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RECAST OF THE MEDICAL DEVICES DIRECTIVES
SUMMARY OF RESPONSES TO THE PUBLIC CONSULTATION

I. Introduction

The public consultation on the "Recast of the Medical Devices Directives" was announced in a press release on 8 May 2008. On the same day, a questionnaire and background information were made available online on the "Medical Devices" website of the European Commission¹.

Stakeholders (authorities, industry, notified bodies, health professionals and patient groups) were informed by e-mail about the launch of the public consultation. The official deadline for comments was 2 July 2008, but interested parties were informed that replies submitted after this deadline would still be taken into account.

The Commission received 200 responses to the public consultation. The principal contributor was industry (federations and individual companies, mainly manufacturers of medical devices) with 92 responses. Healthcare professionals and academics submitted 33 responses. Regulatory authorities submitted 27 responses (19 of which were from the EU/EFTA Member States' competent authorities, 4 from GHTF members, 2 from regional authorities, 1 from NBOG and 1 from another ministry of a Member State). Notified Bodies (including NB-Med and Team-NB) submitted 18 responses. Other contributions came from patients and consumers (8), consultants and medical devices experts (7), standardisation bodies (7), health insurance and social security schemes (4) and others (4).

In terms of regions, 24 responses were received from EU-wide associations, 44 from the UK, 31 from Germany, 21 from France, 13 from the USA, 12 from Belgium, 9 from the Netherlands, 6 from Sweden, 5 from Austria, 4 each from Ireland, Norway and Spain, 3 each from Australia, Malta and Switzerland, 2 each from Denmark, Finland and Italy and one response each from Canada, Czech Republic, Japan, Latvia, Lithuania, Poland and Slovenia.

¹ http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm

The following figures show the breakdown of responses by contributors and by countries.

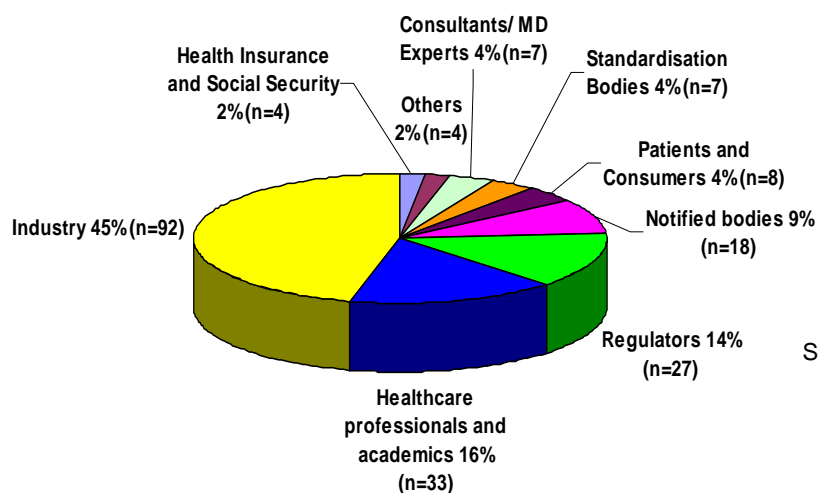


Figure 1 : Responses by contributors

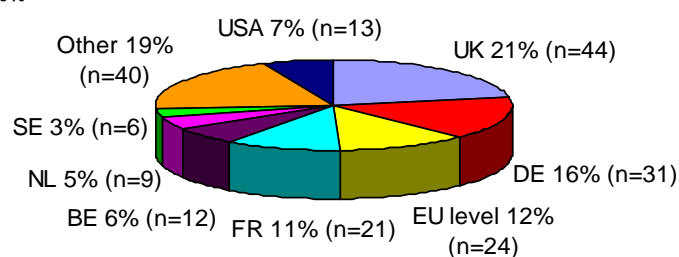


Figure 2 : Responses by countries

Thirty-three respondents asked for their submissions to be treated in confidence. The other responses were published on the Commission's "Medical devices" website mentioned above.

