AmCham EU's position on the revision of the medical devices and in vitro diagnostics regulatory framework

Medical devices and in vitro diagnostics: designing a safer system for the future

POSITION PAPER

Executive summary

The highly innovative medical technology sector is a major contributor to Europe's knowledge economy and is a key partner in healthcare terms. There are over 500,000 medical devices and diagnostic products (10,000 generic groups) on the European market. Products range from relatively simple tools, such as bandages, wheelchairs and self-care medical devices to highly sophisticated products that integrate many technologies, like medical devices containing medicinal substances, pacemakers, defibrillators and also medical equipment. The European market for medical equipment is worth around €28 billion and 8% of revenues on average are reinvested in R&D for advanced medical imaging and health Information and Communications Technology (ICT) products. The European eHealth and mHealth industry is leading in emerging fields such as remote patient monitoring and integrated care solutions. The technology evolution has challenged the current framework but has also made the European Union's medical devices industry one of the most innovative sectors.

AmCham EU strongly supports a modern and effective regulatory system for medical devices which ensures patients' safety while providing timely and continued access to the latest medical technologies, but a number of key elements are required to ensure that happens. These include:

1. **Decentralised system/pre-market authorisation;**
2. **Regulation of the reprocessing single-use devices;**
3. **Increasing harmonisation and coordination across Member States;**
4. **Increasing transparency; and**
5. **Coordinating market surveillance better across Member States.**

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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American Chamber of Commerce to the European Union (AmCham EU)
Avenue des Arts 53, B-1000 Brussels, Belgium
Register ID: 5265780509-97
Tel: +32 (0)2 513 68 92 | www.amchameu.eu

Secretariat Point of Contact: Pierre Bouygues pbo@amchameu.eu +32 (0)2 289 10 32

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The highly innovative medical technology sector is a major contributor to Europe's knowledge economy and is a key partner in healthcare delivery. There are over 500,000 medical devices and diagnostic products (10,000 generic groups) on the European market. Products range from relatively simple tools, such as bandages, wheelchairs or self-care medical devicesto highly sophisticated products that integrate many technologies, like medical devices containing medicinal substances, pacemakers, defibrillators but also medical equipment.The European market for medical equipment is worth around €28 billion and 8% of revenues on average are reinvested into R&D for advanced medical imaging and health ICT products. The European eHealth and mHealth industry has leading positions in emerging fields such as remote patient monitoring and integrated care solutions. The technology evolution has challenged the current framework but has also made the EU's medical devices industry one of the most innovative sectors. For example the telemedicine approach such as remote auscultation monitoring of patients avoiding unnecessary hospital admissions

On 26 September 2012, the European Commission adopted a package of measures revising the Medical Devices Directives (MD). The revised legislation aims to tighten controls for medical devices and in vitro diagnostic medical devices (IVD); it is the biggest regulatory change in the European Union in the last 15 years. A Regulation rather than a Directive has been considered a more appropriate legislative measure to limit national deviations and will help ensure an equal level of patient safety across the EU. The proposed new regulatory framework consists of a Regulation on medical devices and a Regulation on *in vitro* diagnostic medical devices.

The main elements of the proposals include:

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The following elements are key in ensuring that the system will meet its objective to improve patient safety while protecting innovation:

1. **Decentralised system/pre-market authorisation**: The European regulatory model on medical devices has been successfully exported around the world. But the current system can and should be further improved to safeguard patient safety and enhance innovation. The revised regulatory system for medical devices should continue to provide citizens' access to innovative and cost-efficient medical technology while strengthening the oversight and coordination of the Notified Bodies and regulatory authorities. AmCham EU does not believe pre-market approval by a

central agency for medical devices would be an improvement; it would neither enhance patient safety nor prevent illegal activities (e.g. the recent breast implant scandal).

The 'Scrutiny' procedure, as proposed by the European Commission, is essentially a random duplication of the Notified Body product assessment. As such, we consider that the 'Scrutiny' proposal fromthe Commission and the Parliament does not offer any substantive contribution to patient safety, nor does it make best use of competent authority and Commission resources. The procedure essentially adds layers of random duplication at several stages of the approval process and will increase red tape and unnecessary bureaucracy.

Furthermore, improving the quality and consistency of the assessment made by the Notified Bodies could be achieved by strengthening their designation and monitoring procedures; in particular tackling the level of resources and expertise needed. Stricter and more harmonised criteria for designating and monitoring the quality of Notified Bodies is the best way to ensure equal levels of patient safety all over Europe.

