COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.12.2005
SEC(2005) 1742

COMMISSION STAFF WORKING DOCUMENT

Annex to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives

IMPACT ASSESSMENT

{COM(2005) 681 final}

IMPACT ASSESSMENT

Proposed Amendment to the Directive 93/42/EEC concerning Medical Devices including amendments to align Directive 90/385/EEC concerning Active Implantable Medical Devices

DG Enterprise and Industry - Unit F3

DG ENTR, Unit F3

30 September 2005

1. WHAT ISSUE/PROBLEM IS THE POLICY/PROPOSAL EXPECTED TO TACKLE?

Member States, Industry, and other stakeholders believe that more consistent and coherent implementation of the Directive 93/42/EEC concerning medical devices is necessary in order to continue the high level of public health protection. This is particularly true regarding the provisions with respect to conformity assessment.

'Zero risk' in the field of medical healthcare cannot be provided, consequently the regulatory checks and balances, and their implementation, should be of such a nature as to ensure the highest level of confidence by the public. This confidence was placed under scrutiny in the recent past by public debate, in various Member States, mainly regarding long-term implants, such as breast implants and joint replacements, and on the adequacy of current legislation in light of new technologies.

For this reason, the Commission Services, national authorities, notified bodies, European standards organisations and industry, through the Commission services' Medical Devices Expert Group, MDEG, started a review process of the medical device directives in 2001.

This review, whilst concentrating primarily on the main Directive 93/42/EEC concerning medical devices, also included a review of the two other Directives that form the wider regulatory framework for medical devices: Directive 90/385/EC concerning active implantable medical devices and Directive 98/79/EC on *in-vitro* diagnostic medical devices.

Arising from this review process, a Report on the functioning of the Medical Device Directive 93/42/EEC was published in June of 2002. The conclusion of this Report was that whilst the Medical Devices Directives provide in themselves an appropriate legal framework, there is room for improvement in implementation by all interested parties and in this context, and in support of better implementation, certain regulatory clarification is needed. The full text of the Report is available on the Commission's web-site http://europa.eu.int/comm/enterprise/medical_devices/index_en.htm.

The Commission brought forward this conclusion in its Communication COM (2003)386[1] which was welcomed by the Council in its Conclusions of December 2003[2] and was received favourably at Parliament.[3]

The most important areas where improvement should be made concern conformity assessment, including designation and monitoring of notified bodies, clarification of the clinical evaluation requirements, and Post Market Surveillance. A particular concern was the absence of appropriate design documentation and design review for particular groups of medical devices, with various authorities asking for change in the classification rules. The need was identified for having an instrument, under the Directive, to make binding decisions where there are conflicting national interpretations as to whether a product falls within the scope of the Directive or not. The Report also highlighted the need for increased transparency to the general public, in relation to the approval of devices.

---

1 Communication from the Commission to the Council and the European Parliament on medical devices of 2.7.2003 COM(2003) 386 final, OJ C 96, 21.04.2004, p.5.

2 Council Conclusions on 2 December 2003 on Medical Devices (2004/C 20/01), OJ C 20, 24.01.2004, p.1.

3 European Parliament resolution on the health implications of Council Directive 93/42/EEC concerning medical devices (2001/2270(INI)).

Also, in order to present uniformity and consistency across all three Directives which form the legal framework for medical devices, the Communication highlighted that modification was needed to the Directive on active implantable medical devices. This modification would incorporate those changes introduced into the Directive on medical devices by other Directives, such as the *in vitro* diagnostic medical devices Directive, as these changes are equally applicable to all categories of medical devices i.e. the requirements for a European Databank on medical devices (Eudamed), the special provisions for devices incorporating blood or blood plasma and health monitoring measures.

Finally, under this regulatory reform, the Directive 98/8/EC on biocides needs to be modified in order to clarify that, alongside the active implantable medical devices and medical devices, also *in vitro* diagnostic medical devices, now subject of a specific Directive, will be excluded from the scope of the biocides Directive.

