1) SCOPE

Today the legislative framework for medical devices in Europe comprises three main Directives and the six implementing or modifying Directives. The three main Directives cover three main device groups: active implantable medical devices, medical devices and \textit{in vitro} diagnostic medical devices. However, the reason for having three is more historical than technical or legal. While recognising certain specificities in relation to \textit{in vitro} diagnostic medical devices there is the possibility to \textbf{consolidate all existing harmonisation measures} on medical devices into a \textbf{single text}.

\textbf{Item 1 Legal simplification:} Do you see any positive or negative impacts of merging the nine texts into one legal text? Can you give an estimate of the costs of those impacts both in absolute terms and in terms of a breakdown of those cost components (e.g. per year or in man days)?

RE/ We see a positive impact in merging the texts but we think that the IVD directive can not be merged with the directives concerning medical devices and active implantable medical devices.

Reasons for merging MD and AIMD
- many aspects are common to MD and AIMD such as vigilance, clinical evaluation, intervention of notified bodies, essential requirements, intervention of notified bodies, combination products with medicinal products or animal or human tissues or derivates
- specialized doctors frequently use both MD and AIMD
- research made in the universities mixes in most cases MD and AIMD
- manufacturers of AIMD’s produce frequently also MD’s
- the status of accessories for AIMD’s brings confusion

We recognized already some of these facts at national level:
- our national notification requirements for vigilance is the same for MD and AIMD
- the national notification requirements for distributors is extremely similar for AIMD and MD
- in our transposition of directive 2007/47 we merged our national advice commissions for MD and AIMD into a single advice commission: this makes participation more attractive both for specialists in medicine and for university researchers.
- the Federal agency for medicinal products and health products is already in charge of both MD and AIMD
**Positive effect:**

- simplification, clarification and uniformisation of the procedures for vigilance, clinical evaluation and conformity evaluation
- more efficient use of available specialists in medical devices
- more efficient use of Competent authorities resources

It is very difficult to quantify this effect

Harmonisation Task Force for medical devices (GHTF) is proposing a risk-based classification system for in vitro diagnostic medical devices. Such a classification system has the advantages of being in line with the medical devices Directive 93/42/EEC and seems to be robust to technological change.

**Item 2 Risk-based classification:** In your opinion is such a risk-based classification system more desirable than the current European List system? Are you aware of any consequences for the protection of public health? Can you give an estimation of the costs or savings that would result from a change-over to this GHTF classification system?

RE/ See the answers of the Belgian IVD competent authority.
Further to the current scope of the medical device Directives some medical devices are not regulated at a European level, namely those defined as **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 ancillary action to that of the medical device.** As the need to cover these products has been recognised by the European Institutions, the scope of the Directives could be expanded to include such medical devices in order to cover the regulatory gap that exists at the Community level with the adoption of EC Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

**Item 3:** To your knowledge, are these the only medical devices currently not regulated at an EU level? Can you indicate others? Is the definition as given above accurate to describe these medical devices? Can you suggest an alternative definition?

RE/ Other products that we would have considered as medical devices will not be regulated any more at European level: namely the esthetic implants and fillers. A solution needs to be found urgently. Otherwise there will be a regulatory gap that will cause a serious public health threat.

Regarding medical devices containing non-viable human cells or tissues or derivatives we think that these also could be regulated under the Advanced therapy medicinal products regulation.

We remind that veterinary medical devices also need to be regulated at European level

Some **implantable** or **invasive** products are on the market **which are not specifically regulated at the EU level:** they are neither medicinal products nor medical devices, as they do not have a medical purpose, and they are not covered by the definition of cosmetics, as they are implanted or injected. Some examples are cosmetic lip implants, cosmetic wrinkle fillers, tattoo needles and equipment, implanted ‘identification chips’ and contact lenses for cosmetic purposes. However, these products can present the **same risks** as medical devices. This is why it could be appropriate to consider them as ‘**quasi medical devices**’ and to include them under the umbrella of the medical devices regime. The issue of machines used for aesthetic purposes could also be tackled in this context.

**Item 4:** In your opinion is it necessary to ensure full protection of public health to regulate these products as ‘quasi medical devices’? Assuming that a Notified Body assessment would be necessary for these implantable or invasive ‘quasi medical devices’,
can you estimate the impact in terms of cost for each of the three following options (per product, per year, man hours)?