II. General comments

Generally speaking, most respondents confirmed that the current legal framework for medical devices left some room for improvement to strengthen the regulatory system. There was broad support for the view that some weaknesses which the Commission had highlighted in the questionnaire (e.g. inconsistent oversight of notified bodies, no uniform level of expertise in notified bodies, lack of regulation of certain products) needed to be addressed. Also, further elements of centralisation were considered useful, although the suggestion to expand the role of the European Medicines Agency (EMA) to include medical devices was rejected by a majority of respondents.

As regards the timing, by far the majority of respondents (in particular those from the Member States and industry) considered the exercise to be premature. They pointed to the recent revision of Directives 90/385/EEC and 93/42/EEC², to be implemented by 21 March 2010, and the adoption of the New Legal Framework for the Marketing of Products³ which was due to take effect as of 1 January 2010. It was argued that it would be advisable to wait for these changes to be implemented, in order to better assess the need for further adjustments. There was also some criticism of the timing of the launch of the public consultation (May 2008), which had left many stakeholders confused as regards its possible impact on the transposition of Directive 2007/47/EC, which was due on 21 December 2008.

² Directive 2007/47/EC of 5 September 2007

³ Regulation (EC) No 765/2008 of 9 July 2008 and Decision No 768/2008/EC of 9 July 2008.

The rejection of a larger role for EMEA by the vast majority of respondents was mainly based on the fear that the involvement of EMEA would represent a move towards the adoption of a pharmaceuticals-like regulation for medical devices. Such an approach could lead to undue delays and higher costs for placing new devices on the market which, according to the majority of contributions, would have an adverse effect on SMEs, which make up around 80% of the sector. In this context, respondents often quoted the 2002 report of the Medical Devices Experts Group (MDEG), which had highlighted the fundamental difference between the legal framework for pharmaceuticals and the legal framework for medical devices.

In general, respondents were unable to estimate the socio-economic impact of the various proposals outlined in the questionnaire and attributed this to the vague manner in which the proposals were described. Some SMEs were concerned that the costs of putting a medical device on the market would multiply. Several Notified Bodies had made more detailed estimates of the additional costs that would be involved in merging the directives, changing their scope and including the EMEA in the evaluation process.

III. Comments on specific items of the questionnaire

1. Legal simplification

On the issue of whether the existing Directives ought to be merged into a single legal text, no clear trend emerged. The majority of respondents considered that it was feasible to merge Directive 90/385/EEC relating to active implantable medical devices and Directive 93/42/EEC relating to medical devices, and their amending and implementing measures. Some respondents felt that this was desirable, while others adopted a neutral stance, based on the view that such a merger would not bring about significant advantages, but instead would require a considerable amount of human resources.

As regards Directive 98/79/EC on in vitro diagnostic medical devices, the majority of respondents - in particular those from industry - argued in favour of keeping this piece of legislation separate from the legislation for other medical devices. Regulatory authorities were divided on whether the IVD Directive should be kept separate or merged with the other Directives. However, there was broad support from all contributors for a revision of the IVD Directive.

2. Risk-based classification

There was almost unanimous support for the classification of IVD medical devices to be changed to a rules-based risk classification (based on the GHTF guidance) in place of the current list, even though this would lead to more IVDs being subject to third party conformity assessment than under the current system. According to the respondents, such a classification would raise standards of public health, be more flexible and bring the European rules into line with GHTF guidelines.

3. Non-regulated medical devices

Most respondents confirmed that medical devices consisting exclusively of non-viable human cells and/or tissues and/or their derivatives, and medical devices incorporating such cells and/or tissues and/or their derivatives with an action ancillary to that of the medical device, are currently not regulated at EU level. Some respondents felt that the definition should be extended to include those medical devices for which human tissues are “utilised” during manufacture.

Many respondents took the view that medical devices consisting of or incorporating non-viable human tissue or cells should be regulated under the Medical Devices Directives, e.g. by extending (and reforming) the provisions of Directive 2003/32/EC regarding non-viable animal tissues or cells. However, a significant minority of respondents considered pharmaceutical legislation, in particular the 'Advanced Therapies' Regulation, to be more suitable for non-viable human tissues and cells.

