Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

ACCC
AUSTRALIAN COMPETITION & CONSUMER COMMISSION

Memorandum of Understanding

Therapeutic Goods Administration

Australian Competition and Consumer Commission

11 April 2023

1. Introduction

1.1. This Memorandum of Understanding (**MOU**) establishes a framework for coordination between the Therapeutic Goods Administration (**TGA**) and the Australian Competition and Consumer Commission (**ACCC**) (**the Participants**).

2. Purpose

2.1. The Participants have a shared interest to ensure close cooperation in relation to activity in the marketplace which may undermine the shared objective of protecting consumers from unsafe therapeutic goods, and false or misleading representations in relation to therapeutic goods.

2.2. The purpose of this MOU is to provide a framework that facilitates:

(a) efficient administration of regulatory and legislative responsibilities;

(b) effective operational liaison and efficient information exchange between the Participants; and

(c) coordination (where relevant) in relation to public announcements, ministerial briefings and legislative and administrative changes.

3. Statutory roles

TGA

3.1. The TGA is part of the Australian Government Department of Health and Aged Care (**the Department**), and is responsible for regulating therapeutic goods including medicines, cell therapies, sunscreens, vitamins and minerals, medical devices, human cells and tissues and blood components. The regulatory framework is prescribed in the *Therapeutic Goods Act 1989* (**TG Act**), and related regulations and instruments.

3.2. The TGA regulates the import, export, supply and advertising of therapeutic goods through pre-market assessment, post-market monitoring and enforcement, and licensing and inspections of manufacturers to verify compliance. The TGA also coordinates recall and non-recall actions for therapeutic goods supplied, imported into or exported from Australia, as outlined in the *Uniform recall procedure for therapeutic goods* (**URPTG**).

ACCC

3.3. The ACCC is an independent Commonwealth statutory authority whose role is to enforce the *Competition and Consumer Act 2010* (**CCA**), including the Australian Consumer Law (**ACL**), and a range of additional legislation, to promote competition and fair trading and regulate national infrastructure for the benefit of all Australians.

3.4. The ACL is applied as Commonwealth, State and Territory law, administered by the ACCC and State and Territory fair trading agencies respectively (**ACL regulators**). In particular, the ACL:

(a) prohibits false or misleading representations about goods and services including therapeutic goods (Part 3-1);

(b) applies guarantees to the supply of goods and services to consumers, which are enforced by private action (Part 3-2);

(c) sets out provisions dealing with the safety of consumer goods and related services (Part 3-3). These product safety obligations apply to persons in trade or commerce who supply consumer goods or product related services (consumer products) and include:

- notifying the Commonwealth ACL Minister of a voluntary recall under section 128 of the ACL;
- complying with a compulsory recall imposed by a Commonwealth, State or Territory ACL Minister under section 122 of the ACL;
- providing mandatory reports, subject to exemptions, to the Commonwealth ACL Minister of death or serious injury or illness associated with the use or foreseeable misuse of consumer products under sections 131 and 132 of the ACL;
- complying with safety standards imposed by the Commonwealth ACL Minister under sections 104 and 105 of the ACL;
- complying with interim and permanent bans imposed by the Commonwealth ACL Minister under sections 109 and 114 of the ACL, and interim bans imposed by State and Territory ACL Ministers under section 109 of the ACL.

In addition, the Commonwealth, State and Territory ACL Ministers may issue a safety warning notice under section 129 of the ACL;

(d) provides for the Commonwealth ACL Minister to impose information standards (Part 3-4).

4. Effect of this MOU

4.1. This MOU is administrative in nature and does not create any binding legal obligations.

4.2. Each Participant bears its own costs in relation to the activities that it undertakes under this MOU, unless otherwise agreed by the Participants in writing.

5. Therapeutic good recalls and other safety issues

5.1. Schedule 1 to this MOU sets out the roles of the Participants in relation to Part 3-3 of the ACL and safety information standards under Part 3-4 of the ACL.

6. Exchange of information

6.1. The Participants recognise that the exchange of knowledge and an open dialogue enhances the efficiency and effectiveness of the Participants' respective roles.

6.2. The exchange of information between the Participants is governed by the applicable law[1] and each Participant's policies.[2] Key legislative provisions include:

TGA	
TG Act – section 61	Section 61 of the TG Act authorises the Secretary of the Department to disclose therapeutic goods information to government bodies. Relevantly, section 61(3) provides that the Secretary may release to an authority of the Commonwealth that has functions relating to therapeutic goods, therapeutic goods information relating to: • reported problems and complaints concerning therapeutic goods, the Department's investigation of those problems and complaints and any action that the Department has taken or proposes to take in relation to those problems and complaints; • reports of inspections conducted under this Act or the regulations; • decisions to revoke or suspend, or not to issue, licences for the manufacturing of therapeutic goods; • conditions of licences; • reports of the testing of samples of therapeutic goods; or • the issue of, imposition of conditions on, or revocation of, conformity assessment certificates; for use in performance of those functions. Section 61(4A) relevantly provides that the Secretary may release to an authority of the Commonwealth that has functions relating to therapeutic goods, health or law enforcement, therapeutic goods information relating to one or more of the following: • notifications received under section 42T; • action taken by the Secretary under Part 5-3; • action taken by the Secretary under section 30EA (about notification and recall of therapeutic goods); • action taken by the Secretary under section 32HA (about notification and recall of biologicals); • action taken by the Secretary under section 41KA (about notification and recall of medical devices);

[1] The applicable law includes the CCA, TG Act, *Freedom of Information Act 1982* (Cth) and *Privacy Act 1988* (Cth).

