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Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT ON THE REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES Accompanying the documents Proposals for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and on in vitro diagnostic medical devices

Delegations will find attached Commission document SWD(2012) 273 final PART IV - Appendices.

Encl.: SWD(2012) 273 final PART IV - Appendices

EUROPEAN COMMISSION

Brussels, 26.9.2012
SWD(2012) 273 final

PART IV - Appendices

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT ON THE REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES

Accompanying the documents

Proposals for Regulations of the European Parliament and of the Council

on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

and

on in vitro diagnostic medical devices

{COM(2012) 541 final}
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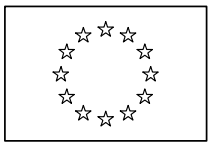

EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Cosmetics and Medical Devices

Brussels, 5 December 2008
ENTR/F/3/D(2008) 39582

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 Commission[1].

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.

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[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.

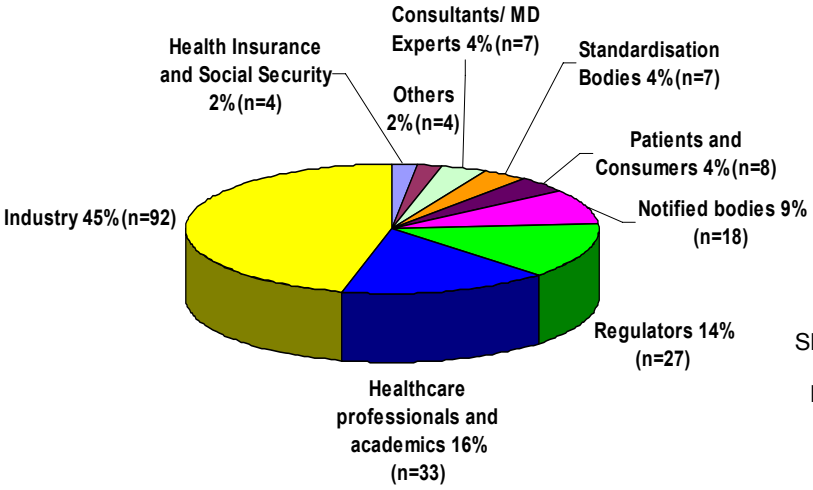

Figure 1 : Responses by contributors

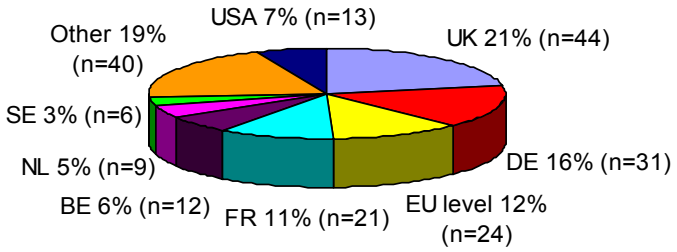

Figure 2 : Responses by countries

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 (EMEA) 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/EEC[2], to be implemented by 21 March 2010, and the adoption of the New Legal Framework for the Marketing of Products[3] 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

[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.

regards its possible impact on the transposition of Directive 2007/47/EC, which was due on 21 December 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 (EMEA)

The question of whether the competences of the EMEA 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 EMEA in the evaluation of medical devices was rejected almost unanimously. While acknowledging EMEA'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 EMEA 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 EMEA'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 EMEA (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 EMEA.

Among healthcare professionals, academics, patients and consumers, there was a higher level of support for EMEA (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 EMEA, and so a revised structure and budget were needed. Some also emphasized the need to be sure that EMEA'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 EMEA 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.

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

Some respondents (e.g. healthcare professionals and patients) supported the idea of entrusting EMEA 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 EMEA.

- **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.

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Consumer Affairs
Cosmetics and Medical devices

Brussels, 23 February 2011

REVISION OF DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 OCTOBER 1998 ON *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

SUMMARY OF RESPONSES TO THE PUBLIC CONSULTATION

I. Introduction

In the context of the simplification of the regulatory environment, and in the light of the technological progress and of emerging weaknesses identified regarding key elements of the regulatory framework, a public consultation was launched in 2008 on the **Recast of the Medical Devices Directives**[4]. This public consultation was mainly focused on horizontal issues regarding the revision of the legal framework for medical devices. Many responses received to the public consultation underlined **the need to revise some specific aspects of Directive 98/79/EC**.

In June 2010, the Commission launched a public consultation targeted on issues related to *in vitro* diagnostic medical devices.

The stakeholders were not consulted on the possible amendments of horizontal aspects such as designation and monitoring of Notified Bodies, vigilance, market surveillance, need for further centralisation etc. which are currently under discussion in the framework of the recast of Directives 90/385/EEC and 93/42/EEC. These amendments would apply, *mutatis mutandis*, also to the revision of the IVD Directive.

Stakeholders were invited to submit their comments by 15th September 2010. Several comments received beyond the date were still taken into account. Altogether, the Commission received 183 responses. The repartition of answers by categories of stakeholders is indicated below. Mainly, answers were received from users (clinical laboratory associations, medical associations, hospitals and healthcare professionals) with 69 responses, from associations and laboratories active in the field of genetics (44 answers), from manufacturers and industry association (32 answers), from Competent Authorities (17 answers) and from Notified Bodies (13 answers).

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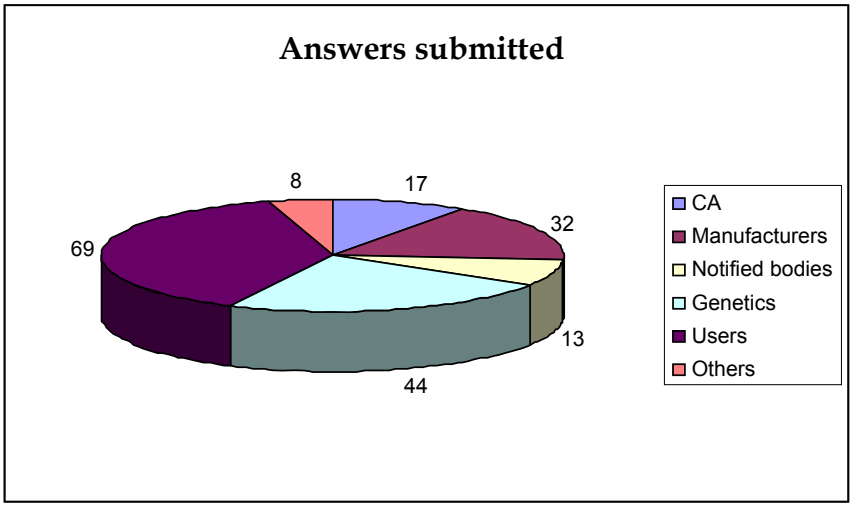
4 http://ec.europa.eu/enterprise/sectors/medical-devices/documents/revision/index_en.htm

As the questionnaire included a broad range of questions which were not of interest for all the stakeholders, the majority of the answers are only partial answers.

Among the 183 responses, 21 specified that the submission should be treated as confidential. The other answers are published together with this summary on the Commission website[5],



II. General Comments

The main message received though this consultation was that the revision of the IVD Directive is welcomed by the stakeholders, which was a confirmation of the feedback received from the previous public consultation.

The main highlights from this public consultation were that there is a broad support for the adoption of a risk-based classification. The second area where a broad consensus emerged was the need to keep an exemption for "in-house" testing. While some clarification would be needed, it was underlined in this public consultation as a major issue for clinical laboratories and users, especially in the field of genetic diseases.

The users (healthcare professionals, clinical laboratories) mainly provided answers only to the specific question regarding "in-house" tests, which was their main focus within this public consultation. Therefore to improve the reading of the results, the statistics presented for the analysis of the answers will be performed for each question based on the number of answers received to this specific question.

[5] http://ec.europa.eu/consumers/sectors/medical-devices/index_en.htm

III. Comments on specific items of the questionnaire

1. Classification

Question 1:

- *Would you consider the adoption of a **risk-based classification** for in vitro diagnostic medical devices as an improvement of the current European regulatory framework?*
- *Are you aware of any **consequences** for the protection of **public health**?*
- *Can you provide **economic data** linked to a change-over to this GHTF classification system?*

The answers provided in the context of this public consultation confirmed the quasi unanimous support from stakeholders regarding the adoption of a risk based classification, which was already highlighted in the 2008 public consultation.

Among the 116 answers received, nearly 93% agreed on the fact that the adoption of a risk-based classification based on the Global Harmonisation Task Force (GHTF) model[6], would have a positive impact in terms of flexibility, allowing for a better protection of public health while being able to ensure a timely access to the market for new tests. In addition, the regulatory framework would become more robust to the technological progress.

Few economic data were provided during this public consultation. However it was underlined by some stakeholders that this alignment would increase the costs for the regulatory requirements, as the risk-based classification based on the GHTF model would require more frequently the involvement of notified bodies for the conformity assessment procedures, in particular for Class B and C tests. The majority of the respondents argued that this would increase costs for manufacturers significantly and finally underlined that these additional costs might be paid by the end users.

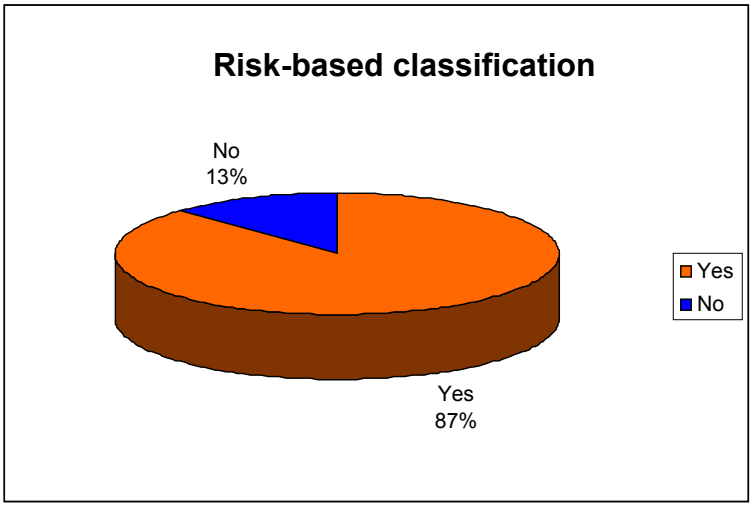
But the same stakeholders also pointed out that these increased costs should be balanced with the improvement of safety for public health brought by the implementation of more stringent regulatory requirements for some categories of tests. The issue of the higher costs might be addressed by allowing manufacturers a sufficient transitional period. According to the manufacturers, a sufficient transitional period (5 years) would avoid a

[6] GHTF/SG1/N045:2008 regarding Principles of In Vitro Diagnostic (IVD) Medical Devices Classification - http://www.ghtf.org/documents/sg1/sg1final_n045.pdf.

disproportionate impact on SMEs and on manufacturers without lowering the benefits of the adoption of a risk based classification.
Additionally, some submissions pointed out that the adoption of a risk-based classification, provided that it would be based on the GHTF model, would facilitate the exports for European manufacturers and would have therefore a very positive impact on competitiveness. Manufacturers underlined that the adoption of a risk based classification not based on the GHTF model would represent additional costs which would not be balanced against any financial benefit.

Another issue raised by some stakeholders was the fact that the risk based classification has to be detailed enough to avoid any controversial or inconsistent implementation. It was pointed out that any inconsistent application of the risk-based classification would lead to discrepancies and fragmentation within the internal market.
Other respondents underlined that the adoption of such a risk based classification should be implemented at the same time as appropriate guidelines or should be followed by the creation of an efficient and rapid mechanism to solve borderline and classification issues at EU level.

Some answers in the field of genetic testing raised concerns about the appropriateness of the GHTF model risk-based classification to genetic tests. These respondents suggested that this classification for genetic tests should take into account the impact of the potential test results on the patient and their family, as well as the likelihood of tests being performed and interpreted correctly, especially by lay users, the risk of incorrect measurement, the purpose for which the test is used and the potential consequences of error in the measurement.

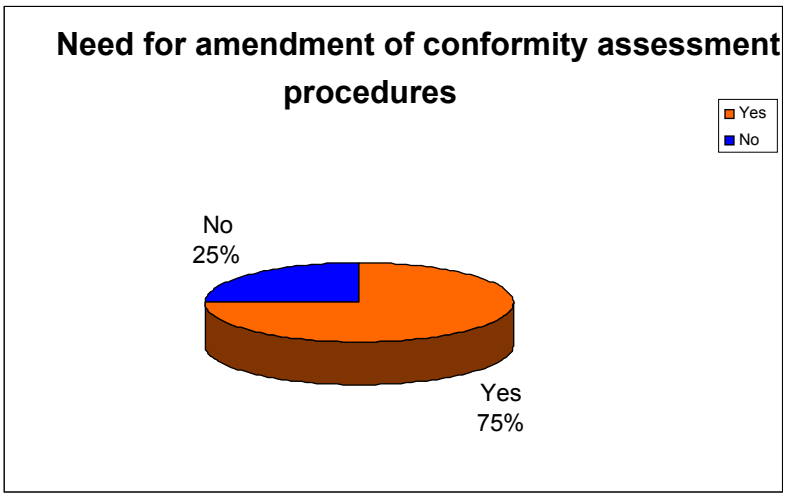


2. Conformity assessment procedure

Question 2:

*In the context of a possible adoption of a **risk-based classification** according to the **GHTF model** (see above 1.) do you see a need for amending the current conformity assessment procedures for in vitro diagnostic medical devices?*

108 answers to this specific question were received. Among these answers, 75% underlined that an amendment of the current conformity assessment procedure would be necessary.



The analysis of the respondents by categories showed that the highest percentage of positive responds came from Competent Authorities, Notified Bodies and manufacturers.

The following question, asked the respondents to provide some details about the conformity assessment procedures to be amended.

Question 3:

*If yes, in your view which are the **conformity assessment procedures** that should be **deleted or amended** and **why**?*

A majority of stakeholders underlined that Annex VI should be deleted, as this conformity assessment procedure is rarely used and does not include an assessment of the vigilance system, or should be limited to specific products like IVD instruments. Few respondents suggested keeping a wide range of possibilities in the conformity assessment procedures.

Many stakeholders underlined the need to align the conformity assessment procedure with the GHTF model.

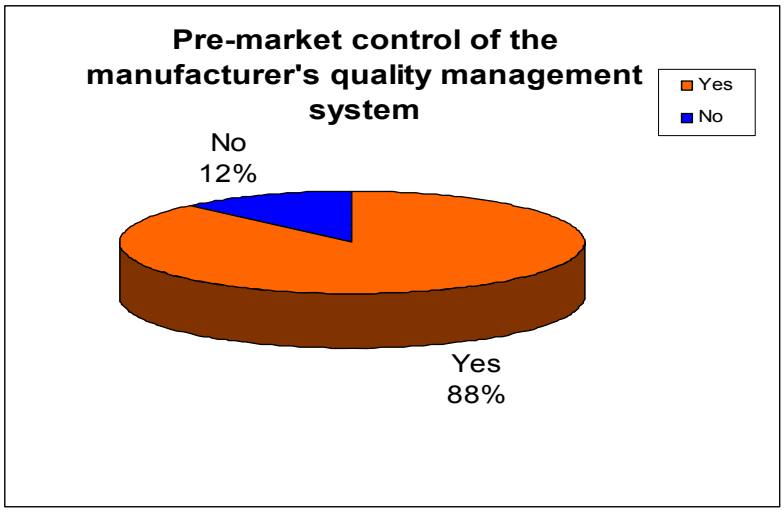
Some respondents identified that the adoption of a risk-based classification system based on the GHTF model will lead to major amendments regarding the conformity assessment procedure to be applied for self-tests. These self-tests will not fall under a particular category within the GHTF classification and therefore will not be classified differently from the same test to be used by healthcare professionals. This will lead to a major change as self-tests have specific requirements regarding the conformity assessment procedure to be applied according to the current Directive. Many answers, in particular from Notified Bodies, suggested deleting the possibility to perform a conformity assessment procedure according to Annex III.6[7] for self-tests, and underlined the need to align the conformity assessment procedures for self-tests to those applied for Annex II List B tests (e.g. tests for the detection and quantification in human samples of rubella, toxoplasmosis…) .

Other stakeholders mentioned the need to clarify the requirements set up in Annex V (Type examination).

Question 4:

*Would you consider appropriate to **require for all IVDs**, except for those in class A of the GHTF classification, at least the **pre-market control** of the manufacturer's **quality management system** by a third party as laid down in GHTF/SG1/N046:2008?*

82 answers were received to this specific question. Among these answers, 72 were positive, representing 88% of positive answers.



Most of the respondents confirmed that a Quality Management System (QMS) should be put in place for Class B, C and D IVD medical devices according to the GHTF

[7] Annex III (EC Declaration of conformity) point 6 foresees that for devices for self-testing the manufacturer shall lodge an application for examination of the design with a notified body.

model and that this QMS should be controlled by a third party, as laid down in the GHTF documents. In addition some respondents underlined that the requirements on the QMS should be extended also to class A IVD medical devices.
However some stakeholders pointed out that even if such a QMS system controlled by a third party would be necessary, this would not be sufficient alone to ensure the safety of the products.

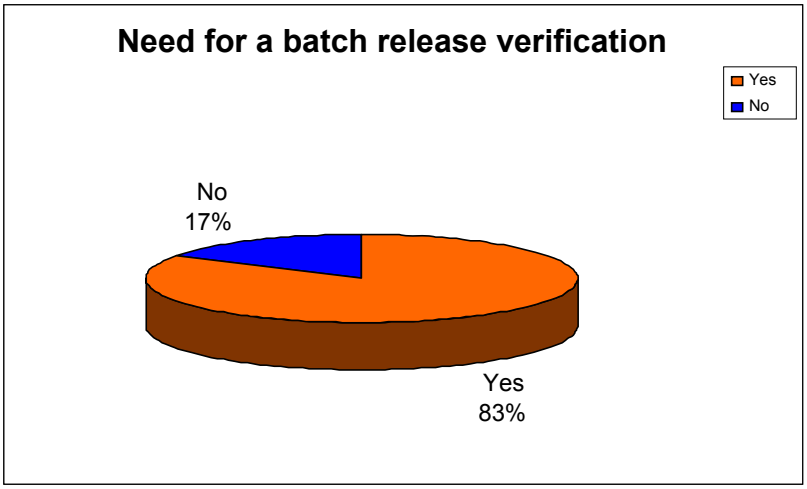
Question 5:

*In the context of the **"batch release verification"**, do you consider that a **control of each batch** of manufactured **high-risk IVDs** should be required prior to their placing on the market?*

*If yes, what would be the **purpose of batch release verification** and **which IVDs** should be subject to such a control?*

*If yes, **how** (testing, verification of the results of the tests) and **by whom** (manufacturer under the control of notified bodies, notified bodies, independent laboratories) these controls should be performed?*

115 answers were received. Among these answers, 83% considered that there is a need to have a batch release testing for high-risks IVD.



