European Commission

Transatlantic Trade & Investment Partnership Advisory Group

Meeting report, 16 February 2016

Trade

1. Introduction

Some members of the group emphasised their dissatisfaction with the lack of access to consolidated texts for the advisors and requested the report of the last meeting on 12 January be edited to reflect this. The Chair agreed to do so.

2. Regulatory cooperation and good regulatory practices

The Chair presented the objectives of regulatory cooperation and good regulatory practices, the two parts of the EU's revised proposals.

The proposal on good regulatory practices (GRP) is intended to set out shared best practices in the EU and the US regulatory systems. The Commission has tried to draft this focusing on what is common rather than what is different. It should serve as a model for future trade agreements. Everything in the draft is fully consistent with EU practice, but it is also sufficiently general not to bind EU internal procedures and commitments for better regulation in an international agreement. Furthermore, it does not cover how the Commission works with other EU institutions. It is also not subject to dispute settlement. All together this preserves policy space for the EU and its Member States, while putting forward solid key provisions for good regulatory practices.

On regulatory cooperation, the Commission has sought to define the objectives more simply. It is based on three principles:

- We are looking only for equal or better regulation: lowering standards of protection is not an option.
- Any action must be based on the mutual interest of regulators on both sides.
- It has to be a fully transparent process, and therefore the proposal mandates an annual regulatory cooperation programme to flag priorities and allow us (and stakeholders concerned) to monitor progress.

The revised proposal on regulatory cooperation does not yet include details of the institutional mechanism, but this will follow discussions on substance.

This meeting has been organised specifically to hear feedback from members on the two proposals, some of which has already been received in writing. The Chair acknowledged various comments had already been received in advance, including detailed, joint analysis from some members of the group and this meeting would address the main concerns. This feedback will be taken into account in the revised drafts to be presented to the US during the next negotiating round.

The following points were raised in discussion:

Good regulatory practices (GRP)

- **Effect on EU regulatory system.** Some members queried to what extent the proposal on GRP would affect the EU's regulatory system, now or in the future, as best practices change over time. Ms Andersone explained that the general provisions make clear that we are working in accordance with our respective frameworks and principles (Art. 1). The aim is to draft the provisions of the chapter in a sufficiently open way for both parties to be able to develop and improve regulatory practices in the future. For example, while the draft is designed to capture the role of impact assessments in a general way, the EU and US will continue to do this in the ways they do now, and will have freedom to change how this works in the future, as long as they meet the principle. No changes to the current systems are envisaged: the principles of GRP must be consistent with established EU and US practice. Including these principles in TTIP will set a valuable frame for both Parties for future negotiations at bilateral or multilateral level, for example in the World Trade Organisation (WTO). The Chair emphasised that no EU trade agreement has direct effect under EU law: this means that private individuals cannot invoke the provisions of the agreement before the courts) and thus force a change to any EU law or guidance.

- **Scope.** One member expressed concern that the GRP proposal appears not to cover non-central acts, which could create imbalance with regards to regulatory cooperation, since sectors such as telecoms, financial services and postal services are partially regulated at state level. This would leave the EU unable to request cooperation on these issues with the US. The Chair explained that the last EU proposal also did not foresee non-central level commitments. In terms of scope of central-level coverage, the "major" acts covered by the draft would include what the two administrations do: for the EU, proposed regulations and directives by the Commission, and for the US, in essence rules put forward by agencies, plus any bills proposed by the administration to Congress but not Congress bills introduced by Members (though the Congress.gov website already fulfils the transparency requirement).

- **Legal nature of the proposals.** One member enquired what certain language ("shall") would mean in the chapter if not subject to dispute settlement. The Chair explained that for the EU, it makes sense to have some principles which are bound by language such as "shall", even if they are not pursuable through the courts or through dispute settlement. This is a strong signal of what each side is committed to do, and valuable in future bilateral and multilateral negotiations.

- **Cost.** One member enquired whether the Commission has undertaken any impact assessment of the costs of the GRP and regulatory cooperation proposals to the EU administration. The Chair explained that everything covered by the proposals already takes

place in the EU, and therefore there is no commitment to any new action. Therefore the Commission does not think that a cost-benefit analysis or impact assessment is needed.

- **Precautionary principle**. One member felt that the precautionary principle should be explicitly enshrined in the text. The Chair took note, and explained that in the EU's view at this stage, this is covered by the language on risk assessment and risk management (in Article 1 par. 2 lit. b), which is sufficiently general to capture the EU and US approaches, as well as footnote 1 (listing the Treaty principles for the EU side).

- **SMEs.** One member noted the specific provisions for SMEs, but questioned what these would mean in practice.

