

This document is the European Union's proposal for an annex on medicinal products. It was tabled for discussion with the US in the negotiating round of 25 -29 April 2016 and made public on 24 May 2016. The actual text in the final agreement will be a result of negotiations between the EU and US.

DISCLAIMER: The EU reserves the right to make subsequent modifications to this text and to complement its proposals at a later stage, by modifying, supplementing or withdrawing all, or any part, at any time.

TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP

EU PROPOSAL FOR AN ANNEX ON MEDICINAL PRODUCTS

Article 1

General principles and objectives

1. Medicinal products may be placed on the market of the Party following a marketing authorisation granted by a competent authority of that Party in accordance with its applicable rules.
2. Nothing in this Annex shall affect the ability of each Party to adopt, maintain, amend and apply measures without delay, in accordance with deadlines under its respective regulatory or administrative procedures, to achieve its public policy objectives, including protection of human health or safety, animal health, or the environment at the level it considers appropriate, in accordance with its regulatory framework and principles. *[N.B. This paragraph may need to be adjusted as discussions on the Regulatory Cooperation Chapter proceed].*
3. Nothing in this Annex shall affect the ability of each Party to take all appropriate and immediate measures when it determines that a medicinal product compromises the human and animal health, the environment or safety in its territory, or that it does not comply with its regulatory framework. Such measures may include suspending, varying or revoking an authorisation or withdrawing the medicinal product from the market, including through a prohibition on imports of the medicinal product.
4. Nothing in this Annex shall affect the powers of the competent authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.
5. The Parties shall ensure a high level protection of public health and promote innovation, competitiveness and trade.
6. The Parties shall promote increased access to high-quality medicinal products, address the threat of antimicrobial resistance and fight against falsified medicinal products.
7. The Parties shall further harmonise their respective requirements and procedures applicable to the authorisation of medicinal products.

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8. The Parties shall remove unnecessary duplications of testing, including animal testing and clinical trials carried out during the research and development phase of new medicinal products and remove duplications of inspections of manufacturing facilities. This can be achieved through the harmonisation of the Parties requirements for applications for authorisations of medicinal products and through the mutual recognition of their manufacturing facilities inspections.
9. The Parties shall promote existing international and bilateral regulatory cooperation in the development, authorisation and access to medicinal products.

Article 2 **Definitions**

For the purposes of this Annex:

“Medicinal product” means medicinal product for human use and veterinary medicinal product.

“Medicinal product for human use” means:

- a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medicinal products for human use include chemical medicinal products, biological medicinal products including vaccines, medicinal products derived from human blood or human plasma, advanced therapy medicinal products (e.g. gene therapy medicinal products, cell therapy medicinal products), herbal medicinal products, homeopathic medicinal products and radiopharmaceuticals.

“Veterinary medicinal product” means:

- a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

“Marketing authorisation” lays down the terms under which the placing on the market of a medicinal product is authorised in the territory of a Party.

“Falsified medicinal product” means:

Any medicinal product with a false representation of:

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(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(c) its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

"Competent authority" means the authority or, where applicable the authorities, responsible in each Party for granting and maintaining marketing authorisations of medicinal products or providing opinions in the framework of authorisation procedures or carrying inspections such as the European Commission, the European Medicines Agency, competent national authorities of EU Member States, the U.S. Food and Drug Administration and the U.S. Department of Agriculture.

Article 3 **Scope**

This Annex applies to medicinal products for human use and veterinary medicinal products.

Article 4 **Relevant international organisations and bodies**

The Parties recognise that international organisations and bodies, in particular the World Health Organisation (WHO), the World Organisation for Animal Health (OIE), the Organisation for Economic Cooperation Development (OECD), the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), are relevant for developing scientific and technical guidelines with respect to medicinal products.

Article 5 **Participation in relevant international organisations and bodies and regulatory convergence**

1. The Parties shall actively participate in the development of scientific or technical guidelines with respect to the authorisation and inspection of medicinal products in the relevant international organisations and bodies in particular those mentioned in Article 4.

2. The Parties shall co-operate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines including, where feasible, through the presentation of joint initiatives, proposals and approaches in the relevant international organisations and bodies in particular those

mentioned in Article 4.

3. The Parties shall implement all ICH and VICH guidelines unless those would be ineffective or inappropriate for the achievement of their legitimate objectives. Each Party should duly consider, when developing or implementing requirements, guidelines and procedures for the authorisation of medicinal products that are not harmonised by ICH or VICH, the scientific or technical guidelines developed by the other organisations mentioned in Article 4.

Article 6

Authorisation of medicinal products

1. Each Party's competent authorities shall decide on a marketing authorisation for a medicinal product in accordance with its relevant legal requirements and procedures for the authorisation of medicinal products on the basis of the information provided by the applicant, including:

- (a) the quality, safety and efficacy of the product, including, where appropriate, pre-clinical and clinical data;
- (b) other matters such as various rules addressing the particularities of certain types of medicinal products including medicinal products for children, orphan medicinal products, advanced therapy medicinal products and traditional herbal or homeopathic medicinal products.