According to the respondents, the purpose of this batch release testing would be to ensure consistency between batches and a uniform level of quality for high-risk tests. Other stakeholders underlined that the purpose of this verification is also to ensure compliance of each batch of a high-risk IVD medical device with the Common Technical Specifications set up for tests listed in Annex II List A of Directive 98/79/EC. Other answers stated that the purpose of the batch release verification is to provide independent evidence that the sensitivity, specificity and quality of each batch of an IVD medical device are acceptable when compared to the original approved assay for

the purpose of the granting the CE marking. Few respondents underlined that this batch release testing performed before the placing on the market of the tests precludes low quality batches of high-risks tests to be placed on the market.

However, if a majority of respondents agree on the general purpose and the benefits of the batch release testing, there are some divergent opinions on how and by whom this batch release verification should be performed. A large amount of answers pointed out that this verification should be performed by the manufacturer, and must be part of the Quality Control and Quality Management System of the manufacturer, under the control of the Notified Bodies. This control could be based on a systematic verification or be subject to periodic inspection by the Notified Body. These respondents also pointed out that the methods, the reference materials and the panels used for this batch release testing should be approved and controlled by the Notified Body.

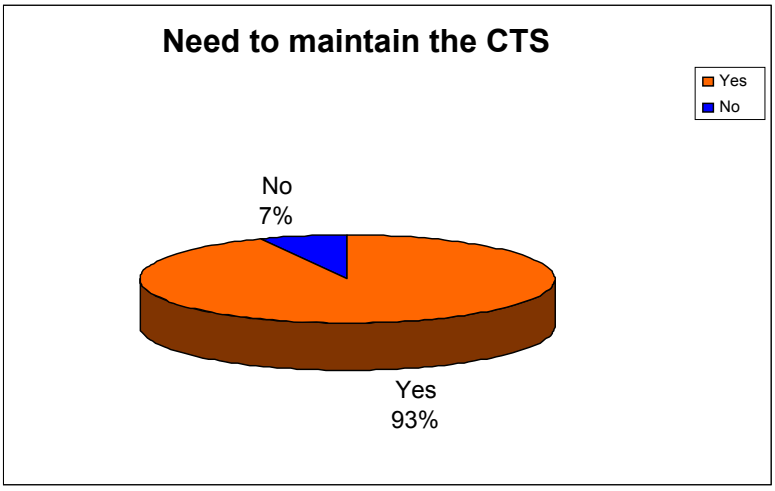
Some answers underlined the need for a batch release testing to be performed by an independent laboratory or by the Notified Body. However, other answers pointed out that the batch release testing performed by an independent laboratory would be too costly and would not bring an added value in terms of safety and quality.

However, the answers from manufacturers underlined quasi-unanimously that an internal batch release testing is already performed by manufacturers as an integral part of their Quality Management System, under the supervision of the Notified Bodies for high-risk products. They pointed out in their replies that a batch release testing performed by independent laboratories would be a duplicate of the manufacturer testing. Furthermore, they suggested that the batch release testing should be performed by the manufacturer and that the procedure to be used for the batch release testing, including the reference methods and the panels to be tested should be validated by the Notified Body. The notified body would then verify the results of this batch testing.

Question 6:

*Should the use of **Common Technical Specifications** (CTS) be maintained for **high-risk IVDs**? Should CTS also be adopted for other IVDs?*

101 answers to this specific question were received. Among these answers, 92% underlined the need to maintain the CTS at least for tests used in the context of blood transfusion and/or for Class D tests, according the GHTF classification.



Although the majority of the respondents were in favour of not extending the CTS to other IVD tests, few answers stated that it might be beneficial to extend the CTS to tests within the Class C IVD medical devices according to the GHTF model.
Among the answers received, the Notified Bodies unanimously pointed out the need to keep the CTS.

3. Scope

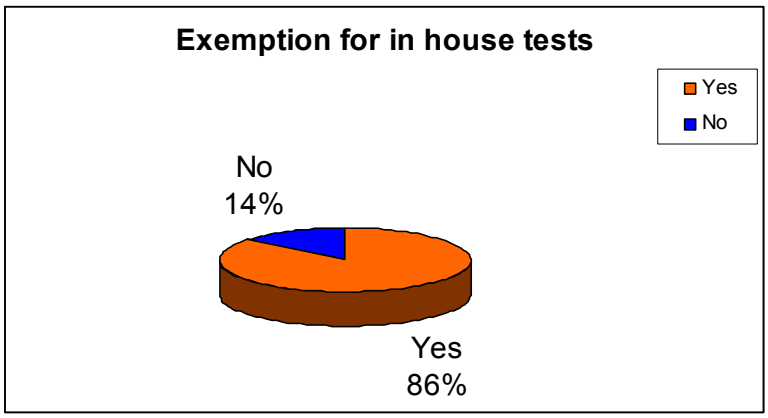
3.1 *Specific exemption for "in-house tests"*

Article 1(5) of Directive 98/79/EC makes provision for an exemption for devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity. These tests are referred below as “in-house tests”.

The question is to determine if there is a need to clarify or limit the scope of this exemption and/or to submit some "in-house tests" to certain requirements of Directive 98/79/EC.

***Question** 7:*

*Would it be necessary **to maintain** the exemption provided for by article 1(5) of Directive 98/79/EC and why?*



144 answers were received.

According to 86% of the respondents the exemption provided in Article 1(5) of Directive 98/79/EC should be kept. In particular some respondents pointed out to some specific situations where the availability of in house tests is necessary. Examples given were for instance for novel analytes, rare disease testing, customized tests for common genetic diseases and population-specific tests and test panels. According to those respondents, the abolition of the exemption would result in the lack of availability of some specific testing and would be detrimental to patients. Another reason pointed out by the respondents for maintaining the exemption was the need for rapid response to changes in test requirements. Reference was made in the contributions to the recent years' rapid emergence of global health threats from infectious agents (e.g. SARS, Influenza H5N1, H1N1). Such outbreaks require the rapid development and deployment of new assays for detection, monitoring and vaccine development and, according to these respondents, it would not be possible to implement such testing in the time-scale required if each new assay had to go through the CE marking process. Contributions also pointed to the economic consequences on healthcare systems as well as to the consequences on research and innovation of an abolition of the exemption provided by Article 1(5) of Directive 98/79/EC.

However, in order to prevent unfair competition between CE marked in vitro diagnostic medical devices and in-house tests, various contributions pointed to the need of better defining the exemption and restricting it to situations were there is no similar commercially IVD devices available or where the commercially available IVD devices does not address the needs of the users with regard to the performances or to the intended purpose of the devices. Other contributions suggested that the exemptions should only apply to low risk, low volume tests and that all high risk tests should be subject to the same standards and level of scrutiny. Some respondents were of the opinion that similar conditions as for custom made medical devices shall be established instead of the current exemption. Finally some respondents considered that any allowed exemption for in-house tests should be specific and kept within strict limits *e.g.* taking into consideration the need for devices for detection of rare parameters, and not be based on just the aspects of being in-house manufacture. These respondents suggested therefore removing the exemption for in-house tests and replacing it by a specific regulation.

Question 8:

If the exemption provided for by article 1(5) of Directive 98/79/EC ***should be clarified or limited****, which of the following items you would consider as appropriate in order to clarify the scope of this exemption and ensure a high level of safety:*

Item 1: *Better* ***define the concepts*** *of "in-house test", "health institution", "premises of a manufacture or premises in the immediate vicinity". Could you suggest an appropriate definition for these terms?*

Item 2: *Require that all "in-house tests" fulfil the* ***essential requirements*** *of the Directive 98/79/EC,* ***without being subject to a CE marking****?*

Item 3: *Require that all* ***high risk*** *"in-house tests" are* ***excluded from the exemption*** *provided for by article 1(5) of Directive 98/79/EC and then have to fulfil the essential requirements of the Directive 98/79/EC including the involvement of a notified body?*

Item 4: *Submit the health institutions and premises referred to in Article 1(5) of Directive 98/79/EC that manufacture "in house tests" to* ***accreditation****, based on ISO 15189, or* ***equivalent regulation*** *at national level?*

Please indicate one or more items *that you would consider* ***as appropriate*** *while explaining* ***why*** *you consider these items as appropriate and providing* ***data*** *where possible.*

With regards to **item 1**, while some respondents were of the opinion that it is more appropriate for the national Competent Authority to continue to provide any further guidance required on these definitions and that the Directive itself does not need to be more prescriptive. 92 contributors were in favour of introducing some clarifications in the concepts of "in-house test", "health institution", "premises of a manufacture or premises in the immediate vicinity" in order to ensure a better implementation of this provision. To the notion of "in-house tests" was sometime preferred the notion of "home brew tests" or "Laboratory Developed Tests (LDTs)". While some respondents were in favour of clarifying the concept of "premises in the immediate vicinity" to address for instance the issue of networks of public service laboratories with shared governance structure, some contributors suggested deleting this geographical concept. Only a few respondents provided with proposals for definitions but some contributors pointed out to the risk of narrowing too much the exemption and to the difficulty of producing definitions that would be acceptable and applicable in all Member States. Some contributors suggested limiting the exemption to public-sector health institution laboratories which are under the regulatory supervision of the national authorities and distinguishing between commercial and non-commercial ventures. On the contrary a few contributions were against any proposition that an exemption should be confined to public health laboratories.

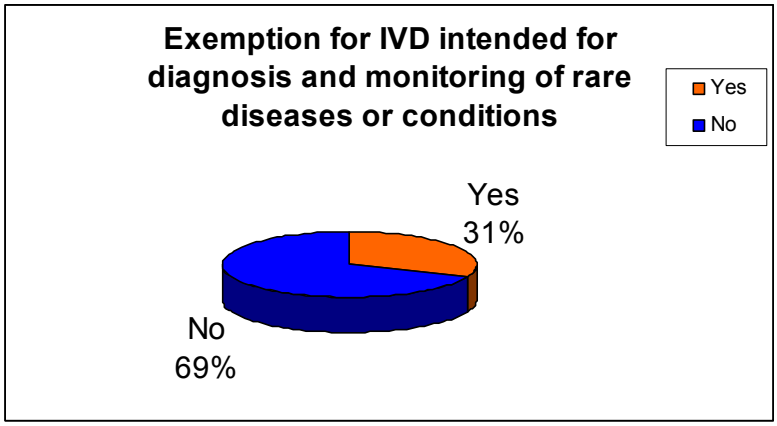
Items 2 and 3 were less supported by the respondents with respectively 41 and 27 supportive answers. In particular, for the item 2, respondents pointed out to the burden of compliance equivalent to that imposed by CE-marking. Some respondents suggested introducing some minimal provisions such as the inclusion of in house tests into the vigilance system, the registration of in house tests and, for in house tests in class D, the compliance with CTS and applicable essential requirements.

The proposal made in **item 4,** *i.e.* to submit the health institutions and premises referred to in Article 1(5) of Directive 98/79/EC that manufacture in house tests to accreditation, based on ISO 15189, or equivalent regulation at national level, was supported by 81 contributors. Extensive reference was also made to ISO 13485 and ISO 17025. Some respondents suggested **combining items 3 and 4,** including high risk devices falling in both Class D and Class C.

Question 9:

If the exemption *provided for by article 1(5) of Directive 98/79/EC* ***should not be maintained****, would you consider it necessary to* ***exempt in vitro diagnostic medical devices*** *intended for* ***diagnosis and monitoring of diseases or conditions affecting not more than 5 in 10,000 persons in the European Union*** *from the scope of the IVD Directive and, if yes, why?*

108 answers were received.



The proposal to exempt in vitro diagnostic medical devices intended for diagnosis and monitoring of rare diseases or conditions as defined above was not supported by 69% of the respondents.

Contributors pointed out to some difficulties in this approach such as cases where there is no commercially available test for infrequent but not rare conditions, cases where

there is no commercially available test for a specific condition e.g. newly identified condition and cases where conditions may be different in the Member States.

3.2 *Genetic test*

The interpretation of the scope of Directive 98/79/EC is that **only genetic tests that have a medical purpose are covered by this Directive.** However the medical purpose might not be so clear for some other tests like predictive tests or lifestyle tests, and may lead to different interpretation on the qualification of these products within the European Union.

***Question 10**:*

*Do you see a need for a **clarification of the scope of Directive 98/79/EC** to make clear that it covers **all genetic tests** that have **a direct or indirect** medical purpose while clarifying that tests without any direct or indirect medical purpose remain outside the scope of the Directive 98/79/EC.*

If you consider that there is a need to clarify the scope of Directive 98/79/EC as regards genetic tests, which of the following items would you consider as appropriate:

Item 1:

*Extend the scope to **all genetic tests** by adding a specific indent in the definition of in vitro diagnostic medical devices regarding devices which pursue the purpose of providing information concerning **"results obtained by analysis of the genome"**. Should, in this case, an **exclusion** be introduced in the Directive 98/79/EC **as regards some categories** of tests (negative list) e.g. paternity, DNA comparison?*

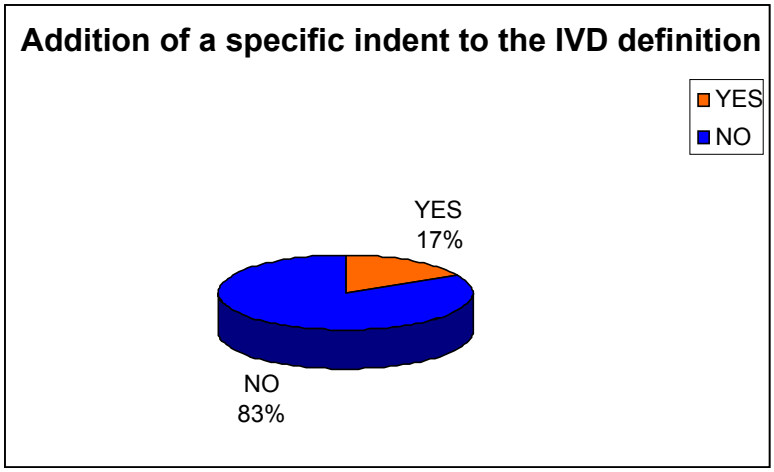
Item 2:

*Clarify that tests, including genetic tests, with a **direct or indirect medical purpose** are included within the scope of Directive 98/79/EC.*

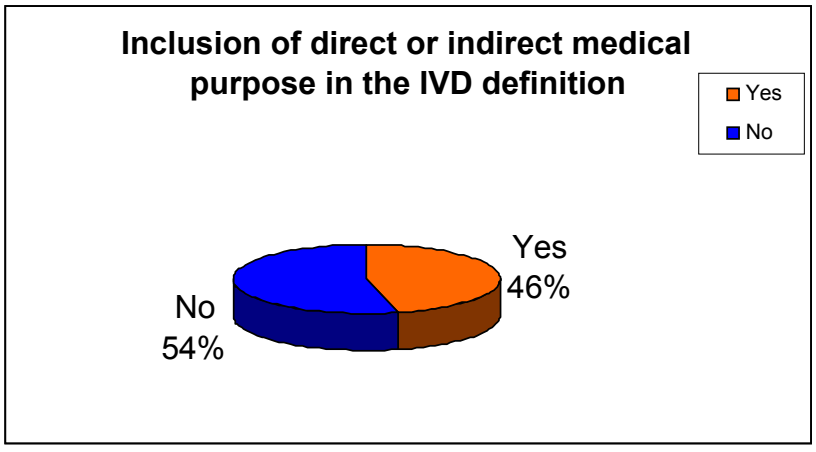
The contributors were asked to choose between two items.

The **item 1** was to enlarge the scope by including "results obtained by analysis of the genome" in the definition of *in vitro* diagnostic medical devices, and by introducing a negative list of some categories of genetic tests. This idea was judged as inappropriate by 83% of the respondents arguing for instance that the proposed additional indent in the definition of in vitro diagnostic medical devices is not broad enough to cover for example some tests based on analysis of RNA, protein or other (combinations of) biomarkers. The suggested wording could leave the status of such tests unclear.

In addition a negative list would be, according to some respondents, difficult to update and to be comprehensive and precise enough.

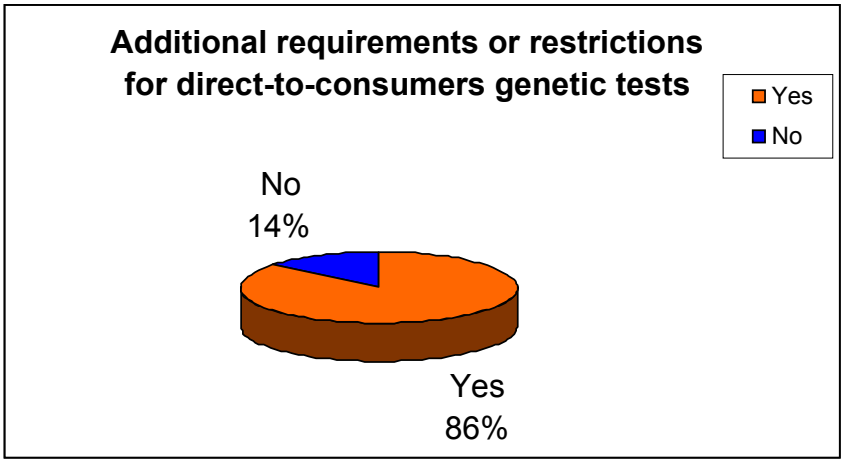


The **item 2** suggested the inclusion of "*direct or indirect medical purpose*" in the *in vitro* diagnostic medical devices definition.
This proposal was not supported by 54% of the contributions. Among those who were in favour of this option, the need of a clear definition of what is a direct and indirect medical purpose was pointed out in several answers. Some contributors were of the opinion that the addition of the word "prediction" to the definition of a medical device in Article 1(2)(a) might help addressing the issue, and in particular the uncertainty around certain tests with a (claimed) predictive value. Some contributors were of the opinion that such clarification should be made in a MEDDEV and not in the Directive itself.



Question 11:

*Do you see a need to create **additional requirements or restrictions for direct-to-consumer genetic tests** in order to ensure a better level of health protection? If yes, on which aspects?*



80 answers were received.

86% of the respondents agreed that additional requirements or restrictions for direct-to-consumer genetic tests should be created to ensure a better level of health protection. Appropriate medical intervention and counselling were mentioned as important aspects to be addressed. Some contributors were of the opinion that the same requirements as those currently requested for self-testing devices should apply.
Some respondents pointed out to the need to ban the direct sale to the public of genetic tests and advertising directly targeting the general public. According to these respondents the genetic tests for health purposes must be carried out by qualified staff in centres accredited by the health authorities. Extensive reference was made to the OECD guidelines on quality assurance for molecular genetic testing.