Submissions from tissue banks raised concerns about the relationship between the possible future regulation of non-viable human tissues and cells and Directive 2004/23/EC concerning quality and safety standards for the donation etc. of human tissues and cells.

In addition, several respondents referred to other devices (or related services) which they considered as currently not or not sufficiently clearly regulated by the Medical Devices Directives. These included:

- IVD manufactured and used within the same health institution (see Art. 1(5) IVD Directive),
- veterinary medical devices,
- assisted reproduction/fertilisation technologies,
- devices to prepare or to administer human autologous cells,
- devices for reprocessing,
- diagnosis services,
- predictive tests,
- devices including materials derived from transgenic animals,
- devices including phytochemistry products, lactic acid bacteria against e.g. vaginosis,
- pharmaceuticals used as a manufacturing agent rather than serving an ancillary role,
- microbial or rhDNA derived proteins / molecules,
- health software,
- “alternative cigarettes”,
- tattooing products,
- invasive and non-invasive custom-made medical devices.

4. Implantable / invasive devices for aesthetic purposes

There was broad support for the regulation of implantable or invasive devices for aesthetic purposes. However, the term "quasi-medical device" was rejected by almost all respondents as inappropriate. Opinions were divided as to the most appropriate regulatory framework. Some favoured the inclusion of such devices in the cosmetics legislation, while others preferred a regulation under the General Products Safety Directive (GPSD) or a 'stand-alone' regulation. Others, in turn, supported inclusion in the regulatory framework for medical devices. Some respondents considered that implantable or invasive devices were already sufficiently regulated either under the GPSD or within the Medical Devices Directive (Article 1(2)(c): "modification of the anatomy").

Most contributions from industry, except for those producing devices which have both a medical and a cosmetic purpose (e.g. corrective and plano contact lenses), stated that the Medical Devices Directives should not be opened up to devices that do not have a medical purpose in order to avoid derogation from the risk/benefit principle and deviating from the GHTF model.

Those contributions which were in favour of a regulation under the Medical Devices Directives regarded option 2 of the questionnaire (item 4) as the most feasible, as it suggested regulating products which belong to a category of devices that includes products with a medical purpose (e.g. contact lenses, wrinkle fillers). A possible wording was suggested, such as "*for the purposes of this Directive ... a device with cosmetic purpose must meet the requirements set out in ...*". While many respondents rejected the idea of drawing up a list of devices with aesthetic purposes to be regulated as medical devices (option 3 of the questionnaire), others considered the combination of options 2 and 3 to be the most suitable way to ensure legal certainty. In such a case, the possibility of adapting the list should be easy.

5. Revision of the "New Approach"

First of all, there was full support for the view that the "New Approach" provides the right regulatory framework for medical devices and that a pre-market authorization procedure by regulatory authorities with longer deadlines and higher fees (EMEA was given as an example) would not increase public health, but would be detrimental to the competitiveness and innovativeness of the industry, and thus ultimately be against patients' interests.

The aspects of the revised "New Approach" which were most frequently mentioned as being of particular relevance were:

- accreditation,
- designation and monitoring of Notified Bodies,
- post-market surveillance,
- obligations for importers and distributors.

Especially on the designation and monitoring of Notified Bodies, almost all contributions tackling this issue urged a more harmonised and/or centralised mechanism (beyond the current work being carried out by NBOG) in order to ensure a uniformly high level of expertise of Notified Bodies.

As regards those aspects where deviations from or requirements additional to the general rules were considered appropriate for the medical devices sector, the following issues were mentioned:

- the possibility of delegating the designation/monitoring of Notified Bodies to non-governmental bodies is deemed unsuitable (concerns over Article R14(3) of Annex I to Decision 768/2008);
- the current expertise of the European co-operation for Accreditation (EA) is considered insufficient for the medical devices sector;
- the need to ensure that the specific competencies of Notified Bodies are verified;
- a specific "CE" marking to distinguish the medical device from other products (e.g. "CE med");
- greater involvement by the regulators in standardisation work.