2. WHAT MAIN OBJECTIVE IS THE POLICY/PROPOSAL EXPECTED TO REACH?

Policy Objective

- The proposal can be seen as part of the Commission services' overall initiative to improve the coherence and effectiveness of legislation.

The policy objective is to maintain a legal framework for an important and politically exposed health care sector that, on one hand allows citizens to benefit from the enormous potential for innovation, and on the other, ensures the necessary checks and balances to safeguard health protection. Authorities must be seen to monitor the market, to use the instruments to intervene that do safeguard health protection, and to adapt the regulatory framework in the light of experience, if public trust and confidence in the regulatory system is to be maintained. The proposed amendment to the legislation is an important element in this strategy.

Whilst the current legal framework is adequate, with implementation needing to be improved, there is, nevertheless, a necessity to make a number of regulatory changes in order to meet the policy objectives.

Objective of Proposal to Amend the Directive

The main objective of the proposed amendment to the Directive is to better specify the obligations of manufacturers, notified bodies and authorities with particular respect to the key issues of conformity assessment, clinical evaluation and post market surveillance, in order to ensure the highest level of safety, to ensure access to the market and to allow for a smooth functioning of the legal framework.

Furthermore, a legal basis was needed to allow for more openness and transparency towards the general public and for clarifying to what extent specific products fall in the scope of the Directive.

The Directive also creates a basis for the Community to participate in global activities on regulatory convergence, as they exist in the form of the Global Harmonisation Task Force for Medical Devices, GHTF, in order to ensure that Europe's position and regulatory framework is fully taken into consideration.

3. WHAT ARE THE MAIN POLICY OPTIONS AVAILABLE TO REACH THE OBJECTIVE?

In order to reach the objective action was considered in key areas of the Directive namely:

Simplification, Better Implementation, Better Conformity Assessment, Legal Certainty (More Binding Rules) in the Directive and Improved Market Surveillance.

1. Simplification

There are three principal Directives pertaining to medical devices; the *in vitro* diagnostic medical devices Directive 98/79/EC (IVDD), the medical devices Directive 93/42/EEC (MDD) and the active implantable medical devices Directive 90/385/EEC (AIMD):

Legislative	– Merge all three Directives into one, or at least two, Directives: the AIMD and the MDD

2. Better Implementation

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

However, to provide for an equal level of health protection, and to aid implementation, consistency across the three main Directives on medical devices should be provided. This would require that Directive 90/385/EEC would need to be updated to include those provisions that are common to Directives 93/42/EEC and 98/79/EC, and which are equally applicable to active implantable medical devices.

Legislative	– Update the Directive 90/385/EEC on active implantable medical devices to include provisions common to all medical devices: - Definitions - European databank for medical devices - Authorised representative - Provisions on blood and blood plasma - Health protection measures
Non- Legislative	– Continued use of the MDEG, Medical devices Expert Group, to drive improvements in implementation and, where concerns arise on certain aspects of the Directives, to create and monitor working groups needed to develop clearer guidance or interpretation.
	– 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 by the Commission services, composed of representatives of national

administrations, dealing respectively with Notified Bodies (Notified Bodies Operations Group, NBOG) and Market Surveillance (Market Surveillance Operations Group, MSOG). Output of their work has been and will be presented in the MDEG.

– 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.

3. Better conformity Assessment

Conformity assessment under the Directive has three main elements: classification of devices, notified bodies and conformity assessment. In order to improve conformity assessment, options were considered under these main elements.

Classification:

Under the Directive, devices are classified according to risk into four classes, I, IIa, IIb and III. In the course of the debates, Member States have indicated a number of devices where reclassification should be considered. This relates not only to upgrades from IIa or IIb to III but also that there may be cases for down-grading. Discussions have also revealed that, in some cases, implementation of the Classification Rules can lead to discrepancies and furthermore in some instances, such as devices in contact with the brain, there was incoherence within the rules themselves. As the classifications rules are contained within the Directive itself the options considered involved modification of the Directive:

Legislative

– Modify the Directive to reclassify certain devices, correct any anomalies and remove incoherence.

