High Level Regulatory Cooperation Forum Stakeholder Session

US/EU Medical Technology Industry Input on the Transatlantic Trade and Investment Partnership (TTIP)

Nicole Denjoy
COCIR, Secretary General
Representing EU Manufacturers

Abby Pratt
Advamed, Associate Vice President
Representing US Manufacturers

Washington, DC
April 10, 2013

1. **Who We Are**

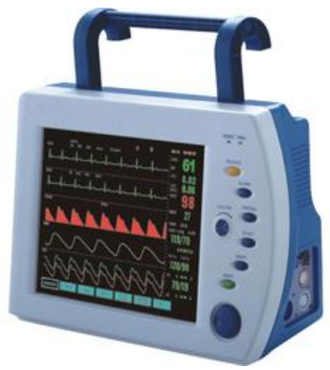
2. **Transatlantic Trade Potential**

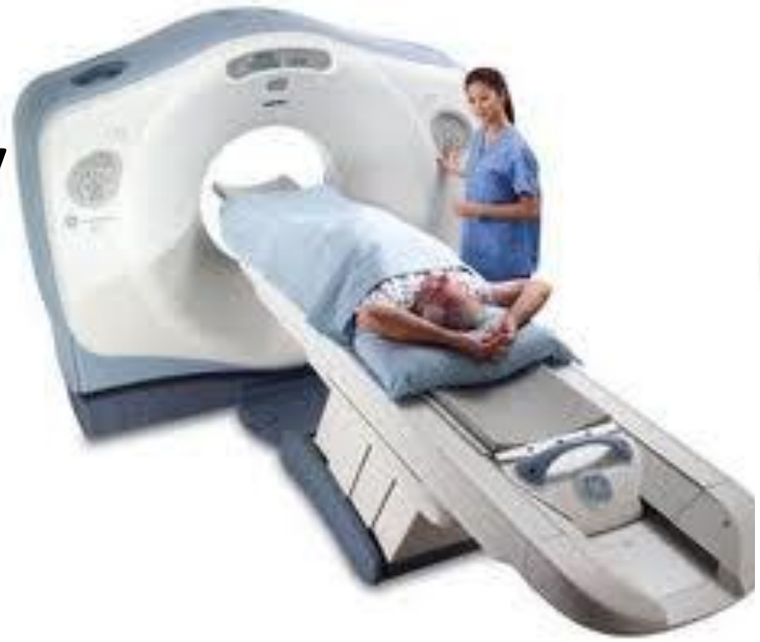
3. **Industry Proposals for TTIP**

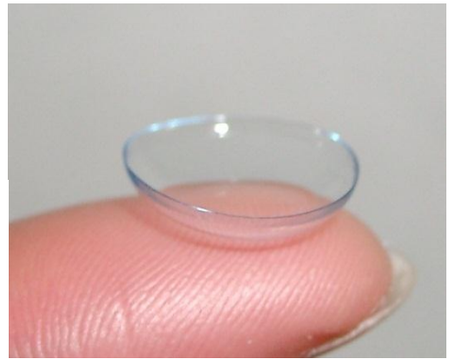
1. Who We Are

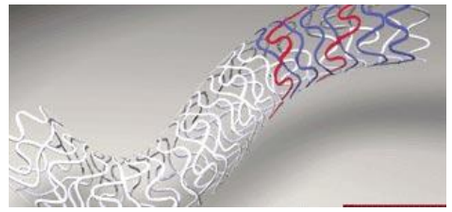
Medical Technologies

- Diverse Products
- Rapid Innovation
- Multi disciplinary









United States

The Advanced Medical Technology Association (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's more than 400 member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed acts as the common voice for these companies, leading the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world.

MITA is the leading organization and collective voice of medical imaging equipment, radiation therapy and radiopharmaceutical manufacturers in the United States. MITA advocates for fair legislative and regulatory proposals that encourage innovation, investment in research and development, as well as being a leading standards-development organization.

European Union

COCIR is the voice of the European Radiological, Electromedical and Healthcare IT Industry. COCIR is a non-profit trade association, founded in 1959, and its members play a driving role in developing the future of healthcare in Europe and worldwide.

EDMA is the industry association that represents the interests of the In Vitro Diagnostic (IVD) industry throughout Europe.

