



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02.07.2003
COM(2003) 386 final

**COMMUNICATION FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**

on medical devices

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1. SUMMARY

This Communication presents the Commission's policy conclusions on the functioning of the medical device directives. They are based on the issues highlighted in the report of the Medical Device Expert Group (MDEG), made available on the Commission 'europa' web-site in June 2002¹.

This Communication fulfils in the first place the requirements of the medical devices directive 93/42/EEC according to which the Commission has to present a report on the operation of the Directive's provisions relating to vigilance, clinical investigations and consultation of the competent authorities dealing with pharmaceutical products. Data provided by Member States on these issues proved rather heterogeneous and it is difficult to draw definitive conclusions. The Commission therefore proposes to step up the work in order to complete the data collection. To the extent that the need has been identified for a more co-ordinated approach between Member States, the Communication announces the elaboration of further guidance documents.

In the second place, it gives a follow-up to the initiative undertaken by the MDEG to carry out an overall assessment of the medical devices directive, going largely beyond the reporting requirements mentioned above. The Commission endorses the MDEG statement that the legal framework established by the medical device directives in itself - even though regulatory changes are needed in certain areas - is appropriate, but that its implementation needs to be improved. From the various issues raised in the MDEG report, the Communication highlights in particular those on conformity assessment, transparency and trust, market surveillance, and co-operation between Member States and Commission.

Improvements in implementation should be achieved by a comprehensive and ambitious action programme, based on various means, involving all actors: implementing measures at national level (including designation of notified bodies and market surveillance), the use of instruments already available under the directive (re-classification, precautionary principle, safeguard clause, formal objection to standards), guidance documents on implementation, regulatory clarification on a number of issues, and increased co-ordination and co-operation activities in different fora, including a new "high level group on medical devices". A great number of initiatives for improvement are already being undertaken.

The Communication draws attention to the international dimension of the implementation of the directive, including the challenge of the enlargement process. It refers to the impact of Mutual Recognition Agreements and the work of the Global Harmonisation Task Force.

¹ http://europa.eu.int/comm/enterprise/medical_devices/index.htm

The Commission takes note that comprehensive data on the medical devices sector are lacking. The Communication therefore announces a study to be carried out in co-operation with national authorities and industry in order to improve knowledge of the sector, of its impact on public health expenditure and of the conditions for increasing competitiveness. Further studies covering key public health issues are foreseen under the programme of Community action in the field of Public Health (2003-2008).

Finally, the Communication contains a number of informative appendices providing background information in relation to the vast and complex sector of medical devices. These relate to medical devices product coverage, the benefits of medical technology and devices for EU citizens, main features of the regulatory framework and details of working groups involved in the implementation of the medical devices directives.

2. INTRODUCTION

Article 11(4) of Directive 93/42/EC on medical devices requires the Commission to present a report to the Council on the Directive's functioning in relation to vigilance, clinical investigation and pharmaceutical consultations.

In preparing this report, the Commission services, national authorities and stakeholders working in the framework of the Commission's Medical Devices Experts Groups (MDEG) decided to proceed to a wider review of the functioning of the regulatory framework, in order to improve both the regulatory framework and its implementation where possible. The consensus view, reflecting the outcome of discussions, was presented as a report made available by the Commission on its web-site in June 2002, hereafter referred to as the MDEG Report.²

The Commission welcomes the MDEG report on the functioning of the medical devices Directive. It considers the MDEG report as a critical analysis that will allow public authorities and stakeholders to draw the appropriate policy conclusions against an agreed statement of issues.

The present Communication should also be seen in the light of an overall review of the New Approach to technical harmonisation and standardisation³, which is the subject of a separate Communication. Elements of the review of the functioning of the medical devices directive have been fed into the overall review. Similarly, some issues identified in the overall review are reflected in the present report, or may have an impact on solving issues raised.

² Report on the functioning of the Medical Devices Directive 93/42/EC of 14 June 1993; Medical Devices Experts Group, 5 June 2002.

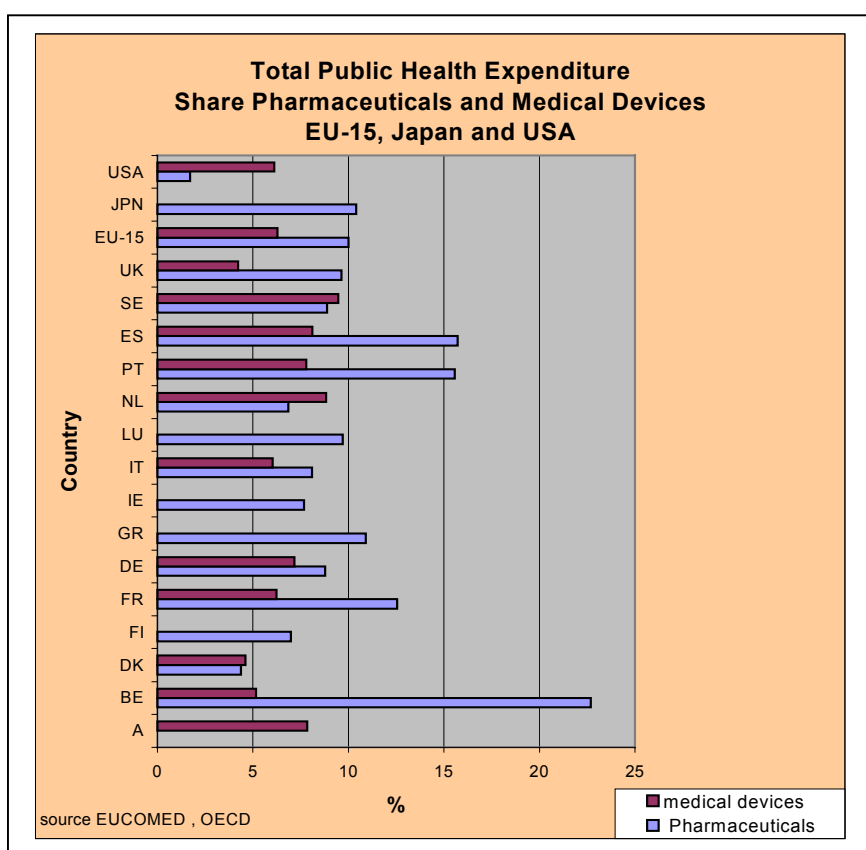
<http://europa.eu.int/comm/enterprise/newapproach/index.htm>

³ Council resolution of 7 May 1985 on a New Approach to technical harmonisation and standards; OJEC C 136 of 4 June 1985. See appendix 3 for the main features of the New Approach regulatory scheme.