– Alternately, as a reclassification mechanism already exists in the Directive under Article 13, use this current mechanism and only modify the Directive to correct anomalies and remove any incoherence in the classification rules.

Notified Bodies

Concerns were expressed regarding Notified Bodies in relation to their competence for the tasks 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 fundamental element in the implementation of the Medical Devices Directives, and thus action would be required by Notified Bodies and national authorities alike. Therefore a number of options arose. The principal ones being:

Legislative	– Modify Annex XI of the Directive with respect to the designation of Notified Bodies to address any concerns
Non- Legislative	– In order to co-ordinate national action, and to create transparency in the exercise of national competencies, the Commission services created a Working Group composed of representatives of national administrations, dealing respectively with Notified Bodies called the Notified Bodies Operations Group, NBOG.
	– Member States to improve Notified Body (NB) performance by, primarily, identifying and promulgating, through NBOG, examples of best practice to be followed by Notified Bodies and Member States.
	– Modify the MedDev guidelines on designation and monitoring of Notified Bodies (The Designating Authorities Handbook) in order to ensure coherence, including Notified Bodies commitment to participation in the Commission services' Notified Body Co-ordination group, NB-MED
	– NB-MED recommendations to be subject of endorsement by the MDEG and be enforced by national authorities responsible for the designation and monitoring of Notified Bodies.

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. Questions have arisen on the evaluation of the design of a product and, in particular, the absence of clear rules on design evaluation, including verifying the sufficiency and adequacy of clinical data by notified bodies, as part of quality assurance assessments and, in the broader sense, the availability of clinical data for all classes of devices. Also, through the public consultation, questions arose as to the equal compliance of custom-made devices manufacturers both inside and outside the EU, to the Directive.

The main options discussed were:

Legislative	– Modify the directive to clarify the tasks of the Notified Body under the quality assurance modules
	– Clinical Evaluation Task Force, CETF, to suggest text for the modification of the Directives provisions on clinical data to eliminate any possible misinterpretation of the current text

– Include administrative requirements that better evidence the compliance of custom-made device manufacturers to the Directive, but that do not add extra burden to manufacturers or authorities.

Non- Legislative

– Develop guidance 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

– Set up a Clinical Evaluation Task Force (CETF), 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.

4. Legal Certainty (More Binding Rules)

Along with a general technical editing of the Directives to make them clearer, including exclusion of *in vitro* diagnostic medical devices from the scope of Directive 98/8/EC on biocides, a number of options were proffered relating to having more detailed or tighter controls within the Directive itself. Included in this is the need to close a 'regulatory gap' between the medical device Directive and the proposed Directive on Advanced Therapy Products, ATPs, that would lead to medical devices that incorporate tissue of human origin with action ancillary to that of the device.

The ATP issue was highlighted through the public consultation process. The other major legal certainty issue that received significant comment through the public consultation was the need to address the reprocessing of 'single use' devices. Here, the trade federation representing the manufacturer's of 'single use' devices claim that the reprocessors of single use devices should be considered as being included in the definition of 'manufacturer' and hence their activities should be regulated under the Directive as, in their opinion, lack of regulation in this field represents a threat to patients safety. For their part, the reprocessor's trade federation would welcome Community wide regulation of their activities, which are currently the subject of national measures, and have highlighted what is, in their opinion, misuse of the 'single use' claim:

Legislative

– Include medical devices that incorporate tissue of human origin with action ancillary to that of the device within the scope of the active implantable and medical devices Directives.

– Exclude *in vitro* diagnostic medical devices from the scope of Directive 98/8/EC on biocides.

– Use Common Technical Specifications, CTS's, similar to those within the in vitro diagnostic medical devices directive.

– Make harmonised standards obligatory rather than voluntary – although this would require a change to the "New Approach" concept.

– Allow authorities have a role in the adoption of harmonised standards.

– Make the MDEG "guidance documents" obligatory rather than voluntary.