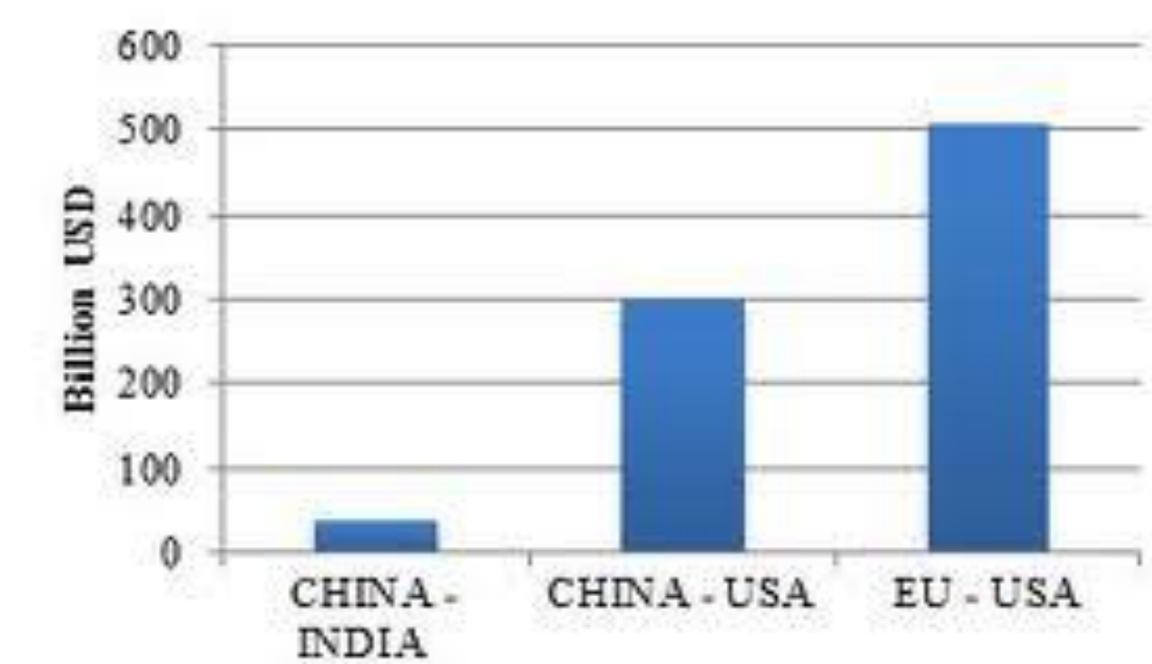
Eucomed represents the medical technology industry in Europe. Our secretariat is in continuous contact with EU stakeholders, and we and our members are committed to ensure that fundamental collaboration with healthcare professionals adheres to the highest ethical and professional standards.

Our vision is to provide products and services that are of…

1. **Highest quality**
2. **Maximum safety**
3. **Easily accessible**
4. **Cost efficient**

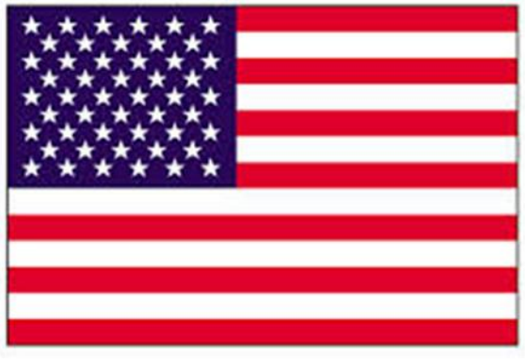
Patient safety: already one of the common goals for all stakeholders

2. Transatlantic Trade Potential



Source: Data from IMF and UN

United States



- Advamed presents <u>80 percent</u> of medical technology firms in the United States

- Members produce nearly <u>90 percent</u> of the health care technology purchased annually in the United States and more than <u>40 percent</u> purchased annually around the world

- The US medical technology industry generates more than 2 million America jobs and sells more than $136 billion of products annually

- MITA member companies sales comprise more than <u>90 percent</u> of the global market for medical imaging technology

- The US medical imaging and radiation therapy industry accounts for more than <u>250,000 American jobs</u>

European Union

- The medical technology industry in Europe encompasses 600 000 to 750 000 jobs, a large proportion of which are from highly qualified professionals.

- The European market for medical technology is 100—120 billion Euros per year.

- Over 500 000 different medical devices are in use within Europe.

3. Industry Proposals for TTIP

We believe that there are several specific, discrete regulatory areas where regulators can work together

US and EU medical technology manufacturers propose the following three key priorities within the healthcare economic sector be included in the Transatlantic Trade and Investment Partnership (TTIP):

1. ***Single Audit of Medical Technology Manufacturer Quality Management Systems***

2. ***Single Harmonized Standard for Marketing Application Format***

3. ***Unique Device Identification (UDI)***

1. Single Audit of Medical Technology Manufacturer Quality Management Systems

What is the situation today?

- Current regulatory requirements are similar, but not identical
- European national authorities, assessment bodies and US FDA do not use each other's reports
- Audits are required by both the US and EU authorities despite similar requirements

- <u>In the European Union:</u>
  - Recognized international standard ISO 13485
  - Depending on risk-based classification, the EU relies on Notified Bodies to audit

- <u>In the United States:</u>
  - FDA has established 21 CFR 820 Quality System Regulation (QSR)
  - QMS inspections are performed by FDA, limited audits by accredited third parties

How to achieve greater compatibility/convergence of regulations & standards?

