EUROPEAN COMMISSION
Directorate-General for Trade

Directorate F - WTO, Legal Affairs and Trade in Goods
TRADE F.3 Tariff and Non–Tariff Negotiations, Rules of Origin

Meeting with EUROCAM on TTIP regulatory issues and CAM (Complementary and Alternative Medicine) 24/03/2015

Participants:

- [redacted], [redacted] (DG TRADE), [redacted] (DG SANTE)
- Board members of the 12 organisations of EUROCAM

Summary:

COM gave some background information on the TTIP negotiations. It was mentioned the negotiations are conducted across a variety of clusters and benefits can primarily arise from the regulatory area of TTIP as the tariffs are already very low. To talk about health in TTIP is particularly challenging because it intersects with diffnert sectors of te agreement (regulatory aspects, tariffs, IPR, services, public procurement and so on0. Negotiation positions (available in the web) resulted from a close cooperation among the several stakeholders of the field, including the pharmaceutical and health regulators of both Parties. In addition, the key elements and objectives of the negotiations of pharmaceuticals were identified in particular the objective of ***mutual recognition of Good Manufacturing Practices (GMP*)** inspections. In the US, the GMP inspection procedure is managed by one government agency (US FDA), while in the EU, GMP inspections are carried out by Member States inspectorates. There is a peer review system where inspectors from two Member States review the GMP inspection process in another MS. EU allowed FDA to observe this internal process and provided them with all the required information to assess the equivalence of the US GMP system with the EU one. The EU is also assessing/evaluating the US GMP system. The objective is that a mutual recognition agreement (MRA) can be concluded between the EU and the US (similarly to MRAs that are already in place with several third countries).

S**everal questions were raised by EUROCAM** concerning the future prospect of CAM products and the delivery of CAM services under a TTIP agreement:

With regard to the potential ***legal provisions will be made for the delivery of CAM services***, COM explained that CAM services will be treated under TTIP as other medical services in previous agreements. Given the sensitivity of the health sector the EU and its MS have the right to restrict the provision of cross-border health services. A number of MS also restrict establishment of non-EU services providers.

In connection with the ***herbal and homeopathic medicines,*** EUROCAM noted that registrations and market authorisations are mainly given at the national level, but a central procedure for herbal

medicinal products can be used in some cases based on Directive 2004/24/EC. Furthermore EUROCAM expressed its concerns on potential changes in EU legislation brought in by TTIP or the possibility for mutual recognition of products/marketing authorizations given that the legal requirements in EU and US are very different for these products. COM noted that herbal medicines have not been discussed under TTIP and are not on the discussion table. TTIP will not interfere with the EU and with US legislation on the matter. The legal status of the products is also not being discussed. As regards accessibility, a product legally placed in the EU market will continue being so and a product originating in the US will have to continue following EU registration/authorization procedures (i.e. it will have to respect EU legal requirements). Any future revision of the EU provisions applicable to herbal medicines, if they are decided, will take their normal course – EU decision procedures.

With regard to TTIP's impact on ***the availability of medical insurance for future refunding of CAM,*** it can be said that the insurance system is not a question of the trade agreement.

On the question of whether ***pricing and reimbursement*** decisions would be included in TTIP, COM answered that the EU has no plans to include pricing and reimbursement in the negotiations, however the US is insisting on this issue to be discussed in TTIP aimed at including rules concerning transparency as regards pricing and reimbursement such as the ones in the US - Korea and the EU-Korea FTAs.

Considering the ***cross border recognition of CAM qualifications*** as well as the potential ***integration of CAM modalities into the health systems of MS***, TTIP could contribute for recognition of professional qualification if associations from both sides ask for. However, TTIP cannot interfere with the way MS organize their health systems or the way they recognize or not CAM qualifications and practitioners.

Reflecting on ***the availability of specific research funds*** within TTIP, COM noted that research funds will continue to be available under EU research framework (FP7; Horizon 2020; funds available by given DGs; Innovative Medicines Initiative (IMI)). TTIP will however not trigger the availability of specific research funds. EUROCAM remarked that the EU lags behind the US significantly in the amount of invested money in R&D of CAM products.

With regard to ***Genetically Modified Organisms (GMOs)*** it was noted that the US have significantly different policies comparing with the EU hence there will be no alignment regarding GMOs.