

**Australia – United States Free Trade Agreement
Medicines Working Group**

Standard Operating Procedures

This document details the Standard Operating Procedures of the Medicines Working Group (“Working Group”) that was established pursuant to Annex 2-C of the Australia-United States Free Trade Agreement (“Agreement”) signed on 18 May 2004.

I. Objectives

1. The objectives of the Working Group shall be to promote discussion and mutual understanding of issues relating to Annex 2C (except those issues covered in paragraph 4), including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.

II. Composition

1. A representative from both the United States Department of Health and Human Services and from the Australian Government Department of Health and Ageing will be designated as “Co-Chairs of the Working Group.”
2. Each Co-Chair may appoint a Co-Vice Chair to act in its capacity as Co-Chair.
3. The Working Group will consist of the Co-Chairs and other officials of federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.
4. Each Co-Chair will designate a point of contact on its respective side for the purposes of communication and organization of administrative staff support for the Working Group.

III. Meetings of the Working Group

1. The Working Group shall meet once a year, unless decided otherwise by mutual agreement.
2. The Working Group shall meet on dates and in locations, including via video- or tele-conference, as decided by mutual agreement of the Working Group Co-Chairs.
3. The Working Group Co-Chair whose country is hosting the meeting will conduct each meeting, unless decided otherwise by mutual agreement of the Working Group Co-Chairs.
4. The Working Group Co-Chairs will be responsible for managing the business of the Working Group.

5. The Working Group Co-Chairs will establish the date and venue for meetings at least 45 days prior to each meeting, unless decided otherwise by mutual agreement of the Working Group Co-Chairs.
6. The Working Group Co-Chairs will propose the agenda for meetings at least 30 days prior to each meeting, unless decided otherwise by mutual agreement of the Working Group Co-Chairs.
7. The Working Group shall meet alternately in each Party's territory, unless decided otherwise by mutual agreement of the Working Group Co-Chairs.
8. The host country for a meeting will provide appropriate administrative support for that meeting, including a summary report of the meeting as agreed between the Co-Chairs.

IV. Modification

1. These Operating Procedures may be modified by mutual agreement in writing by the Working Group.