The present Communication therefore contains the report required by article 11(4) as well as the Commission's conclusions based on the MDEG report.

3. MEDICAL DEVICES - AN INCREASINGLY IMPORTANT SECTOR

Medical devices⁴ have become an increasingly important area in relation to their impact on health and influence on health care expenditure. The Health Council⁵ recently adopted a resolution on medical devices highlighting the sector's importance, which has until now been overshadowed by the other pillar of healthcare, pharmaceutical products.



The term “medical device”⁶ covers a wide range of products. Given the variations in the features of each of these device families, potentially over 400,000 different medical devices could be on the market⁷.

The market for medical devices in Europe is the 2nd largest after the USA, and is followed by Japan.

⁴ Figures advanced suggest that there are over 10,000 different families of medical device types.

⁵ Health Council, 26th June 2002

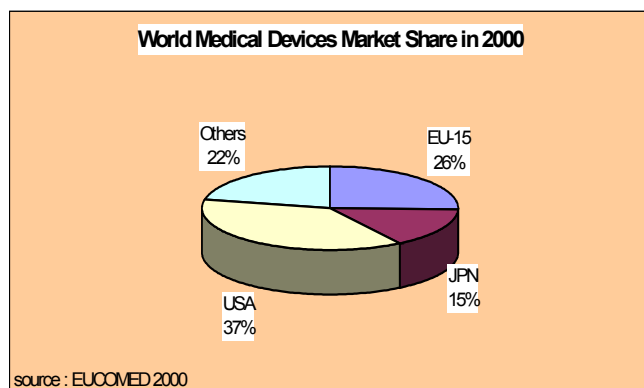
⁶ In this report the term ‘medical device’ (shortened to ‘device’) refers to products covered by the definition in Directive 93/42/EC article 1 (2).

⁷ Appendix 1 contains some illustrative examples of the product coverage for medical devices.

Figures available are incomplete but suggest that public expenditure on medical devices is increasing and in some countries already exceeds that for pharmaceutical products.

However, expenditure must be set off against benefits, both in terms of costs and quality of life for patients and citizens. For instance, the development of new techniques such as minimal invasive surgery have dramatically reduced the treatment time and cost of hospital stays.

Training of healthcare professionals has become a key issue. Authorities at national and Community level have to verify whether there is the correct balance between access to innovation and high protection of health. National authorities have to deal with the reality of scarcity of expertise, particularly for high-risk devices where human resources are said to be insufficient. Medical devices today are based on a variety of technologies, including mechanical engineering, but also biomaterials, electronics, software, diagnostic imaging and optics. Medical technology is characterised by a high speed of innovation and a correspondingly high frequency of new models.



In many of the health areas identified by the European Union as key health priorities medical technology and medical devices provide a major contribution to the reduction of disease and improvement of patient health in Europe⁸.

At the same time the medical devices sector is increasingly exposed to public scrutiny. Patients express a demand for information on medical treatment and medical devices and are sensitised to the risks. Whilst it is generally accepted that medical technology has increased levels of public health and improved the quality of life of patients, recent events such as those experienced with disinfectants, dialysers and breast implants, suggest that when problems do occur, the regulatory system itself can be challenged.

In spite of the quite significant evolution of the medical device sector, detailed comprehensive, reliable and recent data are lacking, both at national and Community

⁸ Examples of the contribution of medical devices in specific disease areas are included in Appendix 2.

level. The Commission therefore intends to launch a study in co-operation with National Authorities and stakeholders, covering three aspects:

- The first objective of the study would be to map the European market by collecting and analysing up-to-date market facts and figures. The study will thereby have to overcome the currently lacking statistical basis for such data collection. It should make appropriate recommendations that will allow collecting this information on a regular basis in the future. This will be of particular importance in order to evaluate the economic relevance of the sector and its contribution to economic growth and employment.
- Technological progress in medical care is often quoted as one of the reasons behind increasing health care costs. However, the contribution of innovation in health care to actually saving health care resources is also increasingly documented (e.g. reduction in period of hospitalisation due to minimal invasive surgery). The study should therefore collect, analyse and document prominent evidence on public costs and savings. It will also identify the relative share of public health expenditure for medical devices with respect to other components of the health care system, such as pharmaceutical products.
- Finally, the study will look at strengths, weaknesses, opportunities and threats of the medical devices sector in Europe. It will look at the current state of the industry in Europe, its competitiveness and its potential to innovate, in particular in comparison with its current main competing regions, US and Japan. The study should in this way allow national and Community authorities to determine framework conditions allowing companies, whilst maintaining the highest level of protection of health, to increase competitiveness and innovation, so as to – eventually – benefit public health.

Similarly, further research will be required to gather more information concerning health aspects, for instance in relation to the use of medical devices. A number of possibilities, such as in the field of improving information in medical technology related areas, are offered under the Communities public health action programme (2003-2008)⁹.

⁹ Decision 1786/200/EC of the European Parliament and of the Council of 23 September 2002, OJEC L 271, 9 of October 2002

4. LEGAL FRAMEWORK

Medical devices are covered by three Directives, dealing with active implantable medical devices¹⁰, adopted in 1990, with in vitro diagnostic medical devices¹¹, adopted in 1998, and medical devices in general¹², adopted in 1993. The 1993 directive was modified by the 1998 in vitro diagnostic devices directive. Special provisions covering medical devices incorporating substances derived from blood were introduced in 2000.¹³ Together, they constitute for the first time a coherent and comprehensive legal framework for medical devices in the Community Member States¹⁴.

The major features of the regulatory framework are given in Appendix 3.

Whilst the legal framework itself is stable, it requires a careful - and resource-intensive - management and implementation, in particular at the national level. As the Directives cover an enormous variety of products and risks, there is a need for wide co-ordination and consultation between authorities and Commission. Furthermore, there may be a need to adopt specific regulatory measures (such as reclassification decision, follow-up to national measures restricting the availability of devices, Common Technical Specifications for in vitro diagnostics devices) in order to complement the legal framework created by the Directives on specific aspects, or to elaborate guidance documents on implementation.

