EUROPEAN COMMISSION
Directorate-General for Trade

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

Brussels,
Trade /F3/ [Art. 4.1(b)]

MISSION REPORT

Subject: **Participation as speaker in Conference on TTIP and Pharmaceuticals and Cosmetics organised by the Ministry of Economy of Poland; Visit to two cosmetics enterprises, participation in brainstorm meeting with industrial stakeholders organised by Polish cosmetics industry (Warsaw, 24-25 February 2015)**

Participants: Article 4.1b **(TRADE),** Art. 4.1b **(SANTE),** Art. 4.1b **(GROW)**

1. SUMMARY

The 2 day mission in Warsaw aimed at attending a conference on TTIP negotiations and in particular on regulatory aspects of relevance for medicinal products and cosmetics. The Conference was organised by the Polish Ministry of Economy and attended by around 50 stakeholder's representatives and included an extensive Q/A session. In addition, a visit to two Polish cosmetics manufacturing sites took place in order to discuss and understand concrete regulatory obstacles enterprises face when exporting to the US. Finally, the polish association of cosmetics organised a brainstorm session with cosmetics industry manufactures to bring forward ideas for the TTIP negotiations.

2. CONFERENCE "TTIP NEGOTIATIONS: PHARMACEUTICALS AND COSMETICS"

The Polish Ministry of Economy organised a half-day conference with Polish stakeholders to provide first-hand information on the TTIP negotiations on Medicinal products and Cosmetics. The meeting was chaired by Mr. Art. 4.1b , Undersecretary of State and was attended by circa 50 representatives. Art. 4.1b provided introductory remarks. He outlined that the TTIP was the most ambitious Free Trade Agreement ever negotiated and the support of Poland to these negotiations. He also indicated that this conference was a unique opportunity for Polish industry to have direct contact with the EU negotiators.

Mr. M. Nogaj, Director of Policy Trade Department of the Ministry of Economy (TPC full member), provided general information on TTIP negotiations. His intervention included a detailed presentation of the state-of play and prospects in terms of timeline for conclusion of the negotiations, the EU internal process and how Polish authorities are closely involved in the preparation of the negotiations. Energy costs were highlighted as a major aspect of the negotiations. The importance of making progress on non-tariff barriers was also highlighted. He welcomed the "fresh start" launched by Commissioner Malmstrom and the different

initiatives increasing the transparency of the negotiations, including the publication of the Commission mandate and the publication of EU position papers on the web. Finally, he outlined that the Polish Ministry of economy was open to close contacts with industry so as to relay their interests in the TTIP negotiations.

1.1. Pharmaceuticals in TTIP

The Commission delegation provided two presentations that were respectively focussed on medicinal products and cosmetics. I have provided a general introduction on the TTIP negotiations, highlighted consultation mechanisms in place, transparency provisions (position papers in the web), and stressed the importance for the EU of the sectoral aspects of the negotiations and the importance of removing non-tariff barriers. Art.4.1b covered aspects related to medicinal products and reviewed the different topics that are part of the negotiation: GMP inspections, Biosimilars, exchange of confidential/trade secret information, generics, paediatrics.

Q/A: The main questions raised regarding medicinal products were related to the process towards mutual recognition of GMP inspections and consequences of possible discrepancies between both systems (some stakeholders argued that US GMP standards were lower than Polish standards) and Intellectual Property Rights issues. The Commission indicated that the process of Mutual Recognition included the evaluation of the equivalence of both systems. Stakeholders were invited to submit more detailed information regarding their experience with the US GMP standards. The industry also enquired on whether a robust evaluation of the potential economic gains linked to these negotiations had been carried out and if the Commission has concrete quantified objectives (e.g. increase exports by x %). The Commission indicated that a global analysis had been carried out. It was however acknowledged that, by contrast to estimates on tariffs that may be relatively straightforward, gains linked to regulatory cooperation are less easy to determine. More accurate estimations will be possible when more precisions will be known on the shape of the agreement.

1.2. Cosmetics in TTIP

As regards Cosmetics, I have explained the main topics being discussed with US FDA notably: cooperation on safety assessment methods of ingredients, the objective to increase the number of UV filters approved in the US, joint promotion of alternative tests methods to animal testing, cooperation on labelling requirements (trivial names, colours etc., allergens labelling), cooperation on testing methods and collaboration on new areas (allergen labelling, market surveillance, etc.). I have also underlined the challenges we are facing on the negotiations (due to very different regulatory regimes and the fact that some products are classified in the US as over the counter drugs (OTC) which triggers a difficult authorization process).

