

**TTIP Meeting with European Coalition on Homeopathic and Anthroposophic Medicinal Products
(ECHAMP)**

07/01/2015

Participants:

COM: [REDACTED], [REDACTED], [REDACTED] (TRADE); [REDACTED] (SANCO).

ECHAMP: [REDACTED], [REDACTED]

Discussion:

COM explained the state of play of TTIP negotiations and gave some explanation of the method and structure followed for TTIP negotiations. Negotiations take place around several pillars. The regulatory pillar comprises the TBT text; regulatory coherence and the different sectors. Pharmaceuticals have been tackled since the beginning of the negotiations (in Pharma there is an emphasis on GMP but other areas are also being looked at). The list of sectors that have been discussed so far is the result of a public call for interest of stakeholders launched in 2012. The information collected from this activity is available to the public. In the US, a similar mechanism was used. In this context there were joint positions received from associations from the EU and the US. On basis of these contributions and regulators input some sectors were selected such as pharmaceuticals, medical devices, chemicals and so on. Currently, around 9 sectors are being discussed. The sectors are handled together by DG Trade and other DGs that have the regulatory expertise. This configuration is also followed by the US, where USTR and the experts (US Food and Drug Administration, when it comes to pharmaceuticals) are present. Furthermore, COM has put a strong communication strategy into place regarding TTIP: stakeholders meetings and publication of position papers, among others.

ECHAMP explained that it represents around fifty companies which are located in around twenty MS. They are mainly SMEs which produce homeopathic or antroposophic medicinal products in the EU. ECHAMP's work is highly specialized in as much as they deal with homeopathic therapies, for which there is a need for a big product range of raw materials. ECHAMP is globally satisfied with the current EU framework and showed concerns about a potential changes negotiated in the context of TTIP. ECHAMP highlighted that there is an important number of Europeans that use these products and, therefore, ECHAMP wants to ensure a proper regulatory framework and to ensure continued availability of these products in the EU market. According to ECHAMP the pharmaceutical industry receives a lot of attention in FTAs; however, herbal and homeopathic products should not be forgotten.

ECHAMP asked whether TTIP may have implications on marketing authorizations that are to a large extent provided at national level. COM explained that national authorisations and mutual recognition of marketing authorizations within the EU is not being discussed in the negotiations. This being said, some aspects/parts of the marketing authorization process are being discussed, e.g. GMP, scientific advice or scientific assessment. These discussions might further harmonise the data that are required in the EU and the US to obtain a marketing authorization but the authorization procedures and the final decision on granting or not a marketing authorization will remain unchanged.

ECHAMP indicated that they were in favor of mutual recognition of Good Manufacturing Practices inspections. ECHAMP explained that their companies are normally audited by MS authorities and if the intention is to export to the US, FDA carries out also a GMP inspection. of the underlying principles of inspections by FDA and the EU are similar although inspections as such are not completely the same (e.g. documentation to be provided might differ). Given the current scenario, it would be good to have further harmonization. For example, there is an agreement of this kind between Brazil and the US. COM asked ECHAMP to provide more information on this agreement.

ECHAMP noted that the status of their products in the EU and the US it is very important, in particular, because some homeopathic products are seen as food supplements in the US where in the EU are considered as medicinal products. This is crucial with regard to licensing of products. COM clarified that the classification of products is not being discussed in TTIP. In this respect ECHAMP inquired whether a US food supplement could be sold as an homeopathic product in the EU after TTIP. COM noted that FTAs do not amount at allowing that any product that is authorized in the US can be directly sold in the EU. EU procedures or legislation will not be amended as a result of TTIP. Furthermore, the products will have to continue complying with the rules/legislation of the country of destination. There is therefore not such risk.

ECHAMP noted that one of the challenges is that these products are not normally regulated via centralized procedure but at national level. Thus, nowadays, this industry is subject to EU Regulations/Directives, national rules and ICH but there are also national guidelines. The implementation of the latter differs upon MS, i.e. there is not a harmonized approach in the EU on the authorization of these products. ECHAMP inquired therefore how to harmonize something that is not even harmonized in the EU. ECHAMP wants to make sure that after TTIP or CETA their products can be kept in the market. COM noted that harmonization on requirements is not being discussed in TTIP.

ECHAMP inquired about ISDS and Dispute Settlement provisions. In particular ECHAMP is concerned about the possibility of American companies bringing actions against the EU or its MS on grounds of the lack of harmonization that governs the EU market in the area of homeopathic and and antroposophic products. ECHAMP illustrated the question by giving an example in which a US product enters the EU market through a MS but finds a barrier when trying to access another MS market (where the same product is not authorized).

COM noted that each party keeps the right to protect its interests on grounds of health and safety as it happens in the scope of the TBT agreement. COM would look into Dispute Settlement provisions and respective safeguards.

On food supplements COM noted that some associations have raised their voice on health claims (e.g. AHPA). COM has also got requests on the maximum level of vitamins and minerals and on botanicals in food supplements. However, COM did not consider it could move forward on these areas, EU legislation is quite clear.

ECHAMP asked whether reimbursement will be affected by TTIP or CETA. COM noted that the EU system legislation will not be changed neither MS competencies. Pricing and reimbursement decisions, as such, are national competences but there is an EU Directive that ensures transparency of the decision process. In the EU-Korea FTA there are provisions on transparency regarding pricing and reimbursement. When the EU negotiates with certain countries that lack this type of transparency provisions, the EU tries to push these provisions into the agreement. Nonetheless, for this to be possible the other party needs to have a similar

system to the EU one. Between the EU and the US, there are too many differences. In addition there is EU legislation on transparency. Therefore, there is no need to put provisions on transparency of pricing and reimbursement decisions in TTIP.

ECHAMP was interested in knowing whether national regulatory agencies are normally involved in negotiations or consultations. COM noted that for technical issues COM works with national agencies. For example, there is a team of inspectors from MS for GMP inspections and COM works very close with EMA on all scientific matters.

ECHAMP asked about how "regulatory cooperation" would work in relation to future legislation. Namely, ECHAMP wanted to know whether there will be a Committee to deal with consultation on upcoming legislation and whether it would constitute a mere consultation or it may influence the legislator's line to take. COM noted that the Regulatory Council was an idea that was launched but it has not been fully developed yet. The Regulatory Council will be a consultative body. At the international level there are already mechanisms of notification for new regulations (SPS, TBT...) but bilateral consultations at early stage could be useful. The usefulness of an FTA in this respect is that, where one of the parties is developing new legislation, consultation with the other party will be carried out. Consultation does not force however parties to change their legislation.

Finally, information on how to participate in Stakeholders meetings was given and potential work with the sister ECHAMP organization in the US was mentioned as a possibility.

ECHAMP committed to further elaborate on the issues of their concern and to provide the COM with a comprehensive document in this regard.