessment procedure does not require intervention of a Notified Body. As the potential risk of reusable non sterile surgical equipment seems higher than of single use surgical instruments, It has been suggested that the same classification should apply for both single use and reusable versions of products with the same intended purpose.

Also here, the mechanism to be used is a Commission measure based on a request introduced by a Member States, based on article 13 of the MDD.

### **7.1.2 Incoherence in Classification Rules.**

Various problems have been raised, for example in relation to the wording of classification rules, 6 and 7 contained in annex IX of 93/42/EEC. Firstly rule 6 relates to surgically invasive devices for transient use( less than 60min) and rule 7 surgically invasive devices for short term use ( not more than 30 days). In rule 7 devices in direct contact with the central nervous system are specifically mentioned and are reassigned to class III while in rule 6 they are not specifically mentioned therefore they will be in class IIA. It is considered that the risks associated with devices in contact with the central nervous system (for example used in brain surgery) do not diminish with duration of contact therefore all these devices should be in class III. Secondly in rules 6 and 7 the term 'control' is missing from the description of devices which are intended for use in and around the heart and circulatory system.

Additionally the definition of the central circulatory system does not contain the aorta descendens and the bifurcation resulting in according to national authorities, a too low classification for certain devices.

#### **Action**

1. Member States to use the possibility to submit requests for re-classification of individual medical devices and groups of medical devices, based on article 13 MDD and to be adopted through the (Regulatory) Committee procedure, in conformity with article 7§2 of the MDD.
2. Commission proposal to be elaborated with a view to a modification of the Classification criteria annex IX, for example on rules 6 and 7, in conformity with the procedures foreseen in article 9 and 7§2 of the MDD.

## **7.2 Conformity assessment**

The Directive contains a number of procedures to be followed for the assessment of conformity of medical devices with respect to the provisions of the Directive. The type of procedure to be followed is determined by the class of the medical device. Class I products, that present low risks, are subject of a manufacturer's declaration, based on a risks analysis and risk management approach carried out by the manufacturer without intervention of a third party. The procedures for class IIA, IIB and III require always the intervention of a Notified Body, i.e. an



organisation, public or private, designated by the Member States to carry out the conformity assessment tasks as specified in the Directive.

For each class, the Directives offer a choice to manufacturers. The options hinge around either a “product based approach” or a “quality approach”

#### Product approach

class	Design	Production
I	Manufacturer's declaration	
IIA	Manufacturer's declaration	<ul style="list-style-type: none"> <li>● EC verification, or</li> <li>● Production quality assurance, or</li> <li>● Product quality assurance</li> </ul>
IIB	EC type examination	<ul style="list-style-type: none"> <li>● EC verification, or</li> <li>● Production quality assurance, or</li> <li>● Product quality assurance</li> </ul>
III	EC type examination	<ul style="list-style-type: none"> <li>● EC verification, or</li> <li>● Production quality assurance</li> </ul>

#### Quality approach

Class	Design	Production
IIA	Full quality assurance, without design dossier examination by Notified Body	
IIB	Full quality assurance, without design dossier examination by Notified Body	
III	Full quality assurance, including design dossier examination by Notified Body	

### 7.2.1 Design evaluation

Questions have arisen on the **evaluation of the design** of a product where the manufacturer chooses the conformity assessment procedure based on a full quality assurance system. Annex II of the Directive makes a design dossier evaluation obligatory for Class III devices. The manufacturer must lodge an application for the examination of the design dossier relating to the product, and the Notified Body will eventually issue an EC design-examination certificate. However, a similar specific design examination under the full quality approach leading to the EC design-examination certificate is not obligatory for Class IIA and IIB devices (for instance long term implants). This raises the question to what extent design evaluation is part of the verification of the quality assurance system for IIA and IIB devices.

The absence of clear rules on design evaluation by notified bodies in the framework of a quality assurance system was mentioned as a cause of concern as regards Class IIB devices. Some national authorities have indicated that in for Class IIB products the Annex II procedure (full quality assurance system) exhibits numerous shortcomings.

It was specifically suggested that Annex II may need to be adapted to make this intervention by

the Notified Body explicit for class IIB devices. It has been further suggested that for class IIA products this check is at the level of types of devices and for class IIB on families of devices

However, bearing in mind the possibility to reclassify devices, the overall consensus that emerged from discussions is an understanding that an assessment based on a full quality system approach cannot take place without any form of design evaluation by the Notified Body. The assessment of whether a manufacturer has indeed the organisational capabilities to carry out a design activity for medical devices, cannot take place without the Notified Body examining - on a sampling basis - technical documentation in relation to design, including the technical files relating to the use of clinical data, risk analysis and design evaluation. The samples must be chosen to reflect *inter alia* the risks associated with the intended use for the device, the complexity of the manufacturing technologies, the range of the devices produced. As the Directive presents a graduation in the conformity assessment procedures commensurate with the risks presented by the device, a proper implementation of the assessment of quality systems implies for Class II B products the review of design documentation in relation to coherent families of devices

These concepts may need further clarification within guidance addressed to Notified Bodies.

### **7.2.2 Validity of certification**

There are conformity assessment options for some classes of products that do not include annexes for which a period of certification is required, thus certificates related to these annexes may be issued without expiry dates. Experience has shown that a smooth-running system can go completely off the rails in the space of three years resulting in the opinion that all conformity assessment certificates should have a period of validity. Issuing certificates with no expiry date deprives the notified bodies of a suitable opportunity to examine the classification or design of the product concerned.

The Directive puts an obligation on manufacturers to take account of the generally acknowledged 'state of the art' in the design and construction of products Annex 1 para 2. However this obligation refers to the placing on the market of medical devices. The validity of the conformity assessment is set by the period of validity of the certification, depending on the conformity assessment module used it could be undefined or 5 years. Furthermore any significant changes must be assessed by the manufacturer/Notified Body for their effect on the product. If this principle were to be challenged it would jeopardise legal certainty. It should be noted that there is no commonly held interpretation of 'state of the art' in Member States<sup>19</sup>.

It has been suggested that manufacturers and Notified Bodies should as a general principle be obliged to regularly monitor the conformity of their products on the basis of the current 'state of the art'. Further discussion is needed for the exact interpretation of what 'state of the art' means in this context and the consequential effect on validity of certification.

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<sup>19</sup> - Legal aspects of standardisation in the Member States of the EC and EFTA, volume 1, comparative report. Harm Schepel, Josef Falke. Published by the European Commission 2000. ISBN 92-828-8907-6

#### Action

3. Guidance should be developed to clearly describe under what conditions design evaluation for individual products, families of products and groups of products has to take place in the framework of conformity assessment procedures based on a quality assurance approach.
4. Commission to develop a proposal to modify the MDD in order to develop a proposal for a period of validity for conformity assessment certificates

### 7.3 Notified Bodies.

Notified bodies (Notified Bodies) are entities (private or public) designated by the Competent Authorities (CA) of Member States to carry out tasks relating to conformity assessment of medical devices. Their duties are limited to those for which they have been found technically and administratively competent. They are subject to continuous surveillance (monitoring) by their CA. Notified Bodies assume responsibilities in the area of public interest and remain answerable to the national CA<sup>20</sup>. The manufacturer is free to choose any Notified Body that has been designated for the required scope of products and conformity assessment.

The Directives contain a number of general criteria for the designation of Notified Bodies. Commission, Member States and other stakeholders have elaborated specific guidance for the designation and surveillance of Notified Bodies.<sup>21</sup>

There are currently 60 entities that have been designated as Notified Body by Member States for all or part of the conformity assessment annexes for the MDD. Details of designations are published in the Official Journal of the EC and are also available on the Europa website <sup>22</sup>.

Concerns expressed in relation to Notified Bodies relate to the competence for the task for which they are designated, differences in interpretation between Notified Bodies and lack of transparency in the performance and control of their activities.

It is probably fair to state that Notified Bodies are seen to be the most critical element in the implementation of the Medical Devices Directives, requiring action by Notified Bodies and national authorities alike.

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<sup>20</sup> - Guide to the implementation of directives based on the new approach and the global approach - EC 2000

<sup>21</sup> - Designation and monitoring of notified bodies within the framework of EC directives on medical devices MEDDEV 2.10/2 rev 1

<sup>22</sup> <http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies.htm>

### **7.3.1 Competence of Notified Bodies.**

National authorities and industry have expressed doubts, whether all Notified Bodies possess the necessary requirements to fulfil all the tasks for which they have been notified. These concerns relate both to the Notified Body itself and the designation and monitoring process by Competent Authorities.

Member States have highlighted shortcomings in the functioning of Notified Bodies in particular in relation to design evaluation in quality assurance system, clinical data, and post market surveillance. Similar concerns have been raised by representatives from industry, for whom a strict application of the conformity assessment procedure may certainly be more costly, but also provides more legal certainty.

The main responsibility for addressing this issue lies with the national authorities, who are primarily responsible for the designation and monitoring of Notified Bodies. If need be, and on the basis of performance, Notified Bodies should be de-notified or their scope of competence should be described in a more precise manner.

Whilst all Member States have designated a number Notified Bodies for products covered by the medical device directives, the wide product coverage of the directives and their increasing complexity (e.g. software, biological risks) suggest that Notified Bodies may have to specialise in future and that their number may decrease.

Aware of their responsibility, Competent Authorities agreed to set up Notified Body Operations Group (NBOG) at their July 2000 meeting in Paris. The aim was to improve Notified Body (NB) performance by, primarily, identifying and promulgating examples of best practice to be followed by Notified Bodies and Member States. A work programme for the group was agreed in Stockholm in December 2000, and updated in Gent in June 2001. Significant progress on the work programme has been made. It is critical that competent authorities pursue their action in the NBOG.<sup>23</sup>

### **7.3.2 Coherence in interpretation.**

Notified Bodies have a prime responsibility in assessing technical solutions adopted by manufacturers to meet the essential requirements of the medical devices directives. This is particularly true where no European standards exist that relate to the essential requirements.

Coherence in assessment is a major issue. Therefore, Notified Bodies have created the Co-ordination Group Notified Bodies medical devices NB-MED in order to discuss

implementation matters. Participation in the NB-MED is high. The outcome of discussions is laid down in NB-MED recommendations.<sup>24</sup>

Although NB-MED recommendations are regularly circulated to Member States, it has been suggested that - as Notified Bodies work under the authority of national authorities - their status should be reinforced. Furthermore, NB-MED recommendations should be made publicly available.

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<sup>23</sup> - This work programme is set out in Annex 5.

<sup>24</sup> - A list of recommendations is in annex 4.

### 7.3.3 Need for more information.

Concerns have been expressed that sufficient information is not available on how Notified Bodies issue certificates or perform conformity assessment tasks, as they are accountable only to the authorities by whom they have been designated. In case national authorities from other countries want to obtain information on activities carried out by Notified Bodies, they have to address themselves to the national authority that designated the Notified Body. Some Member States have indicated that feedback is poor.

The need for more transparency became particularly clear in the debate on the use of tissues of animal origin and the BSE/TSE risk. Authorities expressed their wish to be reassured on the competence of Notified Bodies. Consequently, It has been proposed that this specific issue is addressed within the Commission decision currently being elaborated, through a review of the Notified Body's competence as part of an overall re-examination of certification for these devices incorporating tissues of animal origin and the provision of information on the basis for and outcome of conformity assessment.