3.3 *Diagnostic services*

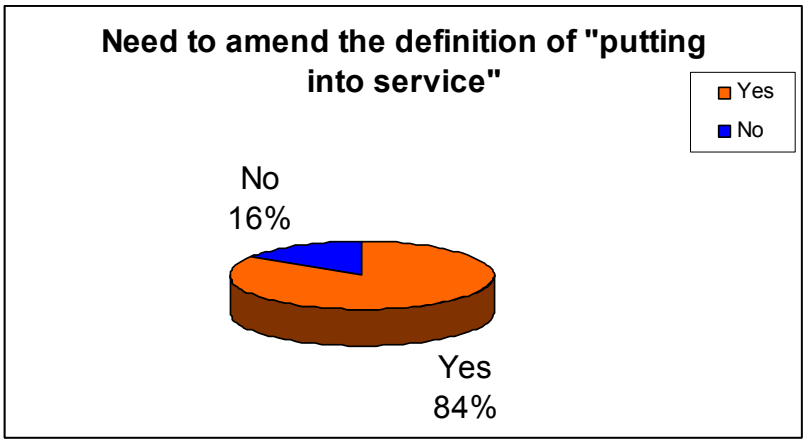
There are an increasing number of tests which are performed within an economic operator's facility (within the EU or outside) **without placing the *in vitro* diagnostic medical devices on the market**. Despite Recital 11 and Article 9(13) of Directive 98/79/EC[8] it may not always be clear that IVD's used in such a situation are subject to Directive 98/79/EC. There are **increasing concerns** regarding the validity and the reliability of the results of such tests and the understanding of the result by lay users. In

[8] Article 9(13) Directive 98/79/EC states: "The provisions of this Article shall apply accordingly to any natural or legal person who manufacturers devices covered by this Directive and, without placing them on the market, puts them into service and uses them in the context of his professional activity."

principle, these tests performed by the manufacturer should be subject to the **same requirements** than *in vitro* diagnostic medical devices that are placed on the market.

Question 12:

*Do you see a need to **amend the definition of "putting into service"** to make it clear that it covers also the in vitro diagnostic medical devices that are not placed on the market but used for the delivery of results within the Community?*



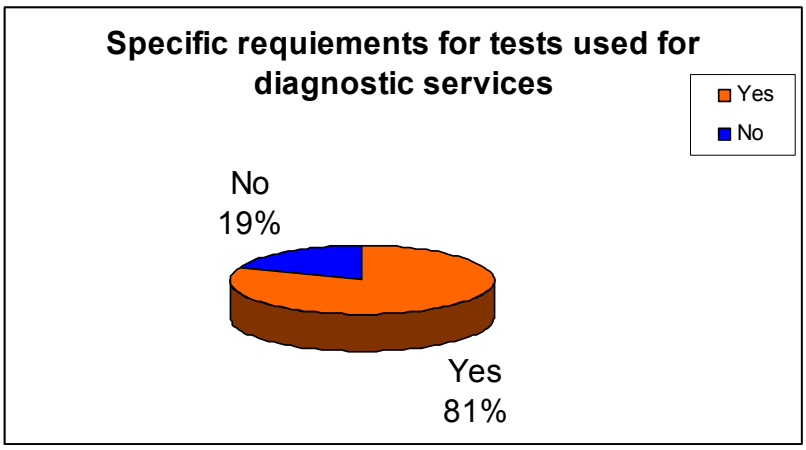
76 answers were received.

Reference was made to Recital 11 and Article 9(13) of Directive 98/79/EC but for the sake of clarity the need to amend the "putting into service" definition was supported by 84% of the respondents. While acknowledging possible difficulties in the implementation, those respondents were of the opinion that the definition of 'putting into service' should also be applicable to diagnostic services, including the diagnostic services which are performed outside the EU, and of which the test result are communicated inside the EU

Question 13:

*Do you see a need **to introduce other specific requirements** for tests used for diagnostic services, especially when the results of the tests are provided directly to consumers, such as minimum requirements for advertising?*

74 answers were received.
81% of the respondents were in favour of introducing specific requirements for tests used for diagnostic services, especially when the results of the tests are provided directly to consumers.



Examples of additional requirements mentioned were requirements for marketing and advertising (for instance CE-mark and Notified Body number mentioned in the advertising), establishment of standard operation procedures, procedures for incident notification and patient information, involvement of healthcare professionals in the delivery or redaction of the results delivered directly to the consumer. The respondents highlighted the importance that the information transmitted to the consumer is comprehensible, objective and not misleading while providing sufficient explanations, for instance with regard to the achieved quality of test results and the limits of validity of the method and with the need for further advice or consultation through a healthcare professional where needed. Information on the institution offering the testing service, such as for instance information on its accreditation, was mentioned by some contributors. Some respondents pointed out to the difficulties of enforcement of certain of these requirements. Extensive reference was made to the Human Genetics Commission's report A "Common Framework of Principles for direct-to-consumer genetic testing services"[9] . Some contributors pointed out that the issue of advertising should be addressed in the context of all three medical devices Directives.

3.4 *Point-of-care / near-patient in vitro diagnostic medical devices*

There is a growing number of tests which are **performed outside a laboratory environment** but **near to a patient** by a **healthcare professional**, who is not necessarily a laboratory professional, in order to make a diagnosis and to determine the appropriate treatment. These tests are often referred to as "point-of-care" or "near-patient" tests[10].

Question 14:

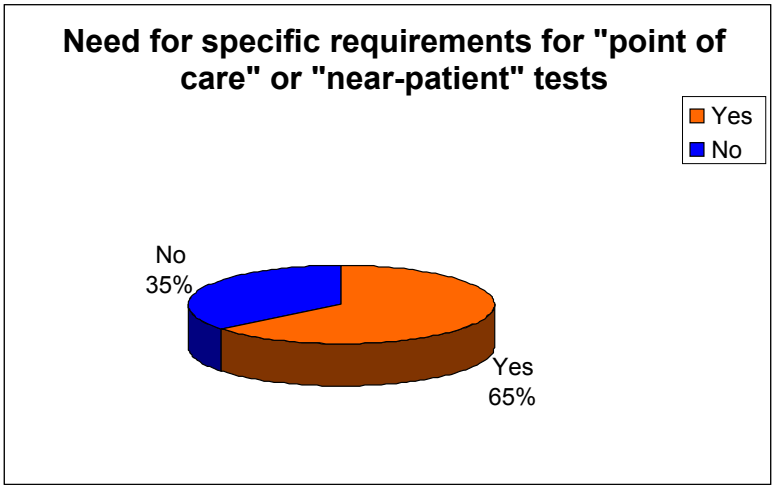
[9] http://www.hgc.gov.uk

[10] GHTF/SG1/N045:2008 regarding Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (see above footnote 6) defines "near-patient testing" as "testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient".

*Do you see a need to **add specific requirements** for **"point of care"** or **"near-patient"** in vitro diagnostic medical devices? If yes, regarding which **aspects** (e.g. information supplied by the manufacturer)?*

93 answers were received.

Among these answers, 60 answers (65%) underlined the need to set up specific requirements for point of care or near-patient testing.



Few respondents pointed out that the current requirements in the Directive already address this issue as the intended user must be taken into account for the CE marking. However most of the respondents underlined that the current requirements are not sufficient. They suggested that the clinical validity of the test must be demonstrated in the same conditions than those in which the test will be used. According to the respondents, the manufacturer shall demonstrate that the tests performed in a point of care environment provide the same level of clinical sensitivity or specificity than the test performed in a clinical laboratory. In addition, it was underlined that these tests and the users of these tests should be subject also to a Quality Management System, including Quality Controls, maintenance and External Quality Evaluation schemes, as well as to an appropriate training to the use of these tests.

Few respondents underlined that a diagnosis should not be performed on the basis solely of such a test and that the results should be confirmed by a clinical laboratory.

Other aspects raised by many respondents were the need to add some specific requirements regarding the handling of these tests by healthcare professionals as well as the need to have the instructions for use understandable by lay person. The aim of the additional requirements would be to avoid any possible misleading tests or inappropriate interpretation of the results. Specifically, the need to have a clear and appropriate explanation on the meaning of the diagnosis sensitivity and the diagnosis specificity as well as on the negative and positive predictive values was underlined by a majority of respondents.

Some respondents pointed out that the IVD Directive should exclude the possibility to perform in house tests in a point of care environment, due to the lack of appropriate instruction for use.
In addition, few respondents underlined that genetic testing should not be performed in a point-of care environment, due to the need to have appropriate information for patients.

4. Clinical evidence

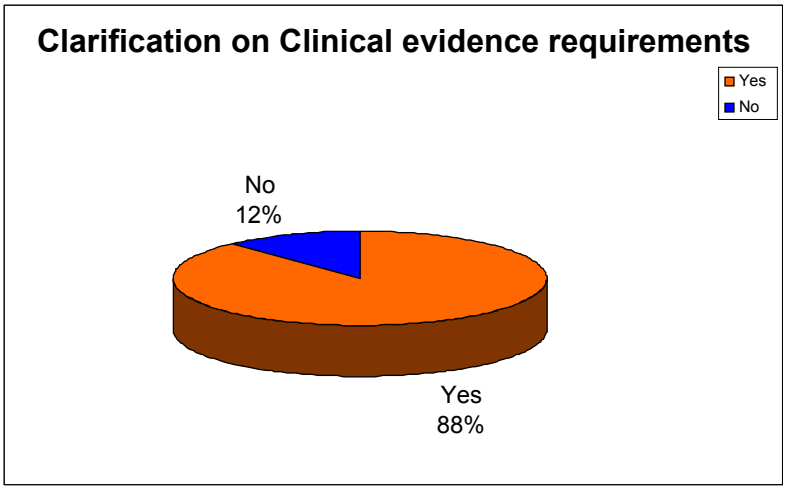
The respondents were asked to answer on the need to clarify the requirements regarding the clinical evidence. The stakeholders were also consulted on the need to extend the requirements regarding the clinical utility and on the need to set up requirements on the clinical utility.

Question 15:

*Do you see a need to **further clarify the requirements regarding clinical evidence** for in vitro diagnostic medical devices?*[11]

110 answers were received.

Among the answers, around 90% of the respondents agree on the fact that the requirements regarding the demonstration of performance for IVD medical devices need to be clarified. For the majority of the stakeholders, the current requirements on the demonstration of performance set up in the IVD directive are misleading and may be interpreted as being only analytical requirements.



[11] The GHTF is currently working on a guidance document on clinical evidence for IVDs.

In addition, the respondents agreed that the requirements regarding the clinical evidence should be more detailed in the Directive and that the Directive should include some requirements on how to demonstrate the clinical evidence.
A suggestion made by the stakeholders was to better align the requirements on clinical evidence for IVD medical devices on those required for medical devices, by introducing a specific Annex on the requirements on clinical evidence, aligned on Annex X of the Directive 93/42/EEC.
A majority of stakeholders also pointed out that the level of requirements regarding the demonstration of clinical evidence should be adapted to the different classes of the IVD medical devices.
Mainly a quasi unanimous opinion on the need of clarification of clinical evidence was expressed by the Notified Bodies and by the stakeholders in the field of genetic testing. Among the users and Competent Authorities, more than 80% of the answers underlined the need to clarify the requirements on clinical evidence.

The next questions are related to the proposition to clarify the requirements on clinical evidence in the Directive in the light of the on going work at GHTF level on the demonstration of clinical evidence for IVD medical devices and to the introduction the concept of clinical validity in the Directive.

4.1 *Clinical validity*

The **clinical validity**[12] was defined within the public consultation as the demonstration of the performance characteristics supporting the **intended use** of the *in vitro* diagnostic medical devices and includes diagnostic sensitivity, diagnostic specificity based on the true disease status of the patient and negative and positive predictive values based on the prevalence of the disease. These two last elements (negative and positive predictive values based on the prevalence of the disease) are currently not clearly mentioned in the Directive 98/79/EC.

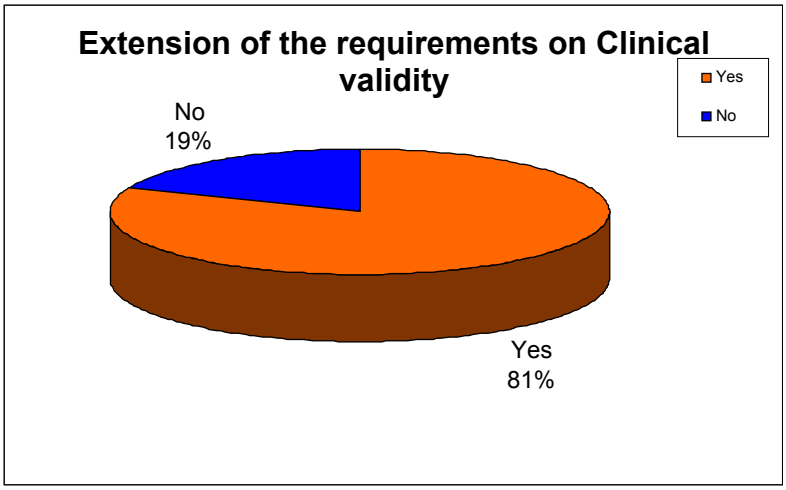
Question 16:

On the basis of the above, do you see a need ***to extend the requirements*** *regarding the demonstration* ***of the clinical validity*** *in Directive 98/79/EC?*

106 answers were received.

Among these answers, 81% expressed some support for extending the requirements in the Directive to the demonstration of the clinical validity for IVD medical devices.

[12] The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes of 27 November 2008 distinguishes between scientific validity and clinical validity. See http://conventions.coe.int/Treaty/EN/Treaties/Html/203.htm



The stakeholders agreed quasi unanimously on the fact that the requirements on the demonstration of the clinical validity should be extended at least to the demonstration of Negative Predictive Value and Positive Predictive Value. Among the respondents, there was a large support to this proposition from Competent Authorities, Notified Bodies and users. Among manufacturers there was little support to this proposition.
Mainly the stakeholders pointed out that the requirements on clinical validity should be proportionate to the risk linked to the use of the IVD medical device and then adapted to the risk based classification.
It was underlined by few respondents that the compliance with the Common Technical Specification should be considered as part of the demonstration of the clinical validity and then that their use should be expanded to other IVD medical devices. This answer is however in contradiction with the answers provided to question 6 where a large majority of stakeholders expressed the view that the CTS should not be extended to non high- risk IVD medical devices.

4.2 *Clinical utility*

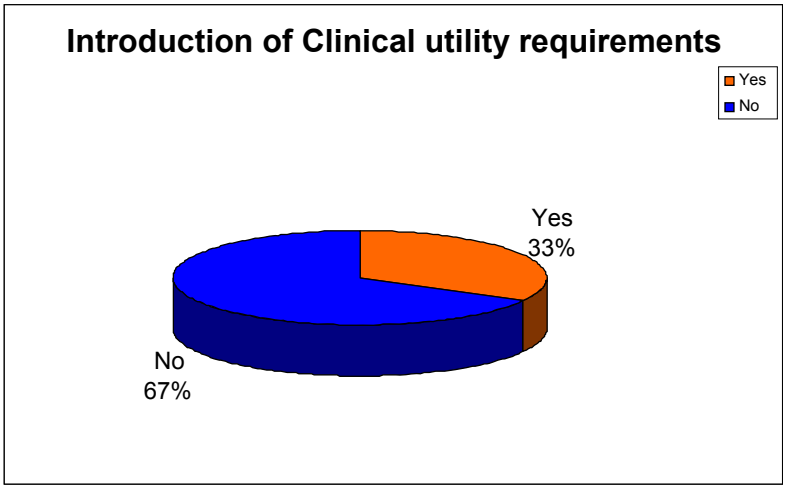
For the purpose of this public consultation, the notion of **clinical utility**[13] was defined as the demonstration of the potential usefulness and added value to patient management decision-making. The notion of clinical utility for the purpose of this document **does not include cost/benefit assessment, reimbursement issues and/or health economics issues.** If a test has a utility, it means that the results provide valuable information for the purpose of making decisions about effective treatment or preventive strategies.

[13] The Additional Protocol mentioned in the previous footnote also introduces the notion of clinical utility.

Question 17:

In the context of the above, do you see a need to ***require the demonstration of the clinical utility*** *of the parameter in Directive 98/79/EC? If yes, how should the clinical utility be demonstrated?*

Regarding the concept of clinical utility, the question raised was the need to define the clinical utility within the legal framework, according to the definition provided above and to require its demonstration by the manufacturer as a part of the conformity assessment process.
115 answers to this specific question were provided. The majority of the respondents (67%) expressed a negative opinion on the need for the demonstration of the clinical utility by the manufacturer.



Mainly, the concerns raised were that the concept of clinical utility is a moving concept that might hardly be addressed in the regulatory framework. In addition, a lot of respondents underlined that the concept of clinical utility should remain outside of the pre-market assessment process.
In addition, it was underlined that the clinical utility should not be demonstrated by the manufacturer, but should be assessed by the user. The user would have to decide on the clinical utility of a specific IVD medical device in a specific context or a specific population. Among the respondents, manufacturers, Notified Bodies and stakeholders active in the field of genetics were against introducing requirements on clinical utility within the Directive. Even users were not favourable to the introduction of such requirements in the Directive.

It was underlined that for new parameters, it will be impossible to demonstrate the clinical utility and therefore, it will limit the market access for innovative IVD medical devices. At the same time, some stakeholders underlined that for the majority of well known parameters, the demonstration of clinical utility should not be required.

However, some of the answers underlined that the demonstration of clinical utility might have an interest for direct to consumers testing or genetic testing.

5. Others

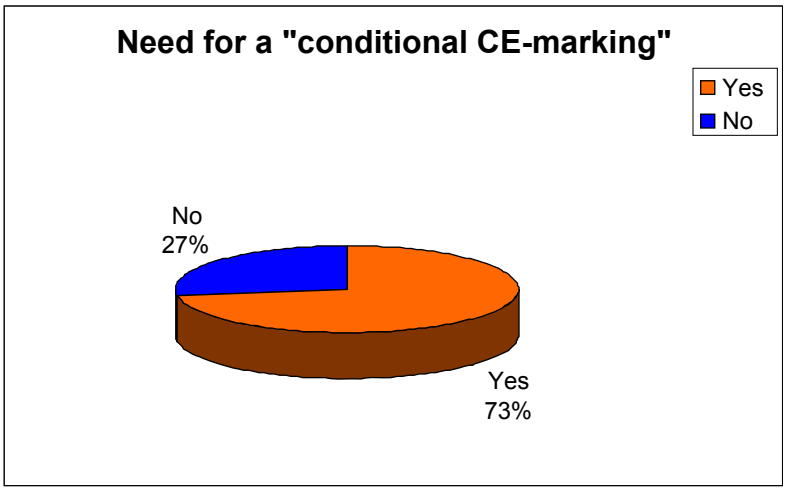
5.1 *"Conditional CE marking"*

For unmet medical needs of patients, for example in the case of rare diseases or in emergency situations such as a pandemic, it might be useful to introduce a mechanism which can allow a rapid market access of certain IVDs subject to certain conditions. Currently, Article 9(12) of Directive 98/79/EC makes provision that Member States can accept IVDs in their respective territories without proper conformity assessment procedure if this is justified in the interest of public health protection. Instead of such national solutions, a **"conditional CE marking"** might be allowed for a limited period of time (*e.g.* one year renewable) and subject to specific obligations imposed on the manufacturer with a view to confirm the safety and performances of the tests.