2. **The reprocessing of single-use devices:** The European Commission's proposal aims to regulate reprocessing of single-use medical devices at European level as a manufacturing activity, covered by the Medical Devices Regulation, like is the case in other major jurisdictions such as the United States. Applying appropriate harmonised controls and allowing the development of the reprocessing activity of single-use devices is an important step towards increasing patient safety throughout Europe. This proposal gives Member States the ability to permit or prohibit reprocessing and reuse of single-use devices. AmCham EU supports the Commission's proposal as it guarantees a better level of patient safety combined with a better level playing field, submitting all reprocessors in the whole European Union to the same rules.

   In contrast, the proposal made by the European Parliament to consider all devices as reusable by default is inconsistent and lacks clarity or appropriate safeguards for patient safety. It reverses the well-established safety principle.

3. **More harmonisation**: There should be better coordination and harmonisation across Member States in Europe, in particular regarding the designation and monitoring of Notified Bodies. Better coordination and harmonisation would also help enhance legal certainty for manufacturers, in particular in the area of classification and borderline decisions. AmCham EU welcomes the proposals to strengthen coordination and harmonisation in this area, as well as in other areas such as the assessment of clinical trial applications and the shift from a Directive to a Regulation, which will limit national deviations across Europe.

4. **Increase transparency**: The revision of the regulatory system for medical devices is an opportunity to make the whole system more transparent and increase the availability of relevant information for patients and healthcare professionals. This will help restore trust among all the stakeholders in the system. To this end, AmCham EU welcomes the creation of the European Databank on Medical Devices (EUDAMED), which will be accessible at various levels to patients, industry and healthcare professionals. However, transparency should be carefully balanced with the protection of intellectual property and commercially sensitive information to secure a favourable environment for innovation.

5. **Better coordination in market surveillance**: The system would also benefit from stronger post-market safety and from more coordination between Member States in the market-

surveillance area. This would be possible through broader stakeholder involvement, in particular in the reporting system, thus increasing the efficiency of the vigilance system. Two examples of what is needed are: a European Union-coordinated system for unannounced visits to manufacturing sites; and a European Union-centralised reporting and surveillance system. However, improved coordination among Member States' regulatory authorities should not be used to justify disproportionate rises in national regulatory fees or charges to manufacturers. This would compromise European competitiveness.

AmCham EU also welcomes the introduction of provisions regarding economic operators within the proposed regulations on medical devices. A further clarification of the respective economic operators' tasks and responsibilities is needed and will benefit the functioning of the internal market while contributing to patient safety. In this context, consideration needs to be given to the delineation of the tasks of the respective economic operators in order to take into account the specificities and the strengths of the current medical devices regulatory framework. In particular, the mandatory labelling obligation for importers has to be balanced with the good functioning of the vigilance system.

However, the following identifies concerns AmCham EU has with the proposal:

1. **The clinical evidence requirements**: The proposal sets stricter requirements regarding clinical evidence which will restore the confidence of the public and the medical community.We believe a good balance should be found between pre-market and post-market requirements. In the medical devices field, post-market clinical evidence has proven to be effective and is critical for medical devices. However, we are concerned that some of the requirements introduced by the European Parliament will have a negative impact on device innovation.

   The demonstration of efficacy is not a concept applicable to all medical devices (e.g. the efficacy of a syringe would be difficult to determine); therefore the proposal needs to clearly define what is meant by 'efficacy'.

   Although a restriction of the definition of clinical equivalence is already in the text, a requirement was introduced to even further restrict its use for all class III devices. As a consequence, clinical investigations would need to be performed for all class III devices, even for modifications having no impact on the clinical performance of the device, thus strongly limiting incremental innovation and improvement of devices.

   An obligation to use Randomised Control Trials (RCT), which are not necessarily appropriate for medical devices, and a mandatory assessment by a third party will not only reduce the number of clinical trials performed in Europe but also the number of new CE-marked products introduced on the European Union market.

   Clinical trials are expensive and we might see fewer CE-marked devices with incremental innovation being introduced on the European Union market. Combined with a more limited ability to rely on clinical equivalence, this will have a negative impact, in particular, on incremental innovations which are improving patients' quality of life.

