ANNEX

PHARMACEUTICAL 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 principles of openness, non-discrimination and transparency;

(b) using international standards, practices and guidelines developed within the framework of relevant international organisations as a basis for their technical regulations.

Article 2

International Standards

The Parties will use international standards, practices and guidelines for pharmaceutical products or medical devices, including those developed the World Health Organisation (WHO), the Organisation for Economic Cooperation Development (OECD), the International Conference on Harmonization (ICH)[1] 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 as a basis for their technical regulations, except in those cases, duly substantiated 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.[2]

Article 3

Transparency

1. Each Party shall ensure that its laws, regulations, procedures, administrative rulings and implementing guidelines of general application (hereinafter referred to as "rules") regarding any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices are

[1] With a view to implement this provision Vietnam commits to amending its legislation in order to abolish the requirement of a minimum period of existing authorisation in the territory of the EU, prior to the submission of a request for a marketing approval in Vietnam, and any extra requirements related to clinical studies going beyond those stipulated in international practices (in particular ICH guidelines).

[2] For Vietnam, the standards, practices and guidelines of the ASEAN Consultative Committee on Standards and Quality (ACCSQ) are also a basis for scientific and technical regulations.

promptly published or otherwise made available at an early appropriate stage, in such a manner as to enable interested parties to become acquainted with them.

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

(a) make publicly available in advance any such rules that it proposes to adopt or significantly amend;

(b) provide reasonable opportunities for interested persons to make comments on any such proposed rules, 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 comment period.

3. Whenever possible, each Party shall allow a reasonable interval between the publication of any such rules and their entry into force.

4. To the extent that an authority established by a Party to operate or administer its health care programmes introduce or operate procedures for the listing, pricing and / or reimbursement of pharmaceutical products, the Party shall:

(a) ensure that all criteria, methodologies, rules and procedures, including guidelines and other implementing measures, that apply to the listing, pricing and/or reimbursement of pharmaceutical products, including those used, if any, to determine comparator products, are transparent, fair, reasonable and non-discriminatory, and are disclosed to the legal right holder of a product promptly upon request;

(b) ensure that decisions on all requests and applications for the pricing or approval of pharmaceutical products for reimbursement are adopted and communicated within a reasonable and specified period from the date of their receipt;

(c) provide the legal right holder of a product with timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes, without prejudice to the Parties' laws on confidentiality;

(d) in case of a negative decision on listing, pricing and/or reimbursement, provide 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, any expert opinions or recommendations on which the decision is based. In addition, this right holder shall be informed of any remedies available to him under the laws in force and of the time limits allowed for applying for such remedies.

Article 4

Origin marking

For pharmaceutical products, Viet Nam may apply obligatory country of origin marking requirements at Member State's level. However, Viet Nam is encouraged to consider to accept the marking "Made in EU" or a similar marking in the local language as fulfilling such requirements.

Article 5

Definitions

For the purposes of this Annex:

Pharmaceutical/Medicinal products[3] 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 products include, for example, chemical drugs, biologics/ biologicals (vaccines, (anti)toxins, blood components, blood derived products), herbal drugs, radiopharmaceuticals, recombinant products. When the following products are regulated as pharmaceutical products by both Parties, gene therapy products, cell therapy products or tissue engineered products will also fall under this Annex.

Medical device[4] 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).

[3] This definition is without prejudice to the Vietnamese law on pharmacy and EC Directive 2001/83/EC.

[4] For Vietnam, this definition is without prejudice to the Vietnamese legislation on medical devices.