Question 18

Would you consider the possibility of a ***conditional CE marking*** *in certain situations useful? Which situations would you think of and which conditions, including procedural requirements, would you consider necessary?*

The stakeholders provided 117 answers to this question. A majority of them (73%) considered that a "conditional CE marking" might be a useful in certain situation.



The respondents raised some questions regarding this "conditional CE marking", in particular regarding the aspect of who would decide to allow such a "conditional CE marking". There is a fear that this "conditional CE marking" would allow the marketing

of low quality tests. Some answers underlined that if such a procedure would be put in place, a committee composed of Competent Authorities' representatives should be responsible for the decision.
It was underlined by the stakeholders that article 9(12) of Directive 98/79/EC already address the emergency situation on a national basis. A majority of Competent Authorities pointed out that they would prefer to keep this "derogation" at national level. It was underlined by the other categories of respondents that it would be useful to have such a "conditional CE marking" at European level to address the emergency, like a pandemic, as the situation of a pandemic would rarely be limited to a Member State.
The broad majority of respondents pointed out that the situations in which such a procedure would be useful are the emergency, (*i.e.* spread of a new disease, pandemics,..) or the timely access of tests for unmet medical needs.. In that case, the test would be subject to a post-marketing collection of data and then to a CE marking on the basis of the data collected.
However it was underlined by the stakeholders that this procedure would not be useful for "rare conditions". It was pointed out that in the case of "rare conditions", the more efficient procedure would be an exemption from the IVD Directive, as mainly these tests are performed in an in-house environment and it is very unlikely that sufficient data might be collected to obtain the CE marking.

5.2 *Companion in vitro diagnostic medical devices (e.g. pharmacogenomic assays, biomarker assays)*

There are a growing number of tests which are **developed** and/or **used** in **direct combination with specific medicinal products** or which are **co-developed** with new medicinal products. These tests may be used for the selection of patients suitable for the respective medication, for optimal and individualized dosing of medicinal products, for the exclusion of populations expected to suffer from severe adverse side effects and / or other medicinal products-related indications. Currently, most companion diagnostics are self-certified by the IVD manufacturer.

***Question 19**:*

*Which options do you see to guarantee a high quality of IVD medical devices used as **companion diagnostics**?*

The respondents provided 125 answers to this question.

Almost unanimously, the respondents underlined that the IVD medical devices used as companion diagnostics must be subject to the IVD Directive, which will ensure an appropriate level of quality and safety for European citizens. The respondents pointed

out that the implementation of a risk-based classification would address the main concerns raised about the insufficient level of scrutiny for these IVD medical devices. It would be necessary to have these IVD medical devices in Class C of the GHTF model, to ensure that a third party would be involved in the CE marking of these devices. However some respondents pointed out the need to have a closer cooperation between IVD medical device sector and the European Medicine Agency.

Some respondents underlined the need to require for these IVD tests the demonstration of the clinical utility of the combination of the medicinal product and the IVD medical device in the context of the CE marking and the marketing authorisation of the medicinal product.

It was underlined by stakeholders in the field of genetic diseases that the competence of the European Medicine Agency should be extended to pharmacogenomics, as the IVD medical device has an impact on the health outcome of the medicinal product and then the analytical and clinical validity of the IVD medical device should be part of the assessment of the benefit/risk assessment of the medicinal product.

APPENDIX 3 – CONCLUSIONS OF THE COUNCIL OF THE EU ON INNOVATION IN THE MEDICAL DEVICES SECTOR

COUNCIL CONCLUSIONS ON INNOVATION IN THE MEDICAL DEVICE SECTOR

(2011/C 202/03, Official Journal of the European Union C 202 of 8.7.2011, p. 7)

THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLING the Council conclusions of 26 June 2002 ([1]) and of 2 December 2003 ([2]) and the subsequent amendments to the legislative framework for medical devices ([3]);
2. DRAWING ATTENTION TO the conclusions ([4]) of the High Level Health Conference on innovation in medical technology held in Brussels on 22 March 2011;
3. BEARING IN MIND:

   the major long-term societal challenges facing Europe, such as an ageing population, which will call for innovative healthcare systems,

   the importance of medical devices in health- and social care, their contribution to improving the level of health protection and the fact that medical devices today account for a significant amount of public health expenditure,

   that the development of medical devices may deliver innovative solutions for diagnosis, prevention, treatment and rehabilitation, that could improve health and quality of life for patients, disabled persons, and their families, could contribute to mitigating the shortage of healthcare professionals and could contribute to addressing the sustainability of healthcare systems,

   that innovation in medical devices should contribute to the continued improvement of patient and user safety,

   the European Innovation Partnership on Active and Healthy Ageing launched by the European Commission with the aim of tackling societal challenges through innovation,

   that the medical device sector in Europe comprises around 18 000 small and medium-sized enterprises (SMEs) and that this fact must be considered when future legislative and administrative measures are being adopted at European Union level and at national level,

   the need to adapt EU medical device legislation to the needs of tomorrow so as to achieve a suitable, robust, transparent and sustainable regulatory framework, which is central to fostering the development of safe, effective and innovative medical devices for the benefit of European patients and healthcare professionals,

   the importance of having the EU continue to play a leading role in the field of international regulatory convergence and best regulatory practice regarding medical devices, for instance through the Global Harmonisation Task Force, and be party to global initiatives such as global vigilance and global instruments for improving identification and traceability of medical devices;

4. STRESSING that in order for innovation to benefit patients, healthcare professionals, industry and society:

   innovation should be increasingly patient- and user-centred and demand-driven, e.g. through increased involvement of patients, their families and users in the research, innovation and development processes in order to improve individual health and quality of life,

   innovation should be a more integrated process, building on experience and knowledge acquired in other sectors, such as IT and the development of new materials,

   innovation should be based on a holistic approach (i.e. it should take into account the whole healthcare process and all patients' needs — physical, social, psychological, etc.),

   innovation should focus on public health priorities and healthcare needs inter alia in order to improve cost-effectiveness,

   there is a need to increase research in order to identify public health needs and priorities still to be addressed and to better define patients' medical needs,

   future legislative actions in this area must, when adapting the European regulatory framework, specifically aim to increase patients' safety while at the same time creating a sustainable legislative framework favourable to medical device innovation that can contribute to a healthy, active and independent life;

5. INVITES THE COMMISSION AND THE MEMBER STATES to:

   promote measures that make use of valuable innovative solutions with proven benefit, and improve information and training for healthcare professionals, patients and patients' families regarding their use,

([1]) Doc. 10060/02.

([2]) Doc. 14747/03.

([3]) Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21).

([4]) http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory_process/hlc_en.pdf

further map and share national and European best practices regarding innovation and enhance the deployment of research to facilitate, where relevant, the transfer of experiences gained in national or regional studies and pilot projects to the multinational, multiregional or European level,

ensure stronger collaboration and dialogue between the various actors involved in the innovation process (e.g. through networks and clusters),

promote valuable innovation through public procurement policies while taking into account safety aspects,

take existing measures into account, and when necessary consider further measures which enhance the capacity for innovation, for instance the use of innovative funding systems directed, in particular, towards SMEs and that are designed to make optimum use of resources from the private and public sectors,

pay particular attention to interoperability and safety issues related to the integration of medical devices in e-Health systems, especially Personal Health Systems and mobile health systems (m-Health) while bearing in mind that the deployment of health ICT systems is entirely a matter of national competence,

encourage better consideration of the needs of patients and healthcare professionals in the design process of medical devices,

consider further improving the involvement of patients and healthcare professionals in vigilance in order to improve the system of notification of adverse incidents relating to the use of medical devices,

promote early dialogue between manufacturers, scientific and clinical experts, competent authorities and, where appropriate, notified bodies regarding 'new products' in particular, and their classification,

enhance cooperation between authorities of relevant sectors, where appropriate,

examine how and at which level the promotion of medical devices can be regulated in the most effective and efficient way;

6. INVITES THE COMMISSION to take the following considerations into account in the course of its future legislative work:

mechanisms are needed to enhance reliability, predictability, speed and transparency in decision-making, and make sure that it is based on scientifically validated data,

the system of risk based classification should be improved (in particular for *in vitro* diagnostic medical devices and 'new products' as appropriate),

clinical data from pre-marketing studies and postmarketing experience (vigilance reports, post-marketing clinical follow-up, European registers) must be collected in a transparent way and to a greater extent in order to provide the clinical evidence which fulfils regulatory purposes and can, where appropriate, assist health technology assessment, whilst fully recognising and respecting national competences for the latter. Consideration should also be given to methods for ensuring that notified bodies are better equipped with the appropriate expertise to analyse such data in a meaningful way,

there is a need for clearer and simpler rules defining the obligations and responsibilities of all economic operators and the role of other stakeholders (in particular national competent authorities and notified bodies),

the development of a modern IT infrastructure for a central and publicly available database must be further pursued with a view to providing key information about medical devices, relevant economic operators, certificates, clinical investigations and field safety corrective actions. In this context, the possibility of introducing a system to improve the traceability of devices, thus enhancing safety, must be studied,

where necessary, clarification should be made regarding the definition of medical devices and the criteria for their classification,

in addition, a simple and rapid mechanism must be set up for accelerated adoption of binding and consistent decisions and the implementation thereof on the determination of products as medical devices and the classification of medical devices in order to address the growing number of 'borderline' cases between medical devices and other products subject to different regulatory frameworks (the framework for pharmaceuticals in particular, but also those for cosmetics, aesthetic products, food or biocides),

as regards the oversight of notified bodies, there is a need to continue to improve the harmonised list of criteria to be satisfied before their designation. In particular the designation process should ensure that they are designated only for the assessment of devices or technologies which correspond to their proven expertise and competencies. The process should also address the need to improve monitoring of notified bodies by national authorities in order to ensure an EU-wide comparable and high-level performance of notified bodies, in this context an enhanced European coordination between competent authorities as well as between notified bodies should also be considered,

the vigilance system for medical devices must be further developed in order to allow a coordinated analysis and a rapid and coherent EU-wide response to safety issues, if needed,

it is desirable to consider a European coordination mechanism founded on a clear legal basis and mandate in order to ensure efficient and effective coordination between national authorities while creating a level playing field. Synergies with existing bodies with relevant expertise should be explored when deciding on the mechanisms for such coordination. Consideration should also be given to which activities are best carried out in cooperation between Member States,

as the medical device sector is a global one, a stronger coordination with international partners is desirable in order to ensure that medical devices are manufactured according to high safety requirements worldwide,

there is a need for a sustainable legislative framework for medical devices which ensures safety and promotes innovation,

it should be considered how to address regulatory gaps in the system, for instance in relation to medical devices manufactured utilising non-viable human cells and tissues,

the need for introducing more harmonised provisions relating to the content, presentation and comprehensi-bility of the instructions for use of medical devices should be further considered.

APPENDIX 4 – FACT SHEET: MEDICAL DEVICE SECTOR

The medical devices sector covers a dynamic, innovation driven, highly competitive industry, with a global market.

I. Product coverage

Medical devices are covered by three EU Directives (see separate fact sheet on the regulatory framework). A medical device is defined as "*instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

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

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

1. Examples for active implantable medical devices (covered by Directive 90/385/EEC):

- Pacemakers
- Diffusion pumps for oncological applications
- Cochlear implants

2. Examples for other medical devices (covered by Directive 93/42/EEC):

Disposables, such as
- Sticking plaster
- Tongue depressors
- Condoms

Hospital equipment, such as

- Anaesthetic equipment and workstations; respiration and inhalation equipment (lung ventilators)
- Diagnostic equipment
- Medical imaging equipment such as X-ray, scanners (e.g. PET or MRI[14])
- Laser applications, electro-cardiography, stethoscopes

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14 PET = Positron Emission Tomography, MRI = Magnetic Resonance Imaging

– Sterilizers
– Operating theatre
– Hemodialysis
– Nuclear therapeutic equipment
– Infusion and transfusion equipment
– Incubators
– Surgery equipment (e.g. forceps, scalpels)
– Catheters
– Medical disposables (e.g. surgical drapes)

Dentistry, such as

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

Devices with a measuring function, such as

– Blood glucose meters
– Fever thermometers

Ophthalmic devices and hearing instruments, such as

– Spectacles, glasses, contact lenses
– Audative prostheses, hearing aids

Protheses, implantable and non-implantable as well as internal and external orthopaedics, such as

– Walking aids
– Artificial limbs
– Hip, shoulder and knee replacements
– Cardiac valves
– Corsets

Aids for disabled, such as

– Wheelchairs
– Portable ventilators
– Rehabilitation equipment

3. Examples for *in vitro* diagnostic medical devices (IVDs)

Reagents and instrumentation for

– Safety of the blood supply (HIV, hepatitis, blood grouping etc)
– Detection of infectious diseases (Specific flu strains, chlamydia, etc)
– Blood chemistry (cholesterol, HDL/LDL, transaminases, etc.)
– Monitoring of diseases (blood glucose in diabetes, etc.)
– Screening assays (PSA for prostate cancer, etc)

– Tests for the determination of pregnancy
– Specimen receptacles for the containment and preservation of human specimens

II. Market data

1. Market volume

Global market (2009): Sales volume of around **€313bn** (€283bn for medical devices including €80bn for medical imaging equipment, plus estimated €30bn for IVDs)

Largest markets (2009): USA (ca. 36%), Europe (ca. 30%), Japan (ca. 11%), China (ca. 3%)

European (EU/EFTA) market (2009): Sales volume of around **€95bn** (€85bn for medical devices including €28bn for medical imaging equipment, plus €10bn for IVDs)

Largest markets in the EU (2009): 1) Medical devices[15]: Germany (€21bn), France (€17bn), UK (€11bn); 2) IVDs: Germany (€2.17), France (€1.7bn), Italy (€1.68bn), Spain (€1.09), UK (€0.7bn)

Annual growth rate: 1) Medical devices: ca. 5% in 2009; 2) IVDs: 3.6% (2008-2010)

Re-investment in R&D (2009): 1) Medical devices: 6-8% (ca. €6.5bn) of sales volume; 2) IVD: ca. 10% (ca. €1bn)

Percentage of health care expenditure spent for medical devices (2009): 1) Medical devices: EU average 4.2% (rates in Member States range from 2% - 11%); 2) IVD: EU average 0.8% (rates in Member States range from 0.3% - 3.9%)

2. Industry

Medical device business entities in Europe: around 22,500

SMEs: more than **80%**; in the IVD sector more than 90%

Employment: around 500,000 individuals in Europe

Big companies: Abbott, Agfa HealthCare, BD, Boston Scientific, Covidien, GE Healthcare, Johnson & Johnson, Medtronic, Philips Healthcare, Roche Diagnostics, Siemens Healthcare, Stryker, Toshiba.

Recent mergers & acquisitions: Synthes by Johnson & Johnson (orthopaedics, $21bn, April 2011), Beckman Coulter by Danaher (diagnostics, $6.8bn, Feb. 2011), Millipore by Merck KGaG (diagnostics, $7bn, Feb. 2010), Alcon by Novartis (eye care, $28.1bn, Jan. 2010)

[15] Medical devices here mean medical devices not including IVDs.

III. European industry associations

- Medical Technologies Industry in Europe (EUCOMED)
- European Coordination of the Radiological and Electromedical Industry (COCIR)
- European Diagnostic Manufacturers Association (EDMA)
- European Hearing Instrument Manufacturers Association (EHIMA)
- European Federation of Precision Mechanical and Optical Industries (EUROM)
- European Industrial Federation Committee on Medical Technology (EUROM VI)
- European Contact Lens and Lens Care Industry's Association (EUROMCONTACT)
- Federation of European Dental Industry (FIDE)
- European Association of Authorized Representatives (EAAR)

APPENDIX 5 – REGULATORY FRAMEWORK FOR MEDICAL DEVICES

I. EU legislation

The EU regulatory framework for medical devices is built on **three main Directives**:

- Council Directive 90/385/EEC on the approximation of laws of the Member States relating to active implantable medical devices (hereafter AIMDD)[16],
- Council Directive 93/42/EEC concerning medical devices (hereafter MDD)[17], and
- Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices (hereafter IVDD)[18].

All three directives are harmonization measures based on the former Article 100a of the Treaty establishing the European Community, which is now Article 114 of the Treaty on the Functioning of the European Union. Their main objectives are the creation of an internal market for medical device whilst ensuring a high level of protection of public health and patient safety.

Special provisions covering medical devices incorporating substances derived from blood were introduced in 2000[19]. AIMDD and MDD were amended for the last time by Directive 2007/47/EC which was due to be implemented by March 2010. The IVDD has not been substantially amended since its adoption.

The legislative acts are complemented by a number of **implementing measures** adopted by the Commission:

- Commission Decision 2010/227/EU on the European Databank on Medical Devices,
- Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices,
- Commission Directive 2003/32/EC introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin,
- Commission Directive 2003/12/EC on the reclassification of breast implants in the framework of Council Directive 93/42/EEC concerning medical devices,

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16 OJEC L189 20 July 1990

17 OJEC L 169 12 July 1993

18 OJEC L 331 7 December 1998

19 Directive 2000/70/EC of the European Parliament and of the Council amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma, OJEC L 313 of 13 December 2000, and Directive 2001/104/EC of the European Parliament and of the Council amending Council Directive 93/42/EEC concerning medical devices, OJEC L 6 of 10 January 2002.

- Commission Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices, as amended for the last time by Commission Decision 2009/886/EC.

Further **implementing measures are currently being prepared** as regards

- variant Creutzfeldt-Jakob Disease (vCJD) assays for blood screening, diagnosis and confirmation (addition to List A of Annex II to the IVDD and amendment of the common technical specifications for IVD),
- electronic instructions for use of medical devices, and
- revision of Commission Directive 2003/32/EC concerning medical devices manufactured utilising tissues of animal origin.

II. Main elements of the EU medical device legislation

The three main Directives are based on the concept of the 'New Approach' to technical harmonisation and standardisation, defined by the Council in 1985[20] and reviewed in 2008 with the adoption of the 'New Legislative Framework for the Marketing of Products'[21].

