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RECAST OF THE MEDICAL DEVICES DIRECTIVES

PUBLIC CONSULTATION

Entity: Malta Standards Authority

Role: National Competent Authority for Medical Devices in Malta

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Notice: This submission represents the opinion of the Malta Standards Authority only. Each Maltese stakeholder was invited to send his comments directly to the Commission. Malta's official consolidated position will be prepared later on.

Section 1 - SCOPE:	
Subject:	**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)?
MSA Reply:	MSA agrees that Directives 93/42/EEC (Medical Devices), 90/385/EEC (Active Implantable Medical Devices), 2007/47/EC (Amendments to MDD and AIMD), 2003/32/EC (Devices manufactured utilizing tissues of animal origin), 2003/12/EC (reclassification of breast implants) and 2005/50/EC (reclassification of hip, knee and shoulder implants) can be quite easily replaced by only 1 Directive. In fact, in our latest transposition of Directive 2007/47/EC, we already combined Directive 93/42/EEC, 2007/47/EC, 2003/32/EC, 2003/12/EC and 2005/50/EC into 1 Legal Notice on Medical Devices. We acknowledge that the requirements

	for active implants can be easily implemented with the requirements for general medical devices. Recasting into a single Directive will be surely beneficial to industry and to authorities, unless the new larger and wider-application Directive would need to be continuously revised. If this will be the case, in a few years time we will have another situation of fragmented legislation. As regards Directives 2000/70/EC and 2001/104/EC on human blood derivatives, these can also be ultimately included in the recast Directive, especially if the relationship between the medical devices sectors and the medicines sectors (including EMEA) is improved. As regards Directive 98/79/EC on in-vitro diagnostics and the corresponding Common Technical Specifications, MSA would prefer that these remain separated since the concepts of conformity assessment are quite different from those in Directives 93/42/EEC and 90/385/EEC.

Subject:	**ITEM 2 - RISK-BASED CLASSIFICATION OF IN-VITRO DIAGNOSTIC DEVICES:** 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?
MSA Reply:	There is no doubt that global alignment of regulations is beneficial to industry. MSA could accept the system proposed by GHTF. However, we have some concerns: (a) Ultimately, even the European List system is based on risk. We acknowledge that the European List system requires more frequent updates when compared to a risk-based approach. However, in terms of simplicity, the European List system is much easier to follow for both industry and authorities. Moreover, in the current European system, devices falling in Annex II List A of Directive 98/79/EC (i.e. the high individual risk and high public health risk devices) must conform to Common Technical Specifications. MSA supports the CTS system we would like that this concept is reflected in GHTF. (b) In Directive 98/79/EC, IVD devices for performance evaluation are classified in a class on their own and have their own specific conformity assessment procedure (Annex VIII). It does not appear that the GHTF document refers specifically to devices intended for performance evaluation or clinical trials. This would imply that devices are classified according to their ultimate purpose and not according to their stage of development. MSA would prefer to have a similar system as the one currently in Directive 98/79/EC as regards IVD devices for performance evaluation.

Subject:	**ITEM 3 – NON-VIABLE CELLS:** 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?
MSA Reply:	During a meeting in September 2007 between interested Member States, it was acknowledged that ex-vivo products (e.g. IVF/ART products) are also not easily regulated at an EU level. Clarification of the medical devices definitions may be required to include ex-vivo products. It is to our understanding that viable cells are, by default, classified as medicinal products. The problem is that non-viable cells are excluded from the Advanced Therapies Regulations and therefore fall in a legal limbo between the Medicines Legislations and the Medical Devices Directives. MSA would like that, in any scenario possible, the general rules of classification will remain based on the intended purpose as specified by the manufacturer and the principal mode of action. Ideally, for the sake of simplicity and legal clarity there should be no legal distinction between viable and non-viable cells. In both cases, it is the safety and efficacy of the overall product that is important. Usefulness and efficacy can be assessed on the combined product as a whole for both drug-device and cell-device combinations. This could be in the form of a benefit/risk assessment for the whole, combined product. Central assessment by the CHMP could be one of the options since all Member States would still be involved and pooling of expertise would be easily obtained. Ultimately, an important concept that should be retained in any scenario is that, irrespective of the overall classification of the product, the device part must still fulfil the essential safety requirements of the MDD. MSA feels that it is important to avoid situations that can possibly allow the possibility of a marketing authorisation being given to a combined product containing a non-CE-marked device part. This should apply to all licensing stages (including clinical trials). Finally, the following aspects would have to be clarified in terms of combined drug-device products containing non-viable cells/tissues: (a) Administration of adverse event reporting; (b) Administrative procedures and clarification of responsibilities regarding conformity assessment of the device part during the evaluation for a Marketing Authorisation; (c) Administrative procedures and communication during Clinical Trial Notifications. We would like to emphasise that in Malta, the administration of Medical Devices and Medicinal Substances is handled by two separate authorities, under two separate Ministries. Any actions taken on these products must take in consideration the practical implications on

