

ANNEX 2-D

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

ARTICLE 1

General Provisions

Recognising that while there are differences between each Party's health care system, the Parties share a commitment to promoting the development of and facilitating access to high-quality patented and generic pharmaceutical products and medical devices, as a means of continuing to improve the health of their populations. In pursuing these objectives, the Parties confirm their shared principles with respect to the importance of:

- (a) adequate access to pharmaceutical products and medical devices while providing high-quality health care;
- (b) sound economic incentives and competitive markets for the efficient development of and access to pharmaceutical products and medical devices;
- (c) appropriate government support of academic and commercial research and development, intellectual property protection and other incentives for innovation in the research and development of pharmaceutical products and medical devices;
- (d) promotion of innovation of, and timely and affordable 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;
- (e) ethical practices by manufacturers and suppliers of pharmaceutical products and medical devices and by health care providers on a global basis in order to achieve open, transparent, accountable and non-discriminatory health care decision-making; and
- (f) cooperation between the Parties in regulatory affairs and in the development of international practices in international organisations such as the World Health Organisation (hereinafter referred to as the "WHO"), the Organisation for Economic Co-operation Development (hereinafter referred to as the "OECD"), the International Council for Harmonization (hereinafter referred to as the "ICH") for pharmaceutical products and the International Medical Device Regulators Forum (hereinafter referred to as the "IMDRF") for medical devices, with a view to improving the safety,

efficacy and quality of pharmaceutical products and medical devices.

ARTICLE 2

Access to Innovation

To the extent that health care authorities in a Party operate or maintain procedures for listing pharmaceutical products or medical devices, for indications entitled to reimbursement, or for setting the amount of reimbursement or any measures related to pricing¹ for pharmaceutical products or medical devices under health care programmes they operate, that Party shall:

- (a) ensure that the procedures, rules, criteria and implementing guidelines that apply to the listing of pharmaceutical products or medical devices, indications for reimbursement, setting the amount of reimbursement, or any measures related to listing, pricing and/or reimbursement for pharmaceutical products or medical devices are fair, transparent, reasonable and nondiscriminatory²; and
- (b) ensure that the health authorities' determination of pricing and reimbursement for a pharmaceutical product or medical device, once approved by the appropriate regulatory authority as safe, efficacious and of good quality, and if based on public bodies' or quasipublic bodies' involvement, shall:
 - (i) appropriately recognise the value of the patented pharmaceutical product or medical device in the amount of pricing and reimbursement it provides;
 - (ii) permit a manufacturer of the pharmaceutical product or medical device to apply, based on scientific evidence of safety, efficacy, quality and benefits, for an increased amount of pricing and reimbursement over those provided for comparator products, if any, used to determine the amount of reimbursement;
 - (iii) permit a manufacturer of the pharmaceutical product or medical device, after a decision on the pricing/reimbursement is made, to

¹ References to pricing in this Annex are only relevant if applicable under the legislation of either Party.

² The Parties understand that under this subparagraph, which does not establish any obligation to reimburse products at any given price or prejudge the specific outcome of price negotiations, the criteria (which may take forms such as guidelines, public notices or "matters to be considered", etc.) on which the decisions on reimbursement and pricing will be based are expected to be objective and clear so as to allow understanding of the basis of such decisions.

apply for an increased amount of reimbursement for the product based on scientific evidence the manufacturer provides on the product's safety, efficacy, quality and benefits;

- (iv) permit a manufacturer of the pharmaceutical product or medical device to apply for the amount of pricing and reimbursement and price adjustment for additional medical indications for the product, based on scientific evidence the manufacturer provides on the product's safety, efficacy, quality and benefits; and
- (v) in case a Party adjusts *ex officio* the amount of pricing/reimbursement of the pharmaceutical products or medical devices for external causes in specific circumstances, including drastic changes in economic indicators, permit a manufacturer of the pharmaceutical product or medical device to submit opinions regarding the adjustment before the adjustment is adopted.

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 the "rules"), regarding any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices are promptly published or otherwise made available at an early appropriate stage, in such a manner as to enable interested persons and the other Party to become acquainted with them.

2. To the extent possible, each Party shall:

- (a) publish in advance in relevant publicly accessible sites any such rules that it proposes to adopt or to significantly amend, including an explanation of the purpose of such rules;
- (b) provide reasonable opportunities for interested persons and the other Party to comment on any such proposed rules allowing, in particular, a reasonable period of time for consultation; and
- (c) address in writing significant and substantive issues raised in comments received from interested persons and the other Party during the comment period and explain any substantive revisions made with respect to such proposed rules, no later than the time the Party adopts them.

3. To the extent possible, each Party should allow a reasonable interval between the publication of any such rules on any matter related to the pricing, reimbursement

or regulation of pharmaceutical products or medical devices and their effective date.