- **Delegated acts.** One member felt it would be important to allow for transparency in the EU's system of delegated acts, as well as draft regulatory acts and consultation documents. Ms Andersone explained that this is not covered by the draft as it is too specific to the EU regulatory system and therefore too detailed for an international agreement. The Chair explained that the Commission is firmly committed to provide transparency on delegated acts for feedback, as covered in the Better Regulation Package, but it cannot be codified in TTIP.

- **Policy evaluation.** One member questioned the concept of retrospective evaluation of policy. Ms Andersone noted that on the EU side this is a well-established practice, with evaluations taking place before a decision to change an existing policy. These evaluations are public. The US also has a system of evaluations in place, though it is less frequently used. This provision (Article 9) is important when it comes to future bilateral and multilateral negotiations.

- **Terminology.** One member noted the importance of clear terminology given the differences between the EU and US systems, and the common principles approach taken by the draft. The Chair took note.

- **Consultation.** Some members highlighted that there is a resource asymmetry between public interest and business interest groups, in favour of the latter, and this should be taken into account, while other Members disagreed on whether the draft could lead to asymmetrical consultation opportunities. The Chair took note of the need to ensure proper consultation opportunities.

Regulatory cooperation

- **Services including financial services.** One member raised a number of points to clarify the extent to which the draft would provide for regulatory cooperation in services, and requested an update on the state of play regarding regulatory cooperation in financial services. Ms Emberger explained that services are fully covered by this draft. Under the new approach, the starting point is to decide whether there is a common interest. If so, then the rules will apply. For non-central regulatory acts this means also that the central level commits to facilitate and encourage the cooperation, where common interest has been established. The only exception is for areas excluded from the whole scope of TTIP, for example audio-visual services. This means also that the central level commits to facilitate and encourage the cooperation, while non-central partners can undertake it if that applies.

- **Institutional mechanism.** One member asked for more detail on the framework that would surround these provisions on regulatory cooperation. There is nothing yet to oblige parties to give input, nor any clear process or deadlines. It is important to be clear how these provisions will interact with the sectoral annexes. Another member noted that the mechanism should be as light as possible. Ms Emberger explained that this new draft provides the mandate to cooperate, general rules (and some more specific) about what needs to happen and how to take into account the other side's approach, a stakeholder mechanism to ensure the regulators consult appropriately, and to ensure that on both sides respective domestic procedures are launched. Details of the institutional mechanism will come later once progress has been made on the substance. Already it is clear that domestic legislators should be properly involved as the EU draft suggests (see annex on institutional set-up).

- **Joint regulatory cooperation programme**. One member asked for more detail on how the joint regulatory cooperation programme would be put together, in particular regarding democratic accountability. It would be important to make sure that neither party treats the other any better than its domestic decision-makers, in terms of sharing information for example. Ms Emberger explained that the joint programme is conceived as a political document and would not replace any of our respective regulatory agendas on either sideof the Atlantic. It would flag areas of common interest as agreed by regulators and it will be mainly a transparency tool. The program could include areas submitted by stakeholders, such as SMEs and non-governmental organisations as well as industry. It will be important to look at ways to facilitate the provision of input for all stakeholders.

- **Strength of the provisions.** One member felt that the new draft was weaker than the previous version, in terms of making sure regulatory cooperation happens and that results are implemented. Ms Emberger explained that the revised draft has stronger disciplines applying to areas of common interest including as regards identification of new areas by

stakeholders – while leaving for regulators the decision on where to focus cooperation, and the revised chapter is designed to provide a framework under which cooperation initiatives can be followed up. To implement results, both sides would have to follow their own procedures. This will be clarified in the institutional part when the time is right.

- **Chilling effect.** One member appreciated the stronger language regarding no lowering of standards, and asked for further assurances on the potential for these provisions to have a chilling effect on normal domestic regulatory procedures. It needs to be clear at what point a legislative proposal becomes a candidate for regulatory cooperation, and what effects this might have. Ms Emberger noted that the approach laid out in this draft will provide the opportunity for cooperation:, but this does not mean domestic procedures need to stop and wait. (This becomes clear from Article x.1 par. 3 lit. a.)

- **SME provisions.** One member noted the importance of this part of TTIP to the SME community, and asked how SME participation could be put into practice. A small business test would be very useful: regulators should take into account SME interests as part of their cooperation, and this should be explicit in the text. The joint annual programme should also reflect this. A transatlantic "Top 10 most burdensome regulations for SMEs" might be a useful first step. Ms Emberger welcomed these comments and took note.

The Chair thanked members of the group for their input and noted that the proposals would be made public after the 12th negotiating round.