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. Further details of these instruments and working groups are given in Appendix 4.

5. REPORTING UNDER ARTICLE 11(4) OF DIRECTIVE 93/42/EC

Article 11(4) of the 1993 medical devices directive requests the Commission to submit a report to the Council;

¹⁰ 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, OJEC L189 20 July 1990

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

¹² Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJEC L 169 12 July 1993

¹³ Council Directive 2000/70/EC of 16 November 2000, OJEC L 313 of 13 December 2000, as modified by Directive 2001/104/EC of 7 December 2001, OJEC L 6 of 10 January 2002. See also: Directive 2002/98/EC of the European Parliament and the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJEC L 033, 08.02.2003, p. 0030-0040

¹⁴ Medical devices containing viable animal tissues and those incorporating human tissues are not regulated at Community level. The Commission is currently working on separate proposals to cover the safety and performance of human tissue engineered products.

- (i) information on incidents occurring following placing of devices on the market (vigilance);
- (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, if 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 (pharmaceutical consultation).

In order to collect information, Commission and national authorities prepared a questionnaire in order to allow a coherent reporting. The information and data provided by Member States are presented in Annexes 1, 2 and 3.

5.1. Vigilance

Incidents can occur with medical devices where they do not perform as intended, leading in the worst case to injury, additional medical procedure or death. The Directive therefore imposes timely co-ordinated action and provision of information between manufacturer and national authority concerned and between national authorities in relation to incidents that present a serious risk and that are related to the device¹⁵. Member States have to take the necessary steps to ensure that any information 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: These provisions relate primarily to information provided by the manufacturer to national authorities concerning medical devices. The Directive's scheme does not relate to errors in use, unless such errors can be explained by shortcomings in the design of the product or of its accompanying labelling or instructions for use. As part of national policy, a 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.

Today, vigilance has an international dimension going beyond the Union. For legal or political reasons, national authorities do share vigilance reports with third countries, in the same way as they receive information from third countries. Furthermore, under the

¹⁵ According to Article 10§1 "Member States shall take the necessary steps to ensure that any information brought to their knowledge regarding the incidents mentioned below involving a Class I, IIa, IIb or III device 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

Global Harmonisation Task Force for Medical devices (GHTF)¹⁶, a global vigilance system is being set up, in which all Member States will participate and this is open to participation by all other European countries.

Details of the number of incidents because of shortcomings of the device reported from Member States, under the vigilance scheme of the Directive, are contained in Annex 1.

The following conclusions can be drawn:

- Statistical data on reported cases received for the purpose of this communication are extremely heterogeneous. In some cases, such as Belgium, Finland, the Netherlands and the United Kingdom, 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. It has been suggested that the information provided does not represent the same categories of vigilance reports, which makes the analysis complicated.
- The Commission is opposed to practices where safety measures are limited by the manufacture or by national authorities to the sovereign territory of a Member State or an EEA member country, without using the mechanisms foreseen by the directive. Under such measures, products remain on the common market, obliging other Member States if they happen to have knowledge of the potential risks to take individual actions. .
- The establishment of the European database on medical devices (EUDAMED) recording incidents community wide will help to ensure a smooth functioning of the Directive's provisions on vigilance.
- Perhaps the major conclusion to be draw is that more research is necessary to identify the causes and the uneven presentation of vigilance reports. It has been suggested that lack of human resources available for the implementation of the directive might be a reason.

Against this background, the Commission will:

- Reinforce, in the framework of the MDEG Working Group on vigilance, co-operate with national authorities on the improvement of national practises on vigilance.
- Make available periodically on its web-site summary reports on statistics regarding vigilance reports.

¹⁶ For the GHTF, see <http://www.ghtf.org/> and section 5.3 of this report on GHTF.

- Launch, under the IDA programme¹⁷, a pilot project from July-December 2003 on EUDAMED, the EU database for medical devices (EUDAMED) that the Directive requires to be set up. On that basis the system will be made operational in 2004.
- Continue to promote participation of Europe in global vigilance schemes under conditions compatible with European rules, implemented under the GHTF. Whilst the Community and other European countries cannot stay out of global developments, the Commission highlights that such global arrangements do not replace the obligations under the Directive. On the other hand, practical arrangements for European and global vigilance will be harmonised as far as possible.

5.2. Clinical investigation

The MDD requires conformity assessment of characteristics and performances to be carried under the normal conditions of use of the device and evaluation of the undesirable side effects to 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. Clinical investigation programmes must 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. Data, randomly distributed and thus difficult to interpret, are presented in Annex 2.

More important are the comments received from national authorities, that can be summarised as follows:

- The current legal framework does not include a specific mechanism for Member States to obtain information on clinical investigations conducted in other Member States.
- The wording of the Directive can lead to doubts on interpretation. The Directive’s provisions need to be detailed and further explained through a series of guidance documents on issues including procedures and assessment of clinical investigation results.
- Variations across Member States in the requirements for reporting adverse incidents during clinical investigations may result in inconsistencies.

¹⁷ IDA, Interchange of Data between Administrations, Decisions of the European Parliament and Council 1719/1999/EC and 1720/1999/EC, OJEC L 203 of 3 August 1999

Discussions further indicated that manufacturers, in particular those of Class I devices, do not always have clinical data available. Furthermore, Notified Bodies do not verify sufficiently the adequacy of clinical data provided with respect to characteristics and performances of the device.

Against this background, the Commission:

- will continue to host, and within the limits of budgetary availability, support the CETF, the Clinical Evaluation Task Force, comprising representatives from Member States, Notified Bodies and Industry, created to reinforce implementation of Annex X of the MDD on clinical data.
- highlights the need to develop guidance and policy documents¹⁸ as a complement to harmonised standards, in order to ensure a coherent implementation of the provisions of the Directive Community wide.
- invites Member States to proceed to a consistent and measured exchange of information on refusals of clinical investigations, side effects and adverse incidents, as allowed under article 20 of the Medical Devices Directive.
- urges Member States to provide the data in order to allow a more comprehensive report to be drawn up before the end of 2003.