Furthermore, it has been suggested that at least for high-risk products (e.g. Class III) more transparency is provided to the public at large, as is the case under pharmaceutical regulation. More transparency could be achieved by making '**EU Notified Body public assessment reports**' available on the Web for high-risk medical devices. The concept of EU Notified Body public assessment reports is currently being discussed by a working group of the Medical Devices Expert Group.<sup>25</sup>

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<sup>25</sup> - Discussions commenced June 2002

#### Action

5. Member States to improve Notified Body (NB) performance by, primarily, identifying and promulgating examples of best practice to be followed by Notified Bodies and Member States (MS). Continuation and completion the work of working group Notified Bodies Operations Group NBOG.
6. Modify the MedDev on designation and monitoring of Notified Bodies so that, in order to ensure coherence, Notified Bodies are committed to participation in the NB-MED
7. To improve administrative co-operation in the feedback on requests from national authorities on information regarding Notified Bodies' performances.
8. NB-MED recommendations to be subject of endorsement by MDEG and be enforced by national authorities responsible for the designation and monitoring of Notified Bodies.
9. NB-MED recommendations to be made publicly available, through publication on the relevant web-site of the European Commission.
10. Discussion by Stakeholders on the exchange of information and the public availability of Conformity assessment reports.

#### 7.4 Clinical evaluation

The MDD requires that confirmation of conformity with the requirements concerning the characteristics and performances under the normal conditions of use of the device and the evaluation of the undesirable side-effects be based – “as a *general rule*” - on clinical data. The adequacy of the clinical data must be based on either a compilation of the relevant scientific literature currently available and a critical evaluation of this compilation, or the results of clinical investigation.

The clinical data must be available for all medical devices, irrespective of classification.

Feedback during discussions indicated that there were shortcomings in the implementation of the Directives' provisions on clinical data. Manufacturers do not always have clinical data available, including for Class I devices. Furthermore, Notified Bodies would not verify sufficiently the adequacy of clinical data provided with respect to characteristics and performances of the device. Finally, concerns have been raised that the wording of the Directive can lead to doubts on interpretation.

Aware of the importance to be attached to clinical data, a **Clinical Evaluation Task Force (CETF)** has been set up, comprising representatives from Member States, Notified Bodies and Industry in order to develop detailed guidelines on how to apply the Directive's provisions on clinical data.

Provisional conclusions of the CETF suggest that problems encountered concern the interpretation of the directive rather than shortcoming in the regulatory framework or ambiguities in the text. Specific guidance documents will have to be developed for clinical investigations of implantable medical devices. Other medical devices are adequately covered by the current

documents on clinical evaluation, developed by the Notified Bodies Recommendations Group<sup>26</sup>. However, such documents are not always properly implemented.

Issues to be dealt with by CETF relate to

- The role of the Notified body including their competence to examine clinical data;
- The need for a clinical investigation to take place;
- Guidance on the compilation of relevant scientific literature;
- The performance of clinical investigations and specifically the clinical investigation plan;
- Post marketing follow up for medical devices ( after the product has been placed on the market);
- The interpretation of specific terms in the MDD;
- A guideline document for the clinical investigation of implantable medical devices;
- Access to clinical expertise;
- Innovative devices and follow up after launch of new technologies;
- Feasibility of setting up a system of decentralised device expert panels to provide clinical expertise.

In relation to the availability of expertise it has been suggested that clinical expertise and clinical guidance should be available on a centralised European basis.

The Directive asks in article 15 of the MDD for clinical investigation programme to be notified to the Competent Authority of the Member State in which the investigation is to be conducted. Member States supplied information on clinical investigations conducted between 1995 and 2000. Only about half of the Member States provided quantitative data on the number of clinical investigations reported. The data is presented in annex 6 the data is randomly distributed and thus difficult to interpret. The Member States also provided comments on the operation of the system. In summary these comments were

- The current system does not include a mechanism for other MS to obtain information on investigations.
- A system of clinical guidance documents was considered necessary.
- Procedures need to be harmonised via a guideline
- A MS commented that it is objecting to about 1/5<sup>th</sup> of notifications the majority of which were due to failure of the manufacturer to demonstrate compliance with the essential requirements.
- There may be inconsistencies in assessment of CIs across the community.
- The current system does not make provision for monitoring of the CI.
- The requirement for reporting adverse incidents during a CI may be inconsistent.

These comments have been fed into the work of the Clinical Evaluation Task Force.

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<sup>26</sup> - NB-MED/2.7/Rec3 "Evaluation of clinical data.; NB-MED/2.7/Rec1, "Guidance on clinicals"

## Action

11. CETF to develop recommendations on clinical evaluation for endorsement by MDEG, including the issue of availability of clinical expertise.

## 7.5 Post Market Surveillance

The Directive asks for the provision of a systematic procedure to review experience gained in the post production phase, i.e. after the devices have been appropriately CE marked and put into service. The manufacturer should have a system to review this information and take appropriate follow up action. Post market surveillance PMS also includes the information gained as a result of vigilance as detailed in article 10.

The gathering of timely information on the performance of products, is important for manufacturers once these products have been placed on the market. Information comes from many sources including information gathered from;

- adverse incidents including vigilance reports (article 10),
- user reports <sup>27</sup>( where such a system exists in MS),
- follow up of patients after clinical evaluation trials,
- service reports,
- evaluation reports,
- scientific papers in peer reviewed journals,
- anecdotal information from the market place,
- reports from handling trials,
- reports on similar products.

Traceability of products, knowing the ultimate destination of products, is important for gathering relevant timely information on the performance of products, especially those where follow up action may be needed, for recall, revision and advisory information to the user. Member States highlighted traceability for long term implants including the follow up of clinical trials to 'end of life' as important. In the Commission's Communication on breast implants the issue of traceability is stressed and the same is valid for types of long term implants such as joint replacements or hydrocephalous shunts.

The implementation of a policy on traceability may require actions at national level, such as implant registries.

Member States have emphasised that for long-term implants the deficiency in gathering PMS information is especially marked. However the consensus is that the extent and nature of the need and means to gather PMS information in general is poorly understood and applied. It has been identified that on many occasions a system to systematically gather such PMS information does not exist and that the Notified Body has not identified shortcomings in this respect. It has been suggested that better guidance should be available. The concepts of 'active' and 'passive'

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<sup>27</sup> - It should be noted that user reports are made because of an adverse event which has occurred with a medical device and such reports may be voluntary or obligatory depending on the MS requirements while a vigilance report concerns an adverse event which meets certain criteria as defined in the Directive and the onus is for the MS to take the necessary steps together with the manufacturer.



systems of information gathering have been put forward for consideration and may be models which can form part of the discussions.

Action

12. Development of guidance on PMS leading to better implementation of the Directive by manufacturers and better enforcement by Notified Bodies.

## 7.6. Vigilance

Member States have to take the necessary steps to ensure that any information, in relation to the following two points, brought to their knowledge in accordance with the provisions of the Directive regarding specific incidents involving medical devices (regardless of their class), is recorded and evaluated centrally:

- (a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling 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 state of health;
- (b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

This article relates primarily to information provided by the manufacturer. The manufacturer is obliged to communicate any information they obtain (see above) to the competent authorities if such risks are involved.

As part of national policy, Member State can also require medical practitioners or the medical institutions to inform the competent authorities of any such incidents. In that case, it shall ensure that the manufacturer of the device concerned, or his authorised representative established in the Community, is also informed of the incident.

After carrying out an assessment, if possible together with the manufacturer, Member States shall immediately inform the Commission and the other Member States of such incidents if relevant measures have been taken or are contemplated.

Vigilance is one of the aspects on which the Directive requires the Commission to present a report to the Council. To this end, the Commission has organised an enquiry with Member States, the results of which are indicated in annex 7. The following conclusions can be drawn:

- The data on reported cases are extremely heterogeneous, particularly between Member States. It could be expected that, over the years, the amount of data should either follow a normal distribution or a gradual increase. In some cases, such as Belgium, nland, the Netherlands and the UK, there is a clear trend – namely a steady increase – in the number of vigilance cases reported, but for some other countries there is a random distribution.

- Perhaps the major conclusion of the questionnaire is that - on the basis of the vigilance data presented more research is necessary to identify the causes and the uneven presentation vigilance reports.

Concern was expressed about a particular situation that occurs when safety measures are restricted by the manufacture or (for legal or practical reasons) by the competent authorities to the sovereign territory of a Member State or an EEA member country, without using the mechanisms foreseen by the directive or without formal national measures. Under the vigilance procedure such a withdrawal would occur for the whole of the community. Consequently the product remained on parts of the community market and Member States had to take individual actions.

<p>Action</p> <p>13. Member States to verify and improve practise on vigilance.</p> <p>14. Member States to refrain from unilateral action outside the mechanism foreseen by the Directive.</p> <p>15. MDEG vigilance working group to intensify activities and co-ordinate national implementation.</p>
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## 7.7 Standards

European standards play an important role under the New Approach. The search for technical solutions to meet the Directives' essential requirements is the responsibility of the manufacturer. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

European standards intervene as they offer technical solutions, agreed by a national enquiry and national vote, deemed to meet the essential requirements and a generally accepted level of "state of the art". Since European standards will have gone through an adoption process during which all interested parties, including national authorities, had the possibility to intervene or object to the technical solutions presented or the link made with essential requirements, New Approach directives attach to the use of such standards a presumption of conformity with the essential requirements. This means that Notified Bodies or authorities have the burden of proof if they consider that the use of a standard does not meet the essential requirements.

Overall, standards provide a "référentiel", increase the level of transparency in implementing the directive and the degree of legal certainty for all interested parties.

Member States and Commission can however challenge European standards through a "formal objection" . If a formal objection is upheld and confirmed by a Commission decision, adopted after consultation of the Member States, the standard ceases to produce a presumption of conformity.

Annex 8 contains a description of the standardisation activities in relation to the Medical devices directives.

References of harmonised standards that, transposed into national standards, give presumption of conformity are published in the Official Journal of the European Community and in national formal publications. An overall list is published and is available on <http://www.newapproach.org/directiveList.asp>

Mainly four issues have been raised in the process of this review.

### **7.7.1 Involvement of public authorities**

Standardization is open to all interested parties, including public authorities. A number of Technical Committees active under the European Standards Organizations is chaired by national authorities. However, the extent of the standardisation programme in relation to the availability of national authorities has raised concerns. Since standards play an important role in the implementation of directives, national authorities have highlighted the **need for a sufficient involvement** in the standardisation process. This situation should be improved in the first place at the national level. However, it has also been suggested that public involvement might be prioritised and co-ordinated at Community level.

### **7.7.2 Quality of standards**

Whilst overall satisfaction is expressed on standardisation, some Member States have raised concerns in relation to the quality of specific European standards. Standards may not always reflect the **state of the art** or be insufficient to provide presumption of conformity with essential requirements. However, whilst in other areas (machinery, gas appliances, toys...) the formal mechanism for objection is being used, no formal objections have as yet been introduced with respect to European standards for medical devices. It was further clarified that in cases where the standard, which was intended to become a harmonised standard, was deemed inadequate, prior consultation could take place between Member States and the Commission in order to refrain, in accordance with the Directive provisions, from publishing the reference in the Official Journal.

