AdvaMed
Advanced Medical Technology Association

ADVAMED COMMENTS ON TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP

Introduction

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide comments to assist the United States Trade Representative (USTR) as it works with other U.S. government agencies and continues to consult with Congress to develop U.S. negotiating objectives and proposals for the proposed Transatlantic Trade and Investment Partnership (TTIP). AdvaMed represents approximately 400 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. AdvaMed members range from the smallest to the largest medical technology innovators and companies. AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality health care technology can make toward achieving those goals.

AdvaMed supports the negotiation of a comprehensive free trade agreement (FTA) between the United States (US) and the European Union (EU), under the framework of the TTIP. The purpose of this paper is to provide official negotiators with a summary of our views on the areas that should be included in the TTIP.

General Comments on Regulatory Cooperation

Although the US and EU use different approaches to determine the safety and efficacy of medical technology, studies have demonstrated that each system delivers similar results in terms of these basic objectives. AdvaMed supports cooperation between the regulatory agencies on both sides of the Atlantic as a way to promote understanding and reduce unnecessary regulatory burdens. Rather than attempting comprehensive "convergence" of these two systems, such as a mutual recognition agreement (MRA), we recommend focusing on specific areas of "convergence." Previous efforts have tried to conclude a workable MRA between the two systems; those efforts failed after considerable time and resources. We believe negotiations on medical technology should focus instead on specific areas – where convergence is possible - and avoid negotiations that pressure either system to fundamentally change.

In this spirit, AdvaMed, MITA and their sister associations in Europe identified the following areas where greater regulatory cooperation would facilitate trade, reduce market access barriers and strengthen the medical device industries on both sides of the Atlantic:

1) mutual recognition of ISO 13485;
2) a single audit process;
3) harmonized format for product registration submission; and
4) a common way to trace products through a single unique device identification (UDI) process with interoperable databases.

The attached proposal for regulatory cooperation in these areas was presented at the U.S.-EU High Level Regulatory Cooperation Forum meeting in April.

AdvaMed also recommends that TTIP include a regular dialogue between the U.S Food and Drug Administration (FDA) and DG-SANCO, involving USTR and U.S. Department of Commerce, to exchange information on regulatory measures being considered by either party that could impact trade and determine areas for additional "convergence." In advance of these meetings, industry would be consulted to provide their views on regulators' proposals. This dialogue could be held under provisions similar to Korea-US FTA (KORUS) Article 5.7, but strengthened to ensure that future measures be explicitly discussed and industry has the opportunity to comment on non-confidential proposals and has access to the results of such meetings.

Specific Recommendations

In addition to regulatory cooperation as outlined in the accompanying document, we urge both governments to address the following issues in the context of a comprehensive Free Trade Agreement.

Tariffs

Border tariffs on medical technology trade between the US and EU are not high. However, those that remain add costs to the free exchange of our products between the two trading partners and ultimately increase costs to patients. We recommend that all remaining tariffs on medical devices be eliminated upon entry into force of the TTIP.

Trade and Customs Facilitation

Our members face obstacles when clearing Customs between the EU and US. For example, currently only certain categories of goods qualify for pre-clearance. We recommend that the TTIP include clear and unambiguous disciplines on the freedom of goods to transit borders with minimum delays and formalities including processes for expedited and/or pre-clearance of merchandise.

In addition, the EU and US should significantly enhance electronic customs procedures and cooperate towards implementing a system of standardized customs processes, efficient central customs clearance and harmonized customs and security related standards. For example, in the EU, many customs regulations are harmonized at EU level but their implementation continues to be enforced by member state authorities which can create inconsistencies in implementation. In the U.S., there is a lack of regulatory coordination between customs/C-TPAT regulations and import/export requirements by regulatory agencies such as the FDA, causing border delays which can deprive patients of the lifesaving technologies they need.

EU Single Market

The regulatory system in the EU is supposed to be a single market for medical technology. After a product obtains the CE mark, that product should be accepted in every Member State without any additional product safety and efficacy requirements

Unfortunately, the experience of medical technology companies is quite different. Individual Member States have adopted differing coverage rules that require additional

clinical evidence to be approved for reimbursement and/or impose registration fees for market access. These internal barriers to the free flow of medical technology within the EU should be harmonized. For example, the CE's "Essential Requirements" should be recognized as sufficient to determine safety and conformance with manufacturers' claims for product performance. In addition, across Member States, individual member states' registration fees should be eliminated. Such changes would move the EU closer to a single market for medical technology.