2. **Chemical substances**: We oppose the proposal from the European Parliament to ban chemical substances classified as carcinogenic, mutagenic or toxic to reproduction (CMR) in medical

devices is a proposal that may deprive European citizens from innovative products that do not pose a risk to patients or medical professionals. Rather, we would welcome any regulatory option which ensures a streamlined, predictable and science-based risk assessment system for chemicals in medical devices. A regime that weighs risks versus benefits of chemicals in medical devices to achieve the best possible outcome for the patient is the most appropriate legislative solution. The European Commission's proposal provides a suitable legislative framework to achieve this goal.

3. **Changing the definition of a 'medical device'**: The European Parliament's proposals to change the European Commission's definition of medical devices to bring products with unspecified 'indirect' medical purposes into the scope of the Regulation is not helpful and could create more, rather than less divergence from globally agreed definitions. When it comes to software, for instance, the new, broad definition would unjustifiably qualify a number of non-invasive, non-medical products such mHealth apps as medical devices when they are simply providing lifestyle and wellbeing advice. More generally, the very vagueness of the term 'indirect' runs the risk of triggering many new disputes about how to regulate borderline products. Many such disputes have taken place in the context of today's Directive and the new Regulation should aim to correct, rather than exacerbate, this situation.

4. **Classification of medical devices**
   - **Nanomaterials**: AmCham EU does not support the proposed up-classification of products containing or consisting of nanomaterials in class III. This would unduly lead to the up-classification of many medical devices such as all devices containing radio-opaque markers, independently of the fact that the nanomaterials are intended to be released in the human body. The up-classification should be limited to products that are intended to release nanomaterials in the human body.
   - **Ingested products**: The Commission proposal for the systematic classification of devices composed of substances or combination of substances as high risk (class III) is a concern of overregulation. Devices that are composed of substances or combination of substances primarily intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by and dispersed in the human body in order to achieve their intended purpose should be in class IIa if they are intended for transient or short-term use, and In class IIb if they are intended for long-term use (Rule 21 in Annex VII).
   - **Devices coming into contact with the spinal column**: The European Commission's proposal to up-classify spinal disc replacements and all devices coming into contact with the spinal column is a concern. Spinal disc replacements are designed to restore or maintain a spinal segment function, similar to a hip, knee or shoulder replacements intended to provide a long-term functional articulation. They have a similar risk profile to joint replacement and therefore can be up- classified within Class III like the other joint replacements. However, this is not true for all devices entering into contact with the spinal column, which are used to fix and stabilize spine elements and should remain classified as Class IIb.

AmCham EU welcomes the revision of the IVD regulatory framework and the move toward more global harmonisation: The proposed IVD Regulation promises widespread changes to the IVD landscape in Europe. Manufacturers and importers, Notified Bodies, Competent Authorities, reference laboratories and the European Commission itself will have to adapt to significant changes to comply with the new requirements expected from the future Regulation. While the intended harmonisation of

rules and checks across Europe is warmly welcomed by the IVD industry and will greatly benefit patient safety, **sufficient time needs to be allowed** for all involved players to successfully implement the immense changes.

The European Commission proposal regarding the classification for IVDs is based on the globally developed and accepted Global Harmonization Task Force (GHTF) standard for classification, which aims to foster convergence of any international classification system. With manufacturers working globally, international standardisation is critical as manufacturers export their products for patients around the world and thus need to comply with various regulatory systems.

Australia, Canada, Saudi Arabia and other countries are already moving towards harmonisation with the GHTF standard for classification. There is huge potential for creating a new system that allows relevant data to be comparable globally and can greatly facilitate vigilance procedures. This is essential for patient safety and enhances the distribution of diagnostic technologies across markets and regulatory jurisdictions, promoting the European IVD sector on the global market.

The IVD industry strongly supports the introduction of a more harmonised classification system that is based on the international GHTF model, as reflected in the European Commission text. European deviation from this model should be avoided to keep the benefit of global harmonisation and bring to the IVD companies a return on investment.

However, there is a big concern regarding the alignment of the IVD regulation with the MD regulation on aspects like the post-market surveillance or the clinical evidence requirements. Those requirements are not useful or relevant for IVD products. IVDs are fundamentally different from other medical devices as they never come into direct contact with the patient.

As a general rule, because of the unique nature of IVDs, their assessment and control and the regulatory process, the requirements applicable to other medical devices on clinical evidence and post-market follow-up are not transferrable to IVDs and should therefore be part of specific discussions leading to more appropriate requirements.

Regulatory convergence/harmonisation: The Presidency of the EU and the Council should take into consideration the ongoing Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US and the need for better harmonisation of regulatory and technical standards for medical devices. Further convergence would bring benefits to the medical devices sector, which operates globally, and to patients by lowering costs.