### **7.7.3 Tools to implement essential requirements.**

Some Member States have suggested that a mechanism be introduced in the Medical Devices Directive allowing the Commission, after consultation of the Regulatory Committee, to adopt binding measures complementing the essential requirements, in addition to voluntary European standards. A similar mechanism exists in the Directive on In Vitro Diagnostic Medical Devices, by which "Common Technical Specifications" (CTS) can be established on performance evaluation and re-evaluation criteria, batch release criteria and reference methods and reference material.

There has not been sufficient support for this idea. The CTS are considered under the In Vitro Diagnostic Devices Directive itself as an "exception to the general principles", and find their origin in a practice in some Member States whereby for selected devices (mainly used for the evaluation of blood supply and of organ donation) such specifications were adopted by public authorities. A similar situation does not exist for medical devices in general. Moreover, such a mechanism should in any case not be seen as an alternative to European standardisation.

#### 7.7.4 Delay in output

Concerns have been expressed on the delays in the output of standards.

##### Action

16. National Authorities and National Standards Bodies to develop mechanisms at the national level to ensure the largest information of and participation by national authorities.
17. National authorities to identify - Community wide - a number of key standards to be followed in more detail, and agree on who will report to the other on potential problems. Co-operation to be implemented under the administrative co-operation arrangements.
18. Member States to formally challenge European standards under the Medical Devices Directives in cases where standards present shortcomings, also prior to publication of the reference.
19. Commission, national authorities, standards bodies and industry to monitor progress on European standards in the framework of the Medical Devices Expert Group and to formulate specific recommendations to the standards bodies.

#### 7.8 Safeguard clause

Under the **safeguard clause**, a Member State is obliged to take all appropriate interim measures to withdraw devices from the market or prohibit or restrict their being placed on the market or put into service, if it ascertains that a medical device when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety. In that case, it shall immediately inform the Commission of any such measures, indicating the reasons for its decision. The Commission shall enter into consultation with the parties concerned as soon as possible.

In case where the Commission concludes that the national measures are justified, it shall inform so the Member State concerned and all other Member States. New Approach Directives do not state that the other Member States are to adopt similar measures. Where the Commission finds that the measures are unjustified, it shall immediately so inform the Member State that took the initiative and the manufacturer or his authorized representative established within the Community.

The review has identified two issues with respect to the safeguard clause.

##### 7.8.1 Involvement of all Member States

First, during the instruction of a safeguard clause introduced by Germany banning catgut it became apparent that Member States were sharply divided as regards the question whether the German measure was justified, and no clear majority view appeared. Instruction of the safeguard clause in conformity with the procedure defined in article 8 of the MDD would have led to an opinion by the Commission in consultation with the German government and manufacturer concerned, that other Member States would have been expected to follow.

## 7.8.2 Role of the Commission.

Second, the issues submitted in safeguard clauses are often of a complex nature. It is a matter of fact that the instruction by the Commission takes a long time. Moreover, in most cases sufficient internal technical expertise at Commission level is lacking. Delays can be increased because the Scientific Committee on Medicinal Products and Medical Devices has to be consulted. However, whilst the Scientific Committee can provide opinion so risk assessment, it will not be qualified to assess matters of risk management or risk/benefit analysis. On the other hand, legitimate concerns of legal certainty and transparency require that the Commission delivers an opinion as fast as possible. The Commission has identified this issue also in the framework of the overall review of the New Approach.

### Action

20. Particularly in sensitive health issues, where Member States can take different views, it is essential that the consultation procedure is extended to all Member States. If a consultative committee were to be established, the Commission would have a formal platform to enter into consultation with Member States where appropriate.
21. Procedural rules to be developed and implemented - *inter alia* in relation to increased transparency in the procedural follow-up - for Commission and Member States.

## 7.9 Particular health monitoring measures

The Directive on vitro diagnostic medical devices (98/79/CE) introduced a new mechanism, extending it also to the medical devices directive, in relation to "particular health monitoring measures".

According to this mechanism, a Member State is entitled to take "any necessary and justified transitional measures in relation to a given product or group

The importance of this debate and the consequences for national health policies became clear in the debates on the **availability of self-tests for Aids and HIV infection**.

Most Member States are in favour of restricting the availability of such devices to the medical profession. Other have taken the view that the public has the right to self-diagnosis, but that precisely for that reason appropriate information should be provided. Basing national restrictions on the health monitoring mechanism, would imply that national measures would have to be superseded by uniform measures adopted at Community level.

The Commission has taken the view that national measures without impact on the technical requirements of a medical device, but merely on their commercial distribution or availability, fall outside the scope of the Directive. Consequently, national differences on the distribution and availability of self tests remain possible, subject to other provisions of Community law.

of products, if it considers that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article 36 of the Treaty, the availability of such products should be prohibited, restricted or subjected to particular requirements. It shall then inform the Commission and all the other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested

parties and the Member States and, where the national measures are justified, adopt necessary Community measures in accordance with the procedure referred to in Article 7(2)." The particular health monitoring measures are intended as an application of the precautionary principle, the conditions of use of which have been defined in the Commission's Communication on the Precautionary Principle (2000/1) of February 2, 2000

On a number of aspects, the mechanism seems fundamentally different from the safeguard clause.

- Under the safeguard clause, a Member States has to "establish" that a device may compromise health or safety. Under the health monitoring mechanism a Member States must be able to provide sufficient evidence for reasonable doubts.
- Under the safeguard clause, the instruction involves Commission, the Member State that introduced the safeguard clause and interested parties. Under the health monitoring mechanism, the Commission must consult interested parties and all Member States.
- Under the safeguard clause, where the Commission confirms that the national measure as justified, Member States will be informed and they will have to adopt appropriate national measures. Under the health monitoring mechanism, the national measure – if justified - will be superseded by a Community measure, adopted after consultation of the Regulatory Committee, leading to a uniform application throughout the Community.

On other aspects, application of the national health monitoring measures raises questions: can it be used as an instrument by authorities implementing the risk management scheme, or as an instrument to decide on the risk/benefit analysis? Does it refer to potential risks, being understood that the safeguard clause refers to established risks?

At various occasions, it has become apparent that different interpretations are given to this meaning of this mechanism, its scope for application and the conditions under which it can be exercised.

#### Action

22. To clarify through a /Guideline/Commission Communication/modification Directive/ the way and conditions under which Member States can use the national health monitoring measures under article 14 ter of the Medical Devices Directive.

### 7.10 Scope

The Directives on medical devices define their scope by a wide definition of medical devices and a number of exceptions of products that normally might fall under the definition<sup>28</sup>. Finally,

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<sup>28</sup> - For instance, article 1§5 of the MDD states that "this Directive does not apply to:

- (a) in vitro diagnostic devices;
- (b) active implantable devices covered by Directive 90/385/EEC;
- (c) medicinal products covered by Directive 65/65/EEC;
- (d) cosmetic products covered by Directive 76/768/EEC (18);
- (e) human blood, human blood products, human plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;
- (f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;

they define as necessary their relation with other directives, such as the directive on personal protective equipment, EMC and Directive 80/836/Euratom.

The scope of the Directive raises various borderline issues.

### **7.10.1 MDD and Pharmaceuticals**

Inevitably, because of the wide definitions of medical devices and medicinal products and the interrelations that may exist between the two sectors, borderline issues do exist. Guidance has been developed on how to handle the borderline between the application of the MDD and medicinal product legislation.<sup>29</sup> However, questions may always be raised, requiring a clarification of a case-by-case basis.

For a number of products<sup>30</sup>, that might qualify as medical devices, but that have traditionally been associated to regulation on medicinal products, it has been suggested that a legal solution be found, preferably in the regulatory framework on pharmaceutical products.

### **7.10.2 MDD and IVD**

The in vitro diagnostic medical devices is a relatively new Directive (1998). However, several issues have already been raised regarding the borderline between in vitro diagnostic medical devices and medical devices. As previously stated the application of the two Directives is mutually exclusive. These issues will be discussed between the stakeholders in order to reach a consensus, this may be described in a guidance document MedDev.

### **7.10.3 Biocides and IVDs.**

Directive 98/8/EC on Biocides includes within its scope in vitro diagnostic medical devices (Directive 98/79/EC) that contain biocides. It specifically excludes all other medical devices. There was a clear intention among all parties involved in the drafting of the « Biocides Directive », to exclude from its scope **all** medical devices. The reason that IVDs are not excluded is the fact that Directive 98/79/EC had not yet been adopted when Directive 98/8/EC was published.

The situation should now be clarified through a modification of Directive 98/8/EC on biocides.

### **7.10.4 Products that can qualify as personal protective equipment and medical device.**

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(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

<sup>29</sup> - Guideline relating to the application of the council directives on medical devices 90/385/EC and 93/42/EC and council directive 65/65/EC relating to medicinal products.

<sup>30</sup> - Med Dev 2.1/3, point 4.2: water for injections, IV fluids and plasma volume expanders, haemofiltration substitution solutions, in vivo diagnostic agents, e.g. x-ray contrast media, NMR enhancing agents, fluorescent ophthalmic strips for diagnostic purposes, carrier solutions to stabilize micro-bubbles for ultrasound imaging, gases for in-vivo diagnostic purposes, including lung function, tests, e.g. carbon dioxide for vascular diagnostic purposes, solutions for peritoneal dialysis, antacids, artificial tears, fluoride dental preparations.

Some products, e.g. gloves, can qualify as personal protective equipment and as medical devices. In deciding whether a product falls under the PPE Directive or under the MDD, particular account must be taken from the principal intended use of the product.

There is a consensus that the possibility should be opened to place such products on the market either on the basis of both directives, or on the basis of one of the two, as declared by the manufacturer.

#### **7.10.5 Products presented as medical devices that do not fall under the directive.**

National authorities have mentioned that too often products are inappropriately described as a medical device (e.g. charlatan or miracle products). This occurs in particular with products presented as Class I devices, where conformity assessment is based on a manufacturer's declaration, without intervention of a third party.

National law should create the mechanisms allowing national authorities to intervene in such cases.

There is a consensus that authorities should exchange information in the framework of market surveillance, and that transparency should be provided as to administrative decisions based on article 18 MDD, to the benefit of all authorities and interested parties.

#### **Action**

23. For products covered by Med Dev 2.1/3, point 4.2, solution to be adopted in the framework of the review of pharmaceutical regulation.
24. Commission to propose modification of Directive 98/8/EC on Biocides in order to exclude from its scope IVD devices.
25. For products covered by Med Dev 2.1/3, point 4.2, solution to be adopted in the framework of the review of pharmaceutical regulation.
26. Member States to verify availability of national provisions allowing national authorities to intervene with respect to products wrongly presented as medical devices. National authorities to intensify exchange of information. Commission/Member States to explore mechanisms to increase major transparency.
27. Discussions to take place between stakeholders to reach a common understanding on IVD MDD borderline issues, the consensus will be described in the form of a guideline, MED DEV

#### **7.11. Wider involvement of Member States**

The three Directives on Medical Devices foresee the use of a Committee composed of representatives of Member States, originally set up under the 1990 Directive on Active Implantable Medical Devices. The rules governing the execution of tasks given to this Committee have been modified by Council decision 1999/468/EC of 28 June 1999 laying down



the procedures for the exercise of implementing powers conferred on the Commission<sup>31</sup>. This decision, amongst others, provides for criteria relating to the choice of committee procedures, with a view to achieving greater consistency and predictability in the choice of type of committee.

