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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Delegations will find attached document COM(2018) 196 final - ANNEX 2 - PART 3/3.

Encl.: COM(2018) 196 final - ANNEX 2 - PART 3/3

EUROPEAN
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ANNEX 2 – PART 3/3

ANNEX

to the

Proposal for a Council Decision

on the conclusion of the Free Trade Agreement between the European Union and the Republic of Singapore

ANNEX 2-B

MOTOR VEHICLES AND PARTS THEREOF

ARTICLE 1

General Provisions

1. This Annex shall apply to all forms of motor vehicles and parts thereof traded between the Parties and falling under Chapters 40, 84, 85, 87 and 94 of the HS 2012 (hereinafter referred to as "products covered by this Annex").

2. With regard to the products covered by this Annex, the Parties confirm the following shared objectives and principles:

   (a) eliminating and preventing non-tariff barriers to bilateral trade;

   (b) promoting compatibility and convergence of regulations based on international standards;

   (c) promoting recognition of approvals based in particular on approval schemes applied under the agreements administered by the World Forum for Harmonization of Vehicle Regulations (hereinafter referred to as the "WP.29") within the framework of the United Nations Economic Commission for Europe (hereinafter referred to as "UN ECE");

(d) establishing competitive market conditions based on principles of openness, non-discrimination and transparency;

(e) securing the protection of human health, safety and the environment; and

(f) enhancing cooperation to foster continued mutually beneficial development in trade.

ARTICLE 2

International Standards

1. The Parties recognise that the WP.29 is the relevant international standard-setting body for the products covered by this Annex.[1]

2. If Singapore decides to introduce a type-approval system for products covered by this Annex, Singapore will consider becoming a signatory of the Agreement concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts which can be Fitted and/or be Used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of these Prescriptions, done at Geneva on 20 March 1958.

[1] This paragraph is without prejudice to the Parties' rights to accept national standards or technical regulations of other countries.

ARTICLE 3

Regulatory Convergence

1. (a) The Parties shall at any time refrain from introducing any new domestic technical regulations diverging from UN ECE Regulations or Global Technical Regulations (hereinafter referred to as "GTR") in areas covered by such UN ECE Regulations or GTR, or where the completion of such UN ECE Regulations or GTR is imminent, unless there are substantiated reasons, based on scientific or technical information, why a specific UN ECE Regulation is ineffective or inappropriate for ensuring road safety or the protection of the environment or public health[1].

(b) A Party which introduces a new domestic technical regulation as referred to in subparagraph (a) shall, upon request from the other Party, identify the parts of the domestic technical regulation which substantially deviate from the relevant UN ECE Regulations or GTR and provide due justification as to the reasons for the deviation.

[1] Paragraphs 1(a) and 2 of Article 3 (Regulatory Convergence) and Article 6 (Other Measures Restricting Trade) of this Annex are without prejudice to Singapore taking traffic management measures such as electronic road pricing, on account of Singapore's specific space constraints.

2. Insofar as a Party has introduced and maintains, in accordance with paragraph 1, domestic technical regulations that diverge from existing UN ECE Regulations or GTR, that Party shall review these domestic technical regulations at regular intervals, not exceeding five years, with a view to increasing their convergence to the relevant UN ECE Regulations or GTR. When reviewing their domestic technical regulations, the Parties shall consider whether the circumstances that gave rise to the divergence still exist. The outcome of these reviews, including scientific and technical information used, shall be notified to the other Party upon request.

3. Singapore shall accept on its market as compliant with its domestic technical regulations and conformity assessment procedures, without further testing or marking requirements to verify or attest compliance with requirements covered by an EC[1] or UNECE type-approval, new[2] Union products covered by this Annex and which are covered by an EC or UNECE type-approval certificate. An EC Certificate of Conformity, in the case of whole vehicles, and an EC or UNECE type-approval mark affixed to the product, in the case of components and separate technical units, shall be considered sufficient proof of the type-approval certificate.

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[1] For greater clarity, the terms "EC type approval", "EC type approval certificate", "certificate of conformity" and "EC type approval mark" shall have the meaning assigned to them under Union legislation, in particular Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (OJ L263 of 9.10.2007, p. 1).

[2] For the purposes of this paragraph, where the term "new Union products covered by this Annex" refers to whole vehicles, this term is understood to mean vehicles which have never been registered before worldwide.

4. The competent administrative authorities of each Party may verify by random sampling in accordance with its domestic legislation that the products comply, as appropriate, with:

(a) all the domestic technical regulations of the Party; or

(b) the domestic technical regulations of which compliance has been attested by an EC Certificate of conformity, in the case of whole vehicles, or an EC or UN ECE mark affixed to the product, in the case of components and separate technical units, as referred to under paragraph 3.

Such verification shall be carried out in accordance with the domestic technical regulations under subparagraphs (a) or (b), as the case may be. Each Party may require the supplier to withdraw a product from its market in case the product concerned does not comply with those regulations and requirements.

ARTICLE 4

Products with New Technologies or New Features

1. Neither Party shall prevent or unduly delay the placing on its market of a product covered by this Annex and approved by the exporting Party on the ground that the product incorporates a new technology or a new feature that the importing Party has not yet regulated, unless it can demonstrate, based on scientific or technical information, that this new technology or new feature creates a risk for human health, safety or the environment.

2. When a Party decides to refuse the placing on its market or requires the withdrawal from its market of a product of the other Party covered by this Annex on the ground that it incorporates a new technology or a new feature creating a risk for human health, safety or the environment, it shall immediately notify this decision to the other Party and to the economic operators[1] concerned. The notification shall include all relevant scientific or technical information considered in the Party's decision.