The delimitation of these products can be done in different ways:

**Option 1:** Regulate as ‘quasi medical devices’ all implantable or invasive products which are not covered by another specific Community legislative regime (medicinal products, cosmetics, medical devices);

**Option 2:** Regulate as ‘quasi medical devices’ those products which belong to a category of products which also includes products with a medical purpose (for example, cosmetic contact lenses, as there are some contact lenses intended to be used for medical purposes, cosmetic wrinkle fillers, as there are some wrinkle fillers intended to be used for medical purpose

**Option 3:** Regulate as ‘quasi medical devices’ those products that would be listed exhaustively in an Annex to the future Medical Devices Legislation.

What would be the socio-economic impact of these options?

Can you suggest any other options?

RE/ It is indispensable to regulate these products with a priority for implantable products.

Option one is not precise enough.

Option 3 would give the best coverage but could lead to long discussions. Moreover, such lists always risk to be incomplete.

Option 2 is the more attractive one. Option 2 has the advantage that less discussions would be needed to define the products that would be covered.

Care should be given to give responsibility for implementation to the Competent authorities and the notified bodies that are already in charge of the medical devices in order to avoid duplication of resources and confusion concerning the conformity assessment procedures.

The economic impact would be negligible for products such as breast implants or esthetic fillers that are presently covered by the MD directive.

For other products (like sterile piercing devices) the economic impact would be significant but this measure would meet a strong demand from the public concerning the safety of these products. There are frequent parliamentary questions regarding the safety of the devices and of the processes.
2. Specific Update following the revision of the New Approach

The medical device legislation comes under the overall umbrella legislative framework for industrial products called the ‘New Approach’. The revision of this New Approach is nearly finalised. The revision of the medical devices regime will go beyond the aspects modified by the revision of the new Approach in order to reflect the public health nature of the sector. But the new regime for medical devices will have to be set up in the light of the revision of the New Approach.

Item 5:
– Which aspects of the revision of the New Approach do you consider of particular relevance to the medical devices sector, and why?
– It could be necessary to deviate, modify or add requirements, as compared to the New Approach, to reflect the peculiarities of the medical devices sector, as unlike other industrial products, medical devices have a direct effect on the health and safety of citizens. What deviations, modifications or additional requirements would you recommend, and why?

RE/ aspects of the revision of the New Approach that you consider of particular relevance to the medical devices sector: reinforcement of market surveillance and the role of the distributors. This is particularly important because the main activity in Europe is distribution.

necessity to deviate, modify or add requirements, as compared to the New Approach, to reflect the peculiarities of the medical devices sector?
Some critical products might need a controlled distribution circuit for better public health protection and specific conformity assessment procedures.
The specific competences of notified bodies in medical devices must be verified

3. Evaluation Procedures

a) Essential Requirements
i. Adaptation/reinforcement of the essential requirements – creation of new essential requirements

Adaptation of the essential requirements could be necessary should the devices referred to in items 3 and 4 (non viable human tissues and/or cells and/or their derivatives and ‘quasi medical devices’) be included into the Medical Devices Legislation. Also, it could be that certain essential requirements are missing or should be reinforced.
More generally, it should be checked if the current requirements are sufficiently robust to innovative technologies and practices (for example, nano-technology, nonviable animal tissues or their derivatives, genetic testing and advancements in information technology).

Moreover, it could be necessary to create new essential requirements in order, for example, to fight against counterfeiting (unique device identification, such as barcoding, for example) and to assure a safe distribution.

**Item 6:** In your opinion what changes are needed to the essential requirements:

a) in general?
b) for nonviable tissues and/or cells and/or their derivatives?
c) for ‘quasi medical devices’?
d) to make medical devices more robust to technology change?

What new essential requirements could be needed and why?
Please also estimate the socio-economic impact of the changes in each case.

RE/

a) the essential requirements are quite satisfactory for the moment. Any adaptations proposed should take into account any eventual new emerging technologies. A systematic review of the present list of essential requirements should be done first in order to decide which ones should be improved or added.
b) 
c) quasi medical devices should have the same essential requirements as the corresponding medical devices (example esthetic implants versus surgical implants).
d) according the annexes the manufacturers must review their products periodically in function of the technological progress, so in principle an evolution is possible. In addition a periodical review of the essential requirements should be done by the competent authorities to evaluate their adequacy in view of the technological evolution.

