



EUROPEAN COMMISSION  
Directorate-General for Trade

Directorate F - WTO, Legal Affairs & Trade in Goods  
**Unit F3: Tariff and Non-Tariff Negotiations, Rules of Origin**

**Conference "TTIP-Increased Trade for Better Living"**  
*15 and 16 June 2015, Brussels*

An European Policy Conference "TTIP-Increased Trade for Better Living" was organised by DEMETER International in collaboration with EPHA (European Public Health Alliance) on 15 and 16<sup>th</sup> June 2015. The conference attended by around 200 participants, featured plenary sessions and workshops focusing on certain negotiating areas (status of the negotiations, sustainable food and farming, health systems and services). The conference aimed at answering a set of key questions in view of producing recommendations for decision makers (*see doc attached*) on how to construct better and fairer international trade relations for the benefit of societies and the environment:

- What practical changes would TTIP in its current form impose on EU sustainable agricultural production and (local) food processing?
- What implications could free trade agreements have on European health systems?
- What impact could mechanisms like regulatory cooperation or ISDS have on the quality of democratic legislative processes?
- What model and structures could be used to mitigate the risks free trade agreements pose for sustainable agriculture, food and public health?
- What standards and rules should be included into the new 5-year EU strategy on trade to make international trade fair, democratic and supportive of sustainable economies?

**Panel I-TTIP negotiations and civil society concerns** discussed the potential positive and negative impact of TTIP on both sides of the Atlantic. COM strongly highlighted that TTIP is not supposed to create a single transatlantic market and it will not lower the existing high level of standards. It was also emphasized that a high level of transparency has already been achieved within TTIP due to the number of stakeholder and civil society meetings as well as the EU position papers published in the web site. **Panel II-TTIP impact on food and farming** discussed why TTIP is needed for both Parties in the agricultural sector. Both the EU and the US main interests were discussed. Easier market access for several products (e.g. dairy products) and export potential for processed products were mentioned as key priorities for the EU. Whereas GMOs are of high importance for the US. Finally **Panel III-TTIP**

**impact on health systems** focused on pharmaceuticals and medical devices as well as healthcare services.

### **Panel III- TTIP impact on health systems**

#### **Panelists:**

- [REDACTED] (DG Trade);
- [REDACTED], (CEEP- European Centre of Employers and Enterprises providing public services and HOSPEEM - Vienna Association of Hospitals);
- [REDACTED], (EPSU - European Federation of Public Service Unions).

#### **Summary:**

[REDACTED] gave an overview of the ongoing TTIP negotiations focusing on the **regulatory aspects of pharmaceuticals and medical devices**. TTIP is expected to be an ambitious and balanced agreement dismantling both tariff and non-tariff barriers. It will positively influence the development of regulations and standards at international based on high levels of consumer and environmental protection. The high level of transparency provided by COM was also highlighted. Among others the Advisory Group with several representatives from very diverse sectors, a number of events taking place during and after each round of talks with representatives of civil society attending as well as comprehensive materials on all aspects of the negotiations posted on the website. No legal text is available yet regarding medical devices, pharmaceuticals and cosmetics regulatory aspects. EU pharmaceutical priorities were outlined: the recognition of each other's Good Manufacturing Practices (GMP) inspections, collaboration on innovative areas such as harmonized requirements for the authorisation of biosimilars and generics as well as the increased exchange of confidential information between regulators. As regards medical devices, the most important possible elements for a medical devices annex in TTIP were presented: Quality Management system Audits (QMS), Unique Device Identification (UDI) and interoperable databases as well as the Regulated Product Submission (RPS).

As regards **health services**, [REDACTED] from CEEP expressed concerns about the possible impact of TTIP on services of public interest in particular on potential decrease of MS competences in this area. Article 168 of the Treaty needs to be respected. According to CEEP, trade agreements are not the place to decide on health standards and patients safety CEEP does not agree with a hybrid approach for services whereby a negative list would be used for national treatment commitments and a positive one for market access. CEEP disagrees with the negative list approach as it might not be able to provide the same level of protection (there might be new services in the future that then will not be legally protected) as a positive list. Considering that the elements negotiated in TTIP are not entirely disclosed to the public, a positive list approach on national treatment could serve as reassurance for the

industry and civil society. CEEP raised also concerns on ISDS. COM was finally asked for clarifications on the WTO Trade in Services Agreement (TiSA) negotiations. [REDACTED] reiterated that EPSU (*see position paper attached*) wants to make sure that the protection of health in TTIP will not be decreased. She called on COM to provide a firm statement about health protection and to defend the European Social Model. Finally, she underlined that there is no need to support further privatisation of healthcare.

### **Discussion:**

**IVAA** (International Federation of Anthroposophic Medical Associations) called for a state of play of Complementary and Alternative Medicines (CAM) discussions in TTIP. COM noted that CAM medicines have not been discussed under TTIP and are not on the discussion table. On one hand the legislation differs significantly in EU and US on the other hand no request has been made by either Party or by stakeholders to discuss it within TTIP.

**BeMSA** (Belgian medical students association) called for clarification on the interpretation of “avoiding unnecessary clinical trials” asking whether it is equal to disclosing clinical trial data or not. COM answered that an appropriate EU Regulation on clinical trials and the European Medicines Agency (EMA) policy on publication of clinical trials data are in place. Those are not being questioned and negotiated within TTIP.

A question was asked whether the US food supplements will be able to enter into the EU market without any product authorization procedure despite some of them being classified as medicines according to the EU regulations. It was emphasized that all products being produced in the US have to fulfil the EU legislation before entering the market. Those products have to be assessed in accordance with the EU rules and EU classification system.

Finally a question was raised on a possible inclusion of a pharma annex in TTIP referring to an article on it recently published in The New York Times. COM explained that a pharma annex is supposed to be included in TTIP but it will not include Pricing and Reimbursement provisions.