Australian Government

Department of Health

Therapeutic Goods Administration

Reviewable initial decisions under the Therapeutic Goods Act & Regulations

Version 1.1, November 2016

TGA Health Safety Regulation

Contents

Therapeutic Goods Act 1989

Under section 60 a person whose interests are affected can seek a review of the following decisions of the Secretary or a delegate of the Secretary:

- under the definition of *therapeutic devices* in subsection 3(1), under subsection 7(1) (declaration of therapeutic goods) and under 41BD(3) (definition of medical device);
- subsection 7C(3) (decisions by computers);
- section 9C or 9D (inspection and variation of entries in the ARTG);
- section 9F (removal of entries from the Australian Register of Therapeutic Goods (ARTG))
- refusing to grant a consent under section 14 or 14A (standards);
- under Part 3-2 (registration and listing of therapeutic goods);
- under Part 3-2A (biologicals);
- under Part 3-3 (manufacturing of therapeutic goods);
- under Part 4-4 (conformity assessment certificates);
- under Part 4-5 (including medical devices in the ARTG), other than: a decision under section 41FH (selecting applications for auditing); or a decision about which aspects of the matters referred to in paragraphs 41FI(1) (a) and (b) to consider in auditing an application under Subdivision C of Division 1 of Part 4-5; or
- under Part 4-6 (suspension and cancellation of medical device from ARTG);
- under Part 4-7 (exempting medical devices from inclusion in the ARTG);
- under Part 4-8 (obtaining information in relation to medical devices);
- under Part 4-9 (public notification and recovery of medical devices);
- refusing to grant, or imposing conditions on a grant of, a consent for the purposes of section 41MA or 41MAA (non-compliance with essential principles); and
- section 42DF, 42DH or 42DI (in relation to restricted representations)

Therapeutic Goods Regulations 1990

Under regulation 48 a person whose interests are affected can seek a review of the following decisions of the Secretary or a delegate of the Secretary:

- subregulation 9(1) (orders about advertisements etc.);
- subregulation 10A(7) (cancellation where registration or listing transferred without notice);
- subregulation 10C(3), (4), (5) or (6) (assignment of registration or listing numbers);
- subregulation 10F(7) (cancellation of medical device where change of name without notice);
- subregulation 10H(9) (cancellation of biological where change of name without notice);
- subregulation 16J(3) (orphan drugs refusal);

- subregulation 22(8) (cancellation where licence transferred);
- subregulation 43AAH(4)(b) (refuse to waive the charge for the financial year)
- regulation 45 (waiver or reduction of fees); and
- regulation 45AA (payment of fees by instalments)

Under regulation 5M an applicant or approved holder who is dissatisfied can seek a review of the following decisions:

- regulation 5G (the granting of an advertising approval);
- regulation 5K (variation of conditions applying to such an approval); and
- regulation 5L (withdrawal of advertising approval)

Therapeutic Goods (Medical Devices) Regulation 2002

Under regulation 10.7 a person whose interests are affected can seek a review of the following decisions of the Secretary or a delegate of the Secretary:

- subregulation 4.10(2) (suspension/revocation of conformity assessment certificate where failure to advise Secretary);
- paragraph 9.4(2)(a) (conformity assessment fee - abridged assessment); and
- subregulation 9.5(1) (payment of assessment fee by instalments)

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Regulatory Integrity	7/9/12
V1.1	Update	Regulatory Pricing & Decision Review Section	1/11/2016

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #R16/856383