**More mandatory rules**

The essential requirements for medical devices are set out in the Directives, but are deliberately technology neutral and do not enter into the technical details. These technical details are set out in harmonised European standards. However these standards are voluntary and there is room for differing interpretations. Moreover, even in cases where there is scientific agreement that a certain device, method or material is not safe, the Directives do not provide a tool to address such
issues efficiently at a Community level. The only tool available to Member States in such cases is the Safeguard Clause, which is not always appropriate or used. In order to solve this type of problem, Member States often seem to use guidance, alerts etc., which effectively leads to a more fragmented market. To ensure the protection of health and to eliminate fragmentation of the internal market, the possibility should be examined to allow more precision or detail to be given in order to specify the essential requirements in relation to certain devices, methods or materials, in a mandatory way, without compromising the existing role of standardisation. Such requirements could be termed harmonised specific requirements.

**Item 7:** Can you cite instances of Member States introducing their own national specific device, method or material requirements? Can you give an estimate of the costs arising from these differing specific device requirements? What would be the socio-economic impacts of the introduction of ‘harmonised specific requirements’?

RE/ we have at least one recent example: France introducing specific requirements for pediatric beds because of severe incidents and the lack of specific requirements in the European standard.

In our case we have for example specific requirements for the content of first-aid kits for cars or buses but the components are CE marked sterile dressings.

The essential requirements listed in annex I are not always covered by harmonized standards. The list of essential requirements covered by specific standards is listed on the standard specification. Member states might wish to specify additional requirements in order to cover the essential requirements that are not covered by existing standards.

On the other side efforts are needed for more involvement of competent authorities in the elaboration of standards. If no sufficient resources are available this task could be transferred to a central expert committee. In the case of small countries for example resources are generally insufficient.

This would avoid situations like the one encountered with EN 1041 where specifications concerning the address of the manufacturer are contradictory with the annex I of the directive.

In order to avoid this kind of situation in the future a rule should be published that a harmonized standard cannot contradict a directive or a regulation.

A better evaluation should be done in case of severe incidents that lead to the conclusion that the relevant standard is inadequate. Systematic action should be taken in such cases (for example: the number of deadly accidents with hospital beds without any standard improvement).
As an example could be seen the provisions foreseen for urgent cases in the Directive on general product safety:

**“Emergency measures (GPSD)”**

Under certain conditions, the Commission may adopt a formal Decision requiring the Member States to ban the marketing of an unsafe product, to recall it from consumers or to withdraw it from the market. Such Decisions at Community level can be taken:

- where the Member States have different approaches to dealing with the risks posed by such dangerous products;
- where urgency is required due to the risk posed by the product, and where no other Community laws deal with that risk;
- where such Decisions are the most effective way of eliminating the risk.

A Decision of this kind is only valid for a maximum of one year.”

The economic impact would be lower with improvements of the standards with true participation of the competent authorities instead of national measures compensating standard shortcomings. This would also avoid market barriers.

We are in favor of the possibility for Competent authorities to agree for critical products on **harmonized specific requirements** in order to cover essential requirements that are not covered by harmonized standards either because the standards do not cover this specific essential requirement or because the fact that the harmonized standard is voluntary which does not guarantee that the essential requirement was covered. This would bring also more flexibility because the process of elaborating new standards is very long and introduce obligatory specifications.

A central expert committee should be able to work according to a flexible and fast procedure. Nevertheless, decisions taken upon its advice should be binding.

The economic impact of these harmonized specific requirements should be low because the majority of the manufacturers would have applied something equivalent anyway.

The social impact would be important because this would guarantee the safety of the devices on some critical aspects.

**The Evaluation Process**

**i. Notified Bodies**

The job of **designation** and **monitoring** of Notified Bodies is the responsibility of individual Member States, with each Member State deciding on the appropriate
method and resources necessary to do this task. Voluntary coordination between Member States ensures consistency. Since the adoption of the main Directive on medical devices in 1993 the EU has expanded from 12 to 27 Member States with upwards of 80 Notified Bodies. To continue to ensure consistency the original system of oversight needs to react accordingly. With potentially 27 differing designation and monitoring regimes it could be argued that not all Notified Bodies are equally designated or monitored, particularly when there is a lack of transparency into the competence, performance and activities of Notified Bodies to counter-act this argument. This creates the situation where the guarantee that the same level of assessment of safety of medical devices being offered throughout the Community can be questioned.

**Item 8:** The Commission intends to make some proposals concerning the functioning and the activities of the Notified Bodies, some of which could be cumulative. Furthermore two options could be put forward to strengthen the system. What is your opinion on each proposal and option and what would be an estimate of the impacts and costs involved?

