

THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (T-TIP)

-- OPPORTUNITY FOR MEDTECH?

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Further, Together

TRADE AGREEMENTS

OUR OBJECTIVES TODAY

Some Basic Points

- Trade Agreements are much more than headlines
- Much more impactful and profound than name indicates
- Affect many more countries than one believes
- Can be directly helpful for MDT and all medtech companies
- Political rhetoric is at its highest point, both in US and in Europe, for many years

Thus today I intend to:

- Provide some key background on T-TIP
- Field your questions and suggestions

TRADE AGREEMENTS

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Trade deals show power politics is back

By Zaki Laïdi

America's objective is to contain China's rise by setting a high regulatory bar, says Zaki Laïdi

Almost everyone seems excited about the prospect of a free-trade agreement between the US and the EU. But not so fast. The pursuit of such deals is eroding multilateralism, the foundation of post-cold war international relations.

In principle, the emergence of a multipolar world, in which the US is no longer the only very powerful country, should boost "multilateralism" – institutionalised co-operation among states in pursuit of shared objectives. It should boost efforts to achieve free trade via the World Trade Organisation, poverty reduction through the

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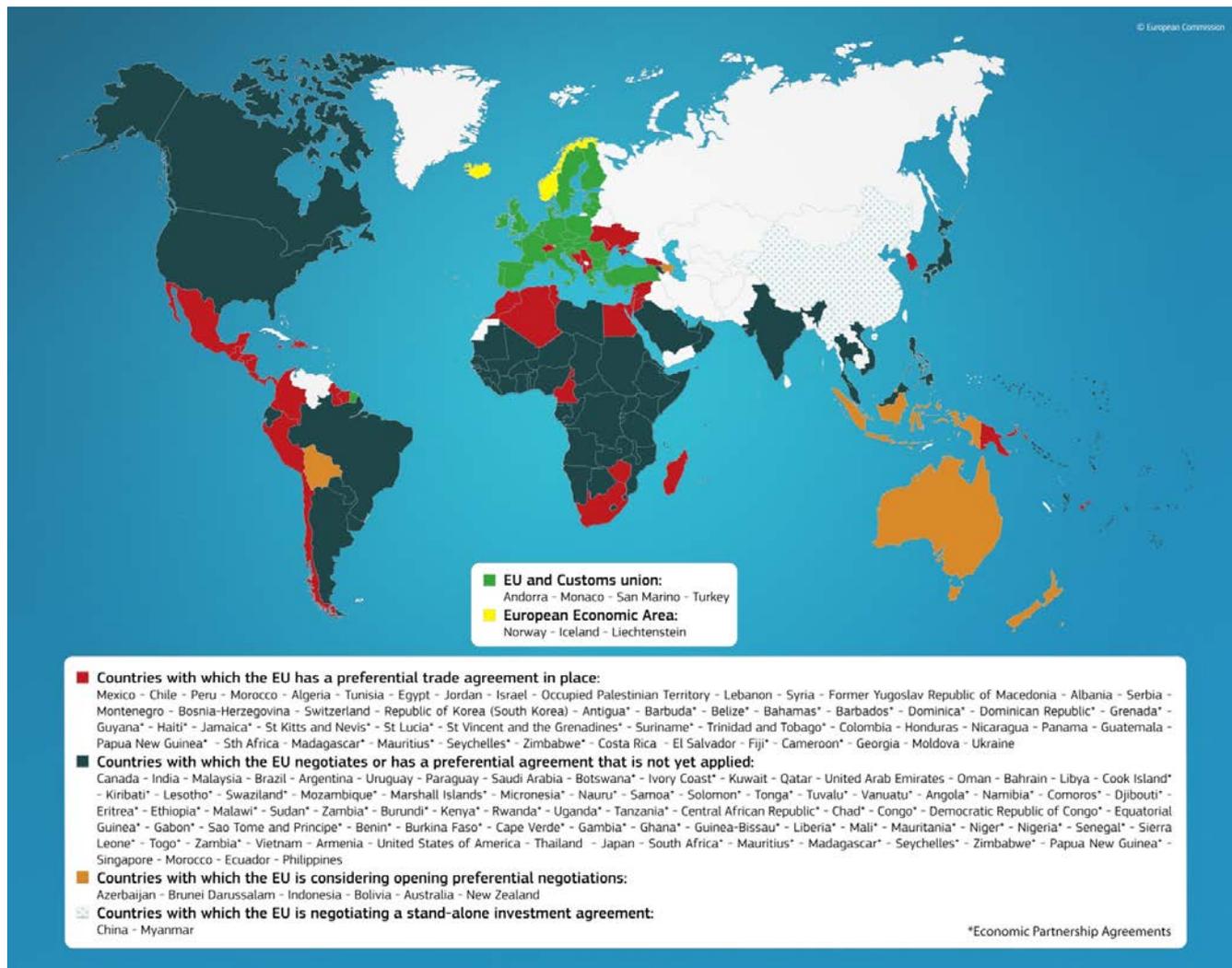
TRADE AGREEMENTS