This Council Decision has been complemented by the Commission's Model Rules of Procedure for Committees.

Under the three Directives, the Committee has a two-fold task.

In the first place, it acts as a **regulatory committee**, that the Commission is obliged to consult where measures have to be adopted in the framework of the directives (e.g. reclassification of medical devices, follow-up to national health monitoring measures, Common Technical Specifications under the IVD Directive).

In the second place, the Committee "**may examine any question connected with the implementation**" of the relevant Directive.

In the course of the review process, Commission services and representatives of national representations have indicated that there is room for a procedure where the Commission can formally consult Member States. Medical devices do raise a number of sensitive issues, where a proper co-ordination and consultation between Commission and Member States is necessary.

A further role for a formal consultation procedure exists for the adoption of guidelines in relation to the implementation of medical devices. Today, such guidelines are based on a consensus between Commission, national administrations and stakeholders, achieved in the Medical Devices Experts Group. Whilst guidelines should continue to be elaborated and consensus should be established in the MDEG, there is nevertheless need for a more formal commitment by the Member States that are to implement and use the guidelines.

The Commission should be able to consult Member States, without being subject to the stringent formal rules related to comitology, justified for regulatory measures, but not necessarily for consultation purposes.

Action

28. Commission to introduce appropriate mechanisms allowing a formal consultation of Member States in relation to the implementation of the Directive.

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<sup>31</sup> Official Journal L 184 , 17/07/1999 P. 0023 - 0026

## 7.12 Confidentiality .

According to article 20 of the MDD, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

The question has been raised as to whether this provision effectively means that any information obtained by a Competent Authority in the course of its work cannot be released to a third party unless it is specifically allowed for elsewhere in the Directive (for example the vigilance provisions contained in Article 10). In practical terms this would mean that:

- *details of Class 1 manufacturers registered under Article 14 register cannot be made public;*
- *the reasons a Member State objects to a Clinical Trial taking place cannot be made know to other Member States (even though the manufacturer may submit exactly the same notification to a second Member State following objection by the first); and*
- *a Member State would be effectively prevented from passing to other Member States information obtained as a result of its post market surveillance activities unless such information had effectively passed into the public domain as a result, for example, of being used in a court action.*

After in-depth discussion, the general understanding emerged that article 20 should be interpreted that Member States have the obligation to ensure that the parties involved in the application of the directive must maintain the confidentiality of information that they obtained in the implementation of their activities. Furthermore, Member States (and Notified Bodies) are required to ensure reciprocal information, the distribution of the warnings and to provide information under criminal law.

Consequently, Member States, far from being held to keep confidential the information that they obtain in relation to medical devices, have to exchange it with other Member States. They can, however, not make public information that is confidential.

### Action

29. Member States and Notified Bodies to proceed with the exchange of information in conformity with article 20, whilst ensuring confidentiality on information.

## 7.13 Market surveillance

Market surveillance is an essential tool for the enforcement of the Medical Devices Directive. Its purpose is to verify that the provisions of the Directive are complied with across the Community, to ensure a common level of safety and to eliminate unfair competition. National Authorities have recognised its importance and work has started on a uniform enforcement procedure. It is clear from discussions at meetings that levels of surveillance vary significantly

between Member States. National measures currently range from the proactive whereby specific product groups are targeted or manufacturers taken from those who have registered under Article 14 to the reactive where allegations of non-compliance are investigated.

Several initiatives have already been undertaken by National Authorities targeting for example class 1 manufactures or manufacturers of specific products .

A Market Surveillance Operation Group MSOG has been formed and a preliminary work programme is at Appendix 3

It is clear that market surveillance requires active monitoring of CE marked products

placed on the market. In order to manage scarce resources, National Authorities should share information on activities and experiences and develop common procedures.

#### **Market surveillance**

For enforcement of the Dutch Decree on medical devices, a method was developed to evaluate the technical files of Class I medical devices. This method itself was evaluated in a trial. The Dutch Inspectorate of Health Care selected 40 manufacturers to provide a technical file for review by the Laboratory for Medicines and Medical Devices. A file evaluation form was used as an aid in the systematic review of the technical file against the requirements deemed essential and the requirements for the file content as described in the decree.

Of the 40 manufacturers, five withdrew their registration of the product. Two of these five manufacturers encountered problems with the supply of products and three appeared not to be manufacturers according to the definition in the decree. 34 Of the remaining 35 manufacturers supplied a technical file in time (one manufacturer did need one year for completing and sending the file). None of these files proved to be complete. On average, each file showed five shortcomings. For 20 of the files supplied, additional information was requested to enable further evaluation of the essential requirements. Since five sets of additional information were received after the closure date of this study, 29 files were left for full evaluation. Each of these contained at least one flaw related to one of the essential requirements (109 flaws in total; average of 3.76; limits: 1-8 flaws). Each file contained flaws in labelling and instructions for use.

#### Action

30. MSOG to elaborate and implement a surveillance work programme on market surveillance.

### **7.14 European Database on Medical Devices. EUDAMED**

The IVDMD Directive introduced the obligation for Commission and Member States to set up a European Database, extending it also to the Medical Devices Directive. The objective of the European Database for Medical Devices, EUDAMED, would be to centralise data on

- manufacturers and their authorised representatives,
- devices placed on the Community market,
- certificates issues, suspended or withdrawn and
- the vigilance procedure, i.e. a system of adverse incident reporting by manufacturers.

A pilot project was launched in 1997 the 1<sup>st</sup> phase February 1997 and 2<sup>nd</sup> phase September 1998. In their meeting of June 2000, in St. Denis, France, national Competent Authorities and

Commission agreed that, building on the experience of the project, a Database should be set up, light in structure, in which Member States could directly feed their input, and the management of which could be easily transferred so as to observe Community rules on public procurement.

Some progress has been made since then. National authorities have agreed on the use of a common notification form, anticipating the launch of EAUDAMED. However, EUDAMED is not yet operational. In 2001, financing was made available to build a common database under the IDA programme by a decision made at the IDA TAC committee. Work started in September 2001.

The main difficulties identified can be summarised as follows.

#### **7.14.1 Nomenclature.**

A common database requires a common nomenclature for medical devices. In 1993, Commission and Member States invited the European standards Committee, CEN, to elaborate a European standard on terminology. This work was undertaken in co-operation with ISO, the International Standards Organisation, and resulted in 2000 in the adoption of ISO/EN 15225<sup>32</sup>. This standard gives a structure for the development of a specific nomenclature. Over the same period of time, and based on that standard, a Working Group ISO/CEN started to elaborate a nomenclature, that resulted in 2001 in the adoption of a technical specification<sup>33</sup>, containing some 14 000 terms, the Global Medical Devices Nomenclature (GMDN)<sup>34</sup>

At present, the GMDN is subject of verification by a number of countries/regions and formal endorsement. Countries like US (FDA), Australia (TGA), Japan (Ministry of Health and Welfare) have indicated their commitment to use GMDN. One may expect that, if FDA adopts the GMDN, also Canada will follow. There are requests from many other countries to apply and use this system (e.g. from Eastern European Countries, from South America, from countries in the Asian Harmonisation Group). WTO has expressed strong interest in the GMDN and has requested observer status in the GMDN Maintenance Agency Policy Group.<sup>35</sup>

One point of concern has been that the degree of detail obtained in the nomenclature is too detailed in relation to the description of the Notified Bodies competencies, that should be based rather on areas of technology than products. CEN/ISO have to be mandated to adapt the European/International standard to foresee in the nomenclature the establishment of categories of technologies.

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<sup>32</sup> EN 15225 - Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange.

<sup>33</sup> CEN CR 14230; ISO.TS 20225

<sup>34</sup> <http://www.bsi-global.com/Technical+Information/GMDN/index.xalter>

<sup>35</sup> The MAPG is responsible for ensuring that the GMDN is regularly updated and promoted. It is a committee with a maximum of 14 named persons, with global representation from the main stakeholders, notably industry and regulators. The MAPG is in charge of designing the procedures for creating new terms and for deciding how the GMDN is to be made available to different users. It manages the copyrights on behalf of the national members of ISO/CEN.

### 7.14.2 Scope of EUDAMED.

During discussions on EUDAMED, most Member States have expressed doubts on the usefulness of covering custom made devices in the current work on a European database. The conclusion was that although custom-made devices should be part of EUDAMED, they would not be included in the current work on the database.

### 7.14.3 Link between Global vigilance and EUDAMED.

In the framework of the Global Harmonization Task Force, a global vigilance system is being proposed. The vigilance system being developed under GHTF is however slightly different from the system set up under the Directives. In some aspects it is wider (for instance by covering user reporting and user errors as opposed to manufacturer reporting and product related problems). In other ways, it is more restrictive: GHTF does not require notification of near incidents. However, the differences between the two systems are not significant enough to make mutually exclusive participation in global vigilance and the creation of EUDAMED.

Action	
31.	National Authorities to unequivocally confirm their commitment to the implementation of GMDN.
32.	Data on custom made devices to be excluded from the present work on the European databank.
33.	Without prejudice to the establishment of EUDAMED the community to support the global vigilance scheme.
34.	Commission and Member States to increase efforts and put into place EUDAMED.

### 7.15 Consultation of the pharmaceutical authorities

A device which contains a medicinal product<sup>36</sup> and which is liable to act upon the body with an action ancillary to the device must have the safety, quality and usefulness of that substance ascertained<sup>37</sup> taking into account the intended purpose of the device. The Notified Body must consult with one of the competent bodies established in the Member States prior to taking a decision. Information was obtained on the functioning of this system as part of the report to the council required in article 11 part 4 of the MDD. The information provided by the Member States is summarised in Annex 9

- (a) Only a few isolated data was given for the number of pharmaceutical cases reported. This makes interpretation of the information very difficult.
- (b) There also seems to be a need for stating more clearly which medical substances should be submitted for consultation. Also here more harmonisation seems necessary.

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<sup>36</sup> as defined in annex 1 of Directive 65/65/EEC

<sup>37</sup> as described in Directive 75/318/EEC

## 7.16 Modification of the Active implantable medical devices Directive (AIMDD)

As has been mentioned in the section 3 on the legal framework, the AIMDD has never been modified. However, there have been changes made to the MDD notably those introduced in 98/79/EC that would be relevant also for AIMDD, for example the provision for a database and introduction of 'particular health monitoring measures'. These modifications could include in particular:

- addendum for EC type-examination certificates
- requirements regarding new devices
- a single person (manufacturer or authorised representative) responsible for placing on the market in the Community
- reference to the importer
- requirement to designate an authorised representative
- documenting of the quality system in the technical documentation

### Action

35. Commission to propose changes to the AIMDD in order to align it with Directives 93/42/EC and 98/79/EC.

## 7.17. Other Issues

### 7.17.1 Definitions

The Directive contains some definitions in article 1 § 2 and within the text of the Directive, However, problems have been experienced, for example, relating to the definition of 'authorised representative' and 'manufacturer'.

