efpia
European Federation of Pharmaceutical Industries and Associations

Mrs Astrid SCHOMAKER
DG ENVIRONMENT
Head of Unit E2 "Global Sustainability, Trade and Multilateral Agreements"
Avenue de Beaulieu 5
1160 BRUSSELS
Sent by email

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9 January 2015

Dear Mrs Schomaker,

We would first like to thank the Commission for providing the stakeholders with a discussion paper and organising a consultation meeting on 9 December 2014, where EFPIA raised a number of issues. In response to your call for comments, you will find attached a joint submission, which was prepared and co-signed by 6 users' associations, including the European Federation of Pharmaceutical Industries and Associations.

These comments identify a number of challenges and areas of uncertainty, where legal and practical clarifications are needed to provide legal certainty to all users. We would like to highlight here a few of these points and make a couple of more specific remarks.

First, we think it is critical that sufficient legal certainty is provided to users as to the implementation in practice of the Regulation. An appropriate balance must be stricken between achieving the objectives of the Protocol and the regulatory burden put on users, so as to not undermine the nature-based research opportunities.

To that purpose, and in particular to ensure the regulatory burden imposed on users is minimised, we believe that the concept of research funding should be understood as public research funding, so that users do not have to file multiple declarations.

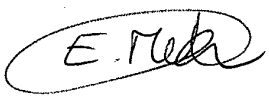
As to the due diligence declaration to be filed at the stage of final development of a product, we highlight in our comment a number of points which we believe require clarification, some of which will need to be sector-specific. We would in this regard seek clarification of whether clinical trials are to be understood as a product being placed on the market (p. 6, l. 30-34). As clinical trials are not undertaken in the course of a commercial activity, we suggest that these should not be considered as placing a product on the market. The due diligence declaration for a pharmaceutical product should therefore be filed when applying for a marketing authorisation. Moreover, where an application for a centralised marketing authorisation is filed, EFPIA suggests that a single

declaration should be made to the Competent Authority of the Member State where the user has its main European headquarter (p.6, l. 3-4).

Finally, EFPIA believes that no declaration should be made where the utilisation of a genetic resource has taken place outside of the Union (p.6, l. 24-25 and p.2, l. 14-16). The Regulation should not apply in cases where a product is marketed in the EU whereas utilisation of a genetic resource, i.e. research and development, has taken place outside the EU, even if the product is manufactured in the EU. Indeed, according to its Article 1, the Regulation establishes rules governing compliance "in accordance with the provisions of the Nagoya Protocol", which provides that Parties are only competent to establish compliance measures regarding "genetic resources utilised within its jurisdiction" (Article 15).
Moreover, Implementing Acts shall be adopted by the Commission only "to establish the procedures for implementing paragraphs 1, 2 and 3" of Article 7. An Implementing Act of the European Commission cannot extend the scope of a Regulation of the European Parliament and of the Council to include something (i.e. "utilisation outside of the Union") that is not included at all in Chapter I "Subject matter, Scope and definitions" of that Regulation. Also, the title of the Regulation, i.e. "Regulation […] on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union", clearly indicates that "utilisation outside of the Union" is out of the Regulation's scope. There is therefore no legal basis to extend the geographical scope of the basic Regulation (p.6, l. 24-25).

We remain at your disposal to elaborate or explain any of the comment we made and would urge the Commission to keep involving the various stakeholders and critically, users, throughout the implementation process.

Yours sincerely,



Elise Melon
Manager Intellectual Property & Trade

Encl.: Joint Comments on Implementing Acts.

Fédération Européenne
d'Associations et d'Industries
Pharmaceutiques

Leopold Plaza Building
Rue du Trône 108 Boîte 1
B-1050 Bruxelles

T +32 2 626 25 55
F +32 2 626 25 66
www.efpia.eu

TVA BE.418.762.559