– Include in the Directive a provision to decide if products fall within the scope of the Directive or not.

– To address the question of the reprocessing of 'single use' devices either include provisions on reprocessing in the directive and/or clarify exactly the conditions for the labelling of devices as 'single use'.

– Technically edit the text to be clearer.

5. Transparency

It is now apparent to all stakeholders that the public should have access to certain information related to the approval of high risk medical devices. Currently, as per Article 20, all data that becomes available under the Directive is considered confidential, which is in direct conflict with this tenet. So the options in this case are limited in the sense that, ultimately, legislative change is required:

Legislative	– Modify the Directive to allow certain information to be categorized as 'non-confidential'
Non- Legislative	– The Commission services, in conjunction with industry, are engaged in a pilot project on this subject analysing the ideal format and level of information to be made available.

6. Improved Market Surveillance

Market surveillance by authorities is a key element to the correct implementation of the Directive and to the safeguarding of public health. The functioning of market surveillance

activities was seen as an area that could be improved both from a legal and implementation perspective. Also as the medical device market is a global market, options related to Europe's role in global regulatory initiatives were discussed:

Legislative	– In order to create a legal basis for vigorously coordinated action and possible financial support, a specific legal basis, as exists in other New Approach Directives, was deemed useful
	– Create a legal basis to allow the European Union to reinforce its presence in the Global Harmonization Task Force on Medical Devices, GHTF, in order to ensure that the European system is duly taken into consideration in all GHTF consensus
	– Modify the directive to include requirements that regulate distributors of medical devices
Non- Legislative	– Commission services created a Market Surveillance Operations Group, MSOG, to coordinate activities and develop guidance
	– Develop guidance on the role of distributors and the General Product Safety Directive and its relation to medical devices

4. WHAT ARE THE IMPACTS – POSITIVE AND NEGATIVE – EXPECTED FROM THE DIFFERENT OPTIONS IDENTIFIED?

General Impacts

General Economic, Social and Environmental Impacts

Since the proposal is more regulatory clarification rather than regulatory change, there are no significant economic impacts expected. Similarly there were no environmental impacts identified by the current proposal. However, three principal impacts, health, economic and social impacts, can be singled out which arise not from any specific option chosen, but from the proposal in its entirety:

– Increased clarity will continue to support a high level of public health protection.

– The proposal will provide more transparency and increase the certainty for all market players and, in particular, the public.

– For enterprises and citizens alike, the improved regulatory framework will continue to support fast technical progress to benefit citizens under better clarified conditions for guaranteeing safety and increased trust.

While, certainly, the regulatory clarification will lead to 'de facto' changes in implementation, for those manufacturers who are correctly implementing the Directive there will be no economic effect.

Global Competitiveness

Medical devices are a global market and one cannot ignore activities, at the global level, to converge regulatory systems. In order to allow Europe to act as driving force instead of undergoing influence from other regions, Europe needs to actively participate in GHTF activities, however, in order to provide financial resources for international cooperation a legal basis is needed. This participation reinforces the competitive position of European industry, bearing in mind that, already, a large portion of guidance at GHTF is inspired on the basis of European legislation and can lead to European citizens benefiting from the experiences of other countries.

Specific Impacts

1. Simplification

Whilst there are broad similarities between the AIMD and the MDD, the IVDD is technically different from the other two and therefore would not lend itself to being merged. Furthermore, manufacturers of in vitro diagnostic medical devices are not necessarily manufacturers of other medical devices and therefore merging may give rise to confusion in interpretation and implementation.

For the remaining AIMD and MDD, this could be a possibility but Competent Authorities, and Industry, have stated that, as this task would not be insignificant, to merger them at this point would greatly delay the legislative amendment foreseen to the MDD, which is at an advanced stage and enjoys widespread support from all stakeholders. What is necessary is a

more consistent and coherent implementation of the Directive. Any merger may thus only be considered once this process is finalised

2. Better Implementation

Rather than leave the inconsistencies between the Directives, it was decided that the active implantable medical device directive should be updated to be coherent with the two other Directives on medical devices. This will ensure a consistently high level of protection of human health across all three medical device categories and remove the anomaly that certain provisions that are seen as fundamental to the overall legislative framework for medical devices are absent from the Directive on active implantable medical devices.