6. Essential requirements

The overall tenor of the responses was that the essential requirements have proved appropriate as a response to technological change and, in general, did not need amending. Several respondents mentioned the July 2007 Report of the N&ET Working Group on nanotechnology, which concluded that adaptation of the essential requirements for devices incorporating or consisting of free nanoparticles was unnecessary. It was often pointed out in the responses that the essential requirements should remain in line with the relevant GHTF guidelines (some suggested awaiting the outcome of the ongoing revision of the GHTF document). In addition to the general satisfaction with the current state of play, many contributions focussed on specific issues to be taken into account.

For example, many respondents suggested that traceability and identification should be addressed in the essential requirements, particularly in the context of the discussion on a "unique device identifier (UDI)".

Several respondents requested that e-labelling should be reflected in the essential requirements. A small number of respondents suggested that the essential requirements could be reduced for well established "low risk" medical devices, quoting the example of the labelling requirements for class I devices.

Some respondents were of the opinion that specific essential requirements (e.g. in line with the requirements set in the Advanced Therapies Regulation) would be necessary if medical devices incorporating non-viable human tissues and cells were included in the scope of the Medical Devices Directives. Others, on the contrary, considered the requirements for non-viable animal tissues and cells (Directive 2003/32/EC) to be appropriate for non-viable human tissues and cells, albeit with an improved consultation mechanism between Notified Bodies and Competent Authorities.

With regard to devices for aesthetic purposes (e.g. non-corrective contact lenses), most respondents considered that these should meet the same essential requirements applicable to devices of the same category with a medical purpose, but that the risk/benefit analysis needed to be adapted (e.g. risk "as low as reasonably possible").

Several respondents suggested explicitly including the relevant essential health and safety requirements of the Machinery Directive, which are currently mentioned only as a general reference in Article 3 of Directive 93/42/EEC. Along the same lines, there were suggestions that aspects from horizontal legislation (e.g. protection of the environment or safety at work) should be included in the essential requirements in order to establish a self-contained regime for medical devices, and thus be excluded from the horizontal legislation.

For IVD, several respondents considered that evidence of their clinical validity and/or utility should be required and that specific requirements should be laid down for genetic tests, in particular for predictive tests (e.g. the ethical, social and legal aspects to be taken into account).

Other specific suggestions to adapt the essential requirements related to:

- wireless interference,
- combination products,
- sterile devices,
- definition of "state of the art".

7. National specific requirements

Respondents reported a number of specific measures adopted by the Member States in the field of medical devices which are liable to create obstacles to the internal market, such as:

- registration requirements,
- the application of pharmaceutical legislation for clinical evaluation of medical devices,
- labelling requirements,
- device identification requirements,
- requirements for latex-free devices,
- requirements for X-ray devices,
- requirements pursuant to Council Directive 97/43/Euratom on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure,
- requirements regarding the contents of first-aid kits,
- requirements for UV cabins,
- requirements for accessory therapeutic devices,
- differences between batch testing and witness testing for IVD.

The Commission was urged, in particular by respondents from the industry but also by some Member States, to take action within the current regulatory framework to ensure a level playing field.

As regards the adoption of more harmonised requirements, the majority of respondents appeared to react negatively, and considered the framing of voluntary (international) standards and/or the drawing up and regular updating of MEDDEV guidance as their preferred option over detailed specifications in a binding Community act. Nevertheless, some suggestions were made regarding, for example, tolerable amounts of dangerous substances in medical devices being made legally binding.

8. Notified Bodies

There was unanimous support for improving the way in which Notified Bodies currently work. Most respondents believed that this should be done first of all by tightening up the designation and monitoring of Notified Bodies to ensure a uniform high level of competence. Many respondents, including the Notified Bodies themselves, supported central oversight of their designation by Member States. In this context, it was often mentioned that NBOG should be given legal status to adopt binding measures (e.g. the NBOG Handbook).

Individual respondents suggested a review of the remuneration of Notified Bodies, which should be kept separate from the individual manufacturer and be dealt with instead by an industry-financed fund.

