

Pharmaceutical/Medicinal Products and Medical Devices

ARTICLE 1

General Provisions

The Parties confirm their shared objectives and principles of:

- (a) eliminating and preventing non-tariff barriers to bilateral trade based on the principles of openness, non-discrimination and transparency; and
- (b) using international standards, practices and guidelines developed within the framework of relevant international organisations as a basis for their technical regulations.

ARTICLE 2

Definitions

For the purposes of this Annex:

- (a) "pharmaceutical/medicinal products"¹ means any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis, to treating or preventing diseases or to restoring, correcting or modifying physiological functions or structures. Pharmaceutical/medicinal products include, for example, chemical drugs, biologics/biologicals (vaccines, (anti)toxins, blood components, blood derived products), herbal drugs, radiopharmaceuticals, recombinant products. Pharmaceutical/medicinal products include gene therapy products, cell therapy products or tissue engineered products if regulated as pharmaceutical/medicinal products by both Parties;

¹ This definition is without prejudice to Viet Nam's law on pharmacy No. 105/2016/QH13 and the Union's Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

- (b) "medical device"¹ means any product fulfilling the definition of medical device and *in vitro* medical diagnostic medical device as stipulated in Final Document GHTF/SG1/N071: 2012 by the International Medical Device Regulators Forum (GHTF/IMDRF); and
- (c) "rules" means any law, regulation, procedure, administrative ruling or implementing guideline of general application.

¹ For Viet Nam, this definition is without prejudice to the Viet Nam's legislation on medical devices.

ARTICLE 3

International Standards

The Parties shall base their technical regulations on international standards, practices and guidelines for pharmaceutical/medicinal products or medical devices¹, including those developed by the World Health Organisation (WHO), the Organisation for Economic Co-operation and Development (OECD), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)² and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) for pharmaceutical products and the International Medical Device Regulators Forum (IMDRF) for medical devices, except in duly substantiated cases on the basis of scientific and technical information, when such international standards, practices or guidelines would be ineffective or inappropriate for the fulfilment of the legitimate objectives pursued.

¹ For Viet Nam, the standards, practices and guidelines of the ASEAN Consultative Committee on Standards and Quality (ACCSQ) are also a basis for scientific and technical regulations.

² With a view to implementing this provision Viet Nam shall amend its domestic legislation in order to abolish the requirement of a minimum period of existing authorisation in the territory of the Union, prior to the submission of a request for marketing approval in Viet Nam, and any additional requirements relating to clinical studies going beyond those stipulated in international practices (in particular ICH guidelines).

ARTICLE 4

Transparency

1. Each Party shall promptly publish or otherwise make available at an early appropriate stage its rules regarding any matter related to the pricing, reimbursement or regulation of pharmaceutical/medicinal products or medical devices, in such a manner as to enable interested persons to become acquainted with them.

2. In accordance with its domestic law and to the extent possible, each Party shall:
 - (a) make publicly available in advance any rules referred to in paragraph 1 that it proposes to adopt or significantly amend;

 - (b) provide reasonable opportunities for interested persons to make comments on any proposed rules referred to in paragraph 1, allowing, in particular, a reasonable period of time for consultation; and

 - (c) address in writing, including by means of electronic communication, significant and substantive issues raised in written comments received from interested persons during the consultation period.

3. Whenever possible, each Party shall allow a reasonable interval between the publication of the rules referred to in paragraph 1 and their entry into force.
4. If a Party has established an authority for the operation or the administration of its health care programmes and that authority introduces or operates procedures for the listing, pricing or reimbursement of pharmaceutical/medicinal products, that Party shall:
 - (a) ensure that all criteria, methodologies, rules, guidelines and other implementing measures, which apply to the listing, pricing or reimbursement of pharmaceutical/medicinal products, including those used to determine comparator products, are transparent, fair, reasonable and non-discriminatory and are disclosed promptly to the legal right holder of a product upon his or her request;
 - (b) ensure that decisions on all requests and applications for the pricing or approval of pharmaceutical/medicinal products for reimbursement are adopted and communicated within a reasonable and specified period of time from the date of their receipt;
 - (c) provide the legal right holder of a product with timely and meaningful opportunities to submit comments at relevant stages in the pricing and reimbursement decision-making processes, without prejudice to the laws and regulations on confidentiality of either Party; and

- (d) provide, in case of a negative decision on listing, pricing or reimbursement, the legal right holder of a product with a statement of reasons, based upon objective and verifiable criteria, that is sufficiently detailed to understand the basis of the decision, including the criteria applied and, if appropriate, expert opinions or recommendations on which the decision is based. In addition, this right holder shall be informed of any available remedies under the domestic laws and regulations and of the time limits for introducing such remedies.

ARTICLE 5

Origin Marking

For pharmaceutical/medicinal products, Viet Nam may apply mandatory country of origin marking requirements at Member State level. Viet Nam is encouraged to consider accepting the marking "Made in EU" or a similar marking in the local language as fulfilling such country of origin marking requirements.