	administrative set-ups such as ours.

Subject:	**ITEM 4 – BORDERLINE COSMETIC PRODUCTS:** Some implantable or invasive products on the market 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. 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 purposes, etc.); **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?
MSA Reply:	In MSA's opinion, the most important aspect to be kept is to classify products on a case-by-case basis using the legislative tools at hand. This problem does not only affect cosmetic-like products but practically all borderline products. A specific "pre-market" list of product classification (as proposed in Option 3 and to some extent in Option 1) would never be exhaustive and would require constant updating. Innovative products would never be included in such lists since the authorities cannot be in a position of being aware of innovative products before they enter the market. Specific lists of product types would only expose legal limbos further. Option 2 presents a contradictory principle since products with a medical purpose can be classified easily as medical devices or medicinal products and there is no need to classify them as "quasi medical devices".

	MSA is not in favour of the introduction of a "quasi medical device" principle. Our modus operandi for all borderline products is that we try to ensure safety as much as possible, but in some cases the products would be accepted under the General Product Safety Directive 2001/95/EC. We acknowledge that there is no Notified Body intervention required under this Directive but at least the economic operator has a clear responsibility of placing safe products on the market and providing customers with all relevant information. We believe that the GPSD should be still used in borderline cases, including these cosmetic-like products. After all, the primary aim of the Directives is free movement of goods and not safety, and even with CE-marking the product is given presumption of conformity, although this may not necessarily guarantee that the product is safe. Classification should ideally be (and remain) based on these 3 principles: - Products are classified on a case-by-case basis instead of a type-basis. - The intended purpose specified by the manufacturer and the primary mode of action must remain the primary criteria for classification. - In case of doubts, the authorities have the right to question the manufacturer's classification claims. We understand that the third indent above may be over-used by authorities, resulting in a non-harmonised market for the same products. However, harmonization in classification can never be achieved in practice since Member States differ on certain basic issues such as whether smoking is considered as a disease or not. Attempts to harmonise classification should involve primarily an emphasis on manufacturers and Notified Bodies, since it is them who classify products in the first place. An improper classification at that stage will surely result in a fragmented market and the onus cannot be placed on the authorities in such case. Sometimes it is the manufacturer himself who tries to abuse of the legal system and produce innovative borderline products to avoid certain responsibilities. From the Medical Devices Directives point of view, an enhancement and clarification of classification rules may be sufficient to improve the situation, but we should not go into an extreme where the application of the MDD is widened too much by introducing principles such as "quasi medical device". Using the same principle, "quasi medical devices" may also be "quasi cosmetic products" and we would find ourselves with the original problem.

Section 2 – REVISION OF THE NEW APPROACH:	
Subject:	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 – NEW APPROACH:** 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?
MSA Reply:	MSA is in favour of aligning the MDD to the New Approach as much as possible. The New Approach must be used as the basis of the MDD. In particular, alignment of the following aspects with the New Approach is essential for proper functioning of the market: definitions of economic operators and their responsibilities, conformity assessment procedures, roles and responsibilities of market surveillance, rules on the affixing of the CE-marking and criteria for the designation of Notified Bodies. However, certain characteristics of the MDD should be retained, even if they go beyond the scope of the New Approach. These include: the vigilance system, the classification rules, special conformity assessment procedures (e.g. custom-made devices) and the registration requirements. As already mentioned before, in principle everyone wants safer medical devices on the market, but the primary scope of the New Approach is free movement of goods.

