



CIVIL SOCIETY DIALOGUE

MEETING ON TTIP AND HEALTH

Date: Wednesday, 27 May 2015

Time: 10:00 – 12:00

Location: Jenkins room, Charlemagne Building, 170 Rue de la Loi, 1049 Brussels

Lead speakers

Mr Fernando Perreau de Pinninck, Head of the unit covering Tariff and Non-tariff Negotiations, Rules of Origin and Acting Director for WTO, Legal Affairs and Trade in Goods, European Commission, Directorate-General for Trade

Ms Ivone Kaizeler - Negotiator in the Unit for Tariff and Non-tariff Negotiations, European Commission, Directorate-General for Trade

Mr Sebastien Goux - Policy officer in the unit covering medicinal products – authorisations, European Medicines Agency, European Commission, Directorate-General for Health and Food Safety

Mr Roman Mokry - Policy officer in the unit covering health technology and cosmetics, European Commission, Directorate-General for Internal Market, Industries, Entrepreneurship and SMEs

Mr Thomas Heynisch - Deputy Head of Unit in the unit covering food and healthcare Industries, biotechnology European Commission, Directorate-General for Internal Market, Industries, Entrepreneurship and SMEs

Mr Marco Dueerkop - Deputy Head of Unit in the unit covering services, European Commission, Directorate-General for Trade

Mr Pedro Velasco Martins - Deputy Head of Unit in the unit covering Intellectual Property Rights, European Commission, Directorate-General for Trade

Ms Elina Laurinen – Policy officer in the unit covering Intellectual Property and Public Procurement, European Commission, Directorate-General for Trade

Moderator

Mr Lutz Guellner - Head of Unit for Information, Communication and Civil Society, European Commission, Directorate-General for Trade

Discussion Highlights / Questions and Replies

Fernando Perreau de Pinninck opened the meeting by expressing his appreciation for having the opportunity to have the exchange with civil society and for a number of position papers submitted by stakeholders ahead of the meeting. He noted that the focus of the meeting was on the regulatory aspects of pharmaceuticals, medical devices and cosmetics but other aspects of relevance for the health sector such as Intellectual Property Rights and Health Services would also be addressed. While the EU approach on regulatory cooperation included good regulatory practices such as stakeholder consultations and early publication of legal texts, the regulator-to-regulator exchanges were also of importance as they would be the main vehicle for promoting greater regulatory coherence. Areas of common interest would be looked at in order to establish a compatible approach where feasible. The advantages of regulatory cooperation within TTIP would not be limited to Europe, he said, but would also have global effects by enabling the development and improvement of international disciplines. The Commission was committed to transparency principles and involvement of all stakeholders.

Following the introductory remarks, **Mr Lutz Guellner** asked the audience to put forward questions in the area of **COSMETICS**.

TACD expressed concerns about the lack of global regulation on nanotechnologies and the fact that in cosmetics there were legal requirements regarding nanomaterials. TACD raised also the question of banned /allowed chemical substances and referred to the different rules being applied in the US and in the EU.

Ivone Kaizeler answered that the list of prohibited/allowed substances would not change in the EU. All cosmetics products would need to comply with EU legislation to enter the EU market, she said. As regarded nanotechnology, several requirements on nano-labelling were already in place regarding cosmetics and food products, and these were not part of the TTIP negotiations. Some aspects of this new area could nevertheless be the subject of regulatory exchanges in TTIP under the chemical or cosmetics regulatory discussions.

On the question of whether the EU ban on animal testing would remain in place and be protected, **Ms Kaizeler** answered that the ban on animal testing would continue to be applied in the EU. The legal situation in the EU and in the US would not change. The EU and the US were however politically committed to foster the development of alternative test methods to replace animal testing. **Roman Mokry** added that a number of cosmetic products were classified as Over the Counter Drugs (OTC) in the US requiring different approval processes where animal testing could still be required. The EU had encouraged the US FDA to come up with recommendations promoting the use of alternative methods in the case of cosmetics which are not considered as OTC drugs.

The **European Federation of Public Service Unions** mentioned that drugs and cosmetics (especially sunscreens) seemed to be discussed as a joint topic in TTIP. In addition, sunscreens had been picked out by the Commission as a flagship example of how EU consumers could benefit from TTIP. The Commission should be aware of risks of overexposure of consumers to these products.

Ms Kaizeler explained that US consumers rather than those in the EU would benefit from a facilitation of the authorisation procedure for UV filters in the US, on basis of the EU experience and scientific safety data provided.

On **MEDICAL DEVICES**, **Ms Kaizeler** gave a brief overview of the ongoing negotiations for TTIP by referring to the position paper recently published in the web. Picking out the most

frequently asked questions, she emphasised that neither the EU nor the US intended to change the legislation, in particular as regarded the procedures for the authorisation of medical devices. The idea of a product already authorised in one region being automatically authorised in the other one was not possible.

