European Federation of Precision Mechanical and Optical Industries

EUROM VI "Medical Technology"
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Enhancing the health of the public European-wide and worldwide and facilitating innovation by harmonising the European and global regulatory environment

COMMENTS AND PROPOSALS ON THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP)

1. Background

EUROM supports an ambitious trade agreement between the European Union and the United States. The aim of the so-called Transatlantic Trade and Investment Partnership (TTIP) to remove significantly trade barriers in order to generate more economic growth and employment on both sides of the Atlantic is welcomed by the European medical technology industry. TTIP is seen as an opportunity to further promote the already existing international co-operation between the EU and the US in the medical technology sector.

2. Non-tariff barriers for the medical device sector

The United States are the main market and trade partner for the European medical technology industry. Despite the good trade relations there are still significant trade barriers which inhibit the growth potential of the transatlantic trade relations. Especially so-called non-tariff barriers (e.g. such as double market access procedures or different norms and standards) still lead to substantial expenses, which particularly affect small and medium enterprises (SMEs).

The market access system in Europe is based on the so-called "New Approach". According to it a product can be put on the market or into service if it has a CE mark. The CE mark can be placed on medical devices only if the essential requirements of the current EU Directive are met and a product-specific conformity assessment has been carried out.

In the United States there is a centralized authorization procedure of the Food and Drug Administration (FDA). In this case, medical devices belonging to the highest risk category require an official permit (Premarket Approval, PMA). In practice it is not only an extremely consulting-intensive procedure but, inter alia, due to a number of formal requirements, also very expensive and lengthy. There are several examples in which medical devices, which passed successfully their marketing phase in Europe, where continuously improved and further technically developed in Europe while in the US only the first generation of the initially same medical devices got approval due to the lengthy approval procedures in the US.

Although both systems are different they share the same objective: ensure the safety of medical devices and secure the highest patient safety. The European system takes into account the peculiarities of the medical devices, such as the heterogeneity of the products and manufacturers, the short innovation cycles and differences between medical devices and pharmaceuticals. Thus, the European system allows patients rapid access to modern and safe technologies.

Other significant trade barriers for the medical technology industry are the different test procedures, i.e. the lack of recognition of each other's audits. Reasons for this are the sometimes different applicable standards. In practice it leads to duplicate testing procedures, which require more efforts and costs without leading to recognizable added value for users and patients.

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3. Expectations of the European medical technology industry

Preservation of high standards and patient's safety

Patient's safety and high standards are fundamental priorities for the European medical device companies. Both the EU and the US are characterized by their high standards in the healthcare sector. They have to be maintained and cannot be weakened in favour of economic growth.

Mutual recognition and standardization of market access procedures

EUROM calls for the mutual recognition of medical devices whose safety and effectiveness have been demonstrated according with the European or US rules. In this sense, it should be possible that medical devices which fulfil the requirements of the European legislation can be freely marketed in the US as in the EU member states, and vice versa, in accordance with the principle "once approved, accepted everywhere".

The industry also calls for the mutual recognition of test reports for medical devices. Further, a simpler preparation of dossiers through common datasets, standardized formats and harmonized electronic systems would increase the efficiency of the industry.

By removing these barriers cost advantages and synergies would be achieved on both sides of the Atlantic. It is not about lowering of safety and health standards, but the recognition of medical devices previously tested and classified as safe.

Focus on SMEs

The vast majority of the medical device companies in Europe are SMEs. SMEs are the driving force behind European medical device industry. They are an important source of innovation and a guarantor of highly skilled jobs. A free trade agreement between the EU and the US must be therefore drafted in accordance with their needs and expectations.

Transparency

EUROM calls for transparent negotiations and for closer involvement of stakeholders. Being TTIP a treaty that aims to benefit the transatlantic trade and enterprises, industry representatives necessarily have to be consulted and heard more frequently.

Investment protection

The necessity of including a special chapter on Investor-State Dispute Settlement (ISDS) is a controversial subject. If such clauses are included in the TTIP-agreement, it is essential to guarantee governments' right to regulate, the transparency of arbitral tribunals and the possibility of appealing arbitral awards. Only a modernized investment protection may be accepted.

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EUROM VI Medical Technology is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises.

The objectives of EUROM VI are:
- to represent European Medical Technology Industry;
- to promote cooperation between members but also with other European organisations;
- to encourage worldwide trade by being involved in harmonisation of legislation, standardisation, mutual recognition and certification procedures;
- to be a partner on works with the European Commission and Standardisation Bodies;
- to support European Industry views on international activities.