As regards the detailed proposals set out in the questionnaire, the feedback was generally positive, albeit with certain reservations:

- **Transparency**

There was broad support for greater transparency in the work and functioning of Notified Bodies. This would increase confidence in the evaluation procedure and lead to a better acceptance of the results, including outside Europe. However, annual reports were only considered useful if they complied with harmonised criteria. Other respondents even questioned the benefit of an annual reporting requirement; a fully workable EUDAMED was considered to be the most suitable means to increase transparency.

- **Information exchange between Notified Bodies and Competent Authorities**

An improved information exchange between Notified Bodies and Competent Authorities was generally considered useful, but there were fears that this could lead to increased bureaucracy. Several Member States pointed to the existing practice of information exchange and considered additional rules to be unnecessary.

- **Cooperation between Competent Authorities**

Strengthened cooperation between Competent Authorities was regarded as key to strengthening the whole system. Suggestions made by several Member States included mandatory "peer reviews" between designating authorities, as well as mandatory inquiries by Competent Authorities in the case of alleged poor performance by a Notified Body. NBOG was mentioned by many respondents as already being a useful platform which ought to be given statutory powers to adopt binding rules. However, it was recognised that NBOG had its limits and that cooperation alone was not sufficient to achieve a uniformly high level of competence of Notified Bodies. Several respondents therefore suggested an 'overarching structure' or a 'central oversight' of the activities of the Competent Authorities.

- **Sanctions and penalties**

The majority of respondents confirmed that legal sanctions and penalties were already in place and ought to be effectively applied, including the ultimate sanction - namely the withdrawal of the designation of Notified Body. NBOG or another "independent body" should ensure the consistent application of sanctions and penalties.

- **'Forum shopping'**

A view commonly expressed by respondents was that manufacturers should retain the freedom to choose the Notified Body, but that any abuse of this freedom (i.e. 'forum shopping') needed to be addressed by measures that ensured a uniformly high level of competence of all Notified Bodies.

- **Safeguard clause and withdrawal of certificate**

The majority of responses to the question of whether a successful safeguard clause should automatically lead to the withdrawal of the certificate for the medical device in question were against an automatic arrangement and in favour of a case-by-case approach. However, at the same time, there was a good deal of support for this proposal, particularly from many of the Notified Bodies.

With regard to the two options presented in the questionnaire (tightening of controls on nomination and monitoring; or centralised system of designation and control of monitoring), by far the majority of respondents were of the opinion that designation and monitoring should remain the responsibility of Member States and not be transferred to the Commission or another central body. However, at the same time, there was strong support for clear rules allowing Member States to take a harmonised approach in their designation and monitoring activities. Accreditation, in particular combined with specific sectoral requirements, was often mentioned as a suitable instrument. Others suggested an expert panel to oversee the Member States' activities.

9. Extension of the role of the European Medicines Agency (EMA)

The question of whether the competences of the EMA should be extended to include medical devices was the most controversial issue in the questionnaire. Within industry and among the Notified Bodies, the involvement of EMA in the evaluation of medical devices was rejected almost unanimously. While acknowledging EMA's skills in the area of pharmaceuticals, it was pointed out that it had no expertise in the field of medical devices. It was feared that long and costly procedures for the pre-market authorisation of pharmaceuticals were not compatible with the rapid pace of innovation and changes in devices or, compared to pharmaceuticals, with the relatively low return on investments. Many respondents argued that any involvement of the EMA in the evaluation process would signal the demise of SMEs in the medical devices sector. Instead, it was proposed that the regulatory Committee provided for in Article 7(1) of Directive 93/42/EEC should be strengthened and used more frequently.

Most consultants and medical devices experts also rejected the extension of EMA's role to include medical devices. However, there was also some support for such an extension and specific proposals were put forward, such as central approval of all medical devices under the umbrella of EMA (timelines between 30 and 120 days), with the centrally accredited and designated Notified Bodies acting as experts to support the work of a Medical Devices Committee in EMA.

Among healthcare professionals, academics, patients and consumers, there was a higher level of support for EMA (or another central body) participating in the evaluation of "high risk" medical devices. However, they warned that a new medical devices division might be the "poor relation" of the pharmaceuticals section of EMA, and so a revised structure and budget were needed. Some also emphasized the need to be sure that EMA's involvement would not create obstacles to timely access to innovative medical devices for patients.

