Therapeutic Goods Information (Sharing of Committee Information) Specification 2017

Therapeutic Goods Act 1989

I, Ross Hawkins, Acting First Assistant Secretary, Regulatory Practice and Support Division, a delegate of the Minister for Health, make this Specification under subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

Dated 4/12/17

(Signed by)

ROSS HAWKINS

Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Sharing of Committee Information) Specification 2017*.

2 Commencement

This Specification commences on the day after it is registered.

3 Repeal

This Specification repeals the *Therapeutic Goods Information (Sharing of Committee Information) Specification 2014*.

4 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

Committee means any of the committees established under Divisions 1A-1EB of Part 6 of the Regulations and includes any of the committees previously established under the Regulations.

Regulations means the *Therapeutic Goods Regulations 1990*.

TGA means the Therapeutic Goods Administration, which is part of the Department of Health.

5 Therapeutic goods information, persons and purposes

The kinds of therapeutic goods information, persons, bodies and purposes, mentioned in Schedule 1 are specified under subsection 61(5AB) of the Act, for the purposes of subsection 61(5AA) of the Act.

Schedule 1 Specified kinds of therapeutic goods information, persons, bodies and purposes

(section 5)

The following kinds of therapeutic goods information, persons, bodies and purposes:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary under subsection 61(5AA) of the Act to the following specified bodies and kinds of persons, for the following specified purposes.

1. Therapeutic goods information:

The following kinds of therapeutic goods information, being information that relates to the Committees and that is held by the TGA:

Item	Information	Description
(a)	Committee advice	The advice and/or recommendations provided by a Committee to the Minister or the Secretary in relation to a matter, under the Regulations.
(b)	Committee agenda papers	Committee meeting agenda papers. The agenda papers may include the name and contact details of committee members and TGA staff.
(c)	Minutes and Outcomes	Minutes of Committee meetings, and/or brief descriptions of any outcomes arising from such meetings. The outcomes (referred to as the meeting statement) will include the contact details of TGA staff for bodies to obtain further information. The minutes will list attending members, special advisors and other guest experts by name only and attending TGA staff by name and position.

2. Persons and bodies:

(a) Advisory Committee on Biologicals (ACB);
(b) Advisory Committee on Complementary Medicines (ACCM);
(c) Advisory Committee on Medical Devices (ACMD);
(d) Advisory Committee on Medicines (ACM);

(e) Advisory Committee on Vaccines (ACV);
(f) Advisory Committee on Medicines Scheduling (ACMS);
(g) Advisory Committee on Chemicals Scheduling (ACCS);
(h) Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR);
(i) Pharmaceutical Benefits Advisory Committee (PBAC);
(j) Drug Utilisation Sub Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee;
(k) Medical Services Advisory Committee (MSAC);
(l) National Centre for Immunisation Research and Surveillance (NCIRS);
(m) National Immunisation Committee (NIC);
(n) Australian Technical Advisory Group on Immunisation (ATAGI);
(o) Prostheses List Advisory Committee (PLAC);
(p) the Panel of Clinical Experts for neurosurgical, plastic and reconstructive, ear/nose/throat, and general and miscellaneous prostheses;
(q) the Cardiac Prostheses Clinical Advisory Group;
(r) the Cardiothoracic Prostheses Clinical Advisory Group;
(s) the Hip Prostheses Clinical Advisory Group;
(t) the Knee Prostheses Clinical Advisory Group ;
(u) the Ophthalmic Prostheses Clinical Advisory Group ;
(v) the Specialist Orthopaedic Clinical Advisory Group;
(w) the Spinal Prostheses Clinical Advisory Group;
(x) the Urogenital Prostheses Clinical Advisory Group;
(y) the Vascular Prostheses Clinical Advisory Group;
(z) any subcommittees of any of the committees mentioned above in (a), (b), (c), (d), (e), (f) and (g); and
(aa) employees, members or agents of the entities mentioned above in (a) – (z).

3. Purposes:

To facilitate the sharing and considering of information in the interest of public health and safety, including in particular the sharing and considering of information relating to the safety and (where relevant) efficacy or performance of therapeutic goods.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislation kept under the *Legislation Act 2003.* See http://www.legislation.gov.au.