5.3. Pharmaceutical consultation

A device which contains a medicinal product 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, taking into account the intended purpose of the device. The Notified Body must consult with one of the competent bodies for medicinal products established in the Member States prior to taking a decision. It should be noted that a similar consultation procedure, involving the EMEA, applies for medical devices substances derived from blood.¹⁹

Recently, questions of interpretation have arisen concerning the obligation of Notified Bodies to consult EMEA and the respective competencies of the Notified Body and the EMEA. Discussions are taking place between Commission, national authorities and EMEA to establish a meaningful and operational interpretation of the Directive's provisions.

¹⁸ See annex 4.

¹⁹ Directive 2000/70/EC amending 93/42/EEC L313 13 Dec 2000, as last amended by directive 2001/104/EC.

Only a few isolated data have been provided by Member States on the number of pharmaceutical consultations reported, summarised in Annex 3. This makes interpretation of the information very difficult.

The Commission therefore

- will, together with Member States, elaborate further guidance on pharmaceutical consultation, including substances to be submitted for consultation and procedures to be followed.
- will on this basis pursue data collection with Member States and, on a regular basis, evaluate the functioning of the system.
- will propose a modification of part 7.4 of Annex I of the Medical Devices Directive clarifying the legislative intent when the discussions between Commission, national authorities and EMEA do not lead to a meaningful accepted interpretation and mode of operation.

6. A NEED TO IMPROVE OVERALL THE IMPLEMENTATION OF THE DIRECTIVES.

On the basis of the MDEG report the Commission takes the view that the legal framework created by the medical devices directive in itself is appropriate, but that its implementation should be improved through a variety of instruments involving all parties:

- Measures at national level implementing and managing the Directive;
- Use of available instruments to address particular market occurrences;
- Guidance in the form of consensus documents between stakeholders;
- Co-ordination and co-operation activities in different fora;
- Regulatory clarification on a number of issues.

Concerns identified in the MDEG report relate in particular to conformity assessment (including clinical investigation and post market surveillance by manufacturers), to market surveillance and to transparency.

A number of these issues have also been identified during the review of the New Approach. The current communication only raises issues as far as they are specific to medical devices and are part of the work programme of the working groups concerned with the MDD.

The Commission takes note that the MDEG Report examines in detail a great number of other issues, such as standardisation and a more precise definition of the scope of the Directives. However, this Communication concentrates on those issues that the

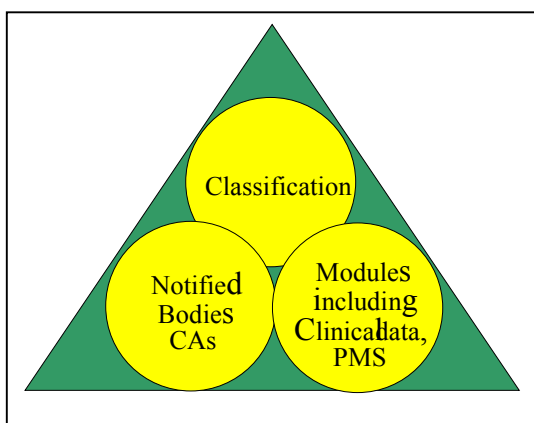
Commission considers as the major ones. he Annexes 4, 5 and 6 to the present Communication - detailing respectively the issues for the elaboration of guidance documents - regulatory change and other measures, also cover such elements of the MDEG Report not specifically highlighted in this Communication.

6.1. Conformity assessment

Conformity assessment is a key to trust and confidence in the regulatory system's capacity to protect patients and citizens. All efforts must be made to ensure a high level of protection. Failure on conformity assessment, even if related to a small number of specific devices, will jeopardise the credibility of the existing regulatory system and of the authorities' capacity to effectively protect public health.

The Directive foresees a classification of medical devices in four classes based on risks that determine the conformity assessment procedures to be followed by the manufacturer. Classification is based on a "classification tree". The directive also creates various mechanisms for authorities to rectify the outcome of these classification rules, by up or downgrading of devices or by imposing specific conformity assessment procedures.

Shortcomings that have been identified in the MDEG Report relate in particular to the designation and monitoring of notified bodies, insufficiencies in design evaluation under the quality approach by notified bodies lack of clinical data available from manufacturers, insufficient verification by notified bodies of post market surveillance arrangements and, with regard to specific products, the need to impose stricter conformity assessment procedures than those resulting of the implementation of the provisions of the Directive.



The Commission considers that improvements in the field of conformity assessment must be based on a combined action in the following three areas. Failure to act on one of these elements will not produce the required improvements.

6.1.1. Obligations under conformity assessment procedures.

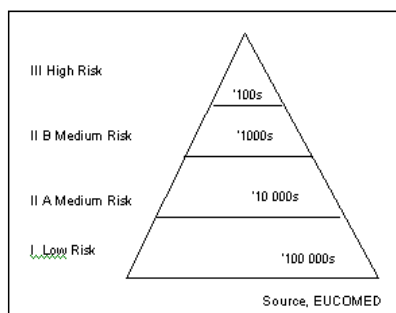
Where a manufacturer intends to declare conformity of Class IIA and IIB devices through the implementation of a full quality assurance system, Notified Bodies have to verify not only the presence of a complete technical file prepared by the manufacturer on a coherent

sample basis but also the correct application of the manufacturer's quality system and the veracity and appropriateness of the data. Furthermore the Directives provisions on clinical data should be implemented in a stricter and more coherent manner. Finally market surveillance should be reinforced. Against this background:

- The Commission will introduce a proposal to modify Annex II of the Medical Devices Directive. Subsequently, appropriate guidance documents will be elaborated as to how Annex II has to be implemented with respect to groups, families or categories of Class IIA and IIB devices²⁰,
- Whilst considering the principles of the Directive on clinical data in themselves appropriate, it urges the CETF to develop guidance on the obligations for manufacturers, Notified Bodies and authorities with respect to implementation regarding specific groups of devices²¹. The Commission stresses the need for the Market Surveillance Operations Group, composed of national authorities in charge of market surveillance, to finalise guidance documents, inter alia, on the post market surveillance obligations of the manufacturer²². It will continue to host and, within the limits of budgetary availability, to support the MSOG.