Section 3 – EVALUATION PROCEDURES:	
Subject:	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 – ESSENTIAL REQUIREMENTS:** In your opinion what changes are needed to the essential requirements: a) in general? b) for non viable 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.
MSA Reply:	In our opinion, a wide revision of the essential requirements at this stage should not rank amongst the highest priorities when discussing the enhancement of the Directives. Stricter essential requirements will only result in harder monitoring and surveillance and may not

	necessarily result in safer products on the market. Stricter and more specified essential requirements would also make the Directive less flexible towards technological changes. In general, we have no specific remarks on the essential requirements. However, as stated before we would not be in favour of introducing the "quasi medical device" principle. As regards innovative technologies, in particular nano-technologies, studies by the New & Emerging Technologies Group and by GHTF have shown that the current legislative framework is sufficient at the moment. However, we cannot exclude at this stage that the essential requirements would need to be specified for these products in the future. As regards barcoding and the unique identification number, we could accept such systems, especially if these enhance the global harmonization of the sector. However, we would like to raise the following points: (a) Barcoding (or RFID or others) should not immediately replace written information accompanying the product. Written information (as requested in Annex I, section 13) is essential for anyone to easily identify the product. This affects economic operators, customers and authorities in carrying out their duties. (b) If the concept of a unique identification number is introduced in the essential requirements, this should be left as open as possible. The Directive itself should explain the obligation, but it should be left up to standardization to provide the actual means.

Subject:	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 the 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 – ESSENTIAL REQUIREMENTS:** 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'?

MSA Reply:	The concept of specific requirements in the Directives has worked in the case of IVD high-risk products (i.e. Common Technical Specifications), but we doubt it would work for any other devices. We strongly believe in the principle that the Directive should provide the legal obligations but it is the standards which provide the means. We also strongly believe in the idea of voluntary standards. The system has worked very well in this regard in the past. The introduction of harmonized specific requirements in the Directives would require active intervention of industry in the drafting of the Directives (as happens when standards are developed) and would require constant updating. This would result in a constantly "moving target" in terms of legal obligations and it will not help in harmonizing the market. If we want a Directive that is flexible to new technologies, the essential requirements must be as general as possible. Fragmentation of the market is not a result of misinterpreted or lacking essential requirements, but rather due to misuse of the definitions of a medical device, a medicinal product, a cosmetic, etc.

Subject:	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. **ITEM 8 – DESIGNATION OF NOTIFIED BODIES:** 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); **Proposal 2** To develop a system of improved information exchange from Notified Bodies to Competent Authorities; **Proposal 3** To ensure an improved cooperation between Competent Authorities with regard to the activities of Notified Bodies; **Proposal 4** To impose the application by the Member States of sanctions and penalties where a Notified Body fails to act properly; **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 favourable opinion; **Proposal 6**

	To create an automatic link between accepted Safeguard Clauses and the withdrawal of certification for the related medical devices. 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; **Option 2** A centralised system of final designation and of control of monitoring by the Commission with the assistance of experts.
MSA Reply:	The designation criteria should be aligned as much as possible to the revision of the New Approach. Here are our comments on each proposal: **Proposal 1** – Transparency should be increased, in particular, on the reasoning behind the classification of products. The latter, in our opinion, is the main factor that leads to market fragmentation. **Proposal 2** – We totally agree with this concept. Maybe Eudamed could be adapted to serve this purpose in the future. **Proposal 3** – This could be improved but it is not a priority if we ensure that the designation system works properly in the first place. **Proposal 4** – The designating authority should remain responsible for the activities of the specific Notified Body. We should avoid a situation in which Notified Bodies may be treated differently in different Member States. **Proposal 5** – This can be avoided by properly enforcing the requirements in the Annexes for conformity assessment where the manufacturer is obliged to state that he is not applying with more than 1 Notified Body at the same time and he must state, in his application, whether his application was refused by another Notified Body. Ultimately, the manufacturer is free to choose the Notified Body he wants. **Proposal 6** – We do not agree with this idea. Withdrawal of certifications is a responsibility of the Notified Bodies. The roles of Notified Bodies and Competent Authorities should be clearly separated. In our experience, the certification withdrawal system is working quite efficiently. As regards Options 1 and 2, both could be valid and acceptable to us. Reinforcing the designation process may improve the situation, but, in line with our reasoning for reinforcement of essential requirements, tightening designation criteria will not necessarily result in a safer system. The idea of having a centralized system of final designation, or at least final assessment, could be useful.