**Proposal 1**
To increase transparency into the activities of Notified Bodies (e.g. obligation for the Notified Body to publish annual reports);

RE/ this could be good if the documents are published centrally. A minimal content should be defined for the annual report.

Notified body should be obliged to put the data concerning refused, delivered and withdrawn certificates on the EUDAMED database and these informations should be made public.

Up to now a significant number of notified bodies doesn’t communicate these data even to their surveillance authority.

**Proposal 2**
To develop a system of improved information exchange from Notified Bodies to Competent Authorities;

RE/ good measure. Two proposals:
-to define informations that should be exchanged systematically
-systematic use of Eudamed in order that the information is available to all competent authorities

**Proposal 3**
To ensure an improved cooperation between Competent Authorities with regard to the activities of Notified Bodies;
RE/ this is certainly useful although in the past the cooperation was sometimes disappointing.

Some examples of unsolved problems:
- notified body delivering CE certificates to a company selling devices under their own name without agreement of the original manufacturer. No valid technical documentation. Certificate maintained despite complaint both to notified body and surveillance authority
- notified body delivering quality assurance certificate for unvalidated processes. Certificate maintained despite complaint to surveillance authority
- notified bodies delivering EN 13485 certificates to contract sterilizers instead of Annex V certificates as requested in the directive
- notified body delivering CE certificates for products that are obviously not medical devices but medicinal products
- notified bodies stating that continue to deliver CE certificates for general purpose disinfectants despite a NBMed consensus that these products are biocides

These problems tend to increase and NBOG can only solve a part of them.

Proposal 4
To impose the application by the Member States of sanctions and penalties where a Notified Body fails to act properly;

RE/ this is a very good idea. There should be an independent body who could decide in cases where the cooperation between the competent authorities has not given satisfactory results. The decisions of this body should be legally enforceable.

It should be imposed upon member states that they are organized in such a way that the competent authority has a role to play in the imposition of these sanctions.

Remark: the safeguard clause already foresees this possibility but the application in practice is unsatisfying for the moment. These articles contain a too cumbersome procedure to apply, so we propose to alleviate the current procedure.

Proposal 5
To introduce measures to stop ‘forum shopping’ by manufacturers. Forum shopping is the informal name given to the practice adopted by some manufacturers of getting their products reviewed by the Notified Body thought most likely to provide a favorable opinion;

RE/ we are in favor of such measures but how can this be done practically?

Remark: improved transparency could improve this situation.

Proposal 6
To create an automatic link between accepted Safeguard Clauses and the withdrawal of
certification for the related medical devices.

RE/ we fully agree

The above proposals could be coupled with one or both of the following options:

Option 1
The reinforcement of controls on the nomination (including setting out and defining the role of accreditation) and monitoring of the Notified Bodies by Member States;

RE/ we are in favor of this approach, combined with option 2 but only for the monitoring, verification and supervision.

Specific measures could be taken for high risk products: for example a more precisely defined scope in case of high risk products together with a closer verification of the notified body qualification for that scope. Due to the limited availability of expertise at member state level this could be taken over by a centralized system.

Option 2
A centralised system of final designation and of control of monitoring by the Commission with the assistance of experts

RE/ a centralized system could be useful for the monitoring, verification and supervision.

Highest risk category medical devices

Currently there is no systematic public authority input or say in the approval of the highest risk category medical devices, such as coronary stents, pacemakers, HIV test kits or diagnostics to accompanying advanced therapy medicinal products, before they are placed on the market. However, the European Medicines Agency (EMEA) or a national medicines authority are involved in the evaluation of some devices - those that are combined with an ancillary medicinal product - and EMEA is always involved in the assessment of medical devices combined with ancillary human blood derivatives.

The question arises as to whether there should be either a de jure or a de facto premarket authorisation of these highest risk category medical devices.

The competence of EMEA could be extended, in particular to the involvement in the evaluation of the highest risk category devices, thus introducing a ‘public health’ component into the evaluation process, with the question being still open as to the involvement of Notified Bodies in the process.

EMEA has over 10 years of experience in the protection and promotion of public health, through the evaluation and supervision of medicines for human and veterinary use in Europe. EMEA already works with Member States’ national authorities, many of whom have dual responsibility for both medicinal products and medical devices. EMEA therefore already has the structures and networks in place
to pool scientific and technical expertise to guarantee a harmonised high level of evaluation.