The responses from the Member States brought to light a number of differing opinions. The involvement of the EMA as such was widely rejected as being inappropriate to the medical devices sector (costs, delays, adverse effects for SMEs and public health). Nevertheless, many Member States argued in favour of a central body or structure (e.g. a separate Medical Devices Agency, Health Products Agency, Management Committee an 'overarching structure' or a network of testing centres) which would bring together the regulatory expertise for medical devices. Such a central body could set out the views of the public authorities on new technologies, exercise scrutiny of the performance of Notified Bodies and give scientific advice to manufacturers during the development phase. Some Member States felt that their views could sufficiently be accentuated if the (improved) consultation procedure under Directive 2003/32/EC regarding non-viable animal tissues were extended to include other devices.

10. Devices for which the EMEA could participate in the evaluation process

Given the widely expressed opposition to EMEA (see under 9.), few respondents supported the proposal to define those highest risk devices subject to EMEA's participation in the evaluation. As regards non-viable human tissues and cells with an ancillary action to that of the device, many respondents rejected the assumption that it was logical to submit them to EMEA for evaluation in the same way as viable human tissues and cells under the Advanced Therapies Regulation (ATMP Reg.). On the contrary, it was argued that in 2007 there had been the political will to exclude non-viable human tissues and cells with ancillary action from the ATMP Reg. and that, consequently, the medical devices regulatory framework (e.g. by analogy with non-viable animal tissues and cells) was the appropriate vehicle. Notified Bodies were seen as sufficiently competent to analyse medical devices incorporating non-viable human tissues and cells. In this context, a mechanism for consultation with EMEA on non-viable human tissues and cells was given favourable consideration. Others, however, took the view that non-viable human cells and tissues should be subject to the ATMP Reg.

As regards other devices suitable for undergoing a procedure involving EMEA (or another central body), respondents who supported EMEA's involvement mentioned class III devices, active implantable devices and HIV-tests. Some respondents mentioned pacemakers, while others took the view that pacemaker technology was well developed and therefore no involvement by EMEA would be required.

Furthermore, one Member State suggested applying a combination of "high risk", "novelty" and "non-existence of standards/guidelines" criteria as conditions for submitting medical devices to a central committee for evaluation.

11. Procedural aspects of EMEA's participation in the evaluation process

The majority of respondents pointed out that product assessment and quality management evaluation should continue being carried out by one entity, namely Notified Bodies, and therefore maintained their opposition to an extension of EMEA's role (see under 9.).

Both option 1 (no Notified Bodies involved in evaluation of highest risk devices) and option 2 (application directly to EMEA and Notified Bodies act as "rapporteurs") were rejected almost unanimously. If it were decided to extend EMEA's role, options 3 (systematic submission of evaluation reports to EMEA) or 4 (informing EMEA of all applications and choice of EMEA to select evaluation reports for scrutiny) combined with possibility 2 (positive opinion of EMEA required) were regarded as the most feasible way forward.

12. Access by EMEA to evaluation reports of Notified Bodies

In general, there was support for access by public authorities to evaluation reports for all devices (not only high risk devices) in order to ensure a high level of evaluation by Notified Bodies. However, opinions were divided as to whether this should be the responsibility of EMEA (or another central body) or of the national Competent Authorities. Many Member States asked that this should remain the responsibility of their authorities. Concern was voiced that this type of "overview" should not weaken the

position of Notified Bodies and should not ultimately lead to the creation of a kind of appeal body for manufacturers to question negative evaluations by Notified Bodies.

13. Vigilance

In principle, respondents supported the further improvement and strengthening of the vigilance system. However, the difference between vigilance for pharmaceuticals and vigilance for medical devices was stressed, especially by industry and Member States, while some respondents from health professionals' and patients' groups suggested establishing closer links between the two vigilance systems (e.g. extension of EudraVigilance to include medical devices).

