



Therapeutic Goods (Advisory Committees— Information Sharing) (Information) Specification 2023

I, Chris Bedford, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 7 June 2023

Chris Bedford
Acting First Assistant Secretary
Regulatory Practice and Support Division
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Advisory Committees—Information Sharing) (Information) Specification 2023*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 July 2023.	1 July 2023

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 61(5AB) of the Act.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

(a) Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

advisory committee means an advisory committee that is established under Part 6 of the Regulations and includes any of the committees previously established under the Regulations.

advisory committee advice means advice or recommendations provided by an advisory committee to the Minister or the Secretary in relation to a matter or item considered by an advisory committee at an advisory committee meeting.

meeting statement means a description of outcomes arising from an advisory committee meeting.

relevant persons or bodies means any of the following bodies, and employees, members or agents of these bodies:

- (a) the Advisory Committee on Biologicals (ACB), and any subcommittee of the ACB;
- (b) the Advisory Committee on Chemicals Scheduling (ACCS), and any subcommittee of the ACCS;
- (c) the Advisory Committee on Complementary Medicines (ACCM), and any subcommittee of the ACCM;
- (d) the Advisory Committee on Medical Devices (ACMD), and any subcommittee of the ACMD;
- (e) the Advisory Committee on Medicines (ACM), and any subcommittee of the ACM;
- (f) the Advisory Committee on Medicines Scheduling (ACMS), and any subcommittee of the ACMS;
- (g) the Advisory Committee on Vaccines (ACV), and any subcommittee of the ACV;
- (h) the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR);
- (i) the Australian Technical Advisory Group on Immunisation (ATAGI);
- (j) the Cardiac Prostheses Clinical Advisory Group;
- (k) the Cardiothoracic Prostheses Clinical Advisory Group;
- (l) the Hip Prostheses Clinical Advisory Group;
- (m) the Knee Prostheses Clinical Advisory Group;
- (n) the Medical Devices and Human Tissue Advisory Committee (MDHTAC), and any subcommittee of the MDHTAC;
- (o) the Medical Services Advisory Committee (MSAC), and any subcommittee of the MSAC;
- (p) the National Centre for Immunisation Research and Surveillance (NCIRS);
- (q) the National Immunisation Committee (NIC);
- (r) the Ophthalmic Prostheses Clinical Advisory Group;
- (s) the Pharmaceutical Benefits Advisory Committee (PBAC), and any subcommittee of the PBAC;
- (t) the Specialist Orthopaedic Clinical Advisory Group;
- (u) the Spinal Prostheses Clinical Advisory Group;
- (v) the Vascular Prostheses Clinical Advisory Group.

Regulations mean the *Therapeutic Goods Regulations 1990*.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

5 Release of therapeutic goods information

For subsection 61(5AA) of the Act, in relation to each item in the table in Schedule 1, the kinds of therapeutic goods information specified in column 2 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a person, body or authority that is specified (or that is of a kind specified) under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Therapeutic goods information

Note: See section 5.

Therapeutic goods information that may be released			
Column 1	Column 2	Column 3	Column 4
Item	Kinds of information	Persons or bodies	Purposes
1	information that relates to an advisory committee, that is contained in any of the following: (a) advisory committee advice; (b) agenda papers for advisory committee meetings; (c) meeting statements; (d) minutes of advisory committee meetings	relevant persons or bodies	to facilitate the sharing and consideration of information that is in the interests of public health and safety, including information relating to: (a) the safety of therapeutic goods; or (b) the efficacy or performance of therapeutic goods

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods Information (Sharing of Committee Information) Specification 2017

1 The whole of the instrument

Repeal the instrument.