Subject:	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 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. 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). **ITEM 9 – ROLE OF EMEA:** 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?
MSA Reply:	We do not agree with the introduction of a "public health component" in the authorization of high-risk medical devices due to numerous factors, including: - Such principle of pre-market "authorization" is not in line with the New Approach; - Further assessment by EMEA would reduce the trust, responsibilities and importance of Notified Bodies; - Such principle may undermine the fact that responsibility of the product lies 100% on the manufacturer – we would like to retain this principle; - Double assessment by Notified Bodies and EMEA would result in increased costs on industry (and ultimately, on consumers); - It would take a longer time for products to be assessed and they would not be able to be placed on the market quickly. This would reduce the availability of medical devices on the market; - Although EMEA may cope with the amount of authorizations for medicines and combined products, definitely no single authority can cope with the volume of medical devices on the market; - We fail to see how this pre-market assessment system would work in the case of devices manufactured outside the EU. If a device is manufactured outside the EU and is CE-marked, then it is free to enter the European market without requiring EMEA assessment. In principle, systems that are working properly in the medicines sector **must not** be extrapolated in the medical devices sector since the sectors are totally different in nature and set-up. With all its shortcomings and defects, MSA still believes in the importance of the New Approach in the medical devices sector, especially with respect to SMEs.

Subject:	**ITEM 10 – ROLE OF EMEA:** 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, 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?
MSA Reply:	As the question itself implies, once EMEA starts to be involved in the assessment of high-risk medical devices, discussions would start so that more categories of medical devices would be assessed by EMEA. As stated in our answer to question 9, we are against the introduction of further assessments after Notified Body evaluation.

Subject:	**ITEM 11 – ROLE OF EMEA:** 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? **(i) in what way does a file get submitted to EMEA for an opinion?** **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.

	(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.
MSA Reply:	MSA is totally against the basic principle of high-risk medical devices being assessed by a "fourth" party.

Subject:	**ITEM 12 – ROLE OF EMEA:** 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?
MSA Reply:	MSA is totally against the basic principle of high-risk medical devices being assessed by a "fourth" party. However, we could accept the idea of a centralized entity having access to evaluation reports of Notified Bodies in the post-market stage, should the need arise. Although this will be most probably tackled by Eudamed.

Section 4 – VIGILANCE:	
Subject:	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; **Proposal 2** Create an obligation for the Notified Body to periodically review the manufacturer's vigilance system;

	Proposal 3 Mandate EMEA to coordinate vigilance reports and to detect signals; **Proposal 4** Allow the Commission to impose restrictive measures, on the basis of the opinion of the Medical Device Committee in EMEA. **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.
MSA Reply:	**Proposal 1** – Such obligation will be impossible to enforce. Assuming that non-reporting would be considered as a breach of the Directive, how will authorities realize that an incident was not reported by the user, especially if occurring in small clinics (e.g. dentists, ophthalmologists)? However, we do agree with the point that corrective actions of the manufacturer should be made public in cases where the devices concerned were sold to the general public. **Proposal 2** – We could agree with this point. The incident processing procedure should be audited by Notified Bodies, for devices where Notified Body intervention was required in the first place. **Proposal 3** – The implications of this option should be studied further. However, centralization of data will be already working better once Eudamed is applied by everyone. **Proposal 4** – We do not agree with the setting up of a Medical Device Committee in EMEA, as described in previous questions. **Proposal 5** – We agree with this point, but we would like that we are only informed of incidents that affect batches present in the EU, otherwise the system would be too burdensome. One also cannot expect that information exchange between continents will be fast enough to prevent further incidents. Ideally, there should be international laws that automatically oblige the manufacturer to carry out corrective actions on all affected batches across the world. Incidents happening outside the EU but affecting devices present in the EU should be included in the Vigilance System.