EXISTING UNITED STATES FTAs

| FTA | | Implementation Date |
|---|--------------------|----------------------|
| U.S.-Israel | | 9/1/1985 |
| NAFTA | Canada | 1/1/1994 |
| | Mexico | 1/1/1994 |
| U.S.-Jordan | | 12/7/2001 |
| U.S.-Singapore | | 1/1/2004 |
| U.S.-Chile | | 1/1/2004 |
| U.S.-Australia | | 1/1/2005 |
| U.S.-Morocco | | 1/1/2006 |
| U.S.-Bahrain | | 8/1/2006 |
| DR-CAFTA | Costa Rica | 1/1/2009 |
| | El Salvador | 3/1/2006 |
| | Guatemala | 7/1/2006 |
| | Honduras | 4/1/2006 |
| | Nicaragua | 4/1/2006 |
| | Dominican Republic | 3/1/2007 |
| U.S.-Oman | | 1/1/2009 |
| U.S.-Peru | | 2/1/2009 |
| U.S.-Colombia | | 5/15/2012 |
| U.S.-Panama | | 10/31/2012 |
| U.S.-South Korea (KORUS) | | 3/15/2012 |
| Trans-Pacific Partnership (TPP): Australia, Brunei Darussalam, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam, and Japan. | | Negotiations Ongoing |

TRADE AGREEMENTS

EXISTING EUROPEAN UNION FTAs



TRADE AGREEMENTS

T-TIP: WHO IS INVOLVED?

United States

Negotiations led by U.S. Trade Representative's Office

- U.S. Trade Representative Mike Froman



European Union

Negotiations led by European Commission Trade Directorate

- EU Trade Commissioner Cecilia Malmstrom (Sweden)

EU Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. **States negotiate as a block.*



TRADE AGREEMENTS

WHAT WILL THE T-TIP FTA ENCOMPASS?

Examples:

- Elimination of tariffs on U.S.- EU trade
- (Possible) section on pricing/ health economic transparency
- Investment protections
- Improved access/process to government procurement
- Regulatory transparency, cooperation and provisions on “behind-the-border” obstacles to trade (e.g., Technical Barriers to Trade)
- Trade-related intellectual property rights (IPR) provisions
- Agreements on Environmental and Labor standards
- Competition-Policy Related Matters
- *Cooperation on new “global” challenges: (oriented to Em Mkts!)*
 - State-owned Enterprises
 - Localization
 - Raw materials and energy
 - Customs and trade facilitation

TRADE AGREEMENTS INDUSTRY ENGAGEMENT

Submission On U.S./ EU Regulatory Compatibility

Medical Imaging & Technology Alliance (MITA) *United States* & European Coordination Committee of the Radiological, Electromedical and Healthcare IT industry (COCIR) *European Union*

- **Single audit system** that would allow relevant authorities to share inspections reports and reduce duplicative audits and inspections. MITA and COCIR propose to accept mutual recognition of ISO 13485 audits.
- **Single harmonized standard for marketing application documentation.**
- **Unique Device Identification (UDI).** MITA and COCIR pledge for efforts to make U.S. and EU UDI systems compatible.

Advanced Medical Technology Association (Advamed) *United States*

- **Unique device Identification (UDI).** A UDI system is being developed in the EU and US legislation and Advamed pledges for efforts to make both systems compatible.
- **Single audit system** that would allow relevant authorities to share inspections reports and reduce duplicative audits and inspections. Advamed proposes an MRA for company inspections and audits when EU finalizes its new regulations for medical devices.
- **Interpretation of ISO 14971** (this is a standard on the management of risk for medical devices). Advamed criticizes that the EU has rejected the use of the ALARP (as low as reasonably accepted) to determine the acceptable risk level.

Health Enterprises (SME, medical devices type I) *United States*

- **Eliminate the need for double registration.**
- **Requests harmonization of medical devices legislation** in both sides of the Atlantic without further specification.

TRADE AGREEMENTS INDUSTRY ENGAGEMENT

Participation In U.S./ EU High-Level Cooperation Forum April 10, 2013

Joint Industry Contribution: COCIR, MITA, EUCOMED, EDMA and ADVAMED**

“Industry is focused on making TTIP a matter of high importance that will bring measurable results in the short and mid-term such as 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.”

MITA [Press Release](#), April 11, 2013



T-TIP NEGOTIATION

WHERE ARE WE NOW, WHERE ARE WE GOING?

MACRO PICTURE

- Negotiators met in Washington for first session in 2012—last session early May in NYC
- Multiple negotiations in multiple European and US cities
- Subsequent negotiating sessions will occur in different EU countries, in various US states (increase visibility)

MDT and INDUSTRY STANDING and EVOLVING POSITIONS

- We are largest medtech company, AdvaMed member and chair Eucomed.
- We strongly believe we have a role to play on behalf of the highly competitive medtech sector
- We are gathering inputs on problems, suggestions and trying to convert them into negotiating objectives
- We will assess shortly if we wish to push objectives greater than trade associations have agreed.
- We are asking questions, beyond the original asks, whether disciplines in Healthcare Services and “Transparency and Procedural Fairness” might be appropriate asks.

CONTACT

Questions? Suggestions?

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