4. To the extent that each Party's health care authorities operate or maintain procedures for listing pharmaceutical products or medical devices, for indications entitled to reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices, including any measures related to the revision of pricing and reimbursement under health care programmes, the Party shall:

- (a) ensure that decisions on all formal requests and applications for the pricing or approval of pharmaceutical products or medical devices for reimbursement are adopted and communicated within a reasonable and specified period from the date of their receipt. 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 detailed additional information is required and resume the original decision-making process upon receipt of this additional information;
- (b) disclose to applicants within a reasonable and specified period of time, all procedures, methodologies, principles, criteria, including those used, if any, to determine comparator products, and guidelines used to determine pricing and reimbursement for pharmaceutical products or medical devices;
- (c) afford applicants timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes for pharmaceutical products or medical devices;
- (d) provide, within a reasonable and specified period of time, applicants with meaningful and detailed written information regarding the basis for recommendations or determinations of the pricing and reimbursement of pharmaceutical products or medical devices, including citations to any expert opinions or academic studies relied upon in making such recommendations or determinations. Specifically, in case of a negative decision on listing, prices and/or reimbursement, or should the decision-making body decide not to permit in whole or in part the price increase requested, the decision-making body shall provide 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;
- (e) make available judicial, quasi-judicial or administrative tribunals, or independent review process³ that may be invoked at the request of an

³ In addition to what is set out in this subparagraph, applicants must be able to avail themselves of remedies ensuring effective legal protection. They must be able to appeal decisions before genuine judicial bodies.

applicant directly affected by a recommendation or determination and at the point of communication of decision on price and reimbursement inform the applicant of his or her rights under the laws of the Party and the procedures and time-lines for seeking such remedies;

- (f) make all reimbursement decision-making bodies open to stakeholders, including innovative and generic companies;
- (g) make publicly available a list of central bodies relevant to the pricing or reimbursement of pharmaceutical products or medical devices; and
- (h) provide access to each Party's national pricing and reimbursement arrangements including a positive list of products covered by the respective public health insurance schemes to be published on an annual basis for stakeholders with legitimate commercial interests. The negative list, if any, shall be published every six months.

5. Each Party shall ensure that all measures of general application respecting any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices are administered in a consistent, objective and impartial manner.

ARTICLE 4

Ethical Business Practices

1. Each Party shall adopt or maintain appropriate measures to prohibit improper inducements by manufacturers and suppliers of pharmaceutical products or medical devices to health care professionals or institutions for the listing, purchasing or prescribing of pharmaceutical products and medical devices eligible for reimbursement under health care programmes.

2. Each Party shall adopt or maintain appropriate penalties and procedures to enforce the measures that it adopts or maintains in conformity with paragraph 1.

3. Each Party shall bring to the other Party's attention any improper inducements conducted by its manufacturers of pharmaceutical products or medical devices. The Parties recall their obligations under the OECD *Convention on Combating Bribery of Foreign Public Officials in International Business Transactions* which entered into force on 15 February 1999.

ARTICLE 5

Regulatory Cooperation

1. The Parties will take into account, as appropriate, international provisions, practices and guidelines for pharmaceutical products or medical devices, including those developed by the WHO, the OECD, the ICH, the IMDRF and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The Parties recognise that their full participation in those relevant international bodies will facilitate regulatory cooperation between them.

2. The Parties will consider the requests by either Party to accept conformity assessments⁴ of that Party when performed in accordance with the Good Laboratory Practices and Good Manufacturing Practices of pharmaceutical products and medical devices and when both Parties' corresponding practices are in accordance with international practices.

3. For the Working Group on Pharmaceutical Products and Medical Devices established pursuant to Article 15.3.1 (Working Groups), the Parties shall provide for adequate participation of officials of agencies or departments responsible for health care or other matters and regulations covered by this Annex.

4. The Working Group shall:

- (a) monitor and support the implementation of this Annex;
- (b) promote discussion and mutual understanding of issues related to this Annex; and
- (c) promote cooperation between the Parties to achieve the objectives set out in this Annex.

5. The Working Group shall meet at least once a year, unless agreed otherwise. The Working Group may also carry out its work by e-mail, teleconference or videoconference or any other appropriate means of communications.

ARTICLE 6

Definitions

1. For the purposes of this Annex:

pharmaceutical products 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,

⁴ For the purposes of pharmaceutical products, **conformity assessment** means marketing authorisation of products, and the supervision/enforcement of manufacturers' or importers' compliance with technical standards/practices.

biologics/biologicals (vaccines, (anti)toxins, blood, blood components, blood-derived products), herbal drugs, radiopharmaceuticals, recombinant products, gene therapy products, cell therapy products and tissue engineered products;

medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for medical purposes such as diagnosis, prevention, monitoring, treatment or alleviation of diseases⁵. Medical device includes software incorporated into the device by its manufacturer and necessary for the proper functioning of the device;

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;

health care programmes operated by a Party means health care programmes in which the health care authorities of a Party make decisions regarding matters to which this Annex applies;

manufacturer refers to the legal right holder of the product in the respective Party's territory;

a negative list is defined as a compilation of pharmaceutical products and medical devices that have been excluded from being prescribed and/or reimbursed under a Party's public health care programme(s); and

a positive list is defined as an exhaustive compilation of pharmaceutical products and medical devices that can be prescribed and/or reimbursed under a Party's public health care programme(s).

2. The definitions for pharmaceutical products and medical devices stated in paragraph 1 are without prejudice to each Party's right to classify products as either pharmaceutical products or medical devices in its legislation.

⁵ For greater clarity, medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.