

ANNEX 2I

REFERRED TO IN ARTICLE 2.11

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

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PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

ARTICLE 1

International Standards

The Parties will use international standards, practices and guidelines for pharmaceutical products or medical devices, including those developed by the World Health Organisation (WHO), the Organisation for Economic Cooperation and Development (OECD), the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) 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. The Parties recognise that their full participation in those relevant international bodies will facilitate regulatory cooperation between them.

ARTICLE 2

Transparency

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; and

- (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/her under the laws in force and of the time limits allowed for applying for such remedies.
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