- Common auditing procedures
- Use of common audit reporting templates/formats
- Application of common criteria by auditors
- Co-development of training for auditors
- Joint training of auditors
- Mutual use of single audit reports
- Recognition of international standard ISO 13485 for quality management system

1. Single Audit Continued…

How should the US and EU authorities address the reported issues?

- US and EU participate in the International Medical Device Regulators Forum (IMDRF)
- Through IMDRF, the US and EU have the opportunity to enhance regulatory compatibility
- Once the IMDRF single guidance documents are finalized, US and EU should adopt them
- Industry is committed to participate in the development of a mutually beneficial pilot

What could be the timeline to achieve those objectives?

- Once the IMDRF guidance is finalized, a single multi-purpose QMS audit program acceptable to the US and EU could be in place 2 years post-trade negotiations

What will be the impact of the proposed measures?

- Continuing regulatory burden for industry due to routine multiple audits
- Uncertainty related to scheduling and allocation of resources for multiple audits
- FDA report found an average savings of 33% in-person days can be expected in most instances when compared to the time of separate audits
- When an issue is detected a single solution would be acceptable for both

2. Single Harmonized Standard for Marketing Application Format

What is the situation today?

- **<u>In the European Union:</u>**
  - Europe requires a single submission to the relevant notified body or regulatory authority following a risk-based classification
  - Technology must demonstrate conformance to “essential requirements” of safety/performance

- **In the United States:**
  - The US requires a single submission to the FDA, the details of the submission depend on the novelty and risk presented by the device
  - Accredited third parties are allowed with final decision-making authority resting with FDA

How to achieve greater compatibility/convergence of regulations & standards?

- Regulatory burden would be reduced if differences were eliminated, allowing similar evidence
- Harmonized format have been developed (STED) & are used in US/EU
- Single protocol and electronic exchange program of compliance evidence would be helpful
- IMDRF is working on the use of electronic formats for Regulatory Product Submissions (RPS)

2. Single Harmonized Standard Continued…

How should the US and EU address the reported issues?

- In the context of their respective regulatory revision processes, attention must be paid to integrate electronic information exchange and safeguard intellectual property
- As the IMDRF RPS work is completed, US & EU should adopt the guidance documents

What could be the timeline to achieve those objectives?

- Timeline will depend upon IMDRF RPS guidance progress and adoption by the EU & US

What will be the impact of the proposed measures?

- US and EU adoption of IMDRF RPS guidance will allow regulatory simplification for both the regulator and regulated, by allowing submission of common data sets

3. Unique Device Identification (UDI)

What is the situation today?
UDI is a global initiative in which both EU & US are deeply involved. Convergence should be possible relatively easily but EU must speed up its implementation (particularly database).

- **In the European Union:**

- EU needs to be clear about marking/labelling levels for products to ensure convergence.
- EUDAMED is the intended system to capture UDI data but it will need extensive modification.
- Cooperation between EU and US on database is desirable.

- **In the United States:**

- FDA has the worldwide database to capture device characteristics associated with a unique device identifier, and contains all core data elements defined within the draft IMDRF UDI Guidance
- US-specific data elements and the globally harmonized HL7 messaging standards are included
- FDA engaged industry to test the database, however input was limited. The focus is on the technology platform and usability.

How to achieve greater compatibility/convergence of regulations & standards?

- Reach convergence on marking/labelling levels for products
- Optimize EU & US databases with harmonized messaging standard/protocol for electronic submission
- FDA has developed the HL7 SPL messaging standard for electronic submissions

3. UDI Continued…

How should the US and EU address the reported issues?

- Specifications of core data elements should be the same in the US and EU, ideally globally
- Establish EU-US working group of database experts from US, EU, industry, IT & HL7 SPL

What could be the timeline to achieve those objectives?

- Urgent and needs to be in the short-term: FDA has an almost final UDI regulation and a developed and tested database

What will be the impact of the proposed measures?

- Achieve convergence between EU and US in terms of UDID
- Keep cost for UDID implementation and daily operation low for regulators and industry
- Implementation of UDI databases in EU and US and ensure interoperability
- If implemented in short-term, UDID can facilitate traceability systems which are urgently required
- Encourage global harmonization of UDI

In Summary, We Call For…

1. Recognition of the standard ISO 13485 for quality management system

2. Mutual use of single audit program performed by either regulators or certified Notified Bodies as demonstrating quality system compliance

3. Harmonization of a single standard for a medical technology marketing application with electronic submission capabilities

4. Urgent development of an EU database for UDI which is compatible with the US database. Uniform use of risk based approach in EU and US.

Our vision remains to provide products and services that are of…

1. **Highest quality**
2. **Maximum safety**
3. **Easily accessible**
4. **Cost efficient**

We need similar regulatory frameworks which foster innovation and facilitates increased transatlantic trade

We thank you for the opportunity to present at this Stakeholder Session, and look forward to continuing to work closely with you in advance of and during TTIP negotiations

Our associations will continue to collaborate on this critical effort and stand ready to contribute

Thank you!