It could therefore be appropriate to adapt the existing structure of EMEA. Specific, multidisciplinary expertise would need to be brought on board to create a specific **Medical Device component of EMEA**, on an **equal footing** with medicinal products. Coupled with this, and, in a similar way to medicinal products, it could also be appropriate to create a specific **Committee in EMEA on Medical Devices**

**COMD**

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**Item 9:** What are the social and economic advantages and disadvantages of extending the role of EMEA in the medical devices legislative framework? If possible, and where appropriate, please express these social and economic advantages and disadvantages in terms of cost.

What in your opinion is an appropriate timeframe for the assessment and approval of a highest risk category device?

RE/ On previous items we insisted on the advantages of having a central decision, particularly in case of disagreement between member states on subjects such as the status of borderline products, classification, notified bodies designation for high risk products, notified bodies decisions.

This kind of decision could be taken by a specific committee within the EMEA This would also entail the cooperation with existing committees within the EMEA, such as the committee on advanced therapies.

The EMEA plays already a role in the conformity assessment of devices combined with medicinal products and devices combined with stable blood derivatives.

The extension to the premarket approval of high risk devices might lead to excessive costs and delays.

We rather see the role of a COMD committee as a body rendering advice upon which decisions are taken centrally and for the monitoring of the surveillance of notified bodies for high risk devices.

This would guarantee a better protection of public health and give more credibility to the notified bodies in charge of the conformity assessment of high risk devices.

The appropriate time-frame for the assessment and approval of a highest risk medical device would be one year

**Item 10:** If EMEA were to participate in the evaluation of highest risk category devices, which products should these be (e.g. 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 ancillary action to that of the medical device, and **certain** products from the following categories: class III medical
devices, devices using nano-materials, in vitro diagnostic and active implantable medical devices)?

As the EMEA expertise and approval process is already foreseen for 'viable' human tissues (under Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004), it would seem logical to also submit 'nonviable' tissues to approval via the same expertise and process. What in your opinion would be the social and economic impacts if this was the case?

RE/ we are in favour of the COMD participating in the evaluation of some highest risk devices as described. The majority of class III devices and AIMD’s should be excluded. We are in favor of the EMEA intervention for devices with non-viable human tissues

**Item 11:** Two basic considerations arise with an expanded role of EMEA in the evaluation of the highest risk category medical devices: (i) in what way does a file get submitted to EMEA for an opinion and (ii) What is the final decision making process?

On both aspects some solutions can be proposed. Which ones, in your opinion, are the best ones and why? Can you suggest other modalities in order to involve of EMEA in the evaluation of the highest risk category devices and to take into account the opinions delivered by EMEA

**Option 1.**

No Notified body involvement, thus obliging direct submission of manufacturers’ files related to highest risk category devices to EMEA for an opinion;

**Option 2.**

A variation of option 1. Obliging manufacturers to directly submit their files related to highest risk category devices to EMEA, and EMEA then selects a Notified Body to act as a ‘rapporteur’. The Notified Body ‘rapporteur’ then assesses the file and sends its recommendation to EMEA for a final opinion;

**Option 3.**

Maintain the Notified Body responsibility for the overall assessment of the files as it is at present, but oblige Notified Bodies to send their preliminary reports concerning highest risk category medical devices to EMEA for an opinion;

**Option 4.**

A variation of option 3. Keep the Notified Body responsibility for the overall assessment of the files but instead of a systematic assessment of the preliminary report by EMEA, oblige Notified Bodies to notify EMEA of all applications for evaluation of highest risk category devices and allow EMEA, on a public health interest basis, to select those evaluation reports on which they will give an opinion.
RE/ we think that option 3 is the best for a limited range of high risk products and 4 in case of a wider range but under the condition that the notified body is obliged to take the opinion of the COMD into account for the final decision

(ii) What is the final decision making process?
Two possibilities can be foreseen:
Possibility 1: For options 1 or 2 above, i.e. an EMEA opinion rather than a Notified Body certificate, the normal decision making process would be a Commission market authorization based on a Comitology decision.
Possibility 2: For options 3 or 4 above, i.e. maintain overall responsibility with the Notified Body, then the system could continue as it is now, with the Notified Body issuing its certificate, but only if it had received a positive opinion from EMEA.

RE/ we favor possibility 2 and option 3 or 4

iii. Devices which do not belong to the highest risk category
To contribute to the monitoring of the conformity assessment by Notified Bodies of devices which do not belong to the highest risk category, the EMEA Medical Devices Committee could also have the possibility to examine any matter concerning a specific device placed on the market or to review any data relating to a specific family of medical devices.