Whilst this will obviously result in some increased costs for manufacturers these are estimated to be non-significant. These provisions have been in place for the majority of all medical devices for some years without adverse impact on the market or device availability. Moreover, there are a concentrated number of operators in this device sector who share a profitable market, and against this background, these increased costs would be negligible.

From the non legislative perspective, continued use of the options identified, that require no regulatory change, will be pursued. The work of the groups will be coordinated at the Commission services level to be more focused on 'Better Implementation'. As these are currently functioning groups, and well supported by all stakeholders, there is no negative impacts expected, and indeed to the contrary, there are already positive impacts through better guidance, such as that for the designation and monitoring of Notified Bodies. Here, the Notified Bodies Operations Group, NOG, has already noted improved harmonisation and 'Better Implementation' through application by authorities of the modified guidelines on designation and monitoring of Notified Bodies (The Designating Authorities Handbook).

3. Better conformity Assessment

Classification

Here, for classification anomalies, the option chosen was to address all identified anomalies, save the anomaly related to reusable surgical instruments, by changing the text to the Directive. It was identified through the public and bilateral consultations that the reclassification of reusable surgical instruments would have a significant effect on the market. Thus it was decided that it would be better to consider this classification more carefully, perhaps by using the procedure and option already identified within Article 13 of the Directive.

The reclassification changes affect a relatively small subsection of the market, and the majority of the devices concerned already involve intervention by notified bodies, so no significant impact is expected on manufacturers. Furthermore, an adequate transition period is provided to allow manufacturers and notified bodies to adapt.

Notified Bodies

Here the chosen options were the non-legislative options as it was seen that the legislation works well but that better implementation is needed. Thus the Commission services have created the Notified Bodies Operations Group, NBOG. The work here will bring no significant negative impact as clear guidance to Notified Bodies, particularly through a

revised guidance on the designation and monitoring of Notified Bodies, facilitates the Notified Body and the Authority alike and promotes 'Best Practice'.

Conformity Assessment

Here all options were taken as all contributed to solving the problem of better implementation but no single option alone would be enough. Here again also, as the options all speak to clarification as opposed to regulatory change, there is no negative impact expected and only a positive impact for the activity of actors and the protection of public health.

4. Legal Certainty (More Binding Rules)

Clarification of the legislation allows for better implementation by manufacturers, notified bodies and national authorities.

Whilst for most problems identified, guidance and use of existing means, provides an appropriate means to solve issues, in a number of cases a number of changes are needed to ensure coherent implementation particularly, for example, to define the conditions under which a product is considered to be under the scope of the Directive. Thus these options were chosen.

Regarding single use, the option to include reprocessing of single use devices into the directive was not chosen. In examining the issue in detail, including bilateral meetings involving the relevant trade federations, it became clear that the issue goes far beyond this Directive and a simple expansion of the definition of 'manufacturer', and raises questions that would require further reflection by the Commission services, in consultation with a wider group of stakeholders, to explore possible development of appropriate legislation in this area.

The substantial issues that preclude addressing the issue in this Directive and that would need wider consultation and consideration include:

– **Interpretation of the term 'single use'**. There are differing interpretations of the use of the term 'single use'. Some see it as meaning that the device should only be used once for a single patient. Others extend the meaning to say that the device cannot be reprocessed. This calls for a clear common understanding of term 'single use' under the Directive.

– **Appropriate Legal Framework**. The medical device Directive may not be the appropriate legal framework as reprocessing can take place after the product has been placed on the market and without the product being placed on the market again and therefore fall out of its scope. In addition, normally the ownership of the device remains with the hospital while it is being reprocessed, reprocessing could be considered a 'service' rather than a manufacturing process, thus the potential for it to be covered by any current or foreseen legislation on provision of services would need to be considered.

