European Commission

The Transatlantic Trade and Investment Partnership (TTIP)

Towards an EU-US trade deal

EU position paper on medical devices

15 April 2015

Trade

1. Introduction

The final report of the US-EU High Level Working Group on Jobs and Growth (February 2013) highlights that as regards regulatory aspects TTIP should contain, in addition to cross-cutting disciplines and TBT plus elements, provisions concerning individual sectors.

This paper outlines the main elements of a possible approach under TTIP to promote regulatory convergence in the medical devices sector. These elements build on existing regulatory co-operation between the EU and the US in the International Medical Device Regulators Forum (IMDRF). The paper contains preliminary ideas that can be complemented and refined at a later stage. In particular TTIP could cover:

- Recognition of manufacturers' quality management systems (QMS) audits
- Convergence of systems for identifying and tracing medical devices (Unique Device Identification - UDI).
- Convergence of models for marketing submissions (Regulated Product Submission - RPS)

These three work items presume the exchange of confidential information between regulators and more generally the reinforcement of multilateral and bilateral co-operation processes.

Discussions are still ongoing and therefore specific actions have not yet been decided. In any case, the three work items could result in gains for industry, regulators and patients, and in greater international cooperation on medical devices approval processes. This can be achieved without compromising protection of public health.

2. Possible elements for a medical devices annex in TTIP

1.1. Quality Management System Audits

Both the EU and the US require an audit of the manufacturers' premises quality management system (QMS) before allowing certain (higher) risk medical devices to be authorised/placed on the market (pre-market phase). There are also regular audits to make sure the production process and the products consistently meet the regulatory requirements in the post-market phase. Currently, a given manufacturing facility is audited by both the US authorities (US Food and Drug Administration - FDA) and by the EU Notified Bodies.

The QMS requirements in the US and the EU are very similar (there is a common body of requirements) but there are also requirements that are specific to the EU legislative framework and others that are specific to that of the US. There is no intention to use TTIP to harmonise EU and US QMS regulatory requirements as this would be a process that would be better tackled at international level.

Rather, the intention is that when auditing a facility QMS auditors check compliance with the requirements of several jurisdictions at the same time – a so-called **single audit**. The concept of the single audit has been developed at international level and is being tested under the 'Medical Device Single Audit Programme - MDSAP'. Both the US and the EU are engaged in this international process.

- In this context, and taking into consideration the work done under the MDSAP, **both sides could develop the necessary legal provisions to allow a formal recognition of quality management system audits carried out by the other party's auditors** provided that the audits are comprehensive and cover all requirements as set by respective legal frameworks (single audit concept).

This approach would entail significant cost savings for the industry (by avoiding double/unnecessary audits) and for the regulators.

In the EU, priority is currently given to the adoption of the draft EU Regulations on Medical Devices and on *In-Vitro* Diagnostics Medical Devices (IVDs), which may also affect how QMS audits are conducted. The negotiation of commitments for accepting inspection reports from US auditors is to be seen in this context and the need, in the EU, for a legal basis to be established.

1.2. Unique Device Identification (UDI) and interoperability of databases

The traceability of medical devices by means of a Unique Device Identification (UDI) system significantly facilitates the monitoring, by competent authorities, of devices once placed on the market.

In December 2013, IMDRF adopted a guidance document on UDI that provides for a framework for those regulatory authorities that intend to develop their UDI Systems. The main objective under IMDRF was to establish a globally harmonised approach to UDI. If the UDI system, as defined in the IMDRF guidance, is implemented by different jurisdictions around the world, competent authorities, healthcare professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a medical device and its key attributes.

Both EU and US regulators participated actively in developing the global UDI specifications. Meanwhile, the US have implemented their US UDI system. It is in line with the IMDRF UDI Guidance and includes the US UDI data base. The system has been in force since September 2014. The EU also intends to implement its UDI system but only after the adoption of the EU Regulations on Medical Devices and on IVDs.

- In this context, both sides could agree to continue co-operating on this matter and in particular **to ensure that the EU and US UDI databases are compatible with the aim of facilitating transatlantic traceability**. Both sides could also agree to **further promote the uptake of the global IMDRF UDI system by other countries** around the world.

The advantage of this approach would be to avoid the proliferation of UDI-incompatible systems across the globe that would hamper traceability of medical devices.

1.3. Harmonised template for data submission (Regulated Product Submission – RPS) and a common/interoperable system for electronic data submission

Currently, a manufacturer seeking to market a medical device in the EU and the US has to submit separate marketing applications to each jurisdiction. In addition, the information and the formatting required are different.

Both Parties, while respecting the different regulatory systems for market access of medical devices in the EU and the US, could **support harmonisation efforts at international level (IMDRF) by agreeing on and implementing a harmonised model format for data submission for the data set common to both parties and by establishing a common/ interoperable electronic system for data submission** that could be used by both EU and US regulators.

1.4. Exchange of confidential information and trade secret information

Both Parties would need to agree on **the exchange of confidential information and trade secret information between EU Notified Bodies/EU institutions and the FDA**, as well as on related confidentiality requirements. This approach would apply not only to QMS inspection reports but also to data and information on marketing authorisation applications and vigilance/device safety data.

1.5. Reinforce cooperation in IMDRF

Both parties could agree to further **strengthen their cooperation within IMDRF** and discuss ways to implement IMDRF guidance in their jurisdictions, as well as bringing a political commitment to reinforce the impetus of IMDRF work.

1.6. Reinforce bilateral regulatory cooperation in new areas

Both Parties could co-operate on new issues and consider developing disciplines and principles aimed at **good regulatory practices specific to the medical device sector**, without duplicating the work done in IMDRF.