

Limits and opportunities in TTIP with respect to medical devices

VdTÜV and its members support the ambitious project of a Transatlantic Trade and Investment Partnership (TTIP) and want to make it a success by contributing specific solutions.¹

The TTIP negotiations are in particular concern the lowering of non-tariff trade barriers. These barriers include different regulatory requirements for putting products into circulation in the USA and in Europe. This also applies with regard to medical devices. In Europe, medical devices are put into circulation on the basis of a self-declaration of conformity by the manufacturer, with the involvement of a notified body if appropriate. In contrast, in the USA governmental approval is specified for medical devices (please see the more detailed explanations of both procedures in the Annex). As a consequence, the CE marking, as an expression of the self-declaration of the manufacturer, is not recognised in the USA for access to the market; the same applies to US approvals in Europe.

The European system for the putting into circulation of medical devices has proven its worth in past years. It ensures that medical devices are conformant and also safe. Current studies come to the conclusion that, despite very different market access systems, the safety level of medical devices is in effect comparable. However, the system in Europe means that new medical devices come onto the market more rapidly than in the USA. European patients can therefore benefit earlier from innovative medical technology.² It follows that within the framework of the TTIP negotiations the tried-and-tested European regulatory approach must be maintained, in order to ensure the supply of innovative and safe medical devices in Europe.

Legal harmonisation or “mutual recognition” as the way towards a common market?

Bringing together the two basically very different systems and the very comprehensive legal frameworks of each by means of legal harmonisation in connection with TTIP is not possible in the short to medium term and is rightly not yet under consideration by the European Commission.³

An alternative route towards creation of a common market, which at first sight appears simpler, would be to use the instrument of “mutual recognition” of the market access procedure for medical devices and this is mentioned repeatedly in the context of the TTIP negotiations.

Europe has many years of experience with the instrument of mutual recognition and creation of a common market. In areas where legal harmonisation has not so far been implemented at the European level, the following principle applies: a product that has legally been put into circulation in one Member State may be sold within the entire EU (compare the judgement on “Cassis de Dijon”). This fundamental principle, which applies to the EU internal market, was developed by the European Court

¹ Please see the position paper of VdTÜV “Making TTIP a success” for a general view of the issues surrounding TTIP http://www.vdtuev.de/dok_view?oid=516458

² This applies in particular to medical devices of the highest risk class. Please see: National Institute for Public Health and the Environment - Comparison of market authorization systems of medical devices in USA and Europe, RIVM Letter report 2015-0001, A. van Drongelen, J. Hessels, R. Geertsma; The Boston Consulting Group - EU Medical Device Approval Safety Assessment - A comparative analysis of medical device recalls 2005-2009, January 2011; The Boston Consulting Group - Regulation and Access to Innovative Medical Technologies - A comparison of the FDA and EU Approval Processes and their Impact on Patients and Industry, June 2012.

³ European Commission – Medical devices in TTIP http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153008.4.5%20Med%20devices.pdf

of Justice from Article 30 of the EEC Treaty (today Article 34 TFEU) on the “free movement of goods”, and therefore has a democratic, clearly legitimised legal basis (“Primary European Law”), consensually agreed by all Europeans and of almost constitutional character.

In order to make use of the Mutual Recognition control tool in TTIP, a basis as solid as the EEC Treaty would be needed, especially for a trade agreement which has such a wide-ranging effect on the everyday life of citizens. The principle of mutual recognition can also only be effective where and to the extent that the participants from the respective other market have sufficient trust in the product-specific rules and regulations and the resulting level of protection which apply in the product’s country of origin. However, experience in the EU shows that products with a particularly high hazard potential for people and the environment cannot be marketed according to the principle of mutual recognition. This also particularly applies to the sale of medical devices. Rather, harmonised legislation was created for such products, based on Directives and Regulations.⁴

Particularly against the backdrop of the fundamentally different market access systems and the differing legal requirements which apply in many areas, it is clear that application of the principle of mutual recognition, if applied to medical devices and technology, would inevitably reach its limits and would not be capable of implementation within the framework of TTIP in the short to medium term.⁵ Therefore in this product area, mutual recognition is not a suitable instrument for creation of a common market between the EU and the USA.

A look at the history of transatlantic trade also confirms this. As early as 1998 an attempt was made to lower barriers to trade between the USA and Europe by means of a “Mutual Recognition Agreement” (MRA). The MRA also covered medical devices, but was not intended to cover devices in Class III. However, in particular because of the different legal requirements and the reciprocal lack of trust in the market access system of the other partner, the MRA was not used in practice.

Instead of legal harmonisation or mutual recognition, a “one stop shopping” solution could be envisaged. In this case, private assessment bodies at the home location would be authorised to assess products in accordance with the legal and standard-based requirements of the other economic area (Transatlantic Conformity Assessment). This approach assumes that both contractual partners delegate authority to non-governmental bodies for the task of conformity assessment of medical devices. However, as the USA makes use of an approval system based on a governmental body, the route of Transatlantic Conformity Assessment cannot be used here to facilitate reciprocal market access.

