COCIR/MITA Joint Contribution

EU and US call for input on regulatory issues for possible future trade agreement

COCIR and MITA welcome the opportunity to share ideas with the United States government and the European Commission on how greater transatlantic regulatory compatibility between the European Union and United States can be achieved in the healthcare sector.

COCIR is the voice of the European radiological, electromedical and healthcare IT industry. A non-profit trade association founded in 1959, COCIR represents the medical technology industry in Europe and its members play a driving role in developing the future of healthcare in Europe and worldwide. The Medical Imaging & Technology Alliance (MITA) is the collective voice for medical imaging, radiation therapy equipment and radiopharmaceutical manufacturers, innovators and product developers in the United States. Combined, COCIR and MITA represent companies whose sales comprise more than 90 percent of the global market for medical imaging technology.

MITA provides leadership for the medical imaging and radiation therapy industries on legislative and regulatory issues at the state and federal level in the US and internationally by working with COCIR and others as part of the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA). COCIR and MITA both serve their constituencies as an advocate for fair legislative and regulatory proposals that encourage innovation, investment in research and development, as well as the continued global competitiveness of the medical imaging and radiation therapy industries.

In 1998, the US and EU agreed to a Mutual Recognition Agreement (MRA) for medical device approvals that was never fully implemented. MITA and COCIR recognize that a comprehensive agreement such as an MRA is not likely achievable. However, we believe that there are several specific, discrete regulatory areas where the regulators can work together towards a harmonized approach.

MITA and COCIR propose that the following three key priorities within the healthcare economic sector be included in the EU-US regulatory compatibility efforts:

A. <u>Single Audits of Medical Device Quality Systems</u>

Medical device manufacturers implement and comply with regulator-specified quality systems to ensure high levels of safety and performance of their finished medical devices. These quality systems include careful controls and testing throughout the

devices' design, development, manufacturing, distribution and post-market surveillance processes. Periodic audits of the manufacturer's quality system by regulators or certified Notified Bodies (third parties) provide regulators with transparency and assurance of the manufacturers' ongoing compliance and product performance.

Currently, the EU DG SANCO and US FDA do not mutually recognize each other's distinct but equally effective quality systems. The EU and its member states (as well as several other global regulators that have participated in the Global Harmonization Task Force (GHTF)) recognize the international standard *ISO 13485, Medical devices – Quality management systems – requirements for regulatory purposes*, whereas, the US recognizes *21 CFR 820 Quality System Regulation*.

Further, the EU Directorate General for Health and Consumers (DG SANCO) and US Food and Drug Administration (FDA) do not mutually accept successful audits of the ISO 13485 as demonstrating evidence of compliance to 21 CFR 820, and vice versa.

COCIR and MITA urge greater regulatory compatibility through:

1) **the recognition of the internationally accepted ISO 13485 quality management system standard, and**
2) **the mutual acceptance of successful ISO 13485 audits (i.e., single audits), performed by either regulators or certified Notified Bodies as demonstrating quality system compliance.**

Mutual acceptance of ISO 13485 audits will greatly increase the efficiencies of inspectors and reduce the burden on regulator resources. Additionally, it will expedite time to market and thereby patient access, while reducing costs for manufacturers by eliminating the need for redundant quality system audits in order to satisfy the requirements of both the US and EU quality systems regulations.

In addition to these proposed single audit efforts by the US and EU for greater transatlantic regulatory compatibility, several global healthcare regulators as part of the newly created International Medical Device Regulators Forum (IMDRF - formerly GHTF), have accepted the single audit of medical device quality systems as one of its five work items.

Both the US and EU medical device regulators are members of IMDRF. Not only will the mutual recognition of the ISO 13485 Quality Systems standard and audits enhance transatlantic regulatory compatibility, it will serve to lead other global regulators in their efforts to develop worldwide and mutually recognized regulatory

frameworks and processes such as the single audit of medical device quality systems.