1. Product requirements

AIMDD, MDD and IVDD lay down the **essential requirements** for safety and performance that medical devices products have to meet when they are placed on the market or put into service in the EU. Before being placed on the market or put into service, devices must be subject of a risk assessment, a risk management process and a risk/benefit analysis by the manufacturer. In this context, 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 devices 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.

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[20] Council Resolution of 7 May 1985 on a New Approach to technical harmonisation and standards, OJEC C 136 of 4 June 1985.

[21] Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance and repealing Regulation (EEC) No 339/93, OJEU L 218/30 of 13 August 2008, OJEU L 218/30 of 13 August 2008, and Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJEU L 218/82 of 13 August 2008.

2. Conformity assessment / Notified Bodies

The Directives contain a number of conformity assessment procedures, the use of which depends on the device's classification in one of the four risk classes (I, IIa, IIb and III). Except for low risk devices (class I) for which the manufacturer itself certified conformity, the conformity assessment procedure involve independent conformity assessment bodies, so-called Notified Bodies, designated and monitored by national authorities. The extent and depth of the Notified Body's assessment depends on the risk class of the device and covers the quality system of the manufacturer and/or the design of the device. Manufacturers must submit intended changes to their quality system and/or to the design of their device to a Notified Body for assessment. Notified Bodies must perform periodic surveillance inspections to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

3. Free movement of medical devices

After successful completion of the applicable conformity assessment (either self-certification or delivery of a certificate by a Notified Body), the manufacturer must affix a CE marking on the product. Member States may not create any obstacle to the placing on the market or putting into service of devices which bear the CE marking. Due to the EEA Agreement, the Mutual Recognition Agreement with Switzerland and the Customs Union with Turkey, the principle of free movement of CE marked medical devices applies to 32 European countries (EU, EFTA, Turkey).

Member States retain the right to adopt restrictive measures against CE marked devices which may compromise the health or safety of patients (safeguard clause), against products on which the CE marking is either unduly affixed or missing (wrongly affixed CE marking) or in relation to a given device or group of devices for which the observance of particular requirements is deemed necessary to ensure protection of health and safety (particular health monitoring measure). The use of the right to adopt such measures is subject to the respect of procedural requirements which include the information of the other Member States and of the Commission. The latter one is required to inform as to whether a safeguard clause measure or a particular health monitoring measure is justified.

4. Clinical investigation and evaluation

With regard to devices other than IVD, the manufacturer must collect **clinical data** to demonstrate the conformity with the essential requirements. 'Clinical data' is defined as the "safety and/or performance information that is generated from the use of a device". The data can be sourced from

- clinical investigation(s) of the device concerned (which is generally required for implantable devices and class III devices), or
- clinical investigation(s) or other studies reported in the scientific literature of a similar device for which equivalence can be demonstrated, or
- published or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence can be demonstrated.

Clinical investigations must be notified to the authorities of the Member States where the investigation shall be conducted. Competent authorities and ethics committees assess the acceptability of the envisaged investigation within a period of 60 days.

The evaluation of the clinical data to demonstrate the conformity of a device with the essential requirements, including side-effects and acceptability of the benefit/risk ratio, (**'clinical evaluation**') must follow a defined methodologically sound procedure based on

- a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, if equivalence can be demonstrated, or
- a critical evaluation of the results of all clinical investigations, or
- a combination of both.

The clinical evaluation is part of the documentation to be submitted by the manufacturer to the Notified Body for conformity assessment.

5. Vigilance

The vigilance procedure is part of the regulatory requirements to ensure the safety of devices after their placing on the market or putting into service. Manufacturers are held to notify the authorities of the Member States of any incident that has occurred with a medical device. Incidents in terms of the Directives are

- any malfunction 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 their state of health, or
- any technical or medical reason in relation to the characteristics or performance of a device leading to a systematic recall of devices of the same type.

Member States have to take the necessary steps to ensure that any information by manufacturers about incidents is recorded and evaluated centrally. 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 EU, is also informed of the incident.

Due to the global market of medical devices, vigilance has an international dimension. In the framework of the Global Harmonisation Task Force for medical devices (GHTF)[22], a system has been set up to inform about serious incidents with a medical device among the participating countries, the so-called National Competent Authority Reports (NCAR) Exchange Programme, which allows exchanging information about incidents at a global scale[23].

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[22] The GHTF was founded in 1992 by Australia, Canada, EU, Japan and USA in an effort to achieve greater uniformity between national medical device regulatory systems.

[23] Besides the GHTF members and individual EU/EFTA countries, several third countries participate in the NCAR Exchange Programme, e.g. Cuba, Hong Kong, Saudi-Arabia, Taiwan and Thailand.

III. Implementation

Whilst the legal framework has remained stable over the last two decades, 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. In order to ensure a coherent implementation of the Directives, Commission, national authorities and stakeholders have created a number of informal working groups[24], in addition to the formal Comitology Committee foreseen in the Directives.

The main platform for discussion on implementation issues is the Medical Devices Experts Group (MDEG), chaired by the Commission. Participants are the national competent authorities and stakeholders such as representatives of industry, Notified Bodies, healthcare professionals and European standards bodies. MDEG has set up a number of specific working groups dealing with issues such vigilance, clinical investigation and evaluation, IVD specific matters or borderline and classification issues. MDEG endorses legally not binding guidance documents, so-called MEDDEVs[25], that reflect the consensus view of authorities and stakeholders on issues of interpretation or implementation. Consensus found on borderline and classification issues are included in the Manual on Borderline and Classification[26] which is regularly updated by the Commission.

Under the oversight of the network of Competent Authorities for Medical Devices (CAMD), national authorities have set up the Notified Bodies Operations Group (NBOG) and the Compliance and Enforcement Group (COEN) to co-ordinate the policies in the fields of, respectively, Notified Body oversight and market surveillance. Meetings are chaired by a national authority and hosted by the Commission. More recently, Member States have set up a Central Management Committee (CMC) aiming at achieving greater consistency in the interpretation and implementation of the Directives by improving decision-making between the national regulatory authorities.

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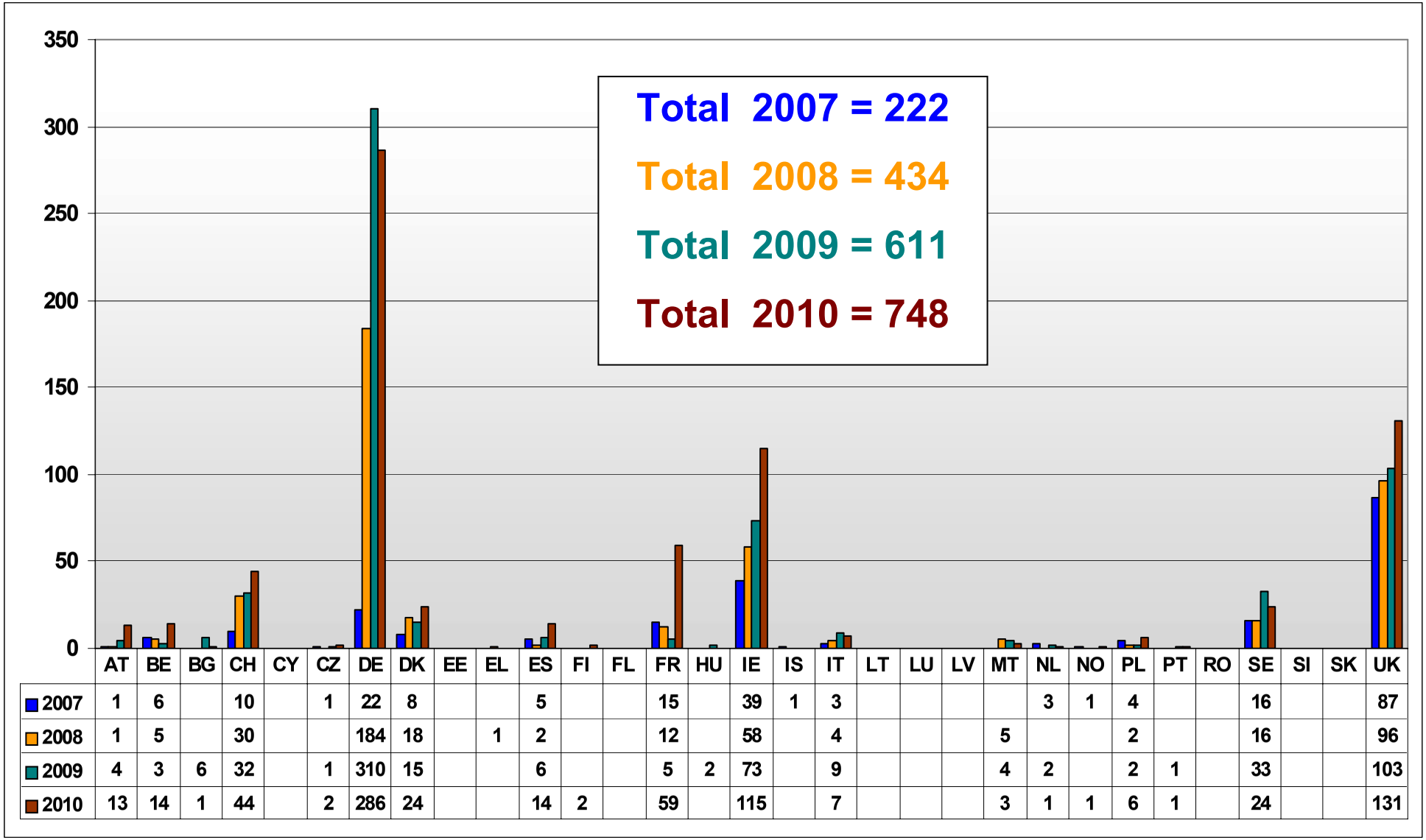
24 See http://ec.europa.eu/health/medical-devices/files/meddev/2_15_3___12-2008_en.pdf

25 See http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm

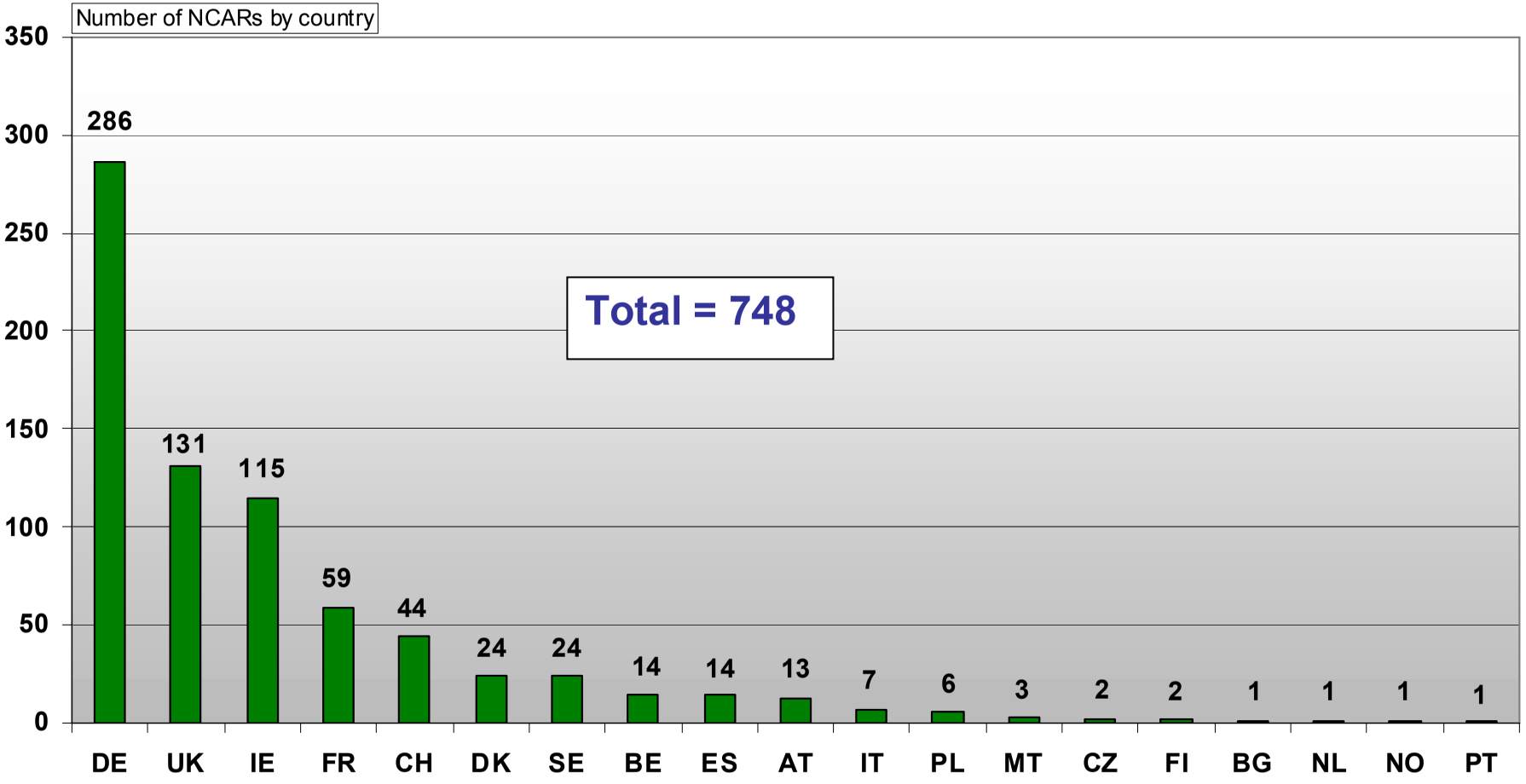
26 http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/version1_9_borderline_manual_en.pdf

General overview of NCARs exchanged at European level (EU/EFTA) from 2007 – 2010



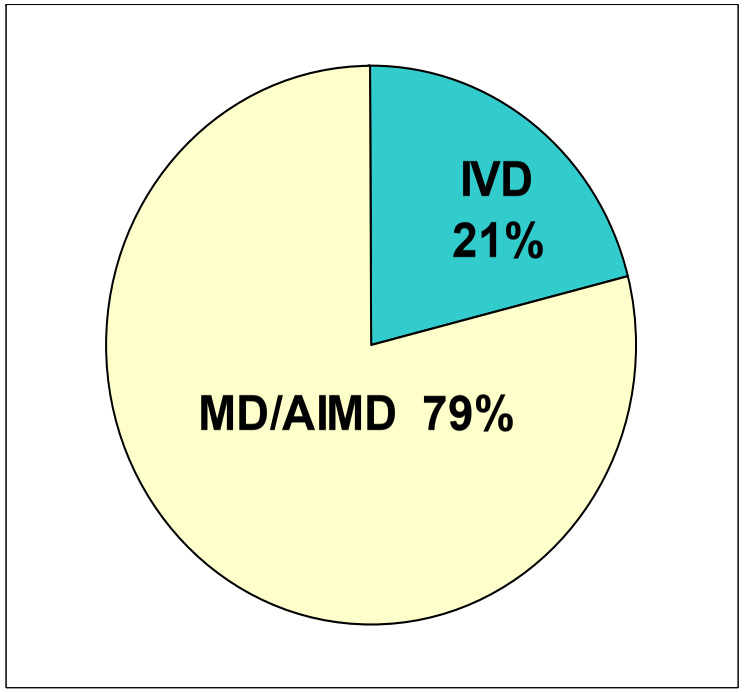
	AT	BE	BG	CH	CY	CZ	DE	DK	EE	EL	ES	FI	FL	FR	HU	IE	IS	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK
2007	1	6		10		1	22	8			5			15		39	1	3					3	1	4			16			87
2008	1	5		30			184	18		1	2			12		58		4				5			2			16			96
2009	4	3	6	32		1	310	15			6			5	2	73		9				4	2		2	1		33			103
2010	13	14	1	44		2	286	24			14	2		59		115		7				3	1	1	6	1		24			131