6.1.2. *Reclassification of medical devices.*

- The Directive describes mechanisms in order to achieve, where necessary, a reclassification or to impose specific conformity assessment procedures with respect to particular devices or categories of devices. Until now, only two requests have been introduced, dealing respectively with breast implants and total joint replacements.



Approximate number of devices

²⁰ Class III devices are always subject to a specific design evaluation by the Notified Body, leading to a EC design examination certificate.

²¹ Annex 4

²² Annex 4 the formal terminology is 'post production phase' however, it has become common practise to refer to it as 'post market surveillance' (PMS). PMS to be carried out by the manufacturer should not be confused with market surveillance to be carried out by national authorities.

- Member States should make use of the existing reclassification mechanisms where they identify a need to intervene with respect to conformity assessment procedures; reclassification requests will be given due priority by the Commission.

6.1.3. Improved designation and monitoring of Notified Bodies.

The Commission takes note that national authorities have identified the need to improve processes in relation to the designation and monitoring of Notified Bodies²³, and have created in relation to medical devices a specific working group to deal with it, the Notified Bodies Operations Group. Concrete expression of increased awareness is ‘de-notification’ of Notified Bodies that has recently occurred.

- The Commission welcomes the creation and work of the Notified Bodies Operations Group (NBOG) composed of representatives from designating authorities²⁴. It will carefully monitor the outcome its activities. The Commission will continue to host and, within the limits of budgetary availability, financially support NBOG.

6.2. Transparency and trust.

It appears that there is no full transparency between authorities and towards the general public concerning the way in which the Directives are being implemented. Questions have been raised to what extent national authorities and Notified Bodies can exchange information in relation to the implementation of the directives between themselves. In addition, complaints have been registered as regards follow-up by national authorities to requests for information by authorities from other countries.

In addition, whilst under Community law for pharmaceutical products and in the United States of America for medical devices,²⁵ summary reports on market approval are made available to the general public, under the current Community legislation a similar practice is not required for medical devices.

Furthermore no transparent and easily accessible data exist at a community level as to what certificates have been delivered by Notified Bodies, and the identification of manufacturers, facilitating the identification of devices on the Community market. Although the Directives impose the creation of a European Database for Medical Devices (EUDAMED), insufficient progress has been made to date.

Similarly, it is regrettable that not all Notified Bodies recommendations and consensus views have been endorsed by the MDEG and made available to manufacturers and the general public.

²³ Designation and monitoring of Notified Bodies is also a key issue in the Commission Communication on enhancing the implementation of the New Approach.

²⁴ Annex 4

²⁵ “Freedom of Information Act”

The Commission takes the view that transparency is a key element in order to ensure trust between all stakeholders, and in particular to the general public. Transparency should be increased, and the following measures should thereto be implemented.

- The Commission will propose regulatory change in relation to the publication of information concerning the conformity assessment of medical devices. In particular information concerning medical devices presenting high risks should be made available to the general public. This can take the form of ‘EU Notified Body public assessment reports’. Due account will be taken of legitimate interests of manufacturers. Experience referred to above indicate that provision of selected information does not cause harm to the legitimate interests of manufacturers, and is beneficial as it increases trust.
- The Commission highlights the need to improve communication and welcomes measures already taken by the Notified Bodies Operations Group (NBOG), Market Surveillance Operations Group (MSOG) and Clinical Evaluation Task Force (CETF).
- In its proposal for a Directive with regard to detailed specifications relating to *transmissible spongiform encephalopathies*, the Commission proposes a mechanism to increase transparency between Member States and Notified Bodies, with due respect to each others’ competencies. The Commission will, in co-operation with national authorities, evaluate the outcome of this exercise and, if appropriate, examine the need to extend it to other sensitive products.
- The Commission will put to the MDEG the endorsement of recommendations and consensus views of Notified Bodies, in order to make them publicly available on the Europa web-site.
- The Commission will inform on a regular basis the Health Policy Forum, i.e. the European platform representing consumers, patients and healthcare professionals of developments in relation to medical devices.
- On the basis of the activities currently undertaken under the IDA programme²⁶, the Commission will present in the course of 2003 a proposal to create EUDAMED. It will submit Member States an implementation plan, ensuring a progressive and coherent implementation Community wide, using as a basis the Global Medical Devices Nomenclature (GMDN). It will, if need be, clarify with the European Committee for Standardisation (CEN) concerning conditions of access to GMDN.

²⁶ Interchange of Data between Administrations, Decisions of the European Parliament and Council 1719/1999/EC and 1720/1999/EC, OJEC L 203 of 3 August 1999.

6.3. Market surveillance

Market surveillance is an essential tool for the enforcement of the Medical Devices Directive, in particular with regard to Class I medical devices, placed on the market without the intervention of a Notified Body in the conformity assessment procedure. 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.

- It is a case of serious concern that levels of market surveillance vary widely between Member States and that experiences reported by some national authorities indicate that the provisions of the Directives' provisions are not respected. The Commission takes note that Member States have identified market surveillance as an issue and started co-operation activities under the Market Surveillance Operations Group (MSOG)²⁷. The Commission fully supports this work. In the framework of the overall review of the New Approach the Commission will define basic rules with which Member States will be obliged to comply, (e.g. sanctions, information exchange provisions), which may require a revision of the legal framework either by means of a horizontal directive or by including these rules in the individual directives. The Commission will also seek to introduce a legal basis for administrative co-operation among Member States in the New Approach directives that do not yet foresee this.
- The Commission will further examine, in the light of the general product safety directive²⁸ and the current provisions of the Medical Devices Directive, whether provisions should be introduced for an early warning exchange between authorities, as proposed in the Communication on the New Approach.
- The Commission will propose regulatory change to ensure that national measures that restrict the placing on the market of medical devices will be communicated to all Member States.

6.4. Co-operation between Commission and Member States.

The Directive confers a number of important tasks to the Commission, such as, the evaluation of classification requests, national health measures and formal objection to standards.