Item 12: Do you see any reason why the EMEA Medical Devices Committee should not also have the possibility to have access to all evaluation reports of the Notified Bodies in order to establish and monitor a high level of evaluation and to require corrective action where needed?

RE/ we agree to full access in cases where the COMD requests the information. It could also be foreseen to have certain data transmitted on a systematic basis.

4) VIGILANCE

Vigilance issues are recorded by e-mail or centrally in the European database for medical devices, EUDAMED. The wide variation of reported vigilance issues points to a significant under-reporting of incidents within the EU. When issues do take place, it should be ensured that the same common reaction takes place in all Member States; however, experience has shown that not all Member States always react in the same way

Item 13: One or more proposals to improve the vigilance system could be foreseen to be appropriate. In each case can you give an estimate of the socio-economic impact of the particular proposal?
Proposal 1
Establish an obligation for the medical institutions and healthcare professionals to report incidents and to invite patients to do the same, to introduce timelines for reporting and corrective actions, to give certain publicity to the corrective actions of the manufacturer;

RE/ We have already an obligation for medical institutions and healthcare professionals but it proved uneffective because they are reluctant to notify. We try to find ways to improve this for example by channeling the notifications through some designated persons in the institutions. We give the corrective actions the publicity that is needed. This should not be exaggerated in order to avoid panic by the public. So only when it is of general public interest.

Proposal 2
Create an obligation for the Notified Body to periodically review the manufacturer’s vigilance system;

RE/ to monitor the manufacturer’s vigilance system is already an essential task of the notified body he must perform during surveillance audits that are done normally every six months. Therefore we consider that this obligation exists already.

It is the duty of the Member States to verify that the notified bodies perform their tasks

Proposal 3
Mandate EMEA to coordinate vigilance reports and to detect signals;

RE/ this is rather a task for the competent authorities. They could request the help from the COMD. The COMD could also take initiatives because it would be informed of all incidents through the Competent authorities reports. In cases where there would be pre-approval advice for certain high risk products, this could be applied.

Proposal 4
Allow the Commission to impose restrictive measures, on the basis of the opinion of the Medical Device Committee in EMEA.

RE/we agree.

Proposal 5
Also, remembering that the medical device market is very much a global one, should there be provision for exchange of information on incidents and corrective measures at an international level? This happens now voluntarily through GHTF but could be strengthened.

RE/we agree. This should be enlarged to other partners as well.
5. MARKET SURVEILLANCE

Member States’ control of the market can vary significantly depending on the availability of adequate resources. A counter-balance to this lack of resources is efficient and effective cooperation between the Member States. However experience has shown that this cooperation is not always optimal. This situation is not helped by confusion on how to operate the current market surveillance tools already contained within the Directives, not least due to the current provisions being unclear and appearing in different and apparently disjointed sections of the Directives.

**Item 14:** In order to reinforce market surveillance, it could be appropriate:
– to have a central European registration system for devices;
– to redraft and rationalise the rules on market surveillance;
– to strengthen the provisions related to the Commission on coordination; and,
– in cases where the Commission has to take a decision, to have the possibility to ask for scientific opinion of the Medical Device Committee in EMEA.

Do you see any problems with these measures to increase the integrity of market Surveillance?

RE/

-although it is in principle a good thing it might be difficult to have a central European registration system for devices due to the very high number of devices. Particularly difficult would be to keep this database up to date. But there is demand from the health care institutions to have such a database. We suggest to observe first what is happening with some similar databases that are already in use now.

-it would be a very good thing to redraft and rationalize the rules on market surveillance particularly the procedures to remove a product from the market in case of wrongly affixed CE mark or unsafe product. For example it is not obvious at all what procedure can be used in case of a Class I device. In general the procedures seem too heavy and complicated and do not encourage member state to take action. They should be alleviated.
-to strengthen the provisions related to the Commission on coordination would be a nice thing if the Commission has sufficient resources. Some experts would be needed to help the Commission in this task. In case a product is removed from the market in one country, the Commission should have it removed from the market in all countries. The coordination tasks of the Commission already foreseen are not applied optimally.

- the Commission should indeed have the possibility to ask for scientific opinion of the medical device committee in EMEA. The Commission’s decisions should then be legally enforceable.

Can you suggest other improvements?