Late Payments

Medical technology companies have been experiencing late payments from Member State governments for many years, especially Greece, Spain and Italy. Such payments often extend to well over a year or more. Exceptional late payments – often four or five times the period specified in the European Directive 2011/7/EU on combating late payment in commercial transactions – inhibit the flow of medical technology across the EU and act as a trade barrier to US exports. We recognize that European governments are experiencing difficult financial stringencies which need to be considered in the short-term, but the TTIP should be viewed as a document for the long-term and include specific provisions strengthening the enforcement of the Late Payments Directive. We ask that the directive be converted into a legally binding regulation, which would be enforceable under the TTIP's dispute settlement provisions.

Procedural Fairness/Transparency

The medical technology industry increasingly faces price and payment cuts from governments around the world. Our industry recognizes that governments face fiscal challenges and are attempting to find ways to contain rising healthcare costs. However, often such price and payment reductions are imposed in an arbitrary manner with no clear and transparent process and methodology. The TTIP should ensure that industry has the right to adequate advance notice and reasonable opportunity to comment on all reimbursement and payment measures affecting trade at the federal level. We have found that Member States, which are sovereign nations with the sole competence for payment policies within their jurisdictions, often do not provide this adequate notice and comment.

Because we see the TTIP as possibly setting precedents in other markets, we request that provisions similar to the KORUS and the Korea-EU FTA be included in the TTIP. For example, under the KORUS:

- Article 5.2 indicates that the procedures, rules and criteria for setting reimbursement rates shall be fair, reasonable and non-discriminatory.
- Article 5.2 states that such rates should be based on competitive market prices or, if not, the rates should recognize the "value" of the medical device, allowing the manufacture to provide evidence to that effect – including the ability to demonstrate the rationale for increased rates. This provision does not indicate that the prices should be published or otherwise provided to anyone.
- Article 5.3 includes clear transparency provisions that allow the medical device industry to provide input into pricing decisions, to have access to "all procedural rules, methodologies, principles and criteria" and guidelines used for pricing, and an independent review process.

- Article 5.7 establishes a committee to monitor implementation and to promote collaboration.

Third Country Issues

Our industry faces an array of issues outside the US and EU. Our member companies source many of their products sold globally from the US and/or the EU. Therefore, governments in both the US and EU should be interested in ensuring that medical technology companies are treated fairly by third country governments. We ask that the TTIP include provisions that encourage the relevant agencies to work on behalf of our medical technology firms. These include the following areas.

Trade and Customs Facilitation

Our members face obstacles when clearing Customs, usually outside the US and EU. Here again, we believe the TTIP could serve as a model for negotiations in the WTO and in other bilateral trade agreements. We recommend that the TTIP include clear and unambiguous disciplines on the freedom of goods to transit borders with minimum delays and formalities. Fees, if required at all, should be based upon the cost of the government service being provided. There should be processes for expedited and/or pre-clearance of merchandise and strong anti-bribery provisions. All laws, regulations and rules impacting customs requirements should be clear and readily available.

Buying Preferences

Governments in some third countries such as Russia, Brazil and Turkey have either introduced or are considering measures that would require that a certain percentage of medical technology acquired through government procurement on their markets must come from manufacturing in their domestic market. The TTIP should prohibit such practices – which are not being used in either the US or EU– as a demonstration for WTO participants.

Informing Other Regulators

Regulatory agencies in other countries – such as Brazil and China – often provide preferences to domestic companies. While we do not expect FDA, DG SANCO or Member State Competent Authorities to favor firms located in the US or EU, we believe the TTIP should include provisions directing the appropriate regulatory agency(ies) to: (1) to promote international regulatory best practices and participate in training sessions with other regulators on those best practices, e.g., those of GHTF, IMDRF, AHWP, and APEC.; and (2) intervene with other regulators to explain how each regulatory system operates and help counter discriminatory treatment.