SPECTARIS raised the question on the timing for the publication of legal written proposals. It also called for easier access to the market without bureaucratic burdens.

DIGITALEUROPE expressed interest in enhancing the convergence of regulatory framework for e-health technologies ensuring greater predictability on both sides. Furthermore, they asked for an update regarding discussions on cross border services and data sharing.

UEAPME noted that the issue of device identification should be handled as a priority within TTIP providing patients with better traceability of products.

SPECTARIS asked for a statement on intellectual property rights in TTIP.

The European Consumer Organisation welcomed the UDI process and the opportunity for the mutual recognition of audits. They noted that it would be a missed opportunity for the EU to not adopt the US style pre-approval system for the safety of medical devices. In their view, potentially dangerous devices could be available on the EU's internal market.

Ms Kaizeler reaffirmed that both the EU and US systems provided a high level of consumer protection. Medical devices would likely continue to be placed on the EU market on the basis of CE mark with the intervention of notified bodies when it was justified (higher risk products) as set out in the EU Draft Regulation on medical devices (still being discussed by the European Council and the European Parliament). As regarded facilitating market access, some of the areas explored in the position paper such as UDI and regulated data submission could be helpful, in particular for SMEs. On the question of legal texts, the Commission was not yet in a position to put legal texts forward for any of the sectors (pharmaceuticals, medical devices and cosmetics). With regard to e-health **Mr Perreau de Pinninck** replied that this issue was being discussed in the context of ICT regulatory discussions.

On **PHARMACEUTICALS** the discussion focused on Health Services, Intellectual Property Rights and several regulatory aspects.

As regards **Health Services**, **Marco Dueerkop** explained the EU approach on public services in TTIP. TTIP negotiators were bound by the Treaty and by Article 168 of the Treaty, he said. It was important to note that there was no intention to create an internal market under TTIP and concepts used in the Internal Market or Services Directive were not applicable in TTIP. Benefits could be secured for Europe's services firms by means of eliminating discriminations and certain quantitative restrictions (e.g. equity caps) while providing public services with a number of exemptions/reservations. This sophisticated system would continue to be protected and the competence of MS in decision-making on health systems financing would be preserved. Finally, some explanation was given in terms of positive and negative list approach underlining that equivalent results can be achieved regardless of how the EU lists its commitments. In TTIP, he said, a negative list was planned to be used for national treatment commitments and a positive one on market access.

Commons Network raised the question of whether it was possible to add exceptions to the negative lists after the agreement had been concluded.

Mr Dueerkop clarified that any additional exception can only be implemented in an agreement by means of amendments. This issue is related to the nature of a legally binding agreement and not so much related with the way the commitments are listed.

EFFAT expressed concern about the lack of legal basis for the agricultural sector as well as asked whether the European standards and health policies will continue to be protected in the future.

Mr Perreau de Pinninck replied that TTIP has to at least ensure the level of protection provided for in the EU regulation. It can be expected that regulatory cooperation would result in more effective and efficient regulations and therefore contribute to improve the level of protection. A high level of protection will thus be maintained.

European Federation of Public Service Unions expressed concern about TTIP's potential impact on health financing systems that could result in an increasing share of the private sector in healthcare. Furthermore, they pointed out a conflict between fostering an ever increasing open market and the ability to ensure universality.

Lutz Guellner noted that trade policy in general is wider than TTIP.

With regard to the potential effects of TTIP on the structure of the health financing systems **Mr Dueerkop** repeated that TTIP has no influence in this area.

On the Intellectual Property Rights chapter, **Mr Pedro Velasco Martins** explained that the US and the EU have an equally highly sophisticated IPR infrastructure hence there are no major EU "offensive interests" to be put forward to the US. The Transatlantic IP Dialogue is intended to be improved. A limited number of specific IPR issues might be addressed in TTIP such as on areas where the US level of protection lags behind the EU one e.g. geographical indications. Given that the EU and the EU have a well-developed, balanced system for the area of health related IP issues there is no major interest to discuss it in detail within TTIP. As regards access to medicines it is highly unlikely that provisions in TTIP could have an impact on third countries, but, as is the case in other trade agreements, the EU is ready to insert specific language to address this concern.