Questions have been raised as to the way in which the "legal manufacturer" should be identified on device which are made by Company A and supplied to Company B for resale under Company B's name and trademarks ("own brand labelling"). Lack of clarity can have a disproportionate effect on Industry, since the cost of changing packaging (e.g. to indicate a different name of manufacturer) can be prodigious. The current revision of the harmonised standard EN 980 might offer a satisfactory solution to the whole matter.

Incoherence has been identified in relation to article 14(2) and Annex III 7.4. As regards 'authorised representative' Article 14 (2) refers to paragraph 1, which covers only Class I and custom-made medical devices and combined packages. Although Annex III refers to authorised representatives, this Annex is not applicable to Class I products. This suggests that the reference in Article 14(2) may be incorrect. Similarly, Annex III (7.4) states that authorised representatives can be based outside the Community, thereby contradicting Article 14(2).

### Action

36. Question of 'legal manufacturer' to be examined in the context of the overall review of the New Approach.

37. Incoherence in reference to the authorised representative to be eliminated through modification of the Directive.

#### 7.17.2 Product files

Regarding the availability of product files, in accordance with the MDD the manufacturer must keep the product file at the disposal of the authorities for a period of at least 5 years after the production of the last product. It has been suggested that this period should be related to the expected lifetime of the medical device. Rules concerning the availability of product files should also be extended to medical devices that were put on the market after clinical trials. There is already guidance from the Notified Bodies Co-ordination Group on technical documentation their retention and availability, but such guidance cannot be enforced.

##### Action

38. Review the text of the MDD in relation to the period of retention for product files.

#### 7.17.4 Expiry dating

The requirements relating to the labelling of products are described in annex 1 section 13 of the MDD. The need for expiry dating is described in para 13.3 (e) as '*where appropriate an indication of the date by which the device should be used, in safety, expressed as the year and the month*'. National Authorities have had problems with the interpretation of this section as it relates to sterile medical devices where there is no expiry dating.

##### Action

39. For sterile medical devices the need for expiry dating should be explicit, changes to the MDD and or common guidance may need to be developed.

#### 7.17.5 Design of reusable devices

The design of reusable devices in relation to the conditions of cleaning and sterilisation is particularly relevant in the control of nosocomial infections in healthcare establishments.

##### Action

40. For re-useable devices discussion on the need for recommendations on their design in relation to cleaning and sterilisation.

### 7.17.6 Good Laboratory practice

The Directive does not include any essential requirements concerning the obligation to apply best laboratory practice for the testing of medical devices on animals, which is provided for in Directive 88/320/EEC

Action

41. The Commission to propose amendments to the MDD to include the requirements relating to good laboratory practice.

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## **8 Conclusions**

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There is a consensus that the legal framework created by the Medical Devices Directive is appropriate in relation to protection of health and provides patients with the benefits of technological innovation. However, its implementation needs improvement by all parties concerned. A number of initiatives are already being implemented in this respect.

Furthermore, the Medical Devices Expert Group, who is the author of this report will finalise a timetable for action and make this publicly available.

The Commission will present a communication highlighting the policy conclusions to be drawn from this review report.

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### **EUCOMED - The Benefits of Medical Technology and Devices for the EU Citizens**

(Extracts relate to devices under the MDD and AIMD)

Approximately 80% of healthcare costs are spent on the management of chronic disease, much of it on hospitalisation and medical intervention. The bulk of these costs are being spent on cardiovascular disease, cancer, diabetes, AIDS, orthopaedic and spinal diseases, arthritis and the full range of neurological diseases. As the population ages, the prevalence of chronic disease will increase dramatically, further accentuating the need for better chronic care. An important opportunity, in the near future, is to improve the quality of life for people with chronic disease. Also with regard to rare diseases is the devices and technology industry making a strong contribution and it is looking how the environment in Europe can encourage companies to do even more in this field.

The medical technologies and devices industry believes the opportunity to improve the management of chronic disease will be greatly facilitated by the integration of information technology with medical technology.

Some examples of areas where medical technologies and devices and the industry are playing a significant role are described below in more detail.

#### ***Cardiovascular Disease***

In the area of cardiovascular disease interventional cardiology, including coronary angiography and coronary stents, arrhythmia management and stroke management provide excellent examples of the contribution of medical technologies and devices to patient care. There has been a continuous trend of innovation in the development of procedures in these areas.

*According to the third monitoring report of the WHO, cardiovascular diseases cause 12 million deaths in the world each year. They cause half of all deaths in major developed countries, and are one of the main causes of death in many developing countries — and the major cause of death in adults.*

The utilisation of devices has contributed to the decline in mortality rate through appropriate diagnosis and treatment.

#### ***Interventional Cardiology***

Interventional cardiology has really come into its own since the 1970's. Technologies have provided much less invasive alternatives for patients who were typically treated by bypass surgery in the 60's and 70's. These modalities include coronary angioplasty, stenting and debulking. However, several

new pioneering techniques are underway to further the advancement of coronary care and to address restenosis, often referred to as the Achilles' heel of coronary interventions.

### ***Coronary Angioplasty***

In 1977, Dr. Andreas Gruentzig revolutionised interventional cardiology when he performed the first Percutaneous Transluminal Coronary Angioplasty (PTCA). PTCA has now become a widespread and relatively simple procedure, involving the use of a balloon catheter to open blocked, or narrowed, coronary arteries. It is estimated that approximately 1.5 million PTCA procedures are performed each year, with approximately 400-500 thousand of them being performed in Europe.

### ***Coronary Stents***

Coronary stents have revolutionised interventional medicine. The worldwide market for these devices was forecast at 2.1 billion in 1999, up from 1.9 billion in 1998. This young market is forecast to reach 4.8 billion by 2002, driven by increasing competition in both the United States and Europe.

Forces that continue to provide momentum in the coronary stent market include the development of smaller stents (permitting a larger group of patients to be treated) and new adjunctive therapies, such as radiation and statin drugs, that are showing promising results in reducing the plaguing problem of restenosis.

### ***The Challenge of Restenosis***

While these less invasive technologies have greatly enhanced cardiac care and have proved successful in huge numbers of patients, continued enhancements and developments are occurring to address some of the continued challenges facing the interventional cardiologist. These advancements include vascular brachytherapy, pharmacological agents and PTMR. The most significant challenge to the interventional cardiologist is restenosis.

### ***Vascular Brachytherapy (VBT) an Emerging Technology***

One of the most significant advancements in the treatment of restenosis involves the use of radiation to treat the balloon injury site, thereby reducing the amount of neointimal cell proliferation. This application is referred to as vascular brachytherapy. There are a variety of different projects, trials and marketing registries under development involving the use of Beta and Gamma isotopes. Recent clinical results from a number of trials have confirmed significant reductions in restenosis rates.

## ***Arrhythmia Management***

One device used for arrhythmia management is the implantable pacemaker. A pacemaker is an electronic device that stimulates the heartbeat. A slow heart rate is called bradycardia. It can occur in various types of heart blocks or arrhythmias (rhythm disturbance). The pacemaker may be needed temporarily or on a permanent basis. Sometimes myocardial infarction (heart attack) causes transient heart block requiring a temporary pacemaker. Most of the time, the need for pacing is permanent.

The global arrhythmia management device market is also growing rapidly, as the world's population ages and the cost-effective diagnosis and management of heart rhythm disorders grows in importance. The total market for these devices (valued at about 4.5 billion in 1998) includes external manual and automated defibrillators, traditional bradycardia pacemakers and implantable cardioverter defibrillators to treat tachycardias and various forms of fibrillation. Electrophysiology and catheter ablation products represent a market growing at 12–15% per year.

## ***Stroke Management***

Stroke diagnosis and treatment is a field in dire need of cost-effective technology, as the incidence of this disorder and treatment costs continue to grow. Worldwide, total stroke management costs are estimated at more than 100 billion. Stroke is the third leading cause of death in the United States (after heart disease and cancer) and is the leading cause of long-term disability and nursing home admissions. The direct clinical and indirect economic costs of stroke are estimated at about 43 billion.

Devices that fall into the stroke prevention and acute-treatment categories—such as implantable atrial pacemakers and defibrillators, carotid stents, least-invasive clot removal/dissolution devices (for ischemic stroke), and novel embolisation products (for haemorrhagic stroke)—are likely to have the greatest long-term potential.

## ***Cancer***

After heart disease, cancer is the second leading cause of death in Europe and the world. Medical technologies and devices are used in many ways to assist and improve the quality of life of cancer patients. These include breast cancer patients and colon/rectal cancer patients.

Breast cancer is the most common cancer among women, excluding skin cancer. Breast cancer is the leading cause of cancer death in women between the ages of 40 and 55. A very high percentage of mastectomies are followed by reconstructive surgery utilising a surgical implant or tissue expander.

More than 300,000 colostomies, mainly caused by colorectal cancer, are performed each year in Europe. Part of the colon is removed and the intestine is re-routed to an outlet (the stoma) in the abdominal wall where waste is then collected in an externally worn pouch. Medical devices are used by these patients to provide them with security and peace of mind to continue their lives in a productive and quality manner.

## ***Diabetes***

Diabetes, a glucose metabolism disorder that can cause a variety of severe complications involving virtually every major organ system, is one of the most costly and debilitating diseases. Worldwide, more than 154 million people are afflicted with diabetes this figure is expected to double by 2025.

Diabetes is an important area where medical technologies play a vital role in patient care and demonstrate a significant potential for increased patient safety, improved quality of life and reduction in healthcare costs. These devices include insulin deliver products (syringes, pens, automatic injectors and external/implantable pumps), glucose monitoring devices and wound care products.

## ***Delivery Systems***

Today, most people who take insulin to manage diabetes inject the insulin with a needle and syringe that delivers insulin just under the skin. Several other devices for taking insulin are available, and new approaches are under development.

## ***Wound Care***

Diabetic foot is a general term that describes a variety of foot problems in patients with diabetes mellitus. These diabetic feet problems range from small breaks in the skin to large, non-healing ulcers that may ultimately require amputation of the toe, foot or leg. Remarkable strides have been made in the treatment of diabetic ulcers. A number of treatments are currently available from several medical technologies and device manufacturers that stimulate new cell growth and help heal skin ulcers or use cultures of human skin cells. Recent advances in biotechnology, biomaterials, and tissue engineering are driving the development of a new generation of advanced products that may dominate wound management early in the next century.

## ***Dialysis***

There are currently about 250,000 patients in Europe who suffer from Kidney Failure or End Stage Renal Disease (ESRD). A patient is diagnosed with ESRD when 80% of their kidney function is lost.

- Transplantation is one option for these patients but less than 50% can expect to receive a kidney transplant, due to a shortage of donor organs.
- The alternative option is dialysis. Close to 200,000 patients regularly undergo this treatment to replace some of their kidney function. There are two dialysis options available:
  - Haemodialysis (HD) is the most common form of treatment with close to 175,000 patients in Europe. HD is usually a hospital-based treatment.
  - The other modality, Peritoneal Dialysis (PD) is a treatment performed at home. Approximately 25,000 patients in Europe currently benefit from this homecare treatment.