3. Pharmaceuticals in TTIP

A member of the group asked for more detail on how regulatory cooperation in the pharmaceuticals sector would improve affordability of medicines, stressing that while the emphasis appears to be on simplifying the procedure to reduce the burdens on companies and regulators, allowing earlier access of products to the market, it is not clear whether TTIP would lead to tangible benefits for patients in the form of reduced prices. It is also not clear why TTIP may be needed to foster cooperation between EU and US authorities, since this is already ongoing. The same member also highlighted concerns regarding trade secrets, pricing and reimbursement, and the patent system. Other members noted the importance of patents to reward innovation and at the same time the need to tackle abuses of the patent system.

In response, Commission experts I. Kaizeler, P. Velasco Martins and S. Goux gave the following explanations.

- **Regulatory cooperation:** The Commission is aiming here to improve cooperation with the US without reducing the EU's already very high standards. For example, TTIP is a way to further support existing EU-US harmonisation activities within the framework of ICH[1]. Shortening regulatory procedures is not the objective. Products may come to market more quickly as a result of harmonising some elements of the applications for authorisation on both markets, for example studies to be performed or administrative requirements. This means companies will be able to apply in both markets at the same time, rather than favouring one market (either the US or the EU) to start with. Getting more generics or biosimilar medicines on to the market more quickly is a clear means to boost competition and affordability of medicines. TTIP is an enabler to speed up progress on this work. The recent EU proposal on generics is a good example in this respect[2].

  Regarding the development of text, as yet this has not happened on cooperation in pharmaceuticals, but both sides hoped to agree on objectives to cover in draft text during the next round. The Commission's position paper sets out what the EU is seeking to negotiate. For example, it is already clear that the text will need to include legally binding provisions on mutual recognition of Good Manufacturing Practices (GMP) inspections, as this is necessary for the EU and US to be able to accept each other's inspections. It will also be necessary to provide for exchanges of regulatory information between the Parties, including information classified as trade secrets, in order for regulators (US Food & Drug Administration, EU European Medicines Agency) to take decisions. This is completely separate to internal EU and US policies on public access to documents, confidential information and trade secrets.

- **Intellectual property**: Intellectual property is very important to transatlantic trade, and both sides have similarly high standards and systems. However, there are some specific issues on which the EU would like to see improvements in the US (such as geographical indications, artists' resale right). The Commission's position paper sets out what the EU is seeking to negotiate in this area. A key element will be cooperation vis-à-vis third countries on IP issues of interest to both EU and US. The Commission is not seeking any changes to any part of the US IP system related to pharmaceuticals, such as patents, in TTIP, and does not intend to make any changes in the EU either. For example, the EU would not introduce a system of patent linkage through an international agreement: if there is an interest in doing this it should begin in the internal market. On data protection, the EU already has a very strong system for protection of test data. There are some differences with the US in cases of classical pharmaceuticals versus biologics, but the Commission sees no need for changes.

[1] International Council on the Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: www.ich.org.
[2] http://trade.ec.europa.eu/doclib/docs/2016/january/tradoc_154172.pdf

- **Trade secrets**: The draft EU directive is now available and strikes a very careful balance between the need for transparency and the need for confidentiality. However, none of this affects what information may be needed to be exchanged by regulators to take regulatory decisions. The discussions in TTIP relate to how to provide for exchange of confidential information between regulators.

- **Pricing and reimbursement:** The Commission does not see the value of including any commitments on pricing and reimbursement in TTIP.

Attendees

Members of the TTIP Advisory Group

BOUCSEIN Dominic (Small business, on behalf of Ilja Nothnagel)
BOWLES Edward (Services)
DE POUS Pieter (Environment)
FEDERSPIEL Benedicte (Consumers)
GOYENS Monique (Consumers)
HODAC Ivan (Manufacturing)
JENKINS Tom (Labour and trade union)
KERNEIS Pascal (Services)
LOGSTRUP Susanne (Health)
MASSAY-KOSUBEK Zoltán (Health, alternate for Nina Renshaw)
NELISSEN Guido (Labour)
PETIT Arnaud (Agriculture, alternate for Pekka Pesonen)
QUICK Reinhard (Manufacturing)
SANTOS Luisa (Business)
TOUBEAU Cecile (Environment, alternate for Jos Dings)

Commission officials

GARCIA BERCERO Ignacio	Chair, TTIP Chief Negotiator
ANDERSONE Liva	Official
DAWKINS Miranda	Official
EMBERGER Geraldine	Official
GOUX Sébastien	Official
HOUBEN Hiddo	Official
KAIZELER Ivone	Official
KOBER Klemens	Trainee
KRESTYNOVA Jana	Official
VELASCO MARTINS Pedro	Official