

EXPLANATORY STATEMENT

Select Legislative Instrument 2009 No. 63

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2009 (No. 1)

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the Regulations is to amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations) to remove restriction on members of the Medical Devices Evaluation Committee being appointed for more than three consecutive terms.

The Department of Health and Ageing is planning to revise the advisory committee arrangements under the Principal Regulations in the near future. The Regulations allow certain members of the Medical Devices Evaluation Committee to be reappointed for a further term to maintain the Committee's membership until the general changes can be introduced.

The Regulations also make an amendment to reflect the change of name of a body that may nominate an observer to the Therapeutic Good Advertising Code Council. The Principal Regulations currently refer to the Cosmetics, Toiletries and Fragrances Association of Australia, but that body recently changed its name to ACCORD Australasia Ltd.

Consultation on these amendments has taken place with the parties affected: members of the Medical Devices Evaluation Committee, ACCORD Australasia Ltd and the Therapeutic Goods Advertising Code Council.

The Committee members were informed of the need to maintain the current composition of the committee until the arrangements for expert advisory committees are revised later this year. The Therapeutic Goods Administration liaised with ACCORD Australasia Ltd and the Code Council about the change of the name of the observer to the Council from the Cosmetics, Toiletries and Fragrances Association of Australia to ACCORD Australasia Ltd.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on the day after they are registered in the Federal Register of Legislative Instruments.

Authority: Subsection 63(1) of the
Therapeutic Goods Act 1989