In most cases, the Directives foresee mechanisms by which Member States are consulted, be this through the Committee set up under the Medical Devices Directives, or the Committee set up under Directive 98/34/CE laying down a procedure for the provision of

²⁷ Annex 4

²⁸ General Product Safety Directive 92/59/EEC of 29 June 1992 on general product safety OJ L 228, 11/8/92 p 24.

information in the field of technical standards and regulations and of rules of information society services.²⁹

However, over the last years it has become apparent that there may be wider need for consultation between Commission and Member States. Furthermore, under a common legal framework, action by one Member State can produce consequences for all. Bilateral co-operation does already exist between some Member States, but should be extended to all Member States. In reality, the technical complexity and political sensitivity of issues in relation to medical devices – that explain to a large extent certain slowness in Commission follow-up to national measures - can require reciprocal “up-stream” consultation and the creation of information mechanisms between authorities, including the Commission. Such consultations and information mechanisms can, however, not interfere or determine the exercise of responsibilities incumbent on the Commission or on national authorities.

In some way, the Notified Bodies Operations Group and the Market Surveillance Operations Group, chaired by national authorities and hosted by the Commission, already reflect the need for co-operation and consultation mechanisms in specific, critical areas where Member States bear specific responsibilities.

Beyond these specific areas, the need for pragmatic consultation mechanisms has recently become apparent in the case of safeguard clauses, where lack of expertise Community wide requires co-operation between all authorities, and where the adoption of a Commission opinion, which has a Community wide impact in a politically sensitive area without proper consultation of all Member States might cause serious concerns with Member States. Similarly, the BSE crisis has shown that in relation to the same issue, Member States have adopted widely divergent policies, using different instruments under the Directive, whilst a prior consultation or mutual information might have been useful. In the view of the Commission, it is also important that national authorities formally express the endorsement of Guidance documents elaborated in the MDEG or its subgroups. Another example where the need for consultation and information has been identified concerns European standardisation: for instance, key standards could be identified where one national authority reports on progress and potential issues to the others.

Such consultation should be able to take place without the strict and formal rules that are inherent to “comitology”, and that determine the exercise of regulatory tasks delegated by the Directives to the Commission.

- Consequently, the Commission foresees the creation of a ‘high level group on medical devices’, composed of senior officials responsible for medical devices of EU Member States, Candidate countries and EFTA, that would allow, as appropriate, for co-operation and consultation between national authorities and the Commission on issues related to medical devices. The group would meet

²⁹ OJEC L 204 of 21 July 1998; modified by Directive 98/48, OJEC L 217 of 5 August 1998.

only when necessary, or when written consultation procedures would appear to be insufficient to allow for a proper consultation.

The creation of such a group would not in any way jeopardise the functioning of the MDEG in which all stakeholders, National Authorities, standards bodies and industry take part. The proper functioning of the Directive needs indeed the input and feedback of all these parties. Furthermore, it would not interfere with the tasks incumbent on the Commission or the formal procedures set out in the directives. The group would liaise as appropriate with the High level Committee on Health.

7. ENLARGEMENT AND THE INTERNATIONAL DIMENSION

An examination of the functioning of the Directives on medical devices cannot be complete without considering enlargement and the international dimension. There is an interaction between the regulatory framework and third countries with whom the Community has established links, sometimes in a formal way, sometimes more informally.

7.1. Enlargement.

As regards countries that will join the Community, it is of utmost importance that they fully participate in all activities and working groups in relation to the medical devices directives. This is, unfortunately, not always the case. The level of safety and quality of life for patients and citizens will depend on levels of safety and quality achieved in single Member States. The challenge of enlargement is not so much a correct transposition of Directives in national law, but a coherent and strict implementation and management with sufficient human resources. The MDEG Report suggests that even between current Member States this is not an easy task.

- The Commission considers it of utmost importance that countries join in the activities of the various working groups. Member States should intensify co-operation through exchange programmes, study visits, trainee-ships, twinning, bilateral consultation, mentoring. Similarly, the Commission considers that European trade federations have a similar role with respect to training and information of industry associations in the candidate countries.
- The Commission will make available on its website information on such initiatives.
- The Commission, together with Competent Authorities of the Member States, is preparing the organisation of two workshops. One, scheduled for summer 2003, will deal with market surveillance. The other, scheduled for the last trimester will cover best practice on implementation of the Directives. These workshops should lead to the definition and implementation of further projects.

- The possibilities of a specific call for tender for a survey and an in depth analysis on “Enlargement and Health Challenges” are being looked at in the framework of the Programme of Community action in the field of public health (2003-2008).

7.2. Mutual recognition agreements.

A different issue is the Mutual Recognition Agreements (MRAs) covering medical devices, signed with the United States, Canada, Australia and Switzerland and foreseen with Japan. Under the MRAs, conformity assessment bodies designated by and working under the responsibility of authorities of the third country will assess products on their conformity with requirements of European directives, and vice-versa. Today, only the MRA with Switzerland (all medical devices)³⁰ and Australia³¹ is operational (with exception for high-risk devices).

Experience gained during the confidence building activities suggests that the European Directives are not always fully understood in third countries. Whilst being in favour of arrangements facilitating trade and increasing the competitiveness of industry, the Commission considers that only when strict guarantees exist as to the capacity of designating authorities and conformity assessment bodies that MRAs should enter into force.

- The Commission suggests that – and only in so far trading partners give concrete signs of interest - activities should be pursued to ensure that the operation of MRAs will ensure full respect of health considerations as defined in the Directives on medical devices.

7.3. Global Harmonisation Task Force.

Today, it has become impossible to ignore the work of the Global Harmonisation Task Force (GHTF) on medical devices. The Global Harmonisation Task Force (GHTF) is an informal platform for representatives from national medical device regulatory authorities and the regulated industry from three geographical areas: Europe³², Asia-Pacific (Japan-Australia) and North America (US, Canada).

The original objective of the GHTF, started in 1992, was to encourage convergence in the implementation of common elements in regulation of participating countries, in particular quality management systems. However, over time the activities of GHTF have expanded, to cover guidance documents on best regulatory practice. The implementation of common projects, such as global vigilance and a Global Medical Devices Nomenclature, and exchange of information and experience through “status reports” on new technologies or new risks. The GHTF also serves as an information exchange forum through which

³⁰ Switzerland is fully aligned on the Community Directives for medical devices.

³¹ Through alignment on GHTF guidance (see 5.3 below), Australian and Community law are since recently de facto fully aligned.

³² Member States, EFTA states and candidate countries.

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.