A common regulatory approach through more intensive cooperation

As the instruments of legal harmonisation and mutual recognition will not be possible in the short to medium term, and one-stop shopping is also not capable of implementation, in the course of the TTIP a common regulatory approach by means of more intensive cooperation between the European and US-American authorities should be the objective. Here, a common approach to the requirements would be particularly promising in certain areas, e.g. as regards unique numbers for each medical device (Unique Device Identification – UDI) for traceability purposes. This common approach could in particular be achieved through development of new international standards and rules along with revision and uniform interpretation and use of already existing standards. A suitable environment for such cooperation would be, for example, the International Medical Device Regulators Forum (IMDRF).

⁴ In particular 93/42/EEC on medical devices, 90/385/EEC on active implantable medical devices and 98/79/EC on in-vitro diagnostic medical devices.

⁵ The different legal requirements apply for example, in the areas of classification of medical devices, requirements for clinical studies/data/assessments, technical requirements, etc.

Nevertheless, even within the framework of stronger regulatory cooperation in the IMDRF or in other bodies, no legally-binding decisions can be made which could replace democratically legitimised legislation. More intensive cooperation to bring requirements closer in the areas in question would nevertheless make a contribution to allowing medical devices to access the market rapidly through removal of barriers whilst maintaining the same safety level or even raising it. This means that patients could have easier access to innovative and safe technologies and the costs for the health services would be reduced.

Reciprocal recognition of the quality management system audits (QMS audits) is only possible if the intensity and frequency of the regular and unannounced audits and also the qualification requirements for the auditing personnel are identical in both economic areas.

Cornerstones for the TTIP negotiations on the subject of medical devices:

- No legal harmonisation towards a system of governmental approval for medical devices.
- No mutual recognition of the market access procedures.
- A common regulatory approach through more intensive cooperation.
- Recognition of QMS audits only with the same intensity of inspection and surveillance.

Annex – Further explanations:

- Market access procedures in Europe

In the EU, the putting into circulation of medical devices is based on Directive 93/42/EEC on medical devices, 90/385/EEC on active implantable medical devices and 98/79/EC on in-vitro diagnostic medical devices. Medical devices may only be marketed in Europe with a CE marking, in other words a self-declaration of conformity from the manufacturer. The manufacturer is therefore responsible for the putting into circulation of medical devices, and himself affixes the CE marking to his products. By affixing the CE marking he declares that his products are conformant with the relevant legal requirements, in particular with the “Basic Requirements” specified in the Directives. Medical devices are divided into four classes (I, IIa, IIb and III) according to fixed rules. IVDs are divided into four groups. The requirements for active implantable medical devices – because of their hazard potential – correspond to those placed on Class III devices as described in Directive 93/42/EEC. In order to put a product into circulation, the manufacturer first determines the Directive that applies to the device based on the purpose and mode of operation. In the next step, he determines the risk class. Among others, the conformity assessment procedure then follows from this.

All medical devices must fulfil the relevant and legally specified “essential requirements”. These requirements provide the foundation for assessment of a medical device and particularly take into account safety and the technical and medical performance and effect of the device, in accordance with its purpose and risk class. In addition, technical documentation has to be presented for each medical device, which describes how the essential requirements are fulfilled. A risk assessment must be performed for all medical devices within the framework of the risk management system. Depending on the risk potential of the products, conformity assessment procedures are performed either on the sole responsibility of the manufacturer or with the involvement of a notified body. The

basic principle applies that the higher the risk potential of the respective medical device, the greater the extent of the third-party control.

A notified body is an independent inspection and certification body which, at the manufacturer's request, examines the conformity assessment performed by the manufacturer and confirms the correctness of the conformity assessment based on common standards of evaluation. A notified body is a neutral and independent organisation which has to provide evidence of its competence and be authorised by the State (notified) and also monitored (surveillance). It examines the specified medical devices, the manufacturing process of the products and/or the product documentation for agreement with the requirements of the corresponding EC Directives. If, within the framework of the conformity assessment procedure, the notified body establishes that the manufacturer has fulfilled the relevant EC Directives, it issues Directive-based approval and the manufacturer can affix the CE marking to the product.

➤ Market access procedure in the USA

In the USA, the Center for Devices and Radiological Health (CDRH), a body within the FDA, is responsible for marketing approval of medical devices. The work is based on the 1976 Medical Devices Regulation Act. This Act defines three risk categories for medical devices: Class I – low risk; Class II – moderate risk; Class III: high risk. Based on this classification there are two different procedures for approval. In the case of some medical devices with a low to medium risk for the patient (Classes I and II), the equivalence to a device or product already on the American market has to be proven. This procedure is known as "Premarket Notification" (510k) and is not an approval procedure as such, but simply a product release. Many products of Class I and some of Class II are exempted from the 510k procedure; here, registration with the FDA is sufficient.

In the 510k procedure, independent third parties are also involved in part, and perform a corresponding evaluation. However, the final decision lies with the FDA.

Devices which involve a potentially high risk for the patient (Class III) are generally subject to "Premarket Approval" (PMA), in other words governmental approval. In this procedure, the safety (which always has to be proven for all product classes) and also the effectiveness have to be proven by means of clinical studies. However, "Premarket Approval" is only carried out for around 1% of all products.