## ***Musculoskeletal Disorders***

Musculoskeletal disorders are on the rise. Osteoarthritis is the most prevalent joint disorder, characterised by joint pain, tenderness, and functional disability. The percentage of individuals over 65 years of age is the fastest growing segment of the population, and is expected to exceed 80 million people by the year 2010. Osteoarthritis will affect at least 70% of this population. Other important areas include work and sport related injuries. Work-related Musculoskeletal Disorders (WMSDs) account for a major component of the cost of work-related illness.

Orthopaedic surgery is a large medical technologies and device area. Ripe with new developments in bone, cartilage, and soft-tissue regeneration that may offset single-digit growth rates in the market for total joint implants. In Europe approximately 450,000 hip joints and 150,000 knee-joints are replaced each year. Recently, companies have turned their attention to one of the most exciting areas in the MSK industry: biologically attuned implants that can mimic the body's own natural repair processes, potentially expedite the healing process, and overcome many of the problems associated with metallic devices. Because biomaterials may be used to repair or regenerate most MSK tissues, including bone, cartilage, meniscus, ligaments, tendons, and even spinal disks, their applications cross the boundaries of traditional orthopaedic segments.

## ***Neurostimulation Therapy for Pain Management***

It is clear that there is an epidemic in Europe: 6% of the population has persistent pain resulting in a reduced quality of life. Spinal cord stimulation (SCS) uses low-voltage electrical stimulation to generate paresthesia in the area(s) of pain. The system consists of three major devices: the lead, the extension and the power source, all fully implanted.

## ***Information Technologies***

Healthcare information systems (HIS) represent another growing medical technology market for the future. The U.S. market for these products—including patient care, clinical data, financial, laboratory, radiology, pharmacy, and other segments—is valued at more than 4 billion. Issues such as the increasing demand for point-of-care (POC) information, and the proliferation of Internet use represent new challenges as well as opportunities for the medical products industry.

The increased reliance on information technology (IT) from a clinical perspective is being driven, first and foremost, by the need to provide remote access to diagnostic information and patient records.

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**Differences between Pharmaceuticals and Medical Devices<sup>38</sup>**

<b>Medical Technologies and Devices</b>	<b>Pharmaceutical Products</b>
◆ Traditionally based on mechanical, electrical and materials engineering	◆ traditionally based on pharmacology and chemistry
◆ industry is made up of a few large companies and a large number of very small companies; the industry is extremely diverse	◆ industry is comprised primarily of multinationals
◆ products engineered to perform certain functions based on specific performance and safety requirements; the therapeutic effect can in many cases be patient triggered or automatically adapted to the patient condition	◆ product development by trial on active substances selected on the basis of safety and efficacy
◆ effective by mechanical and/or electrical action; mainly pharmacologically inactive	◆ pharmacologically active; effective when absorbed into the human body
<ul style="list-style-type: none"> <li>◆ recent regulations: part of the European 'New Approach'</li> <li>◆ CE Marking ensures product conformance to Essential Requirements</li> <li>◆ Assessment, controls and requirements increase in proportion to potential risk, the highest level requiring design and clinical evaluation</li> <li>◆ Notified Bodies are appointed by the governments to certify the conformity assessment procedures</li> </ul>	<ul style="list-style-type: none"> <li>◆ long established EU legislation</li> <li>◆ regulations based on pre-market approval/licensing</li> <li>◆ all pharmaceutical products are subject to product approval</li> <li>◆ pharmaceuticals are registered centrally by EMEA (European Medicines Evaluation Agency) and/or the Member States</li> </ul>
◆ continuous innovation based on new science, technology and available materials	◆ continuous innovation and some improvements based on new science and technology; discovery of active substances with long term evaluation to determine effects and side-effects
<ul style="list-style-type: none"> <li>◆ short product life cycle due to continuous incremental improvements; often user related/driven</li> <li>◆ short payback period</li> <li>◆ more stringent patient specific traceability is imposed to track long-term effects of implants</li> </ul>	<ul style="list-style-type: none"> <li>◆ extensive product life cycle with 'prescription-only' often moving to OTC allowing for:</li> <li>◆ long payback period</li> </ul>

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<sup>38</sup> - Courtesy of Eucomed

### Medical device product coverage

The medical devices sector is covered by three Directives, covering some 10,000 products. Medical devices are instruments, apparatus, appliances, materials or other articles, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and

that do not achieve their principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means.

#### **A - The 1990 Directive on Active Implantable Medical Devices (AIMDD)**

This Directive covers medical devices relying for their functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity, and which are intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Typical products covered are

- Pacemakers
- Diffusion pumps for oncological applications
- Cochlear implants

#### **B - The 1998 Directive on In Vitro Diagnostic Medical Devices. (IVDD)**

This Directive covers any medical device which is a (i) reagent, reagent product, (ii) calibrator, control material, kit, (iii) instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures



Typical products covered are IVDs for

- Reagents for determining pregnancy
- Reagents for determining Aids
- Reagents for determining blood grouping
- Reagents for determining Hepatitis
- Specimen receptacles for the containment and preservation of human specimens

## **C - The 1993 Directive on Medical Devices (MDD)**

This Directive covers medical devices not subject to the AIMDD or to the IVDD.

### **Hospital equipment , such as**

- Anaesthetic equipment and workstations; respiration and inhalation equipment (lung ventilators)
- Tomographic equipment
- Magnetic resonance equipment
- Sterilizers
- Operating theatre
- Diagnostic equipment, such as X-ray, laser applications, electro-cardiography, stethoscopes
- Hemodialysis
- Nuclear therapeutic equipment
- Infusion and transfusion equipment
- Incubators
- Surgery equipment
- Catheters
- Medical disposables

### **Dentistry, such as**

- Equipment, including drills, chairs, UV lighting for hardening of materials
- Dental material, including amalgams, plastics, porcelain
- Dental implants

### **Audio-metric devices, such as**

- Measuring instruments
- Audative prostheses, hearing aids

### **Ophthalmic devices, such as**

- Measurement and diagnostic devices
- Spectacles, glasses, contact lenses

**Protheses, implantable and non-implantable; Internal and external orthopaedics, such as**

- Walking aids
- Artificial limbs
- Hips implants
- Cardiac valves
- Corsets

**Aids for disabled, such as**

- Wheelchairs
- Portable ventilators
- Rehabilitation equipment

**Disposable**

- Barrier contraceptives, Condoms
- Dressings
- Surgical drapes

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### List of consensus statements issued by the Co ordination of Notified Bodies Medical Devices - NB MED group.

#### 1. Introduction

This document reproduces key statements recorded in the minutes of NB-MED meetings and bases on the former "Resolutions-document". On meeting of the NBR-group on 29./30.09.97 it was proposed to change the title of the document from "Resolution" to "Consensus Statement". The word "Resolution" was found not to cover the what was contained in the document, while the expression "Consensus Statements" describes the content of the document in a better way.

In the minutes of the NB-MED meetings prior to 1995, there is no decision taken that is not covered by a separate NB-MED Recommendation or a MedDev-document.

The „consensus statements“

- (i) reflect consensus of those present / represented at the time of the relevant meeting.

*Note: Opinion may change in the light of experience and / or detailed consideration of the issue, for example, by those involved in drafting „Recommendations“ in the area, and thus a particular „statement“ may be superseded.*

- (ii) may take the form of questions and answers, often qualified in relation to specific circumstances, products etc.

*Note: The answer given may not be appropriate to other circumstances, products etc.*

- (iii) will include text in italics below each „statement“

- (a) indicating the actions agreed as necessary that are planed or have been taken
- (b) referring to specific relevant NB-MED „Recommendation(s)“ in the area
- (c) indicating where a „statement“ has been superseded, with appropriate cross-references

## Consensus statements of NB-MED

Reference no	Description
S/01/95	Subcontracting of design and production
S/02/95	Demarcation with Medical Laboratory Equipment
S/03/95	European representative from manufacturers from outside the Community
S/04/95	Expiration date on packaging for sterile products
S/05/95	Packaging for instruments sterilized by the user
S/06/95	Product testing as part of the surveillance of QS
S/01/96	Validation of the technical documentation as part of auditing under Annex V and VI
S/02/96	Classification of ear thermometers
S/03/96	Authorized representative
S/04/96	CE marking of refurbished devices
S/05/96	CE marking of class I devices
S/06/96	Declaration of reversed osmotic systems
S/07/96	Classification of devices for disinfecting, cleaning, rinsing, hydrating
S/08/96	Quality systems in case of complete subcontracting
S/09/96	Beautician equipment
S/10/96	Road motor vehicle for handicapped persons
S/11/96	CE marking of separate sold devices
S/12/96	Oven in dental laboratories
S/13/96	Time limits of certificates
S/14/96	Certification of subcontractor
S/01/97	Nasal rinsing and humidifying solutions; Classification
S/02/97	Custom-made mouth guards; Classification

S/03/97	Laser equipment; Classification
S/04/97	Gas distribution networks in hospitals
S/05/97	Borderline products between medical devices and home training devices, or devices for comfort, or cosmetic devices
S/06/97	Classification of surgical instruments
S/07/97	Status of coatings of implants
S/08/97	Withdrawal or refusal of certificates
S/09/97	Classification of dialysis concentrates
S/10/97	Quality certificates for single products
S/11/97	OEM Products; certification
S/12/97	Certification of class IIb products in combination of Annexes II and V of the MDD
S/13/97	Hearing aids
S/14/97	Programmable electrical Medical Systems
S/15/97	Classification of a medical-diagnostic device for determining woman's fertile and infertile period
S/16/97	Resuscitation masks; categorisation
S/17/97	Wigs and toupees; Classification
S/18/97	Arms rests installed in buildings for handicapped persons; Classification
S/19/97	Brushers with disinfectants for use by healthcare personnel; Classification
S/20/97	Software programmes used for patients to provide rehabilitation; Classification
S/21/97	Products made from latex
S/22/97	Data Management and Exchange
S/23/97	Storage solutions for organs; classification
S/24/97	Complex salt solution for irrigation; classification
S/25/97	Independence of the auditors
S/26/97	Products in the distribution chain and the impact of that in relation to the end of the transition period

S/27/97	Categorisation of devices for preparation of solution bags
S/28/97	Declaration specifying that no application has been lodged with any other Notified Body for the same product/product related quality system
S/29/97	Categorisation of thermosealing machine
S/30/97	Are devices for storage of blood, human cells and sperm which are determined to be returned to the human body medical devices or not?
S/31/97	Devices for use in heart surgery; Classification
S/32/97	Gloves; Classification
S/33/97	Nebulizers (used to administer a medicinal product, which was potentially hazardous in reference to rule II, annex II) ; Classification
S/34/97	Products intended for rinsing; Classification
S/35/97	Storage solutions for organs; Classification
S/36/97	Complex salt solution for irrigation; Classification
S/37/97	Proteins - produced by genetic means - which are used with devices for bone repairing
S/38/97	Dental filling material
S/39/97	Products made from latex
S/01/98	Demarcation Medical Devices, Accessories and Production or Laboratory Devices
S/02/98	Lasers for skin treatment (low level laser therapy); classification
S/03/98	Samples of certificates
S/04/98	Blood bags with preservation solution
S/05/98	Decoupling of certificates
S/06/98	Medical gas pipeline systems in hospitals
S/07/98	Retention periods for documents and quality records
S/08/98	Sterile patient drapes; Classification
S/09/98	Oximeter; Classification
S/10/98	Auditing of internal audits performed by a manufacturer within his QS

