Amendments to Annex 2-D (Pharmaceutical Products and Medical Devices)

1. Footnote 1A is hereby inserted under the Title of Article 2 (Access to Innovation): "**Access to Innovation**[1A]"

"[1A] For the purposes of this Article, all references to pricing or reimbursement shall only take effect to the extent permissible by the applicable laws and rules of the pricing or reimbursement systems of each Party."

2. Article 2 (Access to Innovation) is hereby replaced with the following:

"ARTICLE 2

Access to Innovation[1A]

(a) 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 pricing[1] for pharmaceutical products or medical devices under health care programmes they operate, that Party shall: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, or reimbursement for pharmaceutical products or medical devices are fair, transparent, reasonable, and non-discriminatory[2]; 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 quasi-public 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) consider an increased amount of pricing and or reimbursement over those provided for comparator products, if any, used to determine the amount of reimbursement, based on evidence the manufacturer submits, such as clinical effectiveness and safety;

(iii) permit a manufacturer of the pharmaceutical product or medical

[1A] For the purposes of this Article, all references to reimbursement or pricing shall only take effect to the extent permissible by the applicable laws and rules of the reimbursement or pricing systems of each Party.

[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.

device, after a decision on the pricing or reimbursement is made, to apply for an increased amount of reimbursement for the product based on the evidence submitted by the manufacturer;

(iv) consider an adjusted amount of pricing and reimbursement based on additional medical indications for the product based on evidence submitted by the manufacturer; and

(v) in case a Party adjusts *ex officio* the amount of pricing or 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."

3. Footnote 3A is hereby inserted under the title of Article 3 (Transparency):

"**Transparency**[3A]"

"[3A] For the purposes of this Article, all references to pricing or reimbursement shall only take effect to the extent permissible by the applicable laws and rules of the pricing or reimbursement systems of each Party."

4. Article 3.4 (Transparency) is hereby replaced with the following:

"

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, each Party**,** without prejudice to its applicable domestic laws on confidentiality, 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, the 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 expert opinions, where appropriate, 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 process[3] that may be invoked at the request of an 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 timelines for such remedies;

(f) where applicable, make 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 pricing and reimbursement arrangements including, where applicable, 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. A negative list, if applicable, shall be published every six months."

5. New paragraph 3 is hereby inserted following Article 5.2 (Regulatory Cooperation), with subsequent paragraphs renumbered accordingly:

"3. The Parties shall endeavour to take a mutual decision to enter into negotiations on a *Mutual Recognition Agreement* (hereinafter referred to as "MRA") *on Good Manufacturing Practices* in the future."

6. The reference to "this Annex" at Article 5.4(c) is replaced with "the Annex".

[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.