

DRAFT
SUBJECT TO LEGAL REVIEW FOR ACCURACY, CLARITY AND CONSISTENCY
MARCH 1, 2004

ANNEX 2-C
PHARMACEUTICALS

1. AGREED PRINCIPLES

The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing this objective, the Parties are committed to the following principles:

- (a) the important role played by innovative pharmaceutical products in delivering high quality health care;
- (b) the importance of research and development in the pharmaceutical industry and of appropriate government support including through intellectual property protection and other policies;
- (c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety and efficacy; and
- (d) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

2. TRANSPARENCY¹

To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing of new pharmaceuticals or indications, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:

- (a) ensure that consideration of all formal proposals for listing are completed within a specified time;
- (b) disclose procedural rules, methodologies, principles and guidelines used to assess a proposal;

^{2-c1} Pharmaceutical formulary development and management is considered to be an aspect of government procurement for federal healthcare agencies that engage in government procurement. Government procurement of pharmaceutical products shall be governed by Chapter 15 (Government Procurement) and not the provisions of this Annex.

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- (c) afford applicants timely opportunities to provide comments at relevant points in the process;
- (d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;
- (e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and
- (f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

3. **MEDICINES WORKING GROUP**

- (a) The Parties hereby establish a Medicines Working Group.
- (b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4), including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.²
- (c) The Working Group shall comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

4. **REGULATORY COOPERATION**

The Parties shall seek to advance the existing dialogue between the Australian Therapeutic Goods Administration and the U.S. Food and Drug Administration with a view to making innovative medical products more quickly available to their nationals.

5. **DISSEMINATION OF INFORMATION**

Each Party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers via the manufacturer's Internet site registered in the territory of a Party, and on other Internet sites registered in the territory of a Party

^{2-C2} Nothing in this paragraph shall be construed to require a Party to review or change decisions regarding specific applications.

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linked to that site, truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party's territory as is permitted under each Party's laws, regulations and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceuticals.

6. DEFINITIONS

For the purposes of this Annex:

federal healthcare program means a health care program in which the federal health authorities make the decisions regarding payment and coverage to which this Annex applies.