Section 5 – MARKET SURVEILLANCE:	
Subject:	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 a scientific opinion of the Medical Device Committee in EMEA. Do you see any problems with these measures to increase the integrity of market surveillance? Can you suggest other improvements?
MSA Reply:	**Central Registration System** – we agree with this point but feel that Eudamed will be sufficient, at least for devices that are requested to be registered. **Redrafting of Market Surveillance rules** – this may not be necessary. Reinforcement of the current rules would be sufficient. For instance, COEN/MSOG forms and the vigilance system itself are very useful tools for information exchange. The revision of the New Approach will also help in enhancing the responsibilities of economic operators with respect to providing information to authorities. **Coordination by the Commission** – we could accept this if it does not create additional administrative burdens. **EMEA** – we would not object to the fact that EMEA is consulted in special circumstances.

Section 6 – BORDERLINE CASES:	
Subject:	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?
MSA Reply:	▪ One must acknowledge that certain manufacturers do have a tendency to try to select the classification system that best suits their needs. Borderline cases are not only a result of legal uncertainties.

- Competent Authorities should retain the possibility of questioning the manufacturer's classification claims when these are suspicious.

- Having a centralized system for classification would provide certain benefits, but would still not be sufficient to remove boundaries created by different interpretations of health conditions amongst the Member States. For instance, would this mean that EMEA would be in a position to impose on all Member States that smoking has to be considered as a disease (or not)?

- EMEA/CHMP should remain focused on evaluation of safety and efficacy and should not be involved other pre-market activities such as classification. Since the primary aim of EMEA would be to ensure safety of the product, there may be a tendency to classify products in the strictest category possible. We would prefer that the system of risk-proportionality is not turned into a system based on the precautionary principle.
- The phrase "manufacturers *could* go directly to EMEA" gives the impression that EMEA's intervention would only be introduced on an optional basis. This would definitely not harmonise the classification of products in the same category groups.
- EMEA/CHMP intervention in this case would presumably come at a cost to industry. Would this be a justifiable increase in cost?

Due to certain circumstances, we believe that the borderline cases problem can never be ***removed***. The causes that give rise to borderline cases include:

- **Regulatory Gaps/Overlaps** - Only in a few cases do borderline situations arise due to a regulatory gap. Regulatory gaps can be tackled by closely following what new products are being developed and keep up with industry. On the other hand, overlaps can be solved quite easily using guidelines issued by the Commission together with expert groups.

- **Innovation** - Most borderline cases arise due to the innovative properties of products. New products with new properties or ingredients will obviously not clearly fall in a specific regulatory category immediately. As stated in other answers, the best way to leave the current legislative framework as flexible as possible to new products is to leave the essential requirements as general as possible.

- **Misuse of definition** – The definition of a medical device states that "any material or article" can be a medical device. The justification for this inclusion should be revised and re-discussed. The most problematic and common borderline cases we experience include solutions, lotions and creams. The definition of a medical device is being applied (by manufacturers) to various types of products including products intended to be ingested (e.g. fat-binding capsules). One finds it very hard to understand how a product that has to be ingested or a cream that has to be applied to the skin does not behave in metabolic, pharmacologic or immunologic manner.

- **Misuse of classification principles** – We agree that in practice the best way to classify a product is to use the primary mode of action and the primary intended purpose. However, these are given by the manufacturer. This means that two identical products with slightly

	different claims can be classified in different regulatory regimes. A simple change of wording can classify a product under another class or regulation. This not only shows that the presence of borderline cases is due to regulatory *overlaps* rather than regulatory *gaps*, but shows that such system is highly susceptible to abuse and undermines the idea that classification should be based on the intrinsic risks of the product itself. In MSA's opinion, the main focus of discussions should be on this particular point. The MDD should not become an attractive "dumping site" for manufacturers who want to avoid other regulatory regimes.

