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Medicinal Products: the EU and the US Mutually Recognize Manufacturing Standards

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The European Union ("**EU**") and the United States ("**US**") have reached a sectoral agreement (the "**Agreement**[1]") that will greatly ease the administrative burden when proving compliance with Pharmaceutical Good Manufacturing Practices ("**GMPs**") for certain medicinal products. In formal terms, the Agreement is an annex to the EU-US Mutual Recognition Agreement ("**MRA**"), which was signed in 1998 to facilitate market access by reducing costs and time associated with obtaining product approvals. Even though the MRA already included provisions regarding GMPs for medicines, the Annex in question was never fully implemented: Article 1.3 of the Annex expressly stipulated that "the US and the EC [European Community, now EU] have agreed to revisit these concepts." As such, in May 2014 the competent authorities from both blocs started reviving efforts to reach a revised agreement. The updated Agreement entered into force on March 1, 2017.

Under the current framework, generally speaking, (i) certain marketed finished pharmaceuticals for human use; (ii) certain marketed biological products; (iii) certain in-process material and intermediates; and (iv) active pharmaceutical ingredients or bulk drug substances will all benefit from the Agreement. For the time being, other medicinal products such as vaccines for human use, plasma derived pharmaceuticals, and veterinary products are not subject to the Agreement.

GMPs are a key element to quality assurance of medicinal products; ensuring they are produced and controlled pursuant to quality standards appropriate to their intended use. A lack of harmonization between GMP standards in different countries means companies wanting to export medicinal products must comply with differing requirements in the country of manufacture and the country of export.

The Agreement allows EU and US regulators to rely on each other's inspections in their own territories. A Party to the Agreement shall recognize pharmaceutical inspections and accept official GMP documents issued by a recognized authority of the other Party for manufacturing facilities located in their territory. The recognized authorities are, for the US, the Food and Drug Administration ("**FDA**"), and for the EU, the competent national medicines and healthcare products authorities of each individual Member State of the EU. Practically, for the EU, this means it will no longer be necessary to verify whether medicinal products (that meet certain conditions) have been manufactured in conformity with GMPs prior to authorizing batch release

[1] ANNEX to the Commission Decision on determining the Union position for a Decision of the Joint Committee set up under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, in order to amend the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs).

of products onto the market. Similarly, for the US, it means the FDA will no longer have to conduct drug inspections in the EU. It will allow both blocs to concentrate their efforts and resources on other parts of the world where drug manufacturing for the EU or US markets has greatly increased.

Further, the EU and the US will be able to collaborate more closely in the event of product recalls, additional controls, suspension of distribution, or other problems concerning quality or noncompliance with GMPs. The Parties have agreed to have an alert system that permits authorities of the other Party to be made aware proactively in case of quality defect, recalls, counterfeit or falsified products, or other potential serious shortages.

Many provisions of the Agreement have already entered into force. Others will enter into force on November 1, 2017, when both the EU and the US will have further assessed the other Party's recognized authorities.

In the current political context of EU-US relations; after Transatlantic Trade and Investment Partnership has been put on hold, to say the least; and when there may be transatlantic trade and regulatory tensions in the horizon, the importance of this Agreement goes beyond its material scope and content. The MRA has been welcomed as evidence that cooperation in technical matters with direct trade and economic impacts can exist, and it may act as a potential precedent for other specific deals in other matters.

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