S/11/98	Gases for driving medical tools
S/12/98	Blood bags with preservation solution
S/13/98	Own brand labelling
S/14/98	Refillable glass capsule containing sodium-hydrogen carbonate (used to produce a bicarbonate solution during dialysis)
S/15/98	Surveillance - Inability to carry out unannounced visits in Non-EU States
S/16/98	Sterilisation of reusable medical devices
S/17/98	Low pressure regulators; Classification
S/18/98	Sterilizers used for final sterilisation of medical devices to be put on the market
S/19/98	Re-use of single use devices
S/01/99	Declaration of conformity
S/02/99	Software; Classification
S/03/99	Pools for training disabled persons
S/04/99	Free movement, device intended for special purpose
S/05/99	Carotid shunt; Classification
S/06/99	Aqueous eosin solution; Classification
S/07/99	Which directives must be named in the "declaration of conformity" of active electrical laboratory equipment
S/08/99	Computer for programming hearing aids
S/09/99	Conformity assessment procedures of breast implants
S/10/99	Misuse of Notified Body Identification Number
S/11/99	CE marking and other marks
S/12/99	Coloration of contact lenses
S/13/99	Blood bank refrigerators
S/14/99	Role of Notified Body - French Competent Authority's Fiche D'Enregistrement CERFA 10851 01 section E
S/15/99	Contact lenses and liquid for hydrating contact lenses; Classification

S/16/99	Rigid containers for sterilisation and maintaining sterility
S/17/99	Artificial liver
S/18/99	Mercury and non-mercury containing thermometers
S/19/99	Class I devices – certificates following MDD (Annex I)

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**Recommendation statements from Co ordination of Notified Bodies Medical Devices  
(NB MED) Issue date 12/2001**

			<b>Recommendation-No. (stage) see note at the end of the list for explanation.</b>
<b>2</b>	<b>Recommendation documents</b>		
	<b>2.1</b>	<b>Scope, field of application, explanation of terms</b>	
		- Representative sample	NB-MED/2.1/Rec1 (3)
		- Explanation of Terms	NB-MED/2.1/Rec2 (4)
		- Accessories and other parts for Active Implantable Medical devices	NB-MED/2.1/Rec3 (3)
		- Medical Devices with a measuring function	NB-MED/2.1/Rec4 (5) superseded by MedDev 2.1/5 (11.06.98)
		- Placing on the market of fully refurbished medical devices	NB-MED/2.1/Rec5 (3)
	<b>2.2</b>	<b>Essential requirements</b>	
		- EMC requirements	NB-MED/2.2/Rec1 (3)
		- Treatment of computer used to program implantable pulse generators	NB-MED/2.2/Rec2 (3)
		- "Use-by" date for Medical devices	NB-MED/2.2/Rec3 (3)
		- Software and Medical devices	NB-MED/2.2/Rec4 (3)
	<b>2.3</b>	<b>Reference to standards</b>	
	<b>2.4</b>	<b>Classification</b>	
	<b>2.5</b>	<b>Conformity assessment procedures</b>	

<b>2.5.1</b>	General rules	
	- Content of mandatory certificates	NB-MED/2.5.1/Rec4 (3)
	- Technical Documentation	NB-MED/2.5.1/Rec5 (3)
<b>2.5.2</b>	Quality assurance	
	- Subcontracting - QS related	NB-MED/2.5.2/Rec1 (3)
	- Reporting of design changes and changes of the quality system	NB-MED/2.5.2/Rec2 (3)
	- Translation procedure	NB-MED/2.5.2/Rec3 (3)
<b>2.5.3</b>	Type examination	
<b>2.5.4</b>	Verification of manufactured products	
	- Homogeneous batches	NB-MED/2.5.4/Rec1 (3)
	- Verification of Manufactured Products for the IVDD	NB-MED/2.5.4/Rec2 (3)
<b>2.5.5</b>	Conformity assessment for particular product groups	
	- Conformity assessment procedures of breast implants	NB-MED/2.5.5/Rec1 (deleted) superseded by MedDev 2.5/6 (07/98)
	- Combination of CE-marked and non-CE-marked medical devices and non-medical devices	NB-MED/2.5.5/Rec2 (3)
	- Conformity Assessment of Annex II, IVD's designed and evaluated prior to adoption of Common Technical Specifications (CTS)	NB-MED/2.5.5/Rec3 (3)
	- Assessment of the sensitivity of In Vitro Diagnostic Medical Devices - guidance on the application of the CTS	NB-MED/2.5.5/Rec4 (3)
<b>2.6</b>	<b>CE marking</b>	

<b>2.7</b>	<b>Clinical investigations, clinical evaluation</b>	
	- <b>Guidance on clinicals</b>	NB-MED/2.7/Rec1 (3)
	- <b>Evaluation of clinical data</b>	NB-MED/2.7/Rec3 (3)
<b>2.8</b>	<b>Devices intended for special purposes</b>	
<b>2.9</b>	<b>Systems and procedure packs</b>	
<b>2.10</b>	<b>Notified Bodies</b>	
<b>2.11</b>	<b>Registration procedure</b>	
<b>2.12</b>	<b>Market surveillance; vigilance</b>	
	- Post-Marketing Surveillance (PMS) post market/production	NB-MED/2.12/Rec1 (3)
<b>2.13</b>	<b>Transitional provisions</b>	
	- CE Marking of pre-MDD Devices	NB-MED/2.13/Rec1 (4)
	- CE Marking of established IVD Devices	NB-MED/2.13/Rec2 (3)
<b>2.14</b>	<b>Implementation</b>	
<b>2.15</b>	<b>Other</b>	
	- Voluntary certification at an intermediate stage of manufacture	NB-MED/2.15/Rec1 (3)
<b>3</b>	List of recommendations on directive 90/385/ECC (related to the articles)	
<b>4</b>	List of recommendations on directive 93/42/ECC (related to the articles)	
<b>5</b>	List of recommendations on directive 98/79/EC (related to the articles)	
<b>6</b>	List of keywords	

## Notes on the list

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**Definition:** A NBR is a document developed to assist NB's, manufacturers and interested parties in applying a common approach to the application of the Medical Device Directives.

**Process:** NBR's are developed in the following stages:

Stage 0: A document submitted to and registered by the NB-MED as a proposal for a NBR.

Stage 1: A document accepted or returned by the NB-MED to be further developed as a NBR by the NBRG or an ad-hoc group assigned by the NB-MED. Before presenting the document to the NB-MED plenary, the document shall be circulated with a request for comments to all members of the NB-MED plenary.

Stage 2: A document developed or received for editing by the NBRG for presentation to and approval by the NB-MED plenary.

Stage 3: A document accepted by the NB-MED plenary for presentation to and approval by the Medical Device Expert group.

Stage 4: A document on proposal of the Commission accepted by the Medical Device Expert group for issuance as a MedDev document by the Commission.

Stage 5: A document issued by the Commission as a MedDev document.

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### **Notified Body Operations Group Work Program**

#### ***Production and completion by Member States of a MEDDEV 2.10/2 Checklist.\****

MEDDEV 2.10/2 provides a “blueprint” of how the designation and monitoring of Notified Bodies should be completed. The aim is that providing a simple checklist based on the MEDDEV will help MSs highlight areas where their current practices varies from that recommended and consider what if anything they need to change. Also, comparing checklists between MSs will let organisations benchmark their activities with others.

#### ***Production of a Best Practice Guide (BPG)***

To produce a BPG in order to help MSs and Notified Bodies learn from each other as well as providing a useful depository of key documents, and guidance papers. Eventually the BPG will become a useful training aid as well as a source of information and thus contribute to a consistency of practice by Notified Bodies and MSs.

#### ***Production of a Communication Strategy for Member States***

To facilitate communication between MSs about possible poor NB performance by identifying to whom such reports should be sent and providing for the results of any investigation to be made known to the reporting MS. This should help ensure that problems with Notified Bodies are made known to the responsible MS and acted upon.

#### ***Production of Annual Reports by Notified Bodies***

To ask Notified Bodies to produce Annual Reports could help improve the transparency of how each operated, the decisions it took and how it took them. They could also be a useful source of statistical information, for example, by containing details of the number of audits undertaken, the number which resulted in Certificates of Conformity being issued/refused, the average duration time of audits, etc.

#### ***Observing MSs Auditing Notified Bodies***

To establish a programme by which someone from one MS could accompany an auditor from another MS as they were conducting an audit of a NB. In order to spread best practice and as a learning device.

### ***Training Events***

To identify or set up, training events for MS or NB personnel.

### ***Guidance on Possible NB remedial action***

To describe what constitutes major or minor non-compliances on the part of a NB and suggest possible remedial action the MS could require the NB to undertake.

### ***Notified Body Competence***

To develop relevant and useful guidance to both MSs and Notified Bodies NBOG on the specific competencies required by Notified Bodies in relation to the following areas: the use of animal tissues; the use of human blood and plasma; and the In-Vitro Diagnostic Medical Devices Directive.

### ***Guidance on minimum data set for Certificates of Conformity***

To produce guidance on the minimum data requirements to be included on the Certificate of Conformity issued by Notified Bodies to manufacturers in order to overcome the extremely variable content on such Certificates that MSs currently see.

### ***Sharing Audit Experiences***

To consider ways in which good and bad experiences encountered when auditing Notified Bodies can be shared between MSs. In order help everyone learn from each other's experience and thus avoid common problems.

### ***Vigilance Reporting***

To develop guidance and clarification on the Notified Bodies role in the vigilance system and, particularly, their need to be kept informed of such events (and their outcomes) by the manufacturer. It is suggested that NBOG considers, perhaps with representatives of the Notified Bodies themselves, what needs to be done and to produce appropriate guidance.

### ***Change of Notified Body***

To produce guidance to assist Notified Bodies and MSs in clarifying what actions need to be taken when a manufacturer changes – for whatever reason – its NB. It is hoped that, amongst other advantages, this would facilitate the manufacturer changing its NB easily where it believes that the NB performance has been poor.

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**Summary of information - article 11 section 4 of 93/42/EC – Clinical investigations  
Clinical investigations 1995-2000**

1

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
<b>Austria</b>	8	11	32	43	15	25	Numbers apply to all classes of medical devices	It is suggested to establish a system of clinical guidance documents.
<b>Belgium</b>	-	-	-	-	-	-	No notifications have been received	It is suggested to notify the investigations on a European level to obtain comparability. It should be required to submit the file to all countries where one wishes to conduct a study.
<b>Denmark</b>	-	-	-	-	-	-	This competence is delegated to the Scientific Ethical Committee	No suggestions have been made
<b>Finland</b>	-	4	5	5	8	9	For assessment purposes all classes of devices are treated equally under the Finnish Act. The number of notifications have been relatively small as there are few class IIb or III manufacturers in Finland.	The present system does not include a mechanism where other Member States could get information from investigations. National schemes for assessment are not sufficiently transparent.
<b>France</b>							France did not give any specific number per year. They indicate an average of 200 per year. Clinical investigations are done on CE and non-CE marked products. Clinical evaluation is very often based on literature and not actually on investigations even for AIMD and devices with high risk. 80% of the notifications are incomplete in particular the technical file and the declaration of conformity to the essential requirements. The manufacturers are sometimes reluctant to deliver the certificate.	On national level, it is noted that there is a large non-notification of undesirable serious incidents. It is envisaged to launch a procedure to improve this situation. On European level, it would be advisable to improve the communication between CA, the authorities and NBs.