Q/A: The polish industry highlighted that they were composed of 70% of SMEs for which access to US market is currently extremely difficult to not say impossible. The major issue is the classification of a large part of EU cosmetics as OTC drugs in the US with the associated requirements. Commission was asked to not give up of asking US to classify products that are considered in US as OTCs as normal cosmetics (*need to take into account that the EU definition is the one used/accepted around the world and the US is the only outliner*). Another major issue is the lack of efficient process in the US to review UV filters (i.e. no new UV filters were approved by FDA since 1999). Also as regards test methods where all over the world including in the EU, ISO standards are accepted, Article 4.2 first indent . Finally, industry questioned the impact of discussions on endocrine disruptors (at EU level) on cosmetic products. The industry had expected that

TTIP would solve many of the issues but sees now that that might not be the case and would see with concern if the level of ambition would be lowered.

3. VISIT OF TWO COSMETIC FACTORIES (NUCO AND DR. IRENA ERIS)

1.3. Nuco

NUCO is a company with 250 employees producing a large range of cosmetics (make up)/tailored solutions for customers that then market the products (NUCO does not own market brands). The production of this company is for 12% in Poland, 84% in the EU and 2% in the US. They have recent machinery mostly originating in the EU and own testing and research and development laboratories. This company has initiated efforts to increase its exports to the US market 3 years ago and have faced a number of challenges that were outlined during the visit:

- Administrative issues to be registered by 4.2 as OTC producer (Article 4.2 first indent)

- A number of products containing UV filters authorized in the EU cannot enter the US market as the new generation UV filters have not been authorized in the US. *NB: important to note that many cosmetic products such as day creams contain in the EU, UV filters and the indication SPF 15 (sun protection factor 15). This characteristic and indication gives added value to the product*.

- The products even if they contain UV filters authorized in the US face also problems as they are classified as OTC. As a consequence, the company has to be GMP pharma certified (the company is GMP-cosmetics (ISO) certified but this is not enough for US FDA. It is unfeasible for the company to be GMP-pharma certified)

- Certification of colorants (it is done by the colorants supplier. Represents a higher cost but it is not a unsurmountable issue)

The company acknowledged that if the cosmetic product (e.g. daily hydrating face cream) does not have any claim (SPF protection) nor UV filter added to it, then it can enter the US market as a cosmetic product without much requirements/certification. However, these products are then lower added value products/less sophisticated (lower segment) and there is therefore no commercial interest to export to US. There is also no interest to develop new formulations/products for US market alone.

1.4. Dr. Irena Eris

Dr. IRENA ERIS is a company with 500 employees producing a large range of cosmetics. It produces around 550 different products branded under 4 different names/brands. It has a very strong R&D department and in the last years has filled 7 new patent applications. The company competes with global brands such as L'Oreal and Nivea. It has strong implantation in Poland and in Europe but exports to more than 40 countries. US exports are very minimal/almost inexistent. 2 years ago the company explored possibilities to expand exports to the US but the conclusion was that due to registration difficulties it was not worthwhile/possible expanding to this market. Very few products could be marketed in the US and those were the low ended products with

no claims. Most of company products contain new generation UV filters (not authorized in the US) or claims (e.g. anti-rides, SPF protection) and therefore they are not authorized in the US tout court or they have to pass thought OTC authorization procedures (clinical trials, GMP pharma certification and so on). The company highlighted the same regulatory obstacles as NUCO.

In addition, the company informed that for normal cosmetics, Article 4.2 first indent . The company identifies all ingredients in a portal and info is sent to FDA. Within 2 weeks FDA accepts or rejects the marketing of the product. Article 4.2 first indent .

The company noted also that there is State level legislation (California cosmetics act) and additional restrictions on ingredients used in cosmetics. Some UV filters are allowed at federal level but not in California.

The company noted that there are problems – lengthy procedures - in acceding other markets (China, Japan, Brazil) but access is possible. In the US, access is impossible.

All in all the company would like that the definition of what is a cosmetic is changed in the US (use of EU definition that is used worldwide). If that is not possible, FDA should simplify procedures i.e. accept EU safety data (dermatological studies) without requiring specific studies to be conducted in the US, accept GMP-cosmetics certification instead of requiring GMP-pharma certification, accept SPF ISO test results and so on.

4. BRAINSTORM SESSION ON COSMETICS ORGANISED BY POLISH COSMETICS ASSOCIATION

The meeting was chaired by Mr. M. Nogaj, Director of Policy Trade Department of the Ministry of Economy and gathered several manufacturers and the Polish cosmetics association.Commission was asked to not lower down ambition for this sector. All issues on the EU Cosmetics position paper are still of relevance in particular for SMEs.

Article 4.1b

Cc: I. García Bercero, Article 4.1b , Art. 4.1b , Art. 4.1b , Art. 4.1b , Art. 4.1b, Art. 4.1b , Article 4.1b .