Section 7 – GLOBAL HARMONISATION TASK FORCE:	
Subject:	The medical devices market is a global one, with our major trading partners increasingly aligning their legislation to the 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? What are the positive and negative impacts of Europe harmonising to the GHTF global regulatory model? 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 legislation? If fully aligned, can you estimate the savings this would bring about for European businesses? What would be the added value in terms of protection of public health?
MSA Reply:	We are not in a position to comment on the exact financial repercussions these options would have since we are not an economic entity. However, we could envisage that a full harmonization with GHTF rules would: ▪ be overall beneficial for large companies who have a high potential of being/becoming multi-nationals; ▪ probably not influence SMEs who do not have the potential of exporting outside the EU; On the other hand, if full harmonization with GHTF would result in significant regulatory changes, the costs on industry would definitely increase significantly and the benefits would have to be calculated again. Would full harmonization to GHTF have the worse impact on non-EU entities trying to gain access to the EU market or on EU entities trying to export outside the EU? In the latter case, EU medical devices industry could be at a disadvantage. GHTF will only achieve its purpose if all major markets and manufacturing countries around the world adhere to it. It is essential that everyone is on board on this issue.

Section 8 – IMPORTS, EXPORTS & COUNTERFEITING:	
Subject:	**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?
MSA Reply:	All products, irrespective of their origin, should be treated equally, both in terms of conformity assessment and in terms of market surveillance. It is to our knowledge that at Customs level, more attention is already given to products imported from outside the EU. Introducing specific requirements for products manufactured outside the EU would go against the spirit of the Directive. Moreover, the phenomenon of re-branding would make the enforcement of such requirements impossible.

Subject:	**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 centre 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.
MSA Reply:	This issue should not be decided by the EU, but by the destination countries themselves. Maybe some destination countries would not welcome CE-marked devices at a higher price. The MDD is aimed to regulate medical devices on the EU market. We would not agree that the MDD is extrapolated to regulate medical devices on other markets as well. Moreover, how can the EU be sure that CE-marking or official export certificates from the EU will be recognized or required in all markets across the world?

Subject:	**Counterfeiting:** The Commission is considering introducing traceability requirements into the essential requirements for medical devices to help battle against counterfeiting. 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?
MSA Reply:	▪ Enhanced and clarified traceability requirements would be definitely helpful. But the requirements should be as general as possible to retain the flexibility of the Directive towards innovative ▪ **Registration of Trademarks** – this confers added protection against counterfeits. Once a registered product is suspected to be counterfeit, Customs informs the legal right holder and the latter has 10 days from when he is informed to state whether the product is really counterfeit or not. There is currently no application for the registration of trade marks related to medical devices in Malta. This is regarded as one of the main problems in combating counterfeit products since manufacturers rarely register their trade mark. The advantage of being registered is that for non-registered products, Customs can still initiate an investigation but can only keep products for a maximum of 3 days before being released. Moreover, it is more difficult to contact the manufacturer since the contact points have not been identified. Such products will then be released onto the market and their traceability will be very difficult in case of future problems. ▪ **Information exchange between legal right holders and Customs** – Legal right holders should meet Customs officers more often, in the form of seminars, in order to explain how information is set-out on original packaging and how to identify counterfeit products. ▪ **Internet purchasing** – direct purchasing from Internet is more prone to counterfeiting.

Section 9 – SIMPLIFICATION:	
Subject:	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?
MSA Reply:	The most problematic areas giving rise to legal uncertainty seem to be: ▪ **Borderline cases** – especially due to the vast interpretation of the definition for a medical device and the fact that it is based on the manufacturer's claims on the packaging and instructions for use. ▪ **Obligations of economic operators** – especially for devices imported from outside the EU. These will be already enhanced by the revision of the New Approach.

Subject:	**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? 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.
MSA Reply:	We would find no particular objection to the fact that MDD becomes a Regulation, although the New Approach principles should be retained. Having a Regulation instead of a Directive may be beneficial when it comes to frequent updating of the legal text, especially in view of technological advances or adopting Comitology rulings. Whether MDD becomes a Regulation or remains a Directive will not affect the application of conformity assessment modules. We reiterate that if we want the Legislation concerning Medical Devices to be as flexible as possible with respect to new technologies and new product types, it is essential that the legal text remains as general as possible. The Legislation should not provide the state-of-the-art itself, but it should be up to standards to describe the current state-of-the-art.

Subject:	**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?
MSA Reply:	We would prefer to keep the current choice in conformity assessment modules. Although EN ISO 13485 might be the best possible route, we prefer to keep a principle of flexibility especially in view that there are various risk categories of medical devices on the market and not every SME can afford an EN ISO 13485 system.