Number of NCARs sent by EU/EFTA countries in 2010

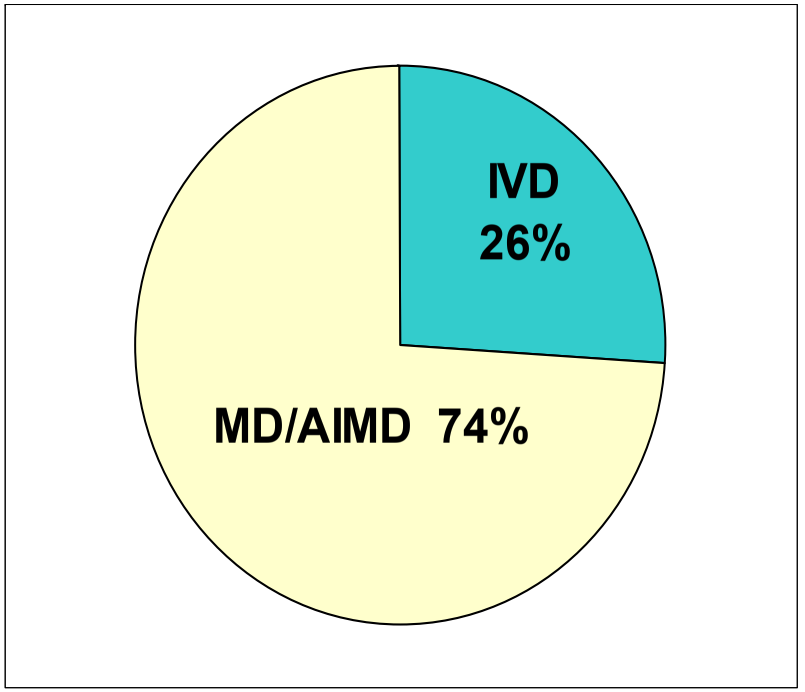


Repartition of NCARs between MD/AIMD and IVD in 2009 and 2010

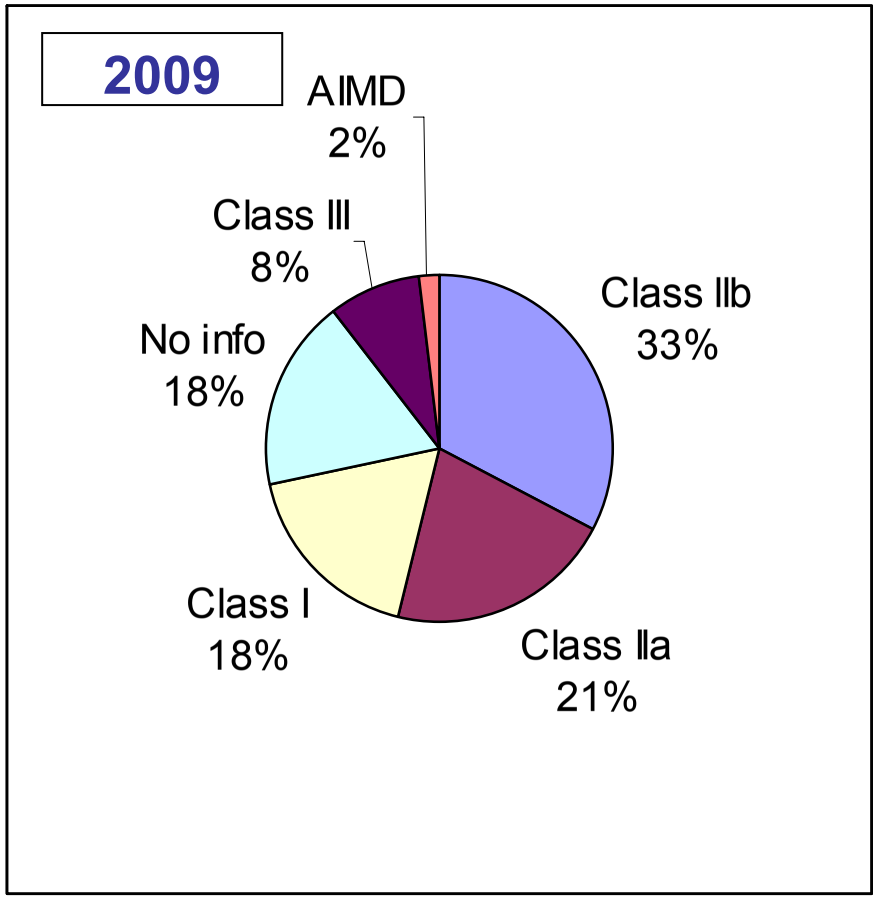
2009

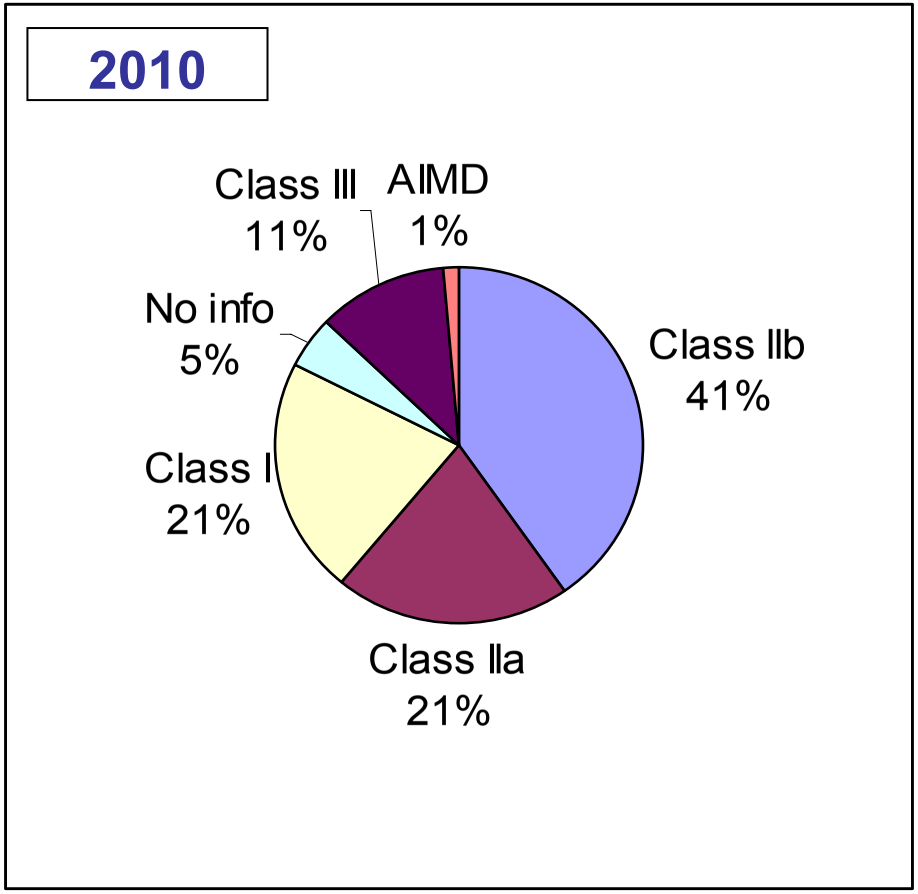


2010



NCARs regarding MD and AIMD according to risk classes in 2009 and 2010





APPENDIX 6b – STATISTICS REGARDING INCIDENT REPORTS IN THE FIELD OF VIGILANCE

According to the public information made available on the websites of the four competent authorities who exchanged the largest number of NCARs in 2010, the numbers of reported incidents are as follows (NB: the criteria for the statistics published by the authorities are not harmonised):

Germany (source: homepage of the Bundesinstitut für Arzneimittel und Medizinprodukte, www.bfarm.de):

Year	2010	2009	2008
Reported incidents	5,780	4,894	4,883

United Kingdom (source: homepage of the Medicines and Healthcare Products Regulatory Authority, www.mhra.gov.uk):

Year (financial year)	2010/11	2009/10	2008/09
Reported incidents	10,449 (investigated: 2,940)	9,270 (investigated: 2,932)	8,884 (investigated: 2,888)

Ireland (source: homepage of the Irish Medicines Board, www.imb.ie):

Year	2010	2009	2008
Reported incidents	1,678	1,335	1,160

France (source: homepage of the Agence française de sécurité sanitaire des produits de santé, www.afssaps.fr):

Year	2010	2009	2008
Reported incidents	10,575	10,097	10,865

- The majority of incidents are reported by manufacturers.

Incidents reported by:	Germany (2004-2010)	UK (2007/08-2010/11)	Ireland (2010)	France (2008-2010)
Manufacturers	76%	43-48%	49%	42%
Users	16%	31-38% (NHS)	6%	52%
Other sources	8%	26-14%	45%	6%

- The numbers of recalls/field safety corrective actions are as follows:

	Germany (2005-2010)	UK (2007/08-2010/11)	Ireland (2009)	France (2010)
Number/percentage of recalls/field safety corrective actions	24%	35%	676 actions with direct impact on Irish market	37%

APPENDIX 7 – POSSIBLE TASKS OF A MEDICAL DEVICE EXPERT GROUP

Possible role of a new statutory Medical Device Expert Group under a future regulatory framework for medical devices

(composed of experts appointed by the EEA Member States, CH, TR)

+

sub-groups for

Notified Bodies' Oversight (ex-NBOG)

Post-Market Safety (ex-Vigilance and ex-COEN)

Clinical Investigations and Evaluation (ex-CIE)

Borderline & Classification (ex-Borderline and Classification WG)

Standardisation and CTS (new + ex-IVD TG)

Eudamed/UDI WG (ex-Eudamed WG)

Notified Bodies' Coordination (ex-NB-Med)

New & Emerging Technologies (ex-NET)

(with appropriate participation of representatives of patients, healthcare professionals, industry and Notified Bodies)

I. Designation and Monitoring of Notified Bodies

1. Scrutinize and provide opinion regarding assessment reports concerning Notified Bodies

2. Elaborate harmonised criteria for the designation and monitoring of Notified Bodies

II. Monitoring of Conformity Assessment Procedures

Select files for submission of a summary evaluation report by a Notified Body and scrutinize these reports

III. Device Specific Requirements

Elaborate harmonised requirements in relation to certain devices or technologies, including their assessment by Notified Bodies (e.g. CTS for IVD)

IV. Borderline and Classification

Provide opinion on a suggested qualification of a product and the classification of a device (incl. participation in a cross-sectoral advisory borderline group)

V. Post-Market Safety (Vigilance and Market Surveillance)

1. Serve as platform for the coordination of the analysis of certain incidents (e.g. in case of high-risk incidents or divergent opinions of competent authorities)

2. Provide an opinion regarding reactions concerning device types with high incident rates (e.g. device specific requirements and/or enhanced monitoring of conformity assessment)

3. Endorse actions for coordinated national market surveillance (e.g. resource sharing, common projects and information campaigns, see for example Art. 25 of Reg. 765/2008) and monitor the follow-up

4. Provide an opinion on national restrictive measures notified to the Commission pursuant to a safeguard clause or a health monitoring measure

VI. Clinical Investigations (CI)

1. Serve as platform for the coordination of the technical analysis of a single submission for a multi-national clinical investigation

2. Serve as platform for the coordination of restrictive measures (halting, modification, temporary interruption of CI) in case of serious issues arising during the CI

Possible tasks to be fulfilled at EU level under a future regulatory framework for medical devices

I. Designation and Monitoring of Notified Bodies

1. Organise and participate in assessments of Notified Bodies (initial assessment and periodical assessment every 3-5 yrs)

- Option 1: Assessment by "EU assessors" together with the Member State were NB is established
- Option 2: Assessment by a 'joint assessment team' composed of assessors from 2 Member States and 1 EU assessor

2. Provide support for the following activities of the MDEG:

- Scrutiny and delivery of opinion regarding assessment reports concerning Notified Bodies
- Elaboration of harmonised criteria for the designation and monitoring of Notified Bodies, in order to feed into delegated or implementing acts for adoption by the Commission, where necessary

II Monitoring of Conformity Assessment Procedures

Provide support for the following activities of the MDEG:

- Selection of files for submission of a summary evaluation report by a Notified Body and scrutiny of these reports

III. Device Specific Requirements

Provide support for the following activity of the MDEG:

- Elaboration of harmonised requirements in relation to certain devices or technologies, including their assessment by Notified Bodies (e.g. CTS for IVD) in order to feed into delegated or implementing acts for adoption by the Commission, where necessary

IV. Borderline and Classification

Provide support for the following activity of the MDEG:

- Delivery of opinion on a suggested qualification of a product and the classification of a device (incl. participation in a cross-sectoral advisory borderline group) in order to feed into delegated or implementing acts for adoption by the Commission, where necessary

V. Post-market Safety (Vigilance, Post-market Clinical Follow-up and Market Surveillance)

Vigilance:

1. Provide support for the following activities of the MDEG:

- Serving as platform for the coordination of the analysis of certain incidents (e.g. in case of high-risk incidents or divergent opinions of competent authorities)

- Delivery of opinion regarding reactions concerning device types with high incident rates (e.g. device specific requirements and/or enhanced monitoring of conformity assessment)

2. Monitor incident reports, identify trends/signals and ensure appropriate follow-up

Market Surveillance:

3. Provide support for the following activities of the MDEG:

- Endorsement of actions for coordinated national market surveillance (e.g. resource sharing, common projects and information campaigns, see for example Art. 25 of Reg. 765/2008) and monitoring of the follow-up

- Delivery of opinion regarding national restrictive measures notified to the Commission pursuant to a safeguard clause or a health monitoring measure, in order to feed into delegated, implementing or others acts for adoption by the Commission, where necessary

VI. Clinical Investigations (CI)

1. Receive applications from sponsors for multi-national CI as single entry point = single submission

2. Provide support for the following activities of the MDEG:

- Serving as platform for the coordination of the technical analysis of a single submission for a multi-national clinical investigation

- Serving as platform for the coordination of restrictive measures (halting, modification, temporary interruption of CI) in case of serious issues arising during the CI

VII. Development and maintenance of IT tools

1. New IT application for secure transmission of data from Notified Bodies

- Repository of reports regarding the assessment of Notified Bodies

- Notification by Notified Bodies of new applications for conformity assessment concerning high risk devices

- Submission of summary evaluation reports by Notified Bodies for selected devices and follow-up

2. Further development of Eudamed

- More developed vigilance module establishing a data-processing network and allowing a central reporting of incidents by manufacturers

- Central registration of economic operators and listing of medical devices with integration of an Unique Device Identification (UDI) database

- Single submission of applications for multi-national clinical investigations

VIII. External Scientific and Clinical Expertise, Reference Laboratories, Informal Clearing Mechanism

1. Set up a panel composed of clinical and scientific experts in different fields of medical devices and provide administrative support

2. Set up and manage a network of Reference Laboratories in the field of medical devices

3. Prepare mandates for expert opinions upon request of the Commission (e.g. to decide about safeguard clause; to prepare implementing measures etc.)

4. Organise scientific and/or regulatory 'early advice' for manufacturers (in particular SMEs) and/or Notified Bodies

5. Set up and manage an informal (web-based) clearing mechanism to support uniform application of legal requirements for manufacturers, Notified Bodies, competent authorities and other stakeholders

IX. Standardisation*

1. Participate in the development of standards in the field of medical devices at international (ISO, IEC) and European (CEN, CENELEC) level

2. Prepare the Commission's decision on the harmonisation of standards

X. Training and Public Information*

1. Provide or organise training for manufacturers, Notified Bodies and competent authorities on regulatory issues

2. Set up public information tools regarding EU regulatory requirements

XI. International Cooperation*

1. Exchange NCAR Reports through the GHTF NCAR Exchange Programme and other confidential information with certain 3rd countries (e.g. FDA, Health Canada, TGA, PMDA)

2. Participate in international cooperation and harmonisation in the field of medical devices

3. Support the promotion of the EU regulatory model at a global level

* Cross-cutting task which would need to be fulfilled by the experts in the relevant fields.

APPENDIX 9 – OVERVIEW OF THE COSTS AND BENEFITS OF THE PREFERRED POLICY OPTIONS

Preferred Policy Options	Costs	Benefits
Problem 1: Oversight of Notified Bodies		
Policy option 1A: New minimum requirements for Notified Bodies	= (cost-neutral)	enhanced level of patient safety and public health level playing field for Notified Bodies and manufacturers
either **Policy option 1B**: Designation and monitoring of Notified Bodies by an EU body	↑ EU (staff costs for 24 FTE + €200K/y travel expenses) ↓ Member States (main responsibility transferred to EU) ↑ Notified Bodies in case of increased fees for designation/monitoring	enhanced level of patient safety and public health level playing field for Notified Bodies and manufacturers reinforced recognition of CE-marking (smoother functioning of internal market and int'l trade) support of competitiveness and innovativeness of EU medical device industry
or **Policy option 1C**: Designation and monitoring of Notified Bodies by Member States with involvement of "joint assessment teams"	↑ EU (staff costs for 9 FTE + €200K/y reimbursement of nat. assessors + €200K/y travel expenses) = Member States (shared responsibility with existing resources) ↑ Notified Bodies in case of increased fees for designation/monitoring	enhanced level of patient safety and public health level playing field for Notified Bodies and manufacturers reinforced recognition of CE-marking (smoother functioning of internal market and int'l trade) support of competitiveness and innovativeness of EU medical device industry
Policy option 1G: Notification requirement regarding new applications for conformity assessment and possibility for ex ante control	↑ EU (staff costs for 8 FTE + IT infrastructure for notification) ↑ Notified Bodies (€100K/y admin. costs for notifications and follow-up)	enhanced level of patient safety and public health level playing field for Notified Bodies and manufacturers reinforced recognition of CE-marking (smoother

		functioning of internal market and int'l trade) support of competitiveness and innovativeness of EU medical device industry
Problem 2: Post-market safety (vigilance and market surveillance)		
Policy option 2A: Clarification of key terms and of the obligations of the parties involved in the field of vigilance	= (cost-neutral)	enhanced legal certainty ensuring appropriate follow-up of incidents enhanced level of patient safety and public health better functioning of internal market
Policy option 2B: Central reporting of incidents and coordinated analysis of certain high risk incidents	↑ EU (staff costs for 8 FTE + IT infrastructure) = Member States (work sharing with existing resources; no duplication of work) ↓ Manufacturers (single reporting of incidents and coherent reaction throughout EU)	enhanced level of patient safety and public health better functioning of internal market support of competitiveness of EU medical device industry
Policy option 2D: Promotion of cooperation of market surveillance authorities	↑ EU (staff costs for 2 FTE) = Member States (work sharing with existing resources; no duplication of work) = Economic operators (no costs for compliant operators)	increased efficiency of resources spent on surveillance activities enhanced level of patient safety and public health
Problem 3: Regulatory status of products		
Policy option 3B: Creation of a cross-sectoral advisory group on borderline issues and possibility to determine the regulatory status of products at EU level in certain areas	↑ EU (increased workload of COM for preparing and adopting decisions on regulatory status; reimbursement of nat. experts) ↓ Member States (possibility to transfer	enhanced legal certainty enhanced level of patient safety and public health better functioning of internal market level playing field for

	decision-making to EU level; avoidance of legal disputes before nat. courts) ↓ Manufacturers (less compliance costs due to application of a single regulatory regime)	manufacturers support of competitiveness and innovativeness of EU medical device industry
Problem 4: Lack of transparency and harmonised traceability		
Policy option 4B: Central registration of economic operators and listing of medical devices placed on the EU market	↑ EU (major part of budget for IT infrastructure estimated at €2mio/y, decreasing to €1.8mio/y as of 2018) ↓ Member States (responsibility for registration transferred to EU) ↓ Economic operators (estimated reduction of admin. costs of between €81-157mio. due to single instead of multiple registrations)	enhanced level of patient safety and public health increased transparency for patients, healthcare professionals and authorities removal of obstacles to the internal market reinforced confidence in the regulatory system support of competitiveness and innovativeness of EU medical device industry
Policy option 4C: Requirement for the traceability of medical devices	↑ EU (development and management of a European UDI system) ↓ Member States (responsibility for UDI system transferred to EU) ↓ Manufacturers (savings due to single UDI system instead of several incompatible national systems, compensating for costs for UDI codes, labelling & upload of information in UDI database)	enhanced level of patient safety and public health avoidance of fragmentation of the internal market synergies with int'l trading partners introducing UDI systems (e.g. FDA) support of competitiveness of EU medical device industry
Problem 5: Access to external expertise		