- **Reporting by healthcare professionals and patients; publication of corrective actions**

Most Member States appear to have provision for mandatory reporting by healthcare professionals/institutions. Some respondents contested the usefulness of such compulsory regulation, pointing to the UK's voluntary reporting scheme which had a comparatively higher reporting outcome than the average. Most respondents believed that, in order to avoid "over-reporting", reporting should be done only by healthcare professionals/institutions, which should act as a "filter", and not by patients. The publication by Competent Authorities of corrective actions taken by manufacturers was considered useful by some respondents, but only when associated with a clear disclaimer that such publication would not constitute an enforcement action.

- **Periodical review by the Notified Body of manufacturers' vigilance system**

Respondents were almost unanimous in their opinion that the review of the manufacturers' vigilance system was already part of the Notified Bodies' duty to carry out periodical audits. Some respondents suggested that class I manufacturers should also be regularly monitored.

- **EMA to coordinate vigilance reports and detect signals**

Some respondents (e.g. healthcare professionals and patients) supported the idea of entrusting EMA with the coordination of vigilance reports. This was widely rejected by industry and Member States, which emphasised Eudamed as the appropriate tool to disseminate vigilance reports throughout the EU. Among the Notified Bodies there was support for setting up a central system to coordinate vigilance reports, but without the involvement of EMA.

- **Commission to impose restrictive measures**

The proposal that the Commission should be given powers to impose restrictive measures in vigilance cases tended not to be endorsed.

- **Exchange of information regarding incidents and corrective actions at international level**

Respondents broadly supported an improved exchange of information between GHTF members and beyond.

14. Market surveillance

In the context of market surveillance, the need for effective and immediate implementation of EUDAMED was emphasised. Industry and Notified Bodies, as well as several Member States, put the case for EUDAMED to become the central registration tool for medical devices in order to do away with costly multiple registration in Member States. However, Member States pointed out that in order for this to happen EUDAMED would need to include all the information necessary to carry out market surveillance.

Many respondents referred to the new rules on market surveillance laid down in Regulation (EC) No 765/2008 which would improve the surveillance system, including for the medical devices sector. However, the involvement of EMEA was widely rejected as inappropriate and/or disproportionate.

15. Borderline cases

The need for an effective procedure to ensure consistency and legal certainty with regard to borderline and classification cases throughout the EU was recognised by the vast majority of respondents. Most of them felt that empowering the Article 7(1) Committee to take decisions in this respect was the most appropriate way forward (as already provided for in Directive 2007/47/EC). A role for the EMEA was rejected by the majority of respondents, although many recognised the advantage of having dual expertise for medicinal products and medical devices within one entity, especially for drug/device combination products.

In many submissions it was argued that the power to decide about borderline issues should not be limited to medical devices vs. medicinal products, but should embrace other sectors such as cosmetics, biocides and food (a kind of "supra-Directives Committee on Borderlines").

16. Convergence on GHTF model

By far the majority of respondents supported further convergence on the GHTF model, but also noted that GHTF had issued *guidance* allowing flexibility in the adaptation to the respective jurisdictions. Some respondents, however, argued that the European model was more advanced in terms of the protection of health and safety. It was also underlined that further convergence would only be useful if other jurisdictions also took over GHTF guidance and if recognition of certificates issued by Notified Bodies by other jurisdictions was ensured (reinforcement of Mutual Recognition Agreements).

Industry, in particular, but also some Member States, called for increased EU representation and participation in GHTF.

17. Imports of medical devices

All respondents stated that, in principle, the requirements for domestic and for imported medical devices ought to be and in fact were the same. The provisions of Regulation (EC) No 765/2008 with regard to importers and distributors, as well as increased controls at customs, would help to enforce requirements with regard to imported products. Government audits outside the EU and increased cooperation with the GHTF members were also suggested.

Several respondents active in the field of dental healthcare called for dental implants originating from outside the EU/EFTA to be subject to an evaluation by a Notified Body. Other individual respondents suggested that ethical labour conditions should become an additional criterion for the evaluation of imported products.