2. The Parties shall promote dialogue on scientific matters and exchange of information between their competent authorities. This scientific dialogue and exchange of information may cover research, development and assessment of different types of medicinal products, including innovative products, generics, biosimilars and medicinal products of major public health interest or that address unmet medical needs, including products eligible for accelerated assessment or related schemes.

3. The Parties shall collaborate on the development of guidelines, recommendations and initiatives to promote the development of rapid diagnostics, alternative treatments, new anti-microbials and their appropriate use in medicinal products, as part of their overall efforts to combat anti-microbial resistance.

[NB: this proposal is to be read in conjunction with the EU text proposal for an article on Anti-Microbial Resistance within the SPS Chapter of TTIP entitled "Collaboration Related to Reduced Use of Antibiotics in Animal Production to Combat Antibiotic Resistance"]

Article 7

Inspections

1. A Party shall accept a certificate/[corresponding US information] of Good Manufacturing Practice (GMP) compliance issued by a competent authority of the other Party, as demonstrating that the manufacturing facility that is covered by the certificate and located in the territory of that Party complies with GMP /[corresponding US information]. The terms

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and conditions under which a Party accepts the GMP certificate/[corresponding US information] issued by a competent authority of the other Party are set out in Annex XX of this Agreement.

2. A Party may accept a certificate of GMP compliance /[corresponding US information] issued by a competent authority of the other Party with respect to a manufacturing facility located outside the territory of any of the Parties. The terms and conditions under which a Party may accept the GMP certificate issued by a competent authority of the other Party with respect to a manufacturing facility located outside the territory of any of the Parties are set out in Annex XX of this Agreement.

3. The terms and conditions under which a Party may recognise or rely on the outcome of inspections, other than GMP inspections, performed by the competent authorities of the other Party, may be developed in accordance with the procedures described under Annex XX.

[NB: the EU will submit a proposal for Annex XX on the basis of ongoing technical discussions between the EU and US]

Article 8

Exchange of regulatory information between the Parties

1. The Parties shall ensure that their competent authorities are allowed to exchange relevant regulatory information, including confidential and trade secret information related to the authorisation and supervision of medicinal products.

2. The type of information that may be exchanged between the competent authorities of the Parties includes, but is not limited to:

- a) All legislation and guidance documents governing medicinal products in each Party. This also includes all position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation.
- b) Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and applications for agreement of paediatric investigation plans
- c) Pharmacovigilance data particularly that of an urgent nature related to adverse drug reactions, as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments.
- d) Information on Good Clinical Practices (GCP) inspections and GCP inspection reports.
- e) Information on Good Manufacturing Practice (GMP) inspections and GMP reports.
- f) Information on GMP non-compliance, recalls, data integrity and risks of shortages of medicinal products.

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3. A Party shall not publicly disclose confidential information of commercial, technical or scientific nature, including trade secrets, which is not in the public domain, and which it has received from the other Party, if and in so far as that information is protected under its applicable legislation on access to information or access to documents.

[NB: In the EU context, Article 4 of Regulation (EC) n° 1049/2001 as interpreted by the Court of Justice of the European Union]

Article 9

Regulatory cooperation between the Parties

[NB: this Article may need to be adjusted as discussions on the Regulatory Cooperation Chapter proceed]

1. A Working Group for the regulatory cooperation on medicinal products between the Parties shall be established. The EU shall be represented in the Working Group by the European Commission with the support of the European Medicines Agency. The US shall be represented by the U.S. Food and Drug Administration and the U.S. Department of Agriculture.

2. The Working Group shall monitor the implementation of the provisions of this Chapter, and support and further develop existing and future bilateral regulatory cooperation between the competent authorities.

3. In accordance with the provisions of the Regulatory Cooperation Chapter, the Working Group shall establish a joint regulatory cooperation work plan for cooperation in areas of common interest. The work plan may include areas which are not fully regulated or not addressed at international level and where bilateral cooperation or a common approach on multilateral cooperation and cooperation in relevant international organisations and bodies could advance science and promote harmonisation of the requirements, guidelines and procedures applicable to the authorisation of medicinal products.

4. The competent authorities of each Party shall implement the joint regulatory cooperation work plan and publish it on their respective websites.

5. The Working Group shall consult stakeholders of both Parties on the regulatory cooperation areas listed in the joint regulatory cooperation work plan. Stakeholders, *inter alia*, Small and Medium Size enterprises and public interest groups shall be invited to submit new concrete and duly substantiated proposals for further bilateral regulatory cooperation.

6. The Working Group shall review annually the joint regulatory cooperation work plan. That review shall take into account, *inter alia*, progress achieved during the preceding year and new emerging areas or health challenges that would benefit from regulatory cooperation.

7. The Working Group shall report annually on the implementation of the provisions of this Chapter and on the joint regulatory cooperation work plan to _____ (relevant body in the Regulatory Cooperation Chapter *tbd*).

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8. The first joint regulatory cooperation work plan should be agreed by the signature of this Agreement.