

Constitution

Australian Pharmaceutical Biostatistics Group

(APBG)

MISSION statement

To ensure high statistical standards within Australia to assist in the decision processes which provide safe, efficacious and cost-effective health care products produced in a regulated environment for the health and quality of life of people.

CONSTITUTION

1. Name

The group shall be named **Australian Pharmaceutical Biostatistics Group**. It shall be commonly known as **APBG**. Throughout this document, the APBG shall be referred to as *the group*.

2. Regulated Health Care Industry

Members of *the group* shall work in the regulated health care industry. The regulated health care industry shall incorporate pharmaceutical products, biologics, medical devices, vaccines, diagnostic tools and any other interventions that are required to be approved by regulating or reimbursing authorities such as the Therapeutic Goods Administration (TGA), Pharmaceutical Benefits Advisory Committee (PBAC) or Medical Services Advisory Committee (MSAC).

3. Purpose and Objectives

The general purposes of *the group* are:

- a. To ensure professional standards of statistical practice in the conduct of research and dissemination of information relating to products produced for the regulated health care industry.
- b. To provide a forum for open discussion of general statistical practice related to research and decision making in the regulated health care industry.
- c. To provide educational opportunities of specific relevance to statisticians in the regulated health care industry.

The specific objectives of *the group* are:

- a. To proactively seek opportunities to work collaboratively with the various regulatory committees and clinical working groups including the Health Economic Committee (HEC) and the Technical Affairs Committee on statistical issues.
- b. To establish professional relations, as appropriate, with national and international regulatory advisory groups and professional societies.
- c. To provide professional educational opportunities of specific relevance to statisticians in the regulated health care industry.

In respect of competition law concerns, *the group* shall not be a forum for discussing any product-specific or market-specific issue.

4. Membership

Members of *the group* shall satisfy the following requirements:

- a. Membership shall be person based.
- b. Members shall be statisticians working within the regulated health care industry.
- c. Other active professions within the regulated health care industry are welcome to be included on *the group's* distribution email list. However, they will not be considered members of *the group*.

5. Organisational Structure

The following describes the structure of *the group*:

- a. Steering Committee
 - i. A steering committee shall be appointed consisting of four (4) members, no more than two of whom will come from one company or entity Chair, Vice Chair, Secretary and Treasurer.
 - ii. The Chair or his/her designee from within *the group* shall be responsible for chairing all meetings and shall serve as the spokesperson for *the group* in verbal and written official communications between *the group* and other bodies.
 - iii. The Vice Chair shall assume responsibilities of the Chair in the absence of the Chair or his/her designee.
 - iv. The Secretary shall be responsible for coordinating and minuting all official meetings and shall be the custodian of all official written communications involving *the group*.
 - v. The Treasurer shall be responsible for all financial matters and shall create and maintain records of all financial transactions involving *the group*.
 - vi. All decisions and communications made on behalf of *the group* shall be approved by at least three (3) members of the steering committee.
- b. Election Process
 - i. The Chair shall serve for a maximum of three (3) consecutive years.
 - ii. Nominations for the Chair shall be made at least two (2) weeks before the annual general meeting at which the current Chair's term expires.
 - iii. The Chair shall be appointed by general election following a necessary nomination and secondment of nomination and secret ballot of the individual representatives.
 - iv. Nominations for the Vice Chair, Secretary and Treasurer shall be made annually at least two (2) weeks before the annual general meeting.

- v. The Vice Chair, Secretary and Treasurer shall be appointed by general election following a necessary nomination and secret ballot of the individual representatives.
 - vi. Each member shall be restricted to only one (1) vote.
- c. Resignations
- i. In the event of resignation of the Chair, the Vice Chair shall assume responsibilities as interim Chair for the remainder of the term of office of the Vice Chair.
 - ii. The interim Chair shall reserve the right to appoint an interim Vice Chair from among the individual representatives.
 - iii. In the event of resignation of the Vice Chair, Secretary or Treasurer, the Chair shall reserve the right to appoint an interim Vice Chair, Secretary or Treasurer from among the individual representatives.

6. Finance

Fundamental financial issues shall be conducted as follows:

- a. The assets and income of *the group* shall be applied solely in furtherance of its above-mentioned objectives and no portion shall be distributed directly or indirectly to the members of *the group* except as bone fide compensation for services rendered or expenses incurred on behalf of *the group*.
- b. Subject to members' company financial approval processes *the group* shall seek opportunities to share the cost of conducting its activities such as workshop, seminars, training and meetings.
- c. In the event of *the group* being dissolved, the amount that remains after such dissolution and the satisfaction of all debts and liabilities shall be transferred to another organisation with similar purpose which is not carried out for the profit or gain of its individual members.

7. Meetings

General meetings shall be handled in the following manner:

- a. An Annual General Meeting (AGM) shall be held in the second half of each calendar year.
- b. The AGM shall serve as a forum to discuss relevant technical issues and share experiences and processes with other national or international regulatory advisory bodies.
- c. The steering committee shall be responsible for managing the general organisation, agenda and guest list for the AGM.
- d. Other ad-hoc meetings may take place as necessary.

- e. The steering committee shall be responsible for managing the general organisation, agenda and guest list for ad-hoc meetings.
- f. The steering committee shall inform all members of the time, date and place of all general meetings at least two (2) weeks in advance through written communication.

8. Relationship to Member's Company

- a) Communications from *the group* shall not normally contain the names of any individual member's company.
- b) Communications from *the group* shall not normally be referred to member's company for approval, unless these communications contain the names of any member's company.
- c) Communications from *the group* shall not purport to indicate the opinions of individual member's company but will represent the consensus of *the group*.

9. Quorum

- a) For general meetings of *the group*, the quorum shall be sixty percent (60%) of members, including three (3) members of the steering committee.
- b) The support of at least two-thirds of members shall be required to approve changes to the constitution.