18. Exports of medical devices

Many respondents supported the idea that medical devices exported to countries which lacked specific legislation on medical devices should meet the EU requirements, but at the same time they stated that the CE marking was already required by many jurisdictions which did not have their own regulations for medical devices. However, there were also major concerns regarding the EU competence to regulate in this field and to subject EU manufacturers to additional burdens compared to their foreign competitors.

The possibility for Notified Bodies to issue export certificates quickly and inexpensively would be welcomed by many respondents, since it could replace the different practices in Member States with regard to certificates of free sale.

19. Measures against counterfeiting

Although counterfeiting was regarded as a limited problem in the field of medical devices, by far the majority of respondents were in favour of preventive measures to ensure the traceability of devices. The preferred options were a unique device identifier (UDI) applied at global level and stricter requirements for importers and distributors. In addition, many respondents suggested that campaigns to raise public awareness of counterfeited products would be useful.

20. Suggestions for simplification

While respondents seem to be generally satisfied with the current regulatory framework, they listed several aspects which ought to be simplified in future legislation, such as:

- registration requirements in Member States,
- overlapping of directives (e.g. applicable requirements of the Machinery Directive and of the Personal Protective Equipment (PPE) Directive),
- classification rules (unclear distinction between I and IIa; classification of dental implants; usefulness of a classification database),
- procedures under Article 14 b of Directive 93/42/EEC and Article 13 of the IVD Directive,
- settlement of borderline issues,
- impossibility of issuing a declaration of conformity for class I devices,
- role of "own brand labellers", distributors, assemblers,
- delimitation of devices and accessories,
- fragmented implementation by Member States and slow reaction by the Commission.

21. Nature of the legal act: regulation or directive?

The advantage of a directly applicable regulation which does not entail the risk of divergent transposition by Member States was widely recognised as a useful way to achieve a level playing field. However, many respondents stated that the benefits would not outweigh the considerable resources needed to transcribe the EU regulatory framework into a regulation. A number of respondents also pointed to the risk that an EU regulation might ultimately lead to stricter rules.

22. Conformity assessment modules

The majority of respondents rejected the idea of condensing the various conformity assessment modules currently in existence into a single module (i.e. Annex II) as being contrary to the principles of the New Approach and not flexible enough for the specific needs, in particular of SMEs. However, at the same time it was frequently suggested that Annex II should be made available to all manufacturers independently of the class of their device.

On the other hand, many respondents supported a reduction in the number and complexity of conformity assessment procedures (deletion of Annex VI was frequently mentioned). For example, it was suggested that the relatively seldom used "type-testing" should be confined to duly justified exceptions.

IV. Miscellaneous issues

Several respondents made suggestions which went beyond the proposals set out in the questionnaire. Among others, these related to:

- regulation of advertising for medical devices,
- inclusion of medical purpose in the legal definition,
- adaptation of conformity assessment procedure for industrially produced individual implants currently considered as custom-made devices,
- prescription requirement for all contact lenses,
- introduction of a "Humanitarian Medical Device" (similar to Humanitarian Use Device under FDA rules) for medical devices intended for patients with rare diseases,
- reduction and replacement of animal testing,
- clinical trials of medical devices, including blood derivatives currently not defined,
- dental surgeon to be considered as a manufacturer of custom-made devices,
- restricted distribution of certain devices (e.g. drug/device products only through pharmacies),
- clarification of the German-language version of Article 1(4) and (4a), section 7.4. of Annex I and Rule 13 of Annex IX to Directive 93/42/EEC ("liable to act") – substances of low concentration not to be regarded as a combination product,
- more exemptions from Rule 17 (animal tissues) if a medical device is not active,
- Class I medical devices with high incident rates to be reclassified or subjected to evaluation with Notified Body involvement,
- possibility for manufacturers from Member States without Notified Bodies to submit applications in English,
- indication of manufacturing site on the label and in the instructions for use,
- requirement for manufacturers of custom-made devices to comply with professional qualification requirements,

- regulation of medical device support products (i.e. those needed for maintenance, service training etc.),
- making available of the statement provided for in Annex VIII to Directive 93/42/EEC for custom-made devices should be compulsory.