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
Netherlands	-	-	44	27	31	41		
Portugal	-	-	-	-	-	5	Detected difficulties in the instruction of technical documentation	It is suggested to harmonize the procedure through a Guideline
Spain	14	16	21	17	9	-	Testing Class I and IIa products are very rare and do not appear to be on the increase. Testing class III and class IIb products with a view to new identifications of products with the EC mark is now being carried out.	It is thought that the system is working adequately and does not need to be changed.
Sweden	25	25-30	25-30	25-30				



Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
UK	83	51	47	50	-	-	MDA sees a downward trend in notifications concerning lower risk devices that may reflect a tendency on the part of these manufacturers to rely more heavily upon existing literature as a source of clinical data.	The government of the United Kingdom is currently objecting to around 20% of notifications, of which 2/3 are due to the failure by manufacturers to demonstrate compliance with the essential requirements. The present system would appear to give rise to some inconsistency in the assessment of clinical investigations across the Community. The UK is also concerned that the present system does not make provision for monitoring of clinical investigations. The requirements for reporting of adverse incidents that occur during a clinical investigation would not appear to be consistent across the MS.

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**Summary of information - article 11 section 4 of 93/42/EC - Vigilance  
Vigilance data 1995- 2000 (not all years are complete)**

1

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
<b>Austria</b>	119	163	231	140	-	-	- 1995-1997 counting of all protocolled vigilance communications; one vigilance case may have various communications  seriousness: including incidents and near incidents, user failures	It would be advisable to have better information on and cooperation in the distribution chain  - manufacturer > distributor > hospital
<b>Belgium</b>	37	49	144	260	-	-	Sent 2 competent authorities vigilance reports in 1997 and 3 in 1998	Belgium finds that more and more products that are not medical devices are presented as such.  The absence of a European database makes market surveillance activities very difficult. It is necessary that incidents be notified asap. It would be useful to have an effective European database.
<b>Denmark</b>	74	98	82	223			The first vigilance report was in 1996. Since then, only 1 report is transmitted. No clear trend is observed. Few reports are not meeting the criteria of serious incident. They include anything from near incident to death of a patient	It is suggested to have a better communication among MS and to encourage a harmonised approach by MS and manufacturers. Manufacturers should be made aware that any action related to a specific product must follow the product to which the incident is linked, and not the borders of MS.

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
<b>Finland</b>	-	12	88	127	137	121	During 1999, NAM received 264 adverse incident reports: 54 from users, 73 from manufacturers and 137 from other Competent Authorities. During the last 5 years the number of reports from users has been quite stable. The manufacturer reports have shown a steady annual increase.	It is suggested that MS should ensure that common and agreed criteria are employed when determining the subject of a competent authority notification.  Finland is currently analyzing vigilance reports from 1995 to the present, report June 2002
<b>France</b>	-	60	79	97	-	-	Vigilance reporting is done on two levels: locally and nationally. The information gathered comes from the manufacturers as well as from the users. No notification has led to a safeguard clause	The Commission should put an up-to-date listing of CAs at the disposal of each MS. It would be advisable - to have a more precise definition of the reporting criteria in order to have harmonised declarations - to improve communication between MS, and - to apply a centralised evaluation method.
<b>Germany</b>				66	69	100		
<b>Netherlands</b>	87	134	248	282	434	467		There still exists disharmonisation in the practical implementation of the legal provisions. The Netherlands still has a concern about the : - Notified bodies - Harmonisation and establishment of European opinions - Carrying out of Annex II on Class IIa and IIb devices - supervision on Class I manufacturers - keeping of product files - adjustment of Annex IX

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
<b>Portugal</b>	2	-	19	53	60	86	Involved 19 cases of medical devices marketed in Portugal and a total of 3 serious cases. Infarmed has adopted the incident report formats suggested by the EC.	<p>Most of the problems are common to other Member States.</p> <ul style="list-style-type: none"> <li>- The absence of the European Database</li> <li>- The need to improve communication between Member States</li> <li>- The lack of information regarding the distribution chain in Europe.</li> </ul>
<b>Spain</b>	20	73	157	219	321	332	Competent authority vigilance reports 1 in 1995 and 1996 3 in 1997 and 1998 and 4 in 1999. During the last 6 years the number of reports from users has been quite stable. The manufacturer reports have shown a steady annual increase.	It would be advisable to have better knowledge about measures adopted by other Member States after a first vigilance report is circulated with national measures adopted.
<b>Sweden</b>	12	52	167	269				
<b>UK</b>	11	33	59	110	-	-	The seriousness of the incidents involved both received and distributed by the MDA appeared to be consistent. MDA continues to receive notifications related to non-CE marked devices.	MS should ensure that common and agreed criteria are employed when determining the subject of a competent authority notification.

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### European Standardisation.

#### 1. Standardisation mandates

The Commission – after consultation of the Member States through the Committee set up under Directive 98/34/EEC - has released six standardisation mandates for medical devices. One mandate concerns for Active Implantable Medical Devices, one In Vitro Diagnostic Devices, and four for Medical Devices in general. The mandates invite the standards bodies to elaborate programmes for standards that needs raised by the Directives.

Normally, mandates are general in nature. However, as the need arises, also mandates on specific issues have been given (e.g. mandate for condoms or the mandate on the Global Medical Devices Nomenclature; another example of a specific mandate - under preparation - concerns breast implants). In specific mandates, Commission and Member States can indicate in detail the specific requirements they ask standards bodies to observe.

In order to ensure a coherence in the standards output, the mandates asks the standards bodies to observed a “hierarchy”:

**level 1 standards or basic safety standards:** standards indicating fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk assessment and control of medical devices);

Examples are EN/ISO 14971 on “Risk management”; EN ISO 14155 parts 1 and 2 on “clinical investigation”.

**level 2 standards or group safety standards:** standards indicating aspects applicable to families of similar products and/or processes making reference as far as possible to basic safety standards

Examples are EN/ISO 14630 “General standard for non-active implants” or standards concerning sterile or electrically-powered medical devices .

**level 3 standards or product safety standards:** standards indicating necessary safety aspects of specific products and/or safety processes, making reference, as far as possible, to basic safety standards and group standards

Examples are standards for infusion pumps, for anaesthetic machines, for breast implants.

Part of the standardisation work is based on or implemented through international standardisation activities. Where European standards bodies work on the basis of international work, they are formally required to verify the adequacy of international work with respect to the needs of the Directives.

European standards can only give a presumption of conformity if their reference has been published in the OJEC. Refusal to publish the reference – or withdrawal of publication - is therefore the ultimate means by which authorities control the quality of standards in relation to the directives. To date, references of more than 200 standards have been published.

## 2. Progress in standardisation.

Area	Number of published mandated standards (ie. past formal vote)	Number of mandated standards under development (ie. below formal vote stage) <sup>39</sup>
Medical device quality standards (supplements to ISO 9000 series)	5	
Clinical investigation of medical devices	1	2
Symbols and info provided with medical devices and nomenclature for regulatory data exchange	3	2
Biocompatibility of Medical and dental materials and devices	16	8
Miscellaneous – (including Risk Management and Traceability or medical devices)	4	1
Dentistry	4	4
Sterilizers for medical purposes	11	14
Ophthalmic optics	5	3
Sterilization of medical devices	9	11
Non-active medical devices	24	19
Respiratory and anaesthetic equipment	49	28
Chemical disinfectants and antiseptics	0	6
Medical vehicles and their equipment	2	6
Non-active surgical implants	11	8
Technical aids for disabled persons	7	6
Medical devices utilizing tissues	5	
Medical electrical equipment	28	
In vitro diagnostic medical devices	13	7
Active Implantable Medical Devices	2	2
<b>Total</b>	<b>196</b>	<b>127</b>

*Details of the standards, and on progress in the standardisation work can be obtained from the New Approach Website: [www.newapproach.org/directiveList.asp](http://www.newapproach.org/directiveList.asp).*

<sup>39</sup> Approximately 35-40% of the current work programme is revision of or amendment to published standards.

**Summary of information - article 11 section 4 of 93/42/EC – Pharmaceutical consultations  
Pharmaceutical consultations 1995-2000**

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
Austria	-	-	-	2	-	-	No specific problems encountered with pharmaceutical cases	
Belgium	-	-	-	-	-	-	Presently, no notified bodies are established in Belgium	
Denmark	-	-	-	-	-	2	Figures are not given per year. Received about 10 requests for information The few consultations did not give indication of main difficulties connected to the system.	Denmark lacks experience to present suggestions in this area.
Finland	-	-	-	-	-	-	- Finland received no consultation requests from NB based in Finland - NAM issued a guidance note based on MedDev 2.1/3 Rev 5	
France	-	-	-	-	-	38	Only the French authority was consulted; No negative opinion was given	
Netherlands	-	-	-	-	-	-		
Portugal	-	-	-	-	-	-	Infarmed did not have any consultation as mentioned	

<b>Spain</b>	-	-	-	-	-	8	<p>Figures are not given per year.</p> <p>It is suggested to: - State more clearly which medicinal substances should be submitted for consultation.</p> <p>- Exclude cases meeting the following criteria:</p> <ul style="list-style-type: none"> <li>a) combination of health product + medicinal substance well known for the intended uses,</li> <li>b) medicinal substance frequently used and with quality specifications fully described in the European Pharmacopoeia monograph,</li> <li>c) origin of medicinal substance guaranteed by a certificate from the health authorities in the country of origin concerning the guarantees of the supplier of the substance,</li> <li>d) specifications of the medicinal substance guaranteed by a supplier's certificate of compliance with the specifications laid down in the relevant European Pharmacopoeia monograph</li> </ul>	<p>Add to the documentation protocol that the manufacturer must state the following for the purpose of consultation of the competent body: "Certificate from the health authorities on the guarantees of the manufacturer of the medicinal substance".</p>
<b>UK</b>	-	-	-	-	-	-	<ul style="list-style-type: none"> <li>- MCA received several consultation requests from NBs based in UK and abroad</li> <li>- MCA issued guidance documents based on MEDDEV 2.1/3 rev. 5</li> <li>- The nature and data submitted is variable but has improved since companies have gained experience in compiling files for combination products.</li> <li>- MCA feels that there are still 3 areas requiring further discussion: <ul style="list-style-type: none"> <li>. Quantitative declaration of content of medicinal substance availability</li> <li>. Stability</li> <li>. Claims</li> </ul> </li> </ul>	<p>MCA understands from discussions held with NB that more detailed guidance on data requirements for the medicinal substance would be required. MCA includes a statement on which the NB can indicate whether the data submitted was sufficient or not.</p>