



Mr Jean-Luc DEMARTY
Director General for Trade
EUROPEAN COMMISSION
Rue de la Loi, 200
1049 Bruxelles

Ref: /Let: 67.674

22 October 2018

Dear Mr. Demarty,

I am writing to you in my capacity as Director-General of EFPIA, the European Federation of Pharmaceutical Industries and Associations (EFPIA), representing Europe's leading large and small biopharmaceutical companies, to express our support for the work being undertaken as a follow-up to the Joint Statement between the European Union and the United States from 25th of July this year.

This work, including engagement on the regulatory front is important for multiple reasons. Firstly, our membership operates globally, with the EU and US being the two most integrated economies for our industry in terms of trade and two-way investments, as well as depth of global value chain integration. Second, for the pharmaceutical industry, the EU-US Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) is currently being implemented (since November 2017) as a tangible EU-US regulatory achievement, on which we can build further.

As such, we welcome regulatory efforts that would lead to further integration, lowering of non-tariff measures by reducing duplicative inspections or other regulatory requirements, while maintaining the high levels of protection for consumers and patients. We would like to suggest four first topics which EFPIA – also having discussed them with PhRMA, our US sister association – believes could benefit from further regulatory convergence in the context of the current process.

1. The first is expanding the scope of the MRA on GMP by including vaccines and veterinary medicines as well as by including Investigational Medicinal Products (IMPs) and Advanced Therapy Medicinal Products (ATMPs). We also believe that third country inspections could be more easily recognized mutually between the EMA and FDA by adopting concepts in the new Standard Operating Procedures of PIC/S, to which both the EU and US are parties.
2. The second is in the area of Good Clinical Practice (GCP), with the aim to reduce unnecessary burdens and bureaucracy due to differences in standards or interpretations of GCP. Duplication of inspections absorbs both industry and regulatory authority resources that could be used in other ways to oversee/reduce risk in more effective ways. Varying levels of convergence and sharing are possible, with an MRA, such as that being implemented for GMP, being the pinnacle option.

3. The third is in the area of paediatric medicines. Better alignment of paediatric scientific approaches between the EU and US would reduce duplication and streamline medicines development for children, reducing the time and costs of conducting trials for industry while avoiding redundant clinical trials in children and ensuring they have faster access to new medicines.
4. Science and technology are developing rapidly and present new opportunities in the development and use of medicines. However, potentially divergent approaches to regulation could lead to duplicative or inconsistent regulatory requirements. Therefore, the fourth topic is to prioritise upstream discussions between the EU and US on evolving science and technology. This could reduce the scope for future regulatory misalignment and increase awareness of regulatory initiatives on both sides of the Atlantic.

In addition to these four immediate topics in support of the upcoming EU-US dialogues in October and November, we look forward to further discussions with the European Commission services and will gladly provide you with a further formal and more detailed policy position on behalf of the innovative pharmaceutical industry in the future.

We wish you fruitful discussions with your US counterparts.

Yours sincerely,



EFPIA

Copy to :

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