RE/
-a central decision procedure on subjects like status or classification with legally enforceable decisions

6) BORDERLINE CASES

Innovators need to be certain as to which regulatory regime their products will fall. Due to the fact that most borderline cases involve medical devices and medicinal products, a strong dual expertise in borderline cases in both areas becomes more and more necessary. It could be useful to provide that manufacturers could go directly to EMEA for an early opinion prior to development of their product. This opinion should be delivered in a defined timeline; Notified Bodies, Competent Authorities and the Commission could likewise seek an opinion.

**Item 15:** The Medical Device Committee in EMEA could provide a joint opinion together with the Committee for Medicinal Products for Human Use (CHMP) on the appropriate qualification of a product.

It can also be envisaged that the Committee on Medical Devices in EMEA could provide an opinion on the classification of a medical device. Or indeed that EMEA could give scientific opinions or advice on other technical matters related to medical devices.

What would be the health or economic impact of such a system in your view?

RE/ A central Committee to give an opinion on borderline products would be a very good thing. The involvement of the CHMP is necessary in case of drug/device combination products. These opinions should amount into a legally enforceable decision. These problems are very frequent and it is sometimes extremely difficult to obtain a consensus of the various Competent authorities. Even when a consensus is obtained some manufacturers and/or notified bodies act in the opposite way because they pretend that these opinions have no legal value. This would be good for public health and to eliminate unfair competition.

The economic impact would be favorable.
We wish to emphasize that there are also other grey areas or "borderline cases". This should not be limited to differences between medical devices and medicinal products. It is possible that more than one regulation/directive is applicable, for instance: medical devices that also have to comply to prescriptions and procedures regarding PPE (personal protective equipment), low voltage, machines ... A committee on Medical Devices in EMEA would in those cases needed to be larger than just "medical" experts to give appropriate advice.

7) GHTF Global Harmonization Task Force

The medical devices market is a global one, with our major trading partners increasingly aligning their legislation to the Global Harmonisation Task Force for Medical Devices (GHTF) model. To keep European industry competitive, the European legislation also needs to further converge on this model.

Item 16: It would be appropriate to evaluate the GHTF guidance documents and carry over as much as possible into the European framework.

Can you (roughly) estimate the costs stemming from international regulatory divergences?
RE/ small

What are the positive and negative impacts of Europe harmonising to the GHTF global regulatory model?
RE/ positive is the simplification and the harmonization with the other developed countries
Negative is the fact that some GHTF documents seem easy to be misinterpreted by people who work according to the letter and not the spirit. This is especially obvious for the vigilance guidelines and we see the same tendency with the documents on technical documentation.

To what extent should European legislation reflect the GHTF global model:
Fully?
Only where possible? Please explain which areas are possible and why?
Not at all? Please explain why?
Which GHTF guidance documents would you recommend to be carried over into European.
RE/ as much as possible without putting public health at risk

We are of the opinion that a profound analysis of the conformity of these documents with applicable European legislation should be done before they are implemented.

The legal reference should remain the national transposition of the directive.

8) IMPORTS , EXPORTS AND COUNTERFEITING

Imports: All medical devices sold in the EU must be CE marked. This means that imported products are subject to the same level of checking and control by Member States’ authorities and Notified Bodies as domestic European products.
This requirement for equal treatment of imported and domestic products has been challenged over the years, particularly in respect to medical devices manufactured in emerging economies. Claims have been made that Notified Bodies do not check foreign manufacturers with the same rigour and due diligence as they do for EU manufacturers. In the same vein, concerns have been voiced that authorities do not actively and thoroughly follow up alleged claims of non-conforming and unsafe imported medical devices, particularly custom-made and lower risk, class I, imported medical devices.

**Item 17:** Can you suggest any specific proposals to strengthen the European system against the criticism of having un-equal checking and control of imported versus domestic medical devices?

Designating authorities should exert more scrutiny at the way notified bodies make conformity assessments outside Europe, for example by making observed audits. We noticed some problems particularly in case of OBL: the notified bodies are supposed to take account of evaluations performed by other notified bodies but there are cases where notified bodies take in account evaluations that are made according other annexes or standards than those requested for the concerned products. Also we were informed of certificates being delivered without any inspection on site. An independent medical device committee as described above could also take some initiatives in that direction. Basically we don’t think that the problems are much bigger in case of imported products. There are many problems too with products made in Europe. But some checks should be done on the basis of representative samples.

**Exports:** Under the current system, it can be argued that the EU has a double standard. While devices that are placed on the Community market are subject to control, unless the country of import themselves have regulations, neither the manufacturing process nor the manufacturers of “export medical devices” are regulated. This would seem at odds with the idea of Europe as a center of safety, excellence and innovation in medical devices.