EPFIA stressed that TTIP is a unique opportunity to create greater compatibility between EU and US regulatory systems, ultimately benefiting patients, science and the economy. To this end, EPFIA proposed four issues to be addressed in TTIP such as mutual recognition of GMP (Good Manufacturing Practice) inspections, common procedures and timing for paediatric plans, establishment of a harmonised list of clinical trials results data fields as well as establishment of a harmonised approach to post-approval variation submissions for CMC (chemistry, manufacturing and control) changes. As regards Intellectual Property the following issues need to be addressed in TTIP: joint commitment to existing high-level standards of IP protection and enforcement and establishment of joint high-level IP principles, joint commitment to substantive patent law harmonisation, including a grace period, as well as effective patent enforcement opportunities by supporting the eventual introduction of an early resolution mechanism. In relation to the patent harmonisation rules, EPFIA pointed out that this might only be achieved in a wider international framework, but TTIP could provide the necessary input. In addition, on the market access area he noted that TTIP can help promote fair and transparent policies on pricing and reimbursement processes.

The European Consumer Organisation asked for the speakers' opinion on the potential impact of TTIP on medicinal products prices for consumers by means of indirect measures as well as direct barriers. They asked also which safeguards could be introduced in terms of IPR provisions.

Brussels Regional Parliament enquired about the possible methodology of an impact assessment survey.

TACD noted that TTIP could lead to a decrease in transparency in clinical trial data by stimulating the protection of commercially confidential information. He enquired how the new regulatory cooperation structures would be set up regarding the way of operation, transparency, voice of consumer/citizens organisations. On early market access, TACD considered that the efficacy and safety of new medicines could be jeopardised by new regulations aimed to stimulate "early market access". On Pricing and reimbursement TACD enquired whether elements of the EU Transparency Directive are planned to be included in TTIP.

Commons Network enquired about the offensive demands of the US as well as about the discussions on biosimilars and clinical trial data.

EGA pointed out the importance of the removal of duplicative clinical trials resulting in significant cost savings for the industry, easier access to medicines while maintaining the high level of safety standards, the powers of regulators and a strong cooperation between several stakeholders. As regards IPR, in EGA view, there is no room for harmonisation between the parties. EGA opposes any proposal aimed at changing the current IPR system.

As regards transparency in Pricing and Reimbursement decisions **Thomas Heynisch** underlined that in contrast with the US, the EU has no intention to include medicinal products pricing and reimbursement transparency provisions within TTIP. Furthermore, there is no intention to get into a EU-Korea type text discussion.

Sébastien Goux noted that the EU policy on disclosure of clinical trials data was defined by the recently adopted Regulation on clinical trials and the EMA policy on the matter. The EU does not intend to negotiate those provisions within TTIP. Mr Goux emphasized that public access to clinical trial data has to be differentiated from the issue of exchange of confidential information amongst regulators.

TACD raised the question whether a medicine already authorized by FDA would follow the US regulation on commercial confidentiality/ trade secret rules in the case of an authorisation on the EU market. This could result in doctors and patients of the EU having a different access to clinical trial data for products authorized in the EU in comparison with products approved by FDA.

Mr Goux clarified that when it comes to the product authorisation, all the data submitted for approval in the EU is subject to the EU policy on public access. He emphasized also that the mutual recognition of product authorisations is not envisaged in the TTIP negotiations. By contrast, the mutual recognition approach of good manufacturing practices (GMP) inspections of the production sites of medicinal product is a major objective of the EU.

Ms Kaizeler added that the Commission position and the fact sheets publicly available contain written answers to the stakeholders' questions on the disclosure of clinical trial data and on transparency in pricing and reimbursement. As regards biosimilars and generics, these areas are very important for the Commission as they are linked to the access to medicines debate. Those matters are being explored during the negotiations. Finally, Ms Kaizeler reiterated that there will be no mutual recognition of medicinal products authorisations.

Mr Martins pointed out that TTIP will not have any significant effect on access to medicines in third countries. Anticompetitive practices are not expected to be enhanced by supporting the

use of IP. The EU supports strong and efficient IP rules but does not condone or allow the anti-competitive abuse of such rights. On the US demands, the US has not yet formally identified publically the areas of their interest. However other Treaties, already concluded by the US, give an idea of the US potential demands on IP. As regards grace period, this area is not contemplated in the EU law and has very little support among European stakeholders. With regard to data protection the EU has no intention to harmonise this area with the US. In reply to a reference made by one of the participants, Mr Martins clarified that the EU has a long history of supporting alternative models for innovation in the EU so that the so-called market failures (for instance, areas where there is no or insufficient incentive for purely private research) can be addressed. These can perfectly coexist with an effective IP system.

Finally, **Mr Perreau de Pinninck** closed the meeting by answering to the question of impact assessment procedures pointing out that EU procedures will not be affected by TTIP. As regards transparency and public involvement, a regulatory cooperation body has been proposed by the Commission which will be in charge of monitoring, supervising and promoting the regulatory cooperation,, but which will in no case have any regulatory powers. Regular interactions and exchanges are foreseen. For the Commission including wide range of stakeholders in the TTIP negotiation process is of paramount importance.