GHTF documents are largely inspired by Community legislation.

The fact that Europe will take the Chair of GHTF for a period of three years from 2004 provides an opportunity to further promote a European role world-wide.

- It is important that Europe continues to play a leading role in the work of GHTF and that Commission and European countries, including the Member States, continue to make sufficient resources available to allow for an efficient European presence. The Commission is examining how, at the European level, such resources can best be made available.

8. CONCLUSIONS

Medical devices have become a major sector in health care, both in terms of markets, of public expenditure and of impact on health. However, it has remained a largely unknown sector, apparently with scarce human and financial resources at the level of public administration. The Commission expects that the vast sector study, to be carried out in co-operation with national authorities and European trade federations, will increase awareness.

The Commission accepts the view expressed in the MDEG Report that the medical devices directives in themselves provide an appropriate legal framework with a view to safety aspects and technological evolution, but that there is definitely a need to improve implementation and to clarify particular aspects.

Improvement should be achieved through a combination of means, to be implemented by all actors involved, be this Commission, national authorities, Notified Bodies, Standards Bodies and manufacturers:

- Implementing measures at national level including market surveillance and designation of notified bodies, made possible through appropriate resources
- Use of available instruments (re-classification, precautionary principle, safeguard clause),
- Guidance in the form of consensus documents between the stakeholders, detailed in Annex 4
- Co-ordination and co-operation activities in different fora, including a new “high level committee for medical devices”

- Regulatory clarification on a number of issues, detailed in Annex 5.
- Implementation of other measures, detailed in Annex 6.

The Commission will carry out an impact assessment of this strategy within a period of five years.

Annex 1 - Summary of information - article 11 section 4 of 93/42/EC - Vigilance

Vigilance data 1995- 2000 (not all years are complete)

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
Austria	119	163	231	140	166	169	- 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
Belgium	18	24	68	120	176	246	Figures only include manufacturers and users reports. Reports received from other Competent Authorities do not appear. Sent 2 competent authorities vigilance reports in 1997 3 in 1998, 3 in 1999, 4 in 2000 and 4 in 2001.	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.
Denmark	74	98	82	223			The first vigilance report was in 1996. Since then, only 1 report is transmitted. No clear trend is	It is suggested to have a better communication among MS and to encourage a harmonized approach by MS and manufacturers.

							observed. Few reports are not meeting the criteria of serious incident. They include anything from near incident to death of a patient	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.
Finland	-	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
France	-	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 harmonized declarations - to improve communication between MS, and - to apply a centralized evaluation method.

Germany			16	51	66	73		
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Ireland					204	196		
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Netherlands	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 - Harmonization 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
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Portugal	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	Most of the problems are common to other Member States. - The absence of the European Database
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							formats suggested by the EC.	- The need to improve communication between Member States - The lack of information regarding the distribution chain in Europe.
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Spain	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
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Sweden	12	52	167	269	397	375		
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UK	15	32	76	107	123	109	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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Annex 2 -Summary of information - article 11 section 4 of 93/42/EC – Clinical investigations

Clinical investigations 1995-2000

Country	1995	1996	1997	1998	1999	2000	Comments	Problems encountered, suggestions for changes and issues
Austria		2	12	17	21	28	Numbers apply to all classes of medical devices	It is suggested to establish a system of clinical guidance documents.
Belgium	-	-	-	24	26	30		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.
Denmark	-	-	-	-	-	-	This competence is delegated to the Scientific Ethical Committee	No suggestions have been made
Finland	-	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.

France							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.
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Ireland				1	1	2		
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Netherlands	-	-	44	27	31	41		
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Portugal	-	-	-	-	-	5	Detected difficulties in the instruction of technical documentation	It is suggested to harmonize the procedure through a Guideline
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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.
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Sweden	25	25	26	39	34	34		
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UK	83	51	47	50	29	54	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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Annex 3 – 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	
Ireland						1		
Netherlands	-	-	-	2	5	3		
Portugal	-	-	-	-	-	-	Infarmed did not have any consultation as mentioned	

Spain	-	-	-	-	-	8	Figures are not given per year. It is suggested to: - State more clearly which medicinal substances should be submitted for consultation. Exclude cases meeting the following criteria: a) combination of health product + medicinal substance well known for the intended uses b) medicinal substance frequently used and with quality specifications fully described in the European Pharmacopoeia monograph 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 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	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".
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UK	-	-	-	-	-	-	MCA received several consultation requests from NBs based in UK and abroad MCA issued guidance documents based on MEDDEV 2.1/3 rev. 5	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.
							The nature and data submitted is variable but has improved since companies have gained experience in compiling files for combination products MCA feels that there are still 3 areas requiring further discussion: - Quantitative declaration of content of medicinal substance availability - Stability - Claims	

Annex 4 - Work programmes for working groups and task forces.

Clinical Evaluation Task Force

- Evaluation of Clinical data: A Guide for Notified Bodies
- Guidelines for Post-Market Clinical Follow-up (PMCF)
- Specific guidelines for certain categories of implantable medical devices namely coronary stents and hip implants
- Transparency of the clinical evaluation reports

Notified Body Operations Group

- Production and completion of a checklist on the designation and monitoring of notified bodies
- Production of a Best Practice Guide (BPG) for Member States and notified bodies
- Production of a Communication Strategy on the exchange of information between Member States
- Production of Annual Reports by Notified Bodies
- Observing Member States Auditing Notified Bodies
- Training Events
- Guidance on Possible Notified Body remedial action(s) to rectify non compliance
- Notified Body Competence requirements
- Guidance on minimum data set for Certificates of Conformity
- Sharing Audit Experiences
- Vigilance Reporting clarification of the notified bodies role
- Change of Notified Body by the manufacturer actions by Member State and notified body

Market Surveillance Operations Group

- Communication strategy to cover exchange of information about individual inspections

- Guidance Notes for manufacturers of class I medical devices
- Guidelines to elaborate the technical documentation related to the annex VII of MDD
- Guidelines to elaborate the EC declaration of conformity
- Compliance check-list for regulatory authority to verify the technical documentation conformity
- Inspection of class I manufacturers
- Guidance notes for importers and distributors
- Protocol for a possible inspection programme for shadow audits, where one Member State is doing the audit together with other one to develop better understanding of procedures
- Criteria for acceptance and assessment “miracle” and other borderline products
- European Inspector’s Hand Book for Best Practice

Medical Devices Expert Group

- Endorsement of Notified Body Recommendations and Consensus statements

Annex 5 - Main areas identified for regulatory modification.