Policy option 5B: Designation of an expert panel and reference laboratories	↑ EU (staff costs for 2-3 FTE, reimbursement of experts)	enhanced science-based decision-making by Member States and COM to the benefit of patients, healthcare professionals, public health and manufacturers support of competitiveness and innovativeness of EU medical device industry
Problem 6: Unclear and insufficient obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales		
Policy option 6A: Alignment with Decision 768/2008, additional requirements for authorised representatives and clarification of obligations in the field of diagnostic services	= (cost-neutral)	enhanced level of safety and public health better functioning of internal market
Policy option 6C: Addressing internet sales by soft-law action	↑ EU and Member States (financing of awareness campaigns, portal or others actions)	enhanced level of patient safety and public health increased efficiency of resources spent support of competitiveness of EU medical device industry
Problem 7: Management of the regulatory system		
either **Policy option 7A:** Extension of the responsibility of the European Medicines Agency (EMA) to medical devices and creation of a Medical Device Expert Group at this agency	↑ EU (€1.4mio/y for reimbursement of nat. experts for meetings of MDEG and sub-groups; transfer of tasks to EMA as such would not lead to costs in addition to those mentioned under the policy options above/below, except for agencies overhead costs) = Member States (work sharing with existing resources)	effective and efficient management for the benefit of patients, healthcare professionals, manufacturers and authorities synergies in the field of drug-device combination and borderline products consistency with majority of Member States and int'l partners support of competitiveness and innovativeness of EU medical device industry
or **Policy option 7C:** Management of the medical device regulatory system by the European Commission and creation of a Medical Device Expert Group supported by this	↑ EU (€1.4mio/y for reimbursement of nat. experts for meetings of MDEG and sub-groups;	effective and efficient management for the benefit of patients, healthcare professionals, manufacturers

institution	accomplishment of tasks by COM would not lead to costs in addition to those mentioned under the policy options above/below) = Member States (work sharing with existing resources)	and authorities use of existing resources support of competitiveness and innovativeness of EU medical device industry
Problem MD-1: Scope - regulatory gaps or uncertainties		
Policy option MD-1B: Regulate products manufactured utilising non-viable human cells and tissues as medical devices	↑ Manufacturers (costs for conformity assessment under MD legislation)	harmonised level of patient safety and public health creation of an internal market support of innovation
Policy option MD-1C: Regulation of certain implantable or other invasive devices without a medical purpose within the MDD	↑↓ Manufacturers (some manufacturers increased costs for conformity assessment under MD legislation; other manufacturers reduced costs due to single regulatory regime for similar products; e.g. corrective and non-corrective contact lenses)	harmonised level of patient safety and public health creation of an internal market
Policy option MD-1F: Harmonized regulation of the reprocessing of single-use medical devices (SUD)	↑ SUD reprocessors (need to enhance their validation process + additional labelling requirement) – mitigation of these costs by the creation of a single market for reprocessed SUD ↑ Manufacturers (decrease of the sales volumes for original SUD)	enhanced level of patient safety and public health enhanced information of patients and healthcare professionals creation of the conditions for an internal market
Problem MD-2: Adaptation of legal requirements to technological, scientific and regulatory developments		
Policy option MD-2B: Review of the classification rules and essential requirements	= (cost-neutral)	enhanced level of patient

regarding specific devices or technologies		safety and public health level playing field for manufacturers better functioning of internal market support of competitiveness and innovativeness of EU medical device industry
Problem MD-3: Clinical evaluation and clinical investigations, in particular those carried out in more than one Member State		
Policy option MD-3A: Introduction of the term "sponsor" for clinical investigations and further clarification of key provisions in the field of clinical evaluation and investigations	= (cost-neutral)	enhanced level of patient safety and public health better functioning of internal market
Policy option MD-3B: Coordinated assessment of multi-national investigations by the competent authorities of the Member States where the investigation is performed	↑ EU (staff costs for 5 FTE, IT infrastructure for single submission) = Member States (work sharing with existing resources; no duplication of work) ↓ Manufacturers/sponsors (single submission; consistent outcome of technical assessment)	enhanced level of patient safety and public health support of competitiveness and innovativeness of EU medical device industry
Problem IVD-1: Scope – regulatory gaps or uncertainties		
Policy option IVD-1C: Clarify the scope of the exemption for "in-house" tests, require a mandatory accreditation for "in-house" tests manufacturers and subject high risk (class D) "in-house" tests to the requirements of the IVDD	↑ Laboratories (accreditation according to ISO 15189 or similar requirements + submission of class D "in house" IVDs to the requirements of the IVDD)	enhanced level of patient safety and public health enhanced legal certainty improving the functioning of internal market level playing field for laboratories
Policy option IVD-1F : Amendment of the legal definition of an IVD to include tests providing information "about the predisposition to a medical condition or a disease"	↑ Manufacturers of genetic tests which currently escape from the IVDD (need to demonstrate compliance, usually with the involvement of a Notified Body in the	enhanced level of patient safety and public health enhanced legal certainty improving the functioning of the internal market level playing field for

	conformity assessment procedure)	manufacturers
Policy option IVD-1G: No legislative change regarding companion diagnostics	↑ Manufacturers (these tests are currently self-certified by the manufacturers but, with the GHTF classification system, they will require the involvement of a notified body in the conformity assessment procedure – see costs and benefits of policy option IVD-2B)	enhanced level of patient safety and public health
Problem IVD-2: Classification of IVDs and their appropriate conformity assessment, including batch release verification		
Policy option IVD-2B: Adoption of the GHTF classification rules and adaptation of the conformity assessment procedures to the relevant GHTF guidance	↑ Manufacturers (adaptation costs and increased involvement of notified bodies in the conformity assessment for class B and C IVDs – mitigation of these costs by the advantages in terms of competitiveness and international trade)	enhanced level of patient safety and public health fostering international trade support of competitiveness, innovativeness of EU medical device industry
Policy option IVD-2C: Batch release verification for high risk IVDs by the manufacturer under the control of a Notified Body (legislative clarification)	↓ Manufacturers (clarification that batch release testing by an independent laboratory could not be required by the individual Member States)	enhanced legal certainty improving the functioning of internal market level playing field for manufacturers support of competitiveness of EU medical device industry
Problem IVD-3: Unclear legal requirements and need for their adaptation to technological progress		
Policy option IVD-3B: Legislative clarification of the requirements for the clinical evidence for IVDs	= (cost-neutral)	enhanced legal certainty improving patient safety and public health better functioning of internal market

Policy option IVD-3E: Clarification of the legal requirements in respect to point-of-care or near-patient IVDs	= (cost-neutral)	enhanced legal certainty improving patient safety and public health better functioning of internal market
Policy option IVD-3G: Alignment with the MDD where appropriate	= (cost-neutral)	enhanced legal certainty improving patient safety and public health better functioning of internal market support of competitiveness and innovativeness of EU medical device industry

APPENDIX 10 – LEGAL FORM OF THE REVISION OF THE MEDICAL DEVICES DIRECTIVES

The two questions which need to be assessed and decided as regards the legal form are

(1) whether medical devices (MD) and in vitro diagnostic medical devices (IVD) should be regulated together, i.e. within one legislative act or within two separate legislative acts, and

(2) whether the current directives should be transformed into a regulation.

1. Options considered

Option 1: Two separate legislative acts: one act concerning MD and one act concerning IVD

Option 1 would consist in the adoption of a legislative act which merges the AIMDD and the MDD, codifies them with their amending directives[27] and at the same time amends existing provisions. A separate legislative act would be adopted for IVD, codifying and amending the IVDD.

Option 2: One legislative act concerning medical devices and IVD

Option 2 would consist in a merger (including codification and revision) of all three medical devices directives (AIMDD, MDD and IVDD) in one legislative act.

Option 3: Maintaining the legal form of a directive

According to option 3, the legislative act(s) outlined in policy options 1 and 2 would continue being in the legal form of a directive in terms of Article 288, paragraph 3, TFEU.

Option 4: Transforming the current directives into a regulation

Option 4 would mean adopting the legislative act(s) outlined in policy options 1 and 2 in the legal form of a regulation in terms of Article 288, paragraph 2, TFEU.

2. Analysis of options

2.1. Option 1 v. option 2 (one or two proposals for MD and IVD)

The AIMDD and the MDD have been separate for historic reasons. Their provisions have converged over time, in particular through amendments introduced by Directive 2007/47/EC and separate regulation of AIMD, on the one hand, and other medical devices, on the other hand, is not justified on any grounds any more. The merger and codification of the AIMDD and MDD has already been envisaged in the 2005 Simplification Programme of the Commission[28].

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[27] Including Commission Directive 2003/12/EC on the reclassification of breast implants and Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements.

[28] COM(2005)535.

Option 1 and option 2 would both result in the adoption of new legislative acts repealing the existing directives. For purely formal reasons, this will have the impact that existing documentation (of manufacturers, Notified Bodies, authorities) that refers to the current directives (e.g. information brochures, websites, forms for certificates and declarations of conformity) would require updating in order to refer to the new legislative texts. If phased in over a sufficient period of time the costs will not bee very high since product developments (average life-cycle 18 months) and legislative changes in any case would require review of existing documentation.

The overall impact of a merger of the AIMDD and the MDD would be positive in terms of simplification, easier management and international alignment. Since the differences between the AIMDD and the MDD are very limited, their merger will have no substantial consequence. Already today, many Member States regulate AIMD as class III medical devices within their regulations applicable to other MD. The few specific provisions applicable to AIMD (e.g. accessories) could be maintained where necessary. Other provisions which unintentionally are out of tune between the two directives could be aligned which would have the positive impact to streamline the applicable requirements, in particular for manufacturers of AIMD which often also produce other devices subject to the MDD. A merger of the AIMDD and the MDD would also align EU legislation with guidance documents of the GHTF that do not distinguish between MD and AIMD, but consider the latter in the context of the GHTF classification criteria as class D devices[29].

In the 2008 public consultation on the recast of the medical devices directives, the question was raised whether, in addition to a merger of the AIMDD and the MDD, also the provisions of the IVDD should be incorporated in one legislative act applicable to all medical devices, including IVD (see policy option 2). As regards this question, it could be argued that the horizontal aspects of the revision which apply to all devices including IVD, such as the designation and monitoring of Notified Bodies or the vigilance procedure, would be better regulated within one and the same legislative act in order to avoid discrepancies arising over time. The majority of stakeholders, however, in particular industry, who responded to the 2008 public consultation were in favour of regulating IVD in a separate piece of legislation[30] in order to respect the specificities of the products (different risks and functioning).

In fact, if policy option 2 was chosen, specific provisions of the one legislative act would need to be applicable only to IVD (e.g. in house tests, clinical evidence, specific essential requirements, classification rules for IVD) while the application of other parts would need to be excluded in order to take account of the specificities of IVD (reprocessing of single-use devices, clinical investigations, specific essential requirements, classification rules for MD). This could have a negative impact on the readability of the legislative act which would need to have parts applicable to all devices, other parts applicable only to MD and again other parts applicable only to IVD. This would run counter to a simplification of the EU legislation. The handling of a more complex legislative text would likely be considered unnecessarily burdensome for the IVD industry which is relatively homogenous with most manufacturers, mostly SMEs, producing only IVD and not other MD.

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[29] See GHTF/SG1/N15:2006 – Principles of Medical Device Classification under Rule 8.

[30] See section 1 of the Summary of responses to the public consultation.

In addition, the separation of requirements for medical devices other than IVD and for IVD is also the trend at international (GHTF) level where specific guidance documents have been adopted for MD other than IVD[31], or only for IVD[32] whilst some other guidance documents are currently being revised to introduce specific parts for IVD[33].

2.2. Option 3 v. option 4 (Directive or Regulation)

Pursuant to Article 296 TFEU the type of the legislative act shall be selected in compliance with the applicable procedures and with the principle of proportionality.

A Directive in terms of the 3rd paragraph of Article 288 TFEU (option 3) would be binding as to the results to be achieved but would "*leave to the national authorities the choice of form and methods*". A Regulation in terms of the 2nd paragraph of Article 288 TFEU (option 4), would "*be binding in its entirety and directly applicable in all Member States*".

The pros and cons of both legal form can be summarised as follows:

Adoption of a regulation:

- Directly applicable in all Member States without the need of transposition into national law with a single regulatory framework for medical devices as reference for economic operators (this would also apply to future amendments);

- National differences regarding the date and/or way of transposition would be eliminated which would enhance a level playing field in the internal market. [NB: Whilst *late* transposition was very frequent in the case of the last amending Directive 2004/47/EC *incorrect* transposition of the medical devices directives has not been a major problem so far. The fragmentation of the internal market rather results in divergent interpretation and implementation practices which occur with regulations and directives alike.] The adoption of a regulation, however, would require that all Member States repeal their existing national regulations in the field of medical devices and that the European Commission would need to monitor this process;

- More 'freedom' to conceive a new, more user-friendly legislative text;

- Faster application because no need for a transposition deadline in addition to a deadline for application.

Adoption of a directive:

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31 SG5/N2R8:2007 – Clinical Evaluation, SG5/N3:2010 – Clinical Investigations; SG5/N4:2010 – Post-market clinical follow-up studies.

32 GHTF/SG1/N045:2008 – Principles of In Vitro Diagnostic (IVD) Medical Devices Classification; GHTF/SG1/N046:2008 – Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices; SG1-N63:2011 – Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices.

33 SG1(PD)/N068R05 on Essential Principles; GHTF/SG1/N070:2011 on Label and Instructions for use.

- Member States could maintain a regulatory framework for medical devices at national level in coherence with their national regulatory system where the product regulation often is interlinked with areas of total national competence (e.g. requirements regarding the use of specific devices or their prescription; reimbursement);

- Possibility to use the technique of a "recast"[34]. This would prevent that provisions in the AIMDD/MDD/IVDD which the Commission does not intend to modify, in particular those recently amended by Directive 2007/47/EC (application as of March 2010), are subject to substantial changes, e.g. most essential requirements incl. labelling, classification rules and requirements regarding clinical evaluation. If all aspects of the current directives were subject to negotiations, the compliance costs for manufacturers (especially SME) would risk to increase, but also the acquired level of safety could be modified;

- The envisaged rules regarding medical devices are less prescriptive and detailed than legislation in the field of chemicals, cosmetics, and food and feed, where many EU directives have been replaced in recent years by regulations. Basically all sector-specific EU legislations in the areas governed by the "new approach" have been adopted in the form of directives. There would be no concerns with regard to the principle of proportionality as guiding principle for the choice of the type of legislative act (Article 296 TFEU);

- Adoption of a directive would not prevent the Commission to adopt subsequent delegated or implementing acts in the form of a regulation.

3. Conclusion

Between option 1 and option 2, the first option provides clear advantages and should be retained. The choice of the type of legislative act is less obvious and more a question of political convenience than of legal constraint. If the EU rules on medical devices were to be conceived today from scratch, the form of a regulation would likely be chosen since it would ensure a higher level of coherence as regards protection of health and safety, on the one hand, and internal market, on the other hand. It would also lead to less administrative burden on the authorities since adoption and management of the legislation would not need to be multiplied by 27. The initiative to revise the whole existing regulatory framework for medical devices therefore offers a unique opportunity to transform directives into regulations.

Based on the above analysis, options 1 and 4 are retained. The AIMDD and the MDD should be merged and transformed into a Regulation concerning medical devices. The IVDD should be transformed into a Regulation concerning in vitro diagnostic medical devices but kept as separate legislative act.

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[34] The Legal Service of the Commission confirmed that the recast technique could be used for the revision of the medical devices directives despite the fact that the new legislative measures would be based on an additional Treaty article, i.e. Article 168(4)(c) TFEU. However, different opinions exist as to whether a directive could be "recast" into a regulation, see Opinion of 14.11.2008 of the Consultative Group of the Legal Services of the Commission, the European Parliament and the Council.

APPENDIX 11 – ANALYSIS OF THE PIP BREAST IMPLANTS CASE IN THE LIGHT OF THE ENVISAGED REVISION OF THE EU REGULATORY FRAMEWORK FOR MEDICAL DEVICES ("STRESS TEST")

Working document for meeting on medical devices 4.5.2012

PIP case Chronology of facts[35]	EU legislation applicable at the time of the facts (Directive 93/42/EEC on medical devices, hereafter MDD[36 37])	EU legislation applicable since March 2010 (amendments introduced by Directive 2007/47/EC)	Envisaged amendments to be presented in the Commission proposals[38] (already envisaged prior to PIP; additional amendments due to lessons learned from PIP are marked with an *)
1. Pre-market			
1.1. Conformity assessment			
In July 1997, the notified body TÜV Rheinland[39] (identification number 0197) carried out the first	For the conformity assessment of breast implants, notified bodies as independent third parties must be	The conformity assessment process for class III MD has not	On a case-by-case basis, individual conformity assessment procedures for **high risk or novel**

[35] According to the information at the disposal of the Commission.

[36] National transposition measures to be applicable as of 1 January 1995.

[37] The transitional provisions for devices in conformity with preceding national regulations do not seem to be relevant for this case.

[38] Subject to adoption by the Commission after completion of the internal procedures (inter-service consultation etc.).

[39] TÜV Rheinland Product Safety GmbH, now TÜV Rheinland LGA Product GmbH.

audit of the manufacturer PIP in the context of the conformity assessment regarding soft tissue breast implants. In 1997, TÜV Rheinland issued a quality system certificate in accordance with Annex II MDD. After recertification audits in July 2002 and Sept. 2007 , TÜV Rheinland renewed the quality system certificate. In 2004, after the reclassification of breast implants, TÜV Rheinland issued also a design dossier examination certificate in accordance with Annex II, sect. 4, MDD. This certificate was renewed in 2009. According to the information provided by the German authorities, the assessment teams consisted of several auditors (lead auditors and auditors) and included qualified personnel for	involved prior to implants being placed on the market. Manufacturers may choose any notified body that is designated for the required tasks. **Until 2003**, breast implants were classified as **class IIb** devices (Annex IX, rule 8, MDD). The notified body's involvement was **thus limited to verification of the manufacturer's quality system** (Annex II, without sect. 4, MDD). Certificates issued in accordance with Annex II have a validity of 5 years. In 2003, on the request of France and UK, breast implants were **reclassified as class III** devices by **Commission Directive 2003/12/EC**. Since 1.9.2003 (or since 1.3.2004 regarding breast implants already on the market), the conformity assessment by notified bodies consists of the assessment of - **the manufacturer's quality system and** - **the design dossier related to the device**. It is required that the body's assessment team includes at least	been significantly amended. But is has been reinforced for IIa and IIb devices for which, in addition to the quality system, notified bodies must examine the design documentation on a representative basis (sampling regime).	**devices** shall be subject to **scrutiny by a committee of national experts** (with rapporteur and co-rapporteur system) prior to the issuance of certificates by the notified body. Possibility to adopt, by implementing or delegated acts, **mandatory requirements** for certain devices regarding the documentation to be submitted by manufacturers to notified bodies and their assessment. * Notified bodies, in the context of the design dossier examination, **should carry out adequate physical or laboratory tests** of the device or of its crucial components or require manufacturers to carry out such tests under their supervision (and possibility to consult reference laboratories where those are designated for specific risks or devices). * Manufacturers should have available in their organisation a **qualified person** responsible for the regulatory compliance of the device released on the market with appropriate qualification, legal status and personal liability.

the device group "soft tissue implants".	one member with past experience of assessments of the technology concerned.		
1.2. Safety and performance requirements, incl. clinical evaluation			
PIP's technical documentation is not available to the Commission. But according to information at its disposal, PIP declared using silicone gel approved for medical use (e.g. *Nusil*©). There is no evidence that at the moment of the first and subsequent conformity assessments, the breast implants did not comply with the legal requirements. It is not clear at what moment and during which periods PIP changed the design of and the material used for the implants in a way that the safety and performance requirements expected from such a medical device were not met any more (e.g. use of industrial grade	Annex I MDD lays down the **essential requirements** to be met by medical devices. The basic requirement is that "*devices must be designed and manufactured in such a way that [...] they will not compromise the clinical condition or the safety of patients, or the safety and health of users [...] provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety*". Specific requirements exist regarding the **chemical, physical and biological properties** of	The essential requirements were reviewed and several amendments introduced such as the requirements to take into account results of validated biophysical or modeling research or to pay special attention to CMR substances.	The essential requirements shall be further updated in the light of technological progress and international guidance. Moreover, there shall be the possibility to adopt, by implementing or delegated acts, **mandatory requirements** for certain devices, incl. the required clinical evaluation.

