

**Meeting with European Social Insurance Platform (ESIP)**  
**(21/10/2014)**

**Participants:**

[REDACTED] (TRADE)  
[REDACTED] (TRADE)  
[REDACTED] (ENTR)  
[REDACTED] (ESIP)  
[REDACTED] (AOK Statutory Health Insurance Germany)  
[REDACTED] (ESIP)

**Summary:**

The European Social Insurance Platform (ESIP) represents over 40 national social security organisations across 16 Member States. Main objectives of the organisation are to preserve high-profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP is following closely TTIP. A position paper will be available soon. ESIP presented its ideas regarding TTIP, in particular on Intellectual Property Rights; biosimilars; pricing and reimbursement; EMA policy on the disclosure of clinical trial data and advertising and internet sales.

In general terms ESIP expressed the hope that TTIP does not limit Member States' control of their own health care strategies and that TTIP does not undermine EU health systems quality.

Commission noted interest to engage with the European Social Insurance Platform and the wish that the organisation puts forward its main interests in this area. The Commission is interested, in particular, to get an insight of the areas ESIP thinks should be brought to the negotiations table i.e. the offensive interests and by which means TTIP could bring benefits to patients and improve access to medicines.

**Intellectual Property Rights**

- ESIP noted that in their view patent protection rights should not be harmonised between EU and US and that patent protection in the EU should not be further extended (important impact on availability of generic medicines).
- The Commission noted that discussions on IPR are still focusing on a detailed exchange of information between regulators. Textual discussions or exchange of texts have not taken place. It is still uncertain what will be US requests in this area. However, taking into account of the US position in other negotiation agreements possible areas of interest to US can be anticipated (e.g. patent linkage, patent extension for administrative delays). EU is not interested in extending the duration of its patent protection.

**Biosimilars**

- ESIP noted interest in Biosimilars regulatory convergence and inquired about the US guidelines on naming and labelling of Biosimiars.
- ESIP asked if there were intentions to work with US on patent protection for biosimilars (biologicals)

- Commission noted that bilateral cooperation (notably on guidelines for the approval of biosimilars) is one of EU priorities in the pharma sector (as highlighted in the EU position paper). The US Guidelines on naming and labelling of Biosimilars are not yet available (US still reflecting on direction to be taken). Patent protection for biologicals is up to 11 years in EU and up to 12 years in US. There is no intention for harmonisation.

#### **Pricing and Reimbursement:**

- ESIP noted concerns with the eventuality of including in TTIP, provisions on transparency in pricing and reimbursement decisions. In their view such provisions could limit the freedom of member states to control their own medicines policies, including cost containment strategies.
- Commission noted that provisions on transparency in pricing and reimbursement decisions do not figure among EU priorities for this sector. The transparency annex with South Korea is not the benchmark to be used in the case of the US.

#### **Disclosure of Clinical Trial Data**

- ESIP noted that the Guidelines published by EMA on 2<sup>nd</sup> October represent an important compromise between different stakeholders. TTIP should not in any way disrupt the levels of transparency already achieved in Europe.
- Commission noted that there are no intentions to revise the Clinical Trials Regulation (entering in force in 2016) nor recent EMA policy on publication of clinical data.

#### **Advertising and Internet sales**

- ESIP noted that US policy that allows pharmaceuticals companies to advertise directly to consumers should not be brought into Europe through TTIP. The same for internet sales: EU approach should be kept.
- Commission noted those matters have not been discussed in TTIP.