Scope

- Exclusion of in vitro diagnostic medical devices from the scope of the Directive covering Biocides.
- Clarify the situation in regard to Personal protective equipment to allow both Directives to apply.

Conformity assessment and classification.

- Modification of the classification criteria in annex IX to eliminate certain classification anomalies.
- Annex II: clarification of obligation of design evaluation under quality assurance.
- Redefine period of validity of conformity assessment certificates
- Definition for the period of retention of product files.
- Clarification of the text of Annex X on clinical evaluation.

Essential requirements.

- Introduce expiry dating for sterile medical devices

Transparency

- Make possible the publication of information concerning the assessment of medical devices. Review the Directive provision for confidentiality (article20)

Post production phase

- Propose regulatory change to ensure that national measures that restrict the placing on the market of medical devices will be communicated to all Member States.

Alignment of the Active Implantable Medical Devices Directive with the Medical Devices Directive.

- Inclusion of provision on particular health monitoring measures
- Extension of database EUDAMED to active implantable devices
- Addendum for EC type-examination certificates
- Requirements regarding new devices

- One 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
- Documentation of the quality system in the technical documentation

Annex 6 - Other Measures

Study on medical devices sector.

The Commission will launch a study in 2003 concerning the medical devices sector, its impact on health and health expenditure, and framework conditions for increasing competitiveness.

Creation of a High Level Group for medical devices

The Commission will create a High Level Group for medical devices allowing for consultation and mutual information between Commission and national authorities on issues in relation to medical devices.

Complete and publish data

The Commission will ask national authorities to complete data on vigilance, clinical investigation and pharmaceutical consultation, to be made available on the Commission's web-site for medical devices.

Support MSOG, NBOG and CETF

The Commission will continue to host and, within the limits of budgetary availability, financially support the work of NBOG, MSOG and CETF.

Health policy Forum

The Commission will inform on a regular basis the Health Policy Forum of developments in relation to medical devices.

Eudamed

The Commission will launch a pilot project on Eudamed in mid 2003, under which national authorities will start to load data, to be implemented throughout the second half of 2003.

Vigilance

MDEG Vigilance group to verify and improve national practise on vigilance.

Pharmaceutical consultation.

Guidance to be developed by MDEG to ensure coherent implementation of relevant provisions in Directive.

Standardisation.

MDEG to monitor and verify on a regular basis issues and progress in relation to European standardisation for medical devices.

Intervention mechanisms

Commission to propose guidance document on the implementation of the Directive's provisions on national health monitoring measures and their relation with safeguard clauses.

Appendix 1 - 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

Appendix 2 - The Benefits of Medical Technology and Devices for EU Citizens³³

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

³³

Extract from the MDEG Report; information supplied by EUCOMED

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 foot 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 parasthesia 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.

Appendix 3 - Main features of regulatory framework

The Directives are based on the concept of the New Approach to technical harmonisation and standardisation, defined by the Council in 1985³⁴. Directives define the essential requirements that products have to meet when they are put on the market or put into service. 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. In this approach, risks to be taken into consideration relate to issues such as chemical, physical and biological properties, infection and microbiological contamination, construction and environmental properties and protection against radiation. Furthermore, medical devices must achieve the performances intended by the manufacturer.

In order to allow technological progress and to ensure that new products placed on the market reflect the current state of the art, the directives do not specify technological solutions to be adopted by manufacturers. Instead, manufacturers have to substantiate how risks have been taken into consideration and dealt with, both at the level of the design and the manufacture of the device. Use of European “harmonized standards” provides a presumption of conformity with the essential requirements to which such standards specifically relate.

The Directives contain a number of conformity assessment procedures, the use of which depends on the type of products and type of risks involved. Except for low risk devices, these risk-based procedures always involve independent conformity assessment bodies, so-called Notified Bodies, designated and monitored by national authorities.

The Directives foresee a number of mechanisms for authorities by which they can intervene in order to ensure the proper functioning of the directives. Such mechanisms relate for instance to the designation and monitoring of notified bodies, reclassification of devices, mandates for standards, formal objections to standards, safeguard clauses, actions under the precautionary principle, market surveillance, administrative co-operation and the creation of guidance documents. A proper implementation and management of the Directives is therefore resource intensive.

This legal framework is stable and does not require regular updating. However, in order to meet its requirements, manufacturers must follow the state of the art. Devices placed on the market today will not be deemed to respect the directives’ requirements if they do not evolve over time with technological evolution.

³⁴ Council resolution of 7 May 1985 on a New Approach to technical harmonisation and standards; OJEC C 136 of 4 June 1985.

Appendix 4 - Working groups involved in the implementation of the Medical Devices Directives.

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

- 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 candidate countries) and stakeholders such as representatives of industry, European standards bodies and of Notified Bodies. MDEG has set up a number of specific Working Groups that report to MDEG, dealing with issues such as BSE/TSE, vigilance. Of particular interest is the recently created clinical evaluation task force.
- 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 web-site.
- More recently, national authorities have come together to co-ordinate policies under the Notified Bodies Operations Group (NBOG) and the Market Surveillance Operations Group (MSOG). Meetings are chaired by a national authority, and hosted by the Commission. NBOG and MSOG inform MDEG of their activities.
- Notified Bodies meet on a regular basis in the framework of the Co-ordination of Notified Bodies Medical Devices (NB-MED) The aim is to co-ordinate the assessment of technical issues. The Commission funds the organisation of these meetings and all Notified Bodies are encouraged to attend. The NB-MED lays down its conclusions in recommendations and consensus statements. These documents are currently not publicly available.
- Scientific advice on particular issues is obtained from the Scientific Committee on Medicinal Products and Medical Devices, created by Committee’s Decision N° 97/579/EC of 23 July 1997³⁵. The list of the Committee’s Opinions adopted so far is available on the web-site of the Commission³⁶.

³⁵ OJEC L 237 of 28.8.97

³⁶ http://europa.eu.int/comm/food/fs/sc/scmp/index_en.html