[40] In 2001, the Commission published Communication COM(2001)666 on Community and national measures in relation to breast implants. Among others, it contains detailed guidance on essential safety requirements and conformity assessment schemes of Directive 93/42/EEC in relation to breast implants.

[41] See EN ISO 14607 which addresses in particular intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

silicone instead of medical silicone, increased and premature rupture, oozing of silicone).	devices (e.g. toxicity and biocompatibility of used material, minimization of risk due to leakage of substances). There are no specific requirements for implants. As regards breast implants, in 2001, the Commission provided guidance[40] as to which aspects should be particularly looked at and issued a mandate for a standard that lays down detailed specifications regarding breast implants[41]. According to Annex X MDD, as a general rule, demonstration of conformity with the characteristics and intended performances must be based on **clinical data**, in particular in the case of implantable and class III devices.	The requirements regarding **clinical evaluation** have been **significantly strengthened**. It is now always required that demonstration of conformity with the essential requirements must include a clinical evaluation (Annex I, sec. 6a MDD). In the case of implantable and class III devices, clinical investigations must be conducted to obtain the data for the clinical evaluation, unless it is duly justified to rely on existing clinical data (Annex X, sec. 1.1a MDD). Manufacturers are obliged to conduct a post-market clinical follow-up as part of the post-	It shall be **further clarified** in the legislation that "equivalence" with another implantable or class III device is not a sufficient justification to omit clinical investigations. Furthermore, manufacturers shall make publicly available a **summary of the safety and performance data**, incl. the relevant clinical data. Criteria for the manufacturer's **post-market clinical follow-up (PMCF)**, as part of his post-market surveillance plan (PMS), shall be laid down.

		market surveillance regarding their devices (Annex X, sec. 1.1c MDD).	
1.3. Designation and monitoring of notified bodies			
In 1994, TÜV Rheinland has been designated by Germany as notified body in the field of medical devices; the designation scope includes soft tissue implants. Between 1994 and 2011, the German authorities conducted at least once a year surveillance assessments (with 2-6 assessors). In 2002 and 2003, the assessment was 'peer reviewed' by an assessor of, respectively, the Dutch and the Danish authorities. There is no evidence that TÜV Rheinland lacked the necessary competence to conduct conformity assessments related to breast implants.	Member States are responsible for the designation and monitoring of notified bodies in accordance with the minimum criteria laid down in Annex XI MDD, but they are vague. In 1998, the requirement was added that notified bodies need to have "*sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified*". No provisions exist as to how the Member States must conduct the control on notified bodies. Since 2000, designating authorities of the Member States meet in the Notified Body Operations Group (NBOG) to improve the overall performance of notified bodies in the medical devices sector by promulgating examples of best practice to be adopted by both notified bodies	The minimum criteria for notified bodies and the designation process have not been amended. But the Commission has been empowered to adopt, by Comitology procedure and in the light of technical progress, detailed measures necessary to ensure consistent application of the minimum criteria to be met by notified bodies for their designation by the Member States. However, efforts had been focussed on a systematic revision of the entire regulatory framework where the designation and monitoring process should be addressed.	The **minimum requirements** to be met by notified bodies laid down in Annex XI MDD shall be **reinforced** and made more detailed. Moreover, the **designation and monitoring process** shall fundamentally be revised. In the future, a Member State shall only designate a body after a **'joint assessment'** conducted with experts from the Commission and other Member States. The draft designation shall be submitted to a committee of national experts that can issue a negative opinion. The monitoring of notified bodies shall also regularly be conducted by a 'joint assessment team'.

	and supervising authorities. In 2003, NBOG adopted a Designating Authorities Handbook to provide guidance for designating authorities in the execution of their responsibilities for the designation and monitoring of notified bodies.		
2. Post-market			
2.1. Surveillance by notified body			
As mentioned above, it is unclear as of when and in which periods PIP silicone breast implants did no longer meet the safety and performance requirements of the MDD. There is no evidence that PIP informed TÜV Rheinland about changes to the design of silicone breast implants such as the change of the design of the devices or the material used for the filling. Between 1998 and 2010, TÜV Rheinland conducted 9 regular surveillance audits (plus 2 recertification audits). Moreover, an extraordinary audit (observed by the German authorities) was conducted in February 2001 further to the UK's Medical Device Alert 2000(07) of	As part of the surveillance, the notified body must periodically carry out **appropriate inspections and assessments**. It **may pay unannounced visits** to the manufacturer and **may carry out or ask for tests** in order to check that the quality system is working properly. The manufacturer is required to inform the notified body of any changes to the approved quality system and/or product design.	For the surveillance by the notified body, the manufacturer must provide it, among others, with clinical evaluation and the results of the post-market clinical follow-up. But there is still no legally defined role of notified bodies in the vigilance system (only addressed in some guidance documents).	The **role of notified bodies in the vigilance system** shall be clarified (e.g. obligation of manufacturers to inform their notified body about incidents; access of notified bodies to the future EU vigilance database; obligation of notified bodies to analyse vigilance data and to take appropriate action in relation to audits and certificates). In addition, there shall be the possibility to set mandatory criteria for surveillance audits. * In the context of their surveillance over manufacturers, notified bodies **shall randomly** perform **unannounced factory inspections** and, in this context, check adequate samples from the production or the manufacturing

December 2000 regarding PIP hydrogel breast implants. As a result, hydrogel implants were withdrawn from the scope of the certificate by TÜV Rheinland. But the findings did not have an impact on the certification of silicone breast implants.			process. The frequency of unannounced visits should be defined in a subsequent implementing measure to ensure a level playing field. * Notified bodies should be required that the composition of their assessment teams assures continuous objectivity and neutrality including a **rotation of auditors** at appropriate intervals. * It could also be foreseen that, at least for crucial components, a notified body should check coherence between quantity of purchased raw material/ components and quantity of output of finished products. The problem is that such obligation comes close to accountability check which does not fall in the competence of notified bodies. * Negative results of an audit shall be communicated to the Member State where the manufacturer or authorised representative is established.
2.2. Market surveillance by authorities			

In 2000 and 2001, the French authorities took a number of measures regarding breast implants, such as a temporary suspension of their placing on the market and putting into service and the request to all manufacturers to provide additional documentation for their reintroduction on the market. Further to correspondence between the French authorities and PIP, AFSSAPS conducted an inspection of PIP in June 2001 in the context of the 'breast implant' campaign and found several non-conformities. Further to extensive correspondence and submission of additional reports by PIP, AFSSAPS concludes in Dec. 2001 that the non-conformities have been remedied. AFSSAPS then conducted inspections of the other breast implants manufacturers.	There is a general requirement that Member States must ensure that only compliant devices are placed or put into service on their markets (Article 2 MDD). But there are no specific requirements in the medical device legislation as to how Member States should conduct the surveillance. Regulation 765/2008[42] (applicable since 1.1.2010) provides general requirements as regards Member States' market surveillance obligation (including proper powers and resources of national authorities and appropriate measures such as physical or laboratory checks). In addition to the product related conformity assessment, a 'manufacturing authorisation' by an authority is not required by EU legislation.	This situation has not changed.	Specific provisions regarding market surveillance shall be introduced in the medical device legislation, such as the obligation to conduct **periodic inspections** (physical or laboratory checks on samples) and the coordination of surveillance programmes. Negative findings should be communicated to the responsible notified body. Member States shall also be obliged to set "effective, proportionate and dissuasive" **penalties** in case of violation of the legal obligations and notify them to the Commission.
On 29 March 2010, the French authorities (AFSSAPS) adopted a decision to recall PIP silicone breast implants from the market	Article 8 and Article 18 require Member States to take action against unsafe and/or non-compliant devices.	This situation has not changed.	The legal instruments for Member States to take restrictive measures against unsafe and/or non-compliant devices shall be

[42] Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products.

and to suspend their placing on the market, distribution, export and use.			clarified to enhance legal certainty for authorities when applying restrictive measures.
On 9 April 2010, the French authorities formally notified the Commission of their decision of 29 March. On 26 April 2010, the Commission informed all EU Member States (PermReps) about the situation and requested them to take the necessary measures to prohibit any placing on the market, distribution, putting into service or use of the PIP implants as well as to alert the medical professionals. In the following weeks and months, Member Sates adopted measures at national level to withdraw the devices from their markets.	National measures that restrict or prohibit the placing on the market of unsafe and/or non-compliant devices must be notified to the Commission and the other Member States. The Commission shall keep Member States informed about progress and outcome of the safeguard clause procedure. (Article 8 and Article 18(b)).	In Article 8 (safeguard clause), an empowerment has been added to enable the Commission to adopt, by Comitology procedure, measures regarding the prohibition or restriction of unsafe products.	Clarification of the conditions when the Commission shall be empowered to take a restrictive measure against unsafe and/or non-compliant devices. Expertise shall be available to the Commission (in house and external experts, e.g. Medical Advisory Board) to help to take a decision on a safeguard clause and to take a measure against unsafe and/or non-compliant devices.
2.4. Vigilance			
A high number of ruptures of PIP implants occurred. Only a limited number seemed to have been reported to national authorities, in particular the French AFSSAPS	Manufacturers must have a systematic procedure in place to review experience gained from their devices on the market (post-market surveillance plan, PMS)	The provision regarding the manufacturer's obligation to have a PMS has been reinforced and extended to post-market clinical follow-up as a continuous and	The obligations regarding the reporting of incidents and the follow-up shall be clarified. In the future, incidents shall be reported by manufacturers to a

and the UK's MHRA, that found unusual high rate (but still below 1%) of premature rupture. On the basis of incident reports from healthcare professionals in France in 2007 (8 incidents = 0.11%), 2008 (27 incidents = 0.41%) and 2009 (29 incidents = 0.56%), AFSSAPS investigates the trend of higher than usual ruptures of PIP implants. But PIP seemed to have received complaints from users (found by AFSSAPS during their inspection in March 2010) that had not been reported to AFSSAPS. This data, after analysis by AFSSAPS, shows rupture rates of between 3.5% (in 2007) to 9.39% (in 2009). In parallel, on the basis of incident reports in the UK, MHRA investigates and concludes that the ruptures of PIP implants (in absolute terms still below 1%) occur unusually early after implantation. MHRA contacted PIP on 22.1. and 18.3.2010.	and are obliged to report incidents[43] to the national authorities. National authorities are obliged to record and evaluate centrally the incidents brought to their attention. But these only concern the incidents reported at national level. Member States are obliged to ensure that manufacturers are informed about incidents reported by healthcare professionals (no EU obligation for healthcare professionals to report). The problem in the present case is that from the current 'incident' definition in the legislation, it is not clear if the individual rupture of a breast implant is to be considered as a "serious deterioration of the state of health" and therefore subject to the reporting requirement or not. Currently, there is no legal obligation of manufacturers to	active update of the clinical evaluation.	**central vigilance database** (part of Eudamed, managed by the Commission) accessible to Member States and notified bodies. The public shall have access to information about measures taken. Manufacturers shall also be obliged to report "trends", i.e. accumulation of adverse events that individually do not need to be reported. Notified bodies would be obliged to analyse vigilance data and to take appropriate action in relation to audits and certificates. Furthermore, in the case of incidents that occur in several Member States, authorities shall **coordinate their assessments** under the lead of a coordinating authority and with support of the Commission. The Commission shall have the necessary resources to analyse reported incidents to identify

[43] Incidents are defined in Directive 93/42/EEC as "(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".

AFSSAPS is informed by MHRA on 6.4.2010. In February 2010, PIP claims in a letter to MHRA that the rupture rate was only 0.3% and provides statistics about sales, ruptures and explantations regarding UK. There was likely significant underreporting by plastic surgeons to the national authorities.	report 'trends', i.e. the accumulation of adverse events that individually do not need to be reported. Moreover, there is no legal obligation of manufacturers to inform their notified body about incidents or field safety corrective actions (some notified bodies oblige manufacturers in their contracts to notify them of vigilance issues). The operation of the vigilance system has already been further detailed by non-binding guidelines (MEDDEVs) which address the issue of trend reporting and the role of notified bodies.		signals and trends which would need action at EU level (e.g. harmonised product requirements). Commission shall be empowered to adopt EU wide measure to ensure uniform reaction to incidents. * Measures could be introduced enhancing the reporting of suspected incidents by healthcare professionals and patients (in analogy to the new pharmacovigilance provisions in Art 107a Dir. 2001/83/EC and Art 25 Reg. 726/2004).
On 30 March 2010, the French authorities alerted the other Member States about increased frequency of incidents in relation to PIP silicone breast implants and about their decision of 29 March 2010 to recall PIP silicone breast implants from the market and to suspend their placing on the market, distribution, export and use.	Member States are obliged to inform the other Member States and the Commission about outcome of evaluation of incidents (Article 10(3) MDD).	Article 10 MDD has been reworded and now requires information about measures taken or contemplated to minimise recurrence of incidents. In addition, the Commission is empowered to adopt, by Comitology procedure, the procedures to implement the Article on vigilance.	A process for the coordination of the assessment of vigilance cases affecting several Member States shall be established (see above).
In 2010 and 2011, exchange of views and update of state of play during informal meetings of the Medical Device Expert Group	MDEG, vigilance and other Commission working groups do not have any statutory basis.	This situation has not changed.	A committee of medical devices experts designated by the Member States shall be set up and supported by the Commission; a

(MDEG) and Vigilance working group			sub-group should be dedicated to vigilance and market surveillance issues.
2.5. Traceability			
PIP did not keep records of the whereabouts of their products. Member States have difficulties identifying the women who received PIP implants.	No traceability requirements in the legislation.	This situation has not changed.	Traceability requirements shall be introduced in the new legislation. Economic operators shall ensure **traceability up and down the distribution chain**. In addition, based on a risk-based approach, traceability of devices shall gradually be implemented by means of a **Unique Device Identification** (UDI) system. * Patients should obtain an "implant card" with key information about the implanted device, incl. warnings or precautions to be taken (e.g. compatibility with diagnostic devices) and expected life cycle and recommended regular follow-up checks.
It seems that PIP produced silicone breast implants also for other companies that marketed them with another name under their own names (so called "Own Brand Labellers", OBL). E.g. the Dutch company Rofil sold implants made by PIP under its	An OBL is considered a manufacturer in terms of the MDD and must meet all the relevant requirements. The Commission has clarified this with an interpretative document in 2008.	A provision has been introduced extending the conformity assessment procedure regarding the manufacturer's quality system to third parties that carry out the design, manufacture, testing etc. on behalf of the manufacturer.	OBL shall continue to be considered as manufacturer. They shall be required to provide information about the original equipment manufacturer (OEM) and about identical devices placed on the EU market under different names.

own name as "M-Implants". The company went bankrupt but seems to have been reestablished in Cyprus. Company structures, bankruptcies and marketing practices are dubious and create additional confusion as to the identification of women having received implants made by PIP. On 20 January 2012, the German authorities informed that the German company GFE Medizintechnik GmbH presumably during the period September 2003 and August 2004 purchased PIP silicone breast implants, processed them with titan and sold them under the name "Tibreeze". The company also went bankrupt.			
3. Risk management and recommendations to patients			
Between 21 December 2011 and 4 January 2012, meetings (by teleconference) of the Health Security Committee were organized by the Commission to exchange information and coordinate follow-up by national authorities.	No provisions in the medical devices legislation. The EU Health Security Committee was set up by the Council of Health Ministers in 2001. It is chaired by the Commission and made up by officials from national governments.	This situation has not changed.	A **committee of medical devices experts** designated by the Member States shall be set up and supported by the Commission. Besides its regular meetings, it would also be convened in crisis situations and provide the platform for regular and structured information exchange between national authorities.

Different recommendations to patients by Member States. In January 2012, Commission has given a mandate to SCENIHR to provide a common risk assessment with regard to PIP breast implants, based on information provided by the Member States	No provisions in the medical devices legislation. The mandate to SCENHIR is given in accordance with Article 2(3) of Commission Decision 2008/721[44] (urgency procedure). But there is no scientific EU body specialised in medical devices[45].	This situation has not changed.	A Medical Advisory Board (with possibly specialised expert panels) composed of external scientific experts in the field of different medical disciplines shall be set up to provide scientific advice to the Commission, Member States, notified bodies and manufacturers. Also EU reference laboratories and a network of national reference laboratories shall be set up for certain hazards or products groups.
4. International			
Between 1996 and 2005, the US Food and Drug Administration (FDA) conducted several inspections of PIP with regard to saline breast implants. Some of the inspections detected major deficiencies regarding quality system and manufacturing. Neither the French nor the German authorities were informed of the FDA inspections and their	No international treaty in place regarding international cooperation. The Global Harmonization Task Force (GHTF) for medical devices (AUS, CAN, EU, JPN, US) is a voluntary regulatory cooperation. Confidentiality arrangements between FDA and European authorities were agreed only later (e.g. with AFSSAPS in 2005 with	International cooperation and information exchange remains voluntary. According to the new Article 20a about cooperation at EU level, such cooperation **may** be part of initiatives developed at international level.	The legal basis should be reinforced for the international cooperation and the exchange of information with 3rd country regulatory authorities, e.g. regarding audits and incidents. On the basis of reciprocity, 3rd countries shall be given access to the future EU vigilance database.

[44] Commission Decision setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment.

1. [45] FROM 1997 TO 2004, A SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES DID EXIST.

findings.	DG ENTR, now DG SANCO, in 2007).		
On 10 January 2012, an information note was sent to 3rd countries about available information regarding PIP.	At international level, cooperation is voluntary. In 2005, a National Competent Authority Report (NCAR) exchange programme has been set up by the GHTF with some other participating 3rd countries in order to facilitate the dissemination of important information regarding adverse events related to medical devices. No traceability requirements as regards exported products.		The current NCAR exchange programme shall be further deepened and extended in the context of the new International Medical Device Regulators' Forum (IMDRF). The UDI system shall be based on a globally recognized standard (currently being developed in the context of the GHTF and further pursued by the new IMDRF).