ARTICLE 5

Licensing

Neither Party shall apply automatic or non-automatic import licensing[2] for the products covered by this Annex.

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1 Where Singapore is the importing Party, "economic operator" shall mean the importer of the product concerned.

2 The terms "import licensing", "automatic import licensing" and "non-automatic import licensing" are defined in Articles 1 to 3 of the WTO Agreement on Import Licensing Procedures.

ARTICLE 6

Other Measures Restricting Trade

Each Party shall refrain from nullifying or impairing the market access benefits accruing to the other Party under this Annex through other regulatory measures specific to the sector covered by this Annex. This is without prejudice to the right to adopt measures necessary for road safety, the protection of the environment or public health and the prevention of deceptive practices, provided such measures are based on substantiated scientific or technical information.

ARTICLE 7

Joint Cooperation

In the Committee on Trade in Goods, the Parties shall cooperate and exchange information on any issues relevant for the implementation of this Annex.

ANNEX 2-C

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

ARTICLE 1

General Provisions

The Parties confirm the following shared objectives and principles of:

(a) preventing and eliminating non-tariff barriers to bilateral trade;

(b) establishing competitive market conditions based on principles of openness, non-discrimination and transparency;

(c) promoting innovation of, and timely access to, safe and effective pharmaceutical products and medical devices through transparent and accountable procedures, without impeding a Party's ability to apply high standards of safety, efficacy and quality; and

(d) enhancing cooperation between their respective health authorities, based on international standards, practices and guidelines within the framework of relevant international organisations such as the World Health Organization (hereinafter referred to as "WHO"), the Organisation for Economic Co-operation and Development (hereinafter referred to as "OECD"), the International Conference on Harmonisation (hereinafter referred to as "ICH"), the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (hereinafter referred to as "PIC/S") for pharmaceutical products and the Global Harmonization Task Force (hereinafter referred to as "GHTF") for medical devices.

ARTICLE 2

International Standards

The Parties shall use international standards, practices and guidelines for pharmaceutical products or medical devices, including those developed by the WHO, the OECD, the ICH, the PIC/S and the GHTF as a basis for their technical regulations, unless there are substantiated reasons based on scientific or technical information why such international standards, practices or guidelines would be ineffective or inappropriate for the fulfilment of legitimate objectives pursued.

ARTICLE 3

Transparency

1. With respect to measures of general application relating to pharmaceutical products and medical devices each Party shall ensure that:

   (a) such measures are readily available to interested persons and the other Party, in a non-discriminatory manner, via an officially designated medium and, where feasible and possible, electronic means, in such manner as to enable interested persons and the other Party to become acquainted with them;

   (b) an explanation of the objective of and rationale for such measures is provided to the extent possible; and

   (c) there is sufficient time between publication and entry into force of such measures, except where not possible on grounds of urgency.

2. In accordance with their respective domestic law, each Party shall, to the extent possible:

   (a) publish in advance any proposal to adopt or amend any measure of general application relating to the regulation of pharmaceutical products and medical devices, including an explanation of the objective of and rationale for the proposal;

(b) provide reasonable opportunities for interested persons and the other Party to comment on such proposed measures, allowing, in particular, for sufficient time for such opportunities; and

(c) take into account the comments received from interested persons and the other Party with respect to such proposed measures.

3. To the extent that a Party's health care authorities introduce or operate procedures for the listing, pricing and/or reimbursement of pharmaceutical products, the Party shall:

(a) ensure that the criteria, rules, procedures, and any guidelines, where relevant, that apply to the listing, pricing and/or reimbursement of pharmaceutical products, are objective, fair, reasonable and non-discriminatory, and are available upon request to interested persons;

(b) ensure that decisions on all applications for the pricing or approval of pharmaceutical products for reimbursement are adopted and communicated to the applicant within a reasonable and specified period from the date of the receipt of the application. If the information submitted by the applicant is deemed inadequate or insufficient and the procedure is suspended as a result, the Party's competent authorities shall notify the applicant of what additional information is required and resume the original decision-making process upon receipt of this additional information;

(c) provide applicants with appropriate opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes without prejudice to the applicable domestic law on confidentiality;

(d) in case of a negative decision on listing, pricing and/or reimbursement, provide the applicant with a statement of reasons that is sufficiently detailed to understand the basis of the decision, including the criteria applied and, if appropriate, any expert opinions or recommendations on which the decision is based. In addition, the applicant shall be informed of any remedies available under domestic law and of the time limits for applying for such remedies.

ARTICLE 4

Regulatory Cooperation

The Committee on Trade in Goods shall:

(a) monitor and support the implementation of this Annex;

(b) facilitate cooperation and exchange of information between the Parties with a view to furthering the objectives of this Annex;

(c) discuss ways to foster the compatibility of regulatory approval processes wherever possible; and

(d) discuss ways to facilitate bilateral trade in active pharmaceutical ingredients.

ARTICLE 5

Definitions

For the purposes of this Annex:

(a) "pharmaceutical products" means:

(i) any substance or combination of substances presented for treating or preventing diseases in human beings; or

(ii) any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

Pharmaceutical products include, for example, chemical medicinal products, biological medicinal products (e.g. vaccines, (anti)toxins) including 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, radiopharmaceuticals;

(b) "medical device"[1] means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, 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 purpose(s) of:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) control of conception;

(v) supporting or sustaining life;

(vi) disinfection of medical devices;

(vii) providing information for medical or diagnostic purposes by means of *in* vitro examination of specimens derived from the human body;

[1] For greater clarity, medical device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

(c) "a Party's health care authorities" means entities that are part of or have been established by a Party to operate or administer its health care programmes, unless otherwise specified; and

(d) "manufacturer" means the legal right holder of the product in the respective Party's territory.