– **Harmonised approach**. There is a lack of a clear and consistent position amongst authorities as to the requirements that should apply in order to protect human health. Interpretation by national authorities differs with respect to reprocessing practices, some allow reprocessing of certain 'single use' devices under controlled conditions and yet others have banned the practice entirely.

– **Differing requirements**. If reprocessed devices did fall under the Directive on medical devices they would have to meet the 'essential requirements' for safety and performance. In discussions with reprocessors, it became evident that they could not meet, in full, all the 'essential requirements' that normally apply to a device and thus they could not comply with the Directive. Generating a specific set of requirements for reprocessed devices would not necessarily solve this issue either, as it is not certain that a second set of requirements could be developed that are scientifically equivalent to the first. Furthermore, even if this approach was taken, the question would arise as to the wisdom of having two different levels of safety existing for medical devices.

– **Global Market**. The medical device market is a global market and so, therefore, are reprocessed medical devices. Any development of legislation in this area by the EU would need careful consideration in respect to its harmony with other third country regulations and any possible adverse affect on trade.

– **Ethical and liability considerations**. A number of questions need careful examination: Does the principal of 'informed consent' apply to reprocessed devices? Who is liable for a failure of the reprocessed device - the hospital? the reprocessor? the manufacturer?

Regarding what has been seen to be the perceived misuse of the labelling of devices as 'single use', text was explored to address this claim, however, in light of discussions with the trade association involved, and for the reasons outlined above, this text was not included in the final proposal.

The options identified for more binding rules could be seen as a way to give clear and unequivocal instruction. However, when discussed in full by all stakeholders they were found to be either in conflict with core concepts supporting New Approach legislation, where use of standards is voluntary and where authorities already can play a role in their development, or to be no more effective than the current legislative text, such as in the case with CTS's – Common Technical Specifications - where experience of their use in the IVD Directive would not suggest that it is necessarily a better approach than the use of standards. Thus these options were not chosen.

As regards making MDEG guidance obligatory, this was not seen as an optimum approach as these documents, themselves by definition guidance, deliberately allow for interpretation in order to cater for technological innovation and novel technology. Also it was unclear as to the impact on specific medical device sectors if guidance, that was developed to reflect the general case, was made obligatory.

Finally, as regards exclusion of *in vitro* diagnostic medical devices from the scope of Directive 98/8/EC on biocides, this removes the legal ambiguity that exists, in certain cases, as to which Directive should apply. Commission services and authorities are clear that *in vitro* diagnostic medical devices that also meet the definition of a biocidal product should be regulated as *in vitro* diagnostic medical devices. Manufacturers of *in vitro* diagnostic medical devices do not normally pursue placing on the market under the biocides Directive, and visa versa. Therefore, this proposal only brings legal certainty to this common interpretation in the market and hence is expected to have a positive impact, bringing legal clarity and certainty, and have little or no negative impact.

5. Transparency

Both options are chosen here. Article 20, on confidentiality, which currently maintains all information available under the Directive as being confidential, could be relaxed, to allow certain information on all devices to be publicly available and to allow, by comitology, a method of making other information non-confidential, such as summary information on the approval of high risk devices.

The proposed changes will benefit citizens in Europe in that, similar to countries such as the USA, information can be made publicly available on the approval of high risk medical devices. It is accepted by all stakeholders that such information should be available.

The precise conditions, by which this is done, as decided by comitology, will be defined in light of the current pilot project presently being implemented, on a voluntary basis, by industry. Initial feedback from the current pilot project indicates that there will not be significant burden on manufacturers and that the trust and acceptability of the public will be increased, thus allowing a regulatory framework to be maintained that otherwise might have been challenged.

6. Improved Market Surveillance

As stated, market surveillance is a key element to the correct implementation of the directive and the safeguarding of public health. Of the options identified, those that spoke to the role of the distributor were seen to be beyond the scope and competence of these Directives. Therefore those aspects related to the control or guidance of distributors could not be considered. Of the remaining options identified, none could be seen to have any negative impact and so were taken on board and the necessary additions to the legislation were included in the proposal.

