

Drafting instructions for proposed amendments to the Bill

Schedule 1

Item 8

Section 52B

Insert new sub-s (3A):

“(3A) The Chair of the Committee must be an independent person who is not a member of the staff of the Department of Health and Ageing, including the Therapeutic Goods Administration.”

Item 12

Section 52E

Insert new sub (1A) and (1B):

“(1A) In exercising a power under s. 52D (2) the Secretary must comply with a guideline issued as a Legislative Instrument by the Minister relating to the studies to be undertaken using the analytical tools to be used in assessing the matters set out in sub-s. (1).

(1B) The guidelines issued by the Minister must be consistent with the Principles of Good Regulation, issued by the Council of Australian Governments in relation to the use of hazard assessment, risk assessment, cost/benefit studies and statistical methods for assessing the probability of adverse events.”

New section 52EAAA

Insert new section:

- (1) Any guidelines issued under sub-section 52E (2)
 - (a) must be consistent with the Principles of Good Regulation issued by the Council of Australian Governments;
 - (b) must be the subject of meaningful public consultation prior to their issue
- (2) the sub-committee referred to in para 52E (2) (b) must publish, as soon as practicable, the minutes of any meeting at which proposed guidelines or amendments to existing guidelines have been considered.

Section 52EAA

Add new sub-sections:

- “(5) A decision made under this section, other than under sub-section (7), is taken to be an initial decision for the purposes of section 60.
- (6) A decision of the kind referred to in sub-section (5) is a decision either to approve or to reject an application made under this section.
- (7) Where a person certifies to the Secretary that their application is commercial-in-confidence, and the application is approved, the Secretary may withhold publication of the decision for a period, other than to the applicant, for a period of not less than six nor more than 12 months.
- (8) In exercising a power under sub-section (7), the Secretary may have regard to
 - (a) the benefits to Australian industry that may accrue because of the encouragement a favourable decision may bring to innovative endeavour; and/or
 - (b) the nature of the outlays, of time and money, made by the applicant.

Schedule 3

Part 2

Item 9

After sub-section (5A) insert new sub-section 5A:

“(5AA) The legislative instrument made under sub-section (5A) must not require a label to be affixed that is misleading or deceptive or likely to be misleading or deceptive within the meaning in sub-section 52 (1) of the Trade Practices Act.”

New amendment

Section 60

Insert new para. (1) (m):

“(m) under sub-section 52EAA (5)”.