[2] These Policies include (as in operation from time to time):

- ACCC: ACCC/AER Information Policy (2014); Accountability Framework for Investigations (2019); and ACCC/AER Privacy Policy.
- TGA: *Uniform recall procedure for therapeutic goods* (URPTG) (currently v2.3, June 2022) and *TGA approach to disclosure of commercially confidential information* (CCI) (2014).

	• contraventions, or possible contraventions, of Part 5-2 or Part 5-3; • any cases, or possible cases, of actual or potential tampering with therapeutic goods; • any cases, or possible cases, of counterfeit therapeutic goods; • information relating to an offence committed against this Act, or alleged to have been committed against this Act, involving therapeutic goods; • information relating to the contravention of a civil penalty provision, or the alleged contravention of a civil penalty provision, involving therapeutic goods; • a breach of a requirement of the TG Act or the regulations. Section 61(13) provides that the Secretary is not required to observe any requirements of the natural justice hearing rule in relation to releasing information under this section. Sub-section 61(1) of the TG Act defines ***therapeutic goods information*** as meaning information in relation to therapeutic goods that is held by the Department and relates to the performance of the Department's functions (including functions relating to the EC Mutual Recognition Agreement, the EFTA Mutual Recognition Agreement or the Australia-UK Mutual Recognition Agreement).
TG Act – section 61(5AA) and (5AB)	Section 61(5AA) provides that the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 5AB, therapeutic goods information of a kind specified under that subsection for a purpose specified under that subsection. Section 61(5AB) provides that for the purpose of subsection 5AA of the TG Act, the Minister may, by legislative instrument, specify one or more of the following: • a person, body, or authority; • kinds of persons, bodies or authorises; • kinds of therapeutic goods information; • purposes.
ACCC	
CCA section 155AAA	Section 155AAA of the CCA deals with the protection of certain information (protected information) including information that was given to the ACCC in confidence and relates to a matter arising under Part XI of the CCA (which applies the ACL as a law of the Commonwealth). Section 155AAA sets out when protected information may be disclosed including where: (a) the person has consented (s 155AAA(15)); or (b) the Chairperson of the ACCC is satisfied that the information will enable or assist the TGA (as an organisation within the meaning of the *Freedom of Information Act 1982*

	(**FOI Act**)) to perform or exercise any of its functions or powers (s 155AAA(12)).
ACL section 132A	Section 132A of the ACL deals with the protection of mandatory reports under sections 131 and 132 of the ACL. Section 132A sets out when this information may be disclosed including where: (a) the person has consented (s 132A(1)); or (b) disclosure to the TGA (as an organisation within the meaning of the FOI Act) is reasonably necessary to protect public safety (s 132A(3)(a)).

Requesting information

6.3. Participants' Requests for information may be submitted to the relevant area of the responding Participant (as set out in clause 9) by email. The template at **Schedule 2** to the MOU may be used to facilitate the request (but its use is not compulsory).

6.4. Each Request for information should contain a clear and specific description of the information requested and how the requesting Participant intends to use that information.

6.5. Each Request for information should also identify:

(a) whether the request is routine or urgent in nature; and

(b) the timeframe in which the information is required.

Use of information

6.6. Any information shared under this MOU will be disclosed and received on the basis that it will be handled in a manner that complies with Commonwealth legal and policy requirements, including those for security, privacy and official disclosure.

6.7. The Participants will protect information they receive and will only use the information for the purpose of performing their functions and will not further disclose the information without the consent of the Participant who provided the information except where it is permitted, authorised or required by law.

6.8. In the event that disclosure of confidential and/or personal information is compelled by law, the Participant receiving the information will notify the other Participant (if permitted) and take all reasonable steps to maintain the confidentiality or privacy of the information after production.

7. Public announcements, ministerial briefings, and legislative and administrative changes

7.1. Wherever practicable, the Participants will consult each other on:

(a) proposed media statements and other public announcements by one that refer to the other;

(b) proposed ministerial briefings and correspondence on matters of overlapping responsibility; and

(c) proposed legislative, policy and procedural changes that may affect the operation of this MOU, including changes to the roles and responsibilities of either Participant.

7.2. Where prior consultation is not practicable, notice of the relevant announcement, briefing or change will be given to the other Participant as soon as possible.

8. Regular meetings

8.1. The Participants agree to meet three times per year to discuss the areas of priority focus and other topics of mutual interest.

8.2. The areas for priority focus may be determined at the first meeting of each year and these focus areas will form the basis for future discussions.

9. Administrative arrangements

9.1. The officers responsible for:

(a) the day-to-day operations under this MOU are:

- Assistant Secretary, Regulatory Compliance Branch, Regulatory Practice and Support Division, Health Products Regulation Group at the Department; and
- General Manager of the Risk Management and Policy Branch, Consumer Product Safety Division, and General Manager, Consumer and Compliance Strategies Branch, Consumer and Fair Trading Division at the ACCC;

(b) the exchange of information between the Participants are:

- for the TGA:
  - Regulatory Compliance Branch
    rcbcompliancegovernance@health.gov.au
    The Regulatory Compliance Branch will direct requests to other internal TGA branches for specific topics as needed
- for the ACCC:
  - Consumer Product Safety Division
    ProductSafetyAdvocacy@accc.gov.au
  - Consumer and Fair Trading Division:
    EnforcementCoordination@accc.gov.au

(c) resolving any difference or dispute that arises under this MOU which cannot be resolved by the officers responsible for day-to-day operations are:

- First Assistant Secretary of the Regulatory Practice and Support Division, Health Products Regulation Group at the Department; and
- Executive General Manager of the