5. How to monitor and evaluate the results and impacts of the proposal after implementation?

The Commission announced in its Communication on medical devices that the Commission services will carry out an evaluation of the initiatives to improve implementation within a period of five years, and the Council welcomed this in its Conclusion.

However, on an ongoing basis, the Commission services is monitoring the program through the MDEG which directs the activities on all working groups and guidance, including the activities of NBOG and MSOG, which were specifically set up as part of the strategy on improved implementation.

A number of initiatives have already produced results that are being put into effect; the NBOG has produced a 'Designating Authorities Handbook' for the coordinated control and monitoring of notified bodies; MSOG has brought forth guidance on custom-made devices and the Clinical Evaluation Task Force, in finalising guidance on clinical data, has submitted clearer text on the requirements as input to the proposed amendment to the Directive.

6. Stakeholder consultation

The review process and proposal has been discussed extensively since 2001 with as wide an exposure as possible. As the nature of the changes envisaged primarily affected national authorities and industry, the principal comments arose from these two stakeholders.

Authorities, whilst satisfied that the Directives provide an appropriate legal framework, sought clarification on certain areas, such as the appropriate design documentation and design review for particular groups of medical devices, and text to aid better implementation on certain aspects of the Directives, such as clinical evaluation. These, and all other comments, were discussed in detail by the Commission services' MDEG and are contained in the Report on the functioning of the Medical Device Directive 93/42/EEC which was published in June of 2002. As part of this proposal, all substantial comments from authorities were considered as options and are presented in this document, and have resulted in either proposed legislative or non-legislative measures.

Industry, whilst welcoming the existence of one single legislative framework across the EU, criticised the apparent un-harmonised interpretation and implementation of the Directives by Member States, which brings inefficiencies and results in excessive administrative burden. This adds to costs and can unnecessarily delay the availability of needed devices to users and patients. Thus any initiative, either legislative or non legislative, that brings clarification and consistency to interpretation and implementation was welcomed. Industry was able to promote this principle into the proposed changes through participation at the MDEG, where it was fully in accordance with the Commission services' and authorities' goal for better implementation, and through bilateral meetings with the Commission services. Furthermore, industry was a key contributor to the Report on the functioning of the Medical Device Directive 93/42/EEC.

Industry also came with specific issues: clarification of the role of a national authority or the European Medicines Agency (EMEA) in consultation for devices containing a medicinal product or blood plasma derivative, the provision of electronic labelling and the prohibition, or control, of reprocessing of 'single use' medical devices. Here text has been proposed that clarifies the role of national authorities or EMEA and that allows for the provision of electronic labelling in a controlled manner. As regards reprocessing, this activity has been consistently seen by the Commission services as being outside the scope of the Directive, as it pertained to devices already 'placed on the market' and 'put into service', two key definitions that limit the scope of all New Approach Directives. Therefore, as the devices in question are already on the market and/or put into service, it is a National and not a Community competence and no text could be proposed.

From the above it can be seen that the key consultation took place through the review and resulting Report that took place in 2001 and 2002. Copies of the MDEG Report and the resulting Commission Communication have been posted on the sector's website since 2002 and 2003 respectively. The proposals, and all other actions, were extensively discussed at the Commission services' MDEG, which includes national authorities, notified bodies, industry and standards bodies, in 2004 and 2005.

The result of these deliberations was a draft proposal that was widely supported by Member States, Industry and the other stakeholders.

Following from this, a public consultation, via the Commission's web-site, took place in May and June of 2005. Here a draft text highlighting the changes, as they would appear in the current text, was set out for comment. More than 80 written submissions were received, resulting in over 300 specific comments, from all types of stakeholders, but primarily from industry, trade associations, consultants and authorities; a small number of individuals and patient groups also responded.

