

*This document is the European Union's proposal for an annex on medical devices. It was tabled for discussion with the US in the negotiating round of 11-15 July 2016 and made public on 14 July 2016. The actual text in the final agreement will be a result of talks between the EU and US.*

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

*The relationship between sectorial annexes and the architecture of TTIP, including the applicability or not of general exceptions and dispute settlement, will be considered at a later stage.*

## **EU PROPOSAL FOR AN ANNEX ON MEDICAL DEVICES**

### *Article 1*

#### **General principles and objectives**

1. Co-operation activities between the Parties shall aim at improving, and not reducing, undermining or otherwise compromising, the level of protection in public policy areas such as the protection of workers' and consumers' health, public health, and the protection of the environment, as considered appropriate by either Party. The Parties share the intention of achieving a high level of protection in these areas.
2. Nothing in this Annex shall affect the ability of each Party to apply its fundamental principles governing regulatory measures in its jurisdiction, for example in the areas of risk assessment and risk management<sup>1</sup>.
3. Nothing in this Annex shall affect the ability of each Party to take appropriate and immediate measures when it determines that a medical device is not safe for the consumer or does not comply with its regulatory framework. Such measures may include withdrawing the medical device from the market or prohibiting the placement in the market of that medical device.
4. The objectives of this Annex are, in particular, to:
  - promote convergence of technical and clinical requirements applicable to medical devices;
  - remove unnecessary duplications of data submission and devices testing and to avoid duplications of inspections of manufacturing sites;
  - promote convergence of standards relevant to medical devices;
  - promote existing multilateral and bilateral regulatory cooperation relating to medical devices;
  - promote cooperation on any other matter of common interest to the Parties

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<sup>1</sup> For the EU, such principles include those established in the Treaty on the Functioning of the European Union as well as in Regulations and Directives adopted pursuant to Article 289 of the Treaty on the Functioning of the European Union.

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while ensuring legitimate policy objectives such as a high level of protection of public health and patients' safety and contributing to the promotion of innovation, competitiveness and trade in medical devices.

## *Article 2* **Definitions**

For the purposes of this Annex:

**'medical device'** means any instrument, apparatus, , appliance, software, implant, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.

**'*in vitro* diagnostic (IVD) medical device'** means a medical device, which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological process or state;
- concerning congenital physical or mental impairments;
- concerning the predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'specimen receptacle' means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

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**‘Medical Device Single Audit Program (MDSAP)’** is an initiative developed by the International Medical Devices Regulators Forum. It allows a single audit of a medical device manufacturer’s quality management system to satisfy the needs of multiple regulatory jurisdictions. Each jurisdiction can decide when and for which purpose the single audit will be used in the process of market approval or conformity assessment of a specific device within their territory.

**‘Unique Device Identification (UDI)’** is a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

**‘Regulated Product Submission (RPS)’** is a message standard for the electronic submission of product information between a company and a regulatory agency for the purpose of gaining market approval or conformity assessment.

**‘Responsible authority’** is an organisation or regulatory authority, responsible for market approval or conformity assessment of a medical device on a Party market and or for market surveillance, such as the European Commission, the competent national authorities of EU Member States, EU Notified Bodies and the U.S. Food and Drug Administration.

**‘International Medical Devices Regulators Forum (IMDRF)’** is a voluntary group of medical device regulators from around the world that has the aim to accelerate international medical device regulatory harmonization and convergence.

**‘National Competent Authority Report (NCAR) Exchange Program’** is an initiative developed by the International Medical Devices Regulators Forum with the aim to exchange information relating to significant concerns or potential trends regarding medical devices that individual authorities have observed in their jurisdictions, but have not yet resulted in recalls or field safety corrective actions.

### *Article 3* **Scope**

This Annex applies to medical devices and in vitro diagnostic medical devices for human use falling under Chapters 28, 30, 38, 84, 87 and 90 of the Harmonized System (HS) of tariff nomenclature.

### *Article 4* **Relevant international organisations and bodies**

The Parties recognise that international organisations and bodies, in particular the International Medical Devices Regulators Forum (IMDRF), the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the Global Medical Device Nomenclature (GMDN) Agency are relevant international organisations for developing scientific and technical guidelines as well as standards with respect to medical devices.