**Item 18:** For those cases where there is no legal requirements in the importing country, a separate export certificate regime could be developing based upon the Directives, say requiring medical devices for export to be treated in the same way as medical devices for the Community market (affixed with CE marking) or requiring the manufacturer to have a quality management system (Device GMP). Please give your evaluation of such proposals in terms of social and economic impacts. RE/ the ideal situation would be the same quality for export products. The economic impact however has to be taken into account.

**Counterfeiting:** The Commission is considering introducing traceability requirements into the essential requirements for medical devices to help battle against counterfeiting [see section 3(a)(i) above]. But other measures outside the essential requirements might also be appropriate.
**Item 19:** Can you suggest appropriate measures within a future legal framework for medical devices that could help battle against the counterfeiting of medical devices?

RE/ traceability requirements such as bar code could help indeed for combating counterfeiting but would also have other advantages. Controlled distribution systems such as the registration of distributors offer a good control also. We have a positive experience in Belgium. Inspection of a representative sample of all distribution and sales circuits in each country is also necessary. Therefore each member state should allocate a sufficient number of inspectors. We plan also training sessions of regulatory affair persons of distribution chains in order to learn them how to detect counterfeited products

### 9. Simplification

Currently, with three main Directives and six modifying or implementing Directives, the legal framework for medical devices has been criticised as being too fragmented and difficult to follow, particularly for SMEs or third country manufacturers and trade partners. Furthermore and probably more importantly, uniform implementation of the Directives has been hampered by national variation concerning, for example, the interpretation of the definition of a medical device and of the rules for classification and the registration procedures. This variation threatens not only the smooth functioning of the internal market, but could also threaten the health and safety of patients, healthcare professionals and other persons. For these reasons, some parts of the text should also be restructured and clarified. Furthermore, it could be useful to examine if it is legally possible to use a Regulation rather than a Directive to ensure uniformity, or to use a combination of a Regulation and a Directive (if a single regulation is not legally possible).

**Item 20:** Which elements in the Medical Devices Directives have given rise to particular legal uncertainty in regard to their application? Did this increase administrative burden, e.g., costs to get familiar and to understand the applicable legislation? Can these costs be quantified, e.g., by assessing the necessary man-hours? How can these costs be reduced without compromising the safety of medical devices placed on the market?

RE/
- there is always confusion about system manufacturers.
- the procedures to be used in case a product has to be withdrawn from the market are not clear.
- there is confusion also about the content of the CE certificates and of the declarations of conformity.
- labeling requirements are not clear but this was improved in the review of the directive.
- the requirement for an authorized representative was not clear but it was improved in the revised directive.
-the fact that the declaration of conformity must be delivered to the customer for a Class IIa custom made device but not for a Class I will be very confusing.

**Item 21:** Would it be preferable to regulate medical devices by means of a Regulation (i.e. a directly applicable legal act, cf. Article 249(2) of the EC Treaty)? What would be the socioeconomic impact of this option?

RE/ this could be an advantage by suppressing transposition delays and decreasing divergent national interpretations.

The variety of conformity assessment modules (Annexes) in the Directives are difficult to follow, except for the most experienced and expert regulatory professional. Since the Directives were first introduced, industrial and international regulatory practice in device quality management has moved on. Device GMP, as described in quality management system standard EN ISO 13485:2003 and related standards, has replaced EN 46001, EN 46002 and EN 46003 (the European standards that spoke to the various modules). It could be the case that Europe is retaining compliance routes that are out of step with the industrial state of the art

**Item 22:** It could be envisaged to collapse all the quality system conformity assessment modules into one module, analogous to the current Annex II module in Directive 93/42/EEC concerning medical devices. Would this be a simplification of the system? What would be the benefits in terms of administrative burden and cost? If certain conformity options are to be retained, which ones and why? What are the convincing social and economic arguments to keep them? Can you estimate the negative impact if they are phased out?

RE/ in principle it could be a simplification of the system but the benefit is uncertain first of all because most of the manufacturers followed already annex II and secondly because the manufacturers of certain types of devices may have an advantage to use other modules.

For critical devices the approval of the design remains necessary in view of the problems we had in the past.

In case of a wider use of annex II it is indispensable that notified bodies verify not only the quality assurance system but also how it is put in practice, on a representative sample as required in the revised directive. This was not always done in the past.