The principal policy issues raised came from industry, where they highlighted concerns regarding the reprocessing of devices designed only for single use, the consistent compliance of custom made devices manufacturers to the Directive and in particular those manufacturers located outside the EU and a potential for the reclassification of reusable surgical instruments to have a significant effect on the market.

Here, in examining the concerns on reprocessing of single use devices in detail, including bilateral meetings involving the relevant trade federations, it became clear that the issue goes far beyond this Directive and a simple expansion of the definition of 'manufacturer', and raises questions that would require further reflection by the Commission services, in consultation with a wider group of stakeholders, to explore possible development of appropriate legislation in this area. For custom made device manufacturers, to better evidence their compliance, there is now an explicit requirement for a post market surveillance system, including reporting to authorities, and a requirement that not only should their 'Statement' under Annex VIII (the prescription as it were) accompany the device, but it should also be given to the patient. And finally, due to the need to more carefully examine the proposal to reclassify reusable surgical instruments, it was decided not to proceed with it as part of the current revision. A reclassification procedure, through Comitology, is available under Article 13 of the Directive,

A more detailed list of consultations is contained in Annex 1.

7. Commission draft proposal and justification

It was the conclusion of the MDEG Report of June 2002 that whilst the Medical Devices Directives provide in themselves an appropriate legal framework, there is room for improvement in implementation by all interested parties.

Non-legislative options were preferred over legislative options, with only legislative options being chosen that clarify the current legal text, support any non-legislative initiatives or provide greater transparency.

Thus it was decided not to modify the Directive to reclassify devices or change the Annex on designation of Notified Bodies, to only consider under more binding rules the decision on scope, not to regulate the distributor concept and not to merge Directives at this time.

Whilst most actions, necessary to improve implementation, could be ensured by better coordination and implementation using instruments provided by the current legal framework, the Report also concluded that there was a definite need to modify some of the Directive's provisions.

The Commission brought forward this conclusion in its Communication COM (2003)386[4] which was welcomed by the Council in its Conclusions of December 2003[5].

The proposed legislative modification supports the Communication's recommendations in particular regarding:

– conformity assessment modules

– clinical data

– legal certainty regarding scope including applicability of other directives

– measures to increase transparency on the approval of high risk devices

– legal basis for better coordination and communication of market surveillance activities

– clarification regarding drug/device provisions

– alignment of text on certain aspects, such as authorised representative, across all three medical device directives

Non-legislative measures already enacted by the Commission services include the setting of the Notified Body Operations Group (NBOG), the Market Surveillance Operations Group (MSOG) and the Clinical Evaluation Task Force (CETF).

---

4 Communication from the Commission to the Council and the European Parliament on medical devices of 2.7.2003 COM(2003) 386 final, OJ C 96, 21.04.2004, p.5.

5 Council Conclusions on 2 December 2003 on Medical Devices (2004/C 20/01), OJ C 20, 24.01.2004, p.1.

Annex 1

The review process was exposed in many presentations by the Commission services, national authorities and industry. Presentations were made to the Commission's Health Forum which includes representatives of patient organisations.

The proposal itself was a subject initiated after the Commission Communication and Council Conclusions in 2003 and was further developed through 2004 with close cooperation with the MDEG. Also a special meeting was convened by the Commission services, at the premises of the Dutch Presidency in The Hague, for competent authorities only, to review of the proposal.

A presentation was also made to the major trading partners through the GHTF at their Steering Committee meeting in Paris, in June 2004.

The functioning of the Directive was discussed at Parliament which led to their resolution on health implications of the Directive.[6]

The draft amendment has also been presented by the Commission services to major trade federations at their conferences and also to notified bodies through their Notified Body Forum.

In May and June of 2005 an internet consultation, giving a synopsis of the proposal and including a draft of the impact assessment, was launched on the Commission's web-site attracting over 80 submissions and 300 individual comments.

Finally, the proposal was sent for interservice consultation and subsequently notified to the World Trade Organisatio

[6] European (Parliament resolution on the health implications of Council Directive 93/42/EEC concerning medical devices 2001/2270(INI)).