### *Article 5*

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### **Participation in relevant international organisations and bodies and regulatory convergence**

1. Each Party shall actively participate in the development of scientific or technical guidelines with respect to the regulation of medical devices in the International Medical Devices Regulators Forum.
2. The Parties shall cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines relating to medical devices including, where feasible, through the presentation of joint initiatives, proposals and approaches in the International Medical Devices Regulators Forum.
3. Each Party shall implement the International Medical Devices Regulators Forum guidelines unless those would be ineffective or inappropriate for the achievement of their legitimate objectives.
4. Each Party shall encourage active participation of the standardisation bodies located within their respective territories in the work of the International Organisation for Standardisation and of the International Electrotechnical Commission in order to contribute to the harmonization, at international level, of standards applicable to medical devices.
5. Each Party shall take into account the relevant International Organisation for Standardisation, and International Electrotechnical Commission standards when developing its own technical regulations and conformity assessment procedures and referencing standards applicable to medical devices unless those standards are not yet available or would be ineffective or inappropriate for the achievement of each Party's legitimate objectives.
6. The Parties shall cooperate on evolving areas and emerging technologies relating to medical devices regulation.

#### *Article 6*

### **Quality management system audits**

[Place holder for Medical Devices Single Audit]

#### *Article 7*

### **Unique Device Identification of medical devices**

1. Each Party shall support international efforts and actively participate in the International Medical Devices Regulators Forum work on establishing and maintaining a globally harmonised approach on the identification of medical devices and establish and maintain a globally accepted unique device identification system for medical devices.

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2. Each Party shall align, to the greatest extent possible, its rules and requirements on unique device identification with the guidance documents adopted by the International Medical Devices Regulators Forum.
3. In order to ensure the interoperability of unique device identification databases at global level, each Party shall develop its unique device identification database in line with the guidance documents adopted by the International Medical Devices Regulators Forum. For that purpose, each Party shall promote the use of a common format for data exchange between unique device identification databases, and take into account relevant specifications and semantic standards existing in the area.

#### *Article 8*

#### **Data submission - Regulated Products Submission (RPS)**

1. Each Party shall actively participate in the efforts of the International Medical Devices Regulators Forum to establish a globally harmonised format -Regulated Products Submission Standard- for the electronic submission, by the manufacturers, of the product information and data needed for the assessment of a medical device by the responsible authorities of each Party.
2. Each Party shall develop its submission database in line with the guidance documents and technical specifications adopted by the International Medical Devices Regulators Forum in order to ensure the interoperability of data submitted at a global level.

#### *Article 9*

#### **Cooperation with regard to exchange of information on non-compliant medical devices**

1. The responsible authorities of the Parties shall endeavour to cooperate in assessing potential risks posed by medical devices before they recall such medical devices from their market or before they adopt field safety corrective actions.
2. The responsible authorities of the Parties shall exchange relevant post-market safety information on non-compliant devices and recalls primarily through the use of the National Competent Authority Report Exchange Program system developed and operated by the International Medical Devices Regulators Forum.

#### *Article 10*

#### **Cooperation on standards relevant to medical devices**

1. The Parties shall encourage cooperation between the standardisation bodies located within their respective territories and with standardisation bodies from other International Medical Devices Regulators Forum members in view of jointly developing new medical devices standards and adopting, to the extent possible, common international standards. This cooperation may include sharing information, at an early stage, regarding new medical devices standards to be developed or referenced in each Party's legislation and facilitating participation of a Party's standardisation bodies in the standardisation activities of the other Party.
2. The Parties shall identify and explore possibilities to improve the process of

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developing international standards used for regulatory purposes in the medical technology domain.

3. The Parties shall encourage cooperation between the standardisation bodies located within their respective territories in view of further aligning their existing medical devices standards with the standards adopted by the International Organisation for Standardisation the International Electrotechnical Commission.

#### *Article 11*

### **Exchange of regulatory information between the Parties**

1. The Parties shall ensure that their responsible authorities are allowed to exchange regulatory information, including confidential and trade secret information related to conformity assessment, approval and supervision of medical devices.
2. 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 12*

### **Regulatory cooperation**

*[NB: this Article may need to be adjusted as discussions on the Institutional, General and Final Provisions Chapter and on the Regulatory Cooperation Chapter proceed. This Article is to be read in conjunction with the functions and roles of the Joint Committee, the Transatlantic Regulators' Forum and the Working Group on sectors as defined in the Chapter on Institutional, General and Final Provisions]*

1. The regulatory cooperation between the responsible authorities of the Parties shall be guided by a joint regulatory cooperation work plan which sets out short and medium term priorities for regulatory cooperation under this Annex.
2. The joint regulatory cooperation work plan shall be endorsed by the responsible authorities of the Parties at political level.
3. The responsible authorities of the Parties shall transmit the joint regulatory cooperation work plan to the Transatlantic Regulators' Forum [established under the Institutional, General and Final Provisions Chapter] and publish it on their respective websites.
4. The responsible authorities of the Parties shall regularly review the joint regulatory cooperation work plan. In this review, the responsible authorities of the Parties shall take into account, *inter alia*, progress achieved [during the preceding years] and consider new areas that would benefit from regulatory cooperation. For the review of

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the joint regulatory cooperation work plan, the responsible authorities of each Party shall consult stakeholders including small and medium size enterprises, employers and workers representatives and public interest groups.