

Therapeutic Goods Regulations (Amendment) 1992 No. 332

EXPLANATORY STATEMENT

STATUTORY RULES 1992 No. 332

Issued by Authority of the Minister for Aged, Family and Health Services

Therapeutic Goods Act 1989

Therapeutic Goods Regulations (Amendment)

The Therapeutic Goods Act 1989 (the Act) has for its objective the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia.

The Act was recently amended to accommodate recommendations made by Professor Peter Baume in his "Report on the Future of Drug Evaluation in Australia", the contents of which were adopted as a package by the Government in July 1991.

Paragraph 57(1)(c) of the Act was amended to enable the Governor-General to make regulations prescribing offices and appointments the holder of which may be delegated the Secretary's or the Minister's powers and functions under the Act. This was in response to the recommendation by Professor Baume for the appointment, on a contract basis, of a person of high national and international standing in the drug regulatory area with high level management skills, to be given the authority and responsibility for achieving the missions and targets set by Government in relation to this area. To achieve this objective, the new National Manager would need to exercise many of the powers and functions under the Act and the Therapeutic Goods Regulations as a delegate of the Secretary or the Minister.

Subsection 61(6) of the Act prescribes the circumstances in which the Secretary may release information concerning therapeutic goods included in the Australian Register of Therapeutic Goods. In his Report, Professor Baume recommended that greater dissemination of the outcome of deliberations by the Australian Drug Evaluation Committee should be made through, for example, publication in journals and gazettals of the recommendations of that Committee for new approvals.

Paragraph 63(2)(c) of the Act enables the Governor-General to prescribe requirements for the advertising of therapeutic goods.

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Accordingly, the amending Regulations incorporate changes that:

- (a) enable the new National Manager, who is employed on contract and is not an officer under the terms of the Public Service Act, to perform functions under the Act and regulations as the Secretary's or the Minister's delegate;
- (b) enable the Secretary to gazette decisions or deliberations of the Australian Drug Evaluation Committee in the Commonwealth Gazette; and

(c) include two additional professional bodies in Schedule 1 of the Therapeutic Goods Regulations, so that advertising restrictions under Part 2 of the Regulations designed principally for consumers will not affect members of those bodies;

(d) update the definition of "drugs" in regulation 2 of the Therapeutic Goods Regulations to bring it in line with the amended definition of "therapeutic device" contained in subsection 3(1) of the Act (as amended by section 83 of the Health, Housing and Community Services Legislation Amendment Act 1992 on 31 July 1992); and

(e) enable appeals to be made to the Administrative Appeals Tribunal in respect of decisions made under paragraph 11(2)(d) of the Regulations, concerning what therapeutic goods would be unsuitable for inclusion in listable "kits".

In addition, the amending Regulations correct a number of typographical errors appearing in some of the Schedules to the current Therapeutic Goods Regulations.

Further details of the Regulations are set out in the Attachment.

ATTACHMENT

DETAILS OF REGULATIONS

Subregulation 2.1 brings the definition of "drugs" in line with the newly amended definition for a "therapeutic device" in s.3(1) of the Therapeutic Goods Act 1989 (the Act).

Subregulation 3.1 will enable the Secretary to gazette decisions or deliberations made by the Australian Drug Evaluation Committee for the purposes of s.61 of the Act.

Subregulation 4.1 inserts new **Regulation 46A** to enable the Minister and the Secretary to delegate their powers under the Principal Act to the National Manager, Therapeutic Goods Administration.

Subregulations 5.1 and 6.2 amends Regulation 47 to enable the Minister and the Secretary to delegate their powers and functions under the Regulations to the National Manager, Therapeutic Goods Administration.

Subregulation 6.1 permits an appeal to the Administrative Appeals Tribunal against a decision made under paragraph 11(2)(d) of the Regulations declaring therapeutic goods to be unsuitable for inclusion in a "kit". "Kits" are required to be listed in the Australian Register of Therapeutic Goods (ARTG) before they may be supplied for use in Australia. The effect of excluding certain therapeutic goods from being included in a "kit" is that a sponsor would have to supply such therapeutic goods separately (and therefore have such goods listed separately in the ARTG), rather than as part of a "kit".

Subregulations 7.1 and 7.2 correct two typographical errors, where Items in Schedule 1 to the Regulations have been misnumbered.

Subregulation 7.3 adds two further professional associations under Schedule 1 of the Therapeutic Goods Regulations. Members of professional bodies listed under Schedule 1 are not affected by the advertising prohibitions applying to advertisers when they advertise their products to consumers.

Subregulations 8.1, 8.2 and 8.3 correct typographical errors. No changes have been made to paragraph (j), Item 7, Schedule 5. Subregulation 8.1 simply clarifies that the three existing items under paragraph (j), Item 7, Schedule 5, are separate items.

Regulation 9 adds a further heading "Prescription Drugs" to assist readers.

The Regulations commence on Gazettal.