B. Single Harmonized Standard for Marketing Application Documentation

Both the EU DG SANCO and US FDA require medical device manufacturers to gain marketing clearance/approval from regulators on most classes of medical devices before placing them on the market. To gain approval, manufacturers submit extensive documentation as part of the medical device marketing application. The types of information submitted includes but is not limited to: device description and photographs/schematics, the device use(s) and targeted patient demographics, operator manuals, device design testing data, and often clinical testing data.

Currently, manufacturers must complete two separate marketing applications utilizing two separate templates for the same medical device, one for the EU and one for the US. For the most part, both templates request medical device information that is either the same or similar.

Additionally, some portions of the marketing application may be submitted electronically, whereas for other portions this capability does not yet exist.

COCIR and MITA urge greater EU-US regulatory compatibility through the harmonization of a singular standard for a medical device marketing application with electronic submission capabilities.

The US FDA recently released its draft guidance for a new "eCopy Program for Medical Devices". This program will allow for the electronic submission of US marketing applications. While the eCopy program is intended to improve efficiencies in the US FDA review process, it is not intended to change the data required in the submission or to be a globally harmonized standard for electronic market applications.

A harmonized standard for electronic submission of medical device marketing applications will expedite time to market, thereby improving patient access to the latest technologies, and reduce costs for manufacturers by eliminating the need for redundant submissions.

IMDRF has accepted Regulated Product Submissions (RPS) as one of its five work items. The goal of this IMDRF group is to develop an ISO standard that supports the electronic submission for product licensing applications between industry and regulatory authorities. The testing and development of the RPS

standards is through Health Level Seven (HL7) which is an ANSI accredited standards organization and global authority on standards for interoperability of healthcare technologies.

A harmonized EU and US submission documentation template represents an opportunity to lead other global regulators in their efforts to develop worldwide and mutually recognized regulatory frameworks and standards for the electronic submission for medical device marketing applications.

C. Unique Device Identification Database

Both the EU DG SANCO and US FDA, along with other global regulators, are developing a common system for identifying/labeling medical devices that will enhance their ability to track postmarket performance of marketed medical devices (i.e., the UDI, Unique Device Identification).

As part of this system, a global UDI database (GUDID) will be developed. The GUDID is currently in a conceptual phase with many aspects of its design, implementation and maintenance still to be addressed. Questions concerning the GUDID have been raised by manufacturers. They include but are not limited to:

- whether or not the GUDID is a single worldwide database or is it a system of local databases linked together that contain the same data sets for all medical devices,
- which regulator will be responsible for maintaining the GUDID,
- control and security (per existing restrictions/requirements for encrypted content) around data entry by manufacturers and access by global regulators,
- whether or not the GUDID supplants or supplements the Global Data Synchronization Network ("GDSN"), and,
- additional questions related to coded value clarification and compatibility with electronic health records, and report generating features.

COCIR and MITA urge greater EU-US regulatory compatibility through the recognition and acceptance of a singular standard for a Global Unique Device Identification Database for medical devices.

The US FDA recently released its *Proposed Rule to establish a Unique Device Identification ("UDI") System.* Many aspects of this proposed rule will need alignment with the IMDRF voluntary draft guidance for UDI (initially issued by GHTF). Subsequent to this content and process alignment, the GUDID design must be finalized and implemented by regulators.

IMDRF represents an existing forum for the EU-US to address and resolve the outstanding GUDID issues. Mutual development and acceptance of a singular standard for a Global Unique Device Identification Database by the EU and US, represents an opportunity to lead other global regulators in their efforts to develop mutually recognized regulatory frameworks and standards worldwide.

COCIR and MITA appreciate the opportunity to share these recommendations, and look forward to concrete achievements in regulatory convergence. This would be an important advance in our mutual goal of fair competition and removal of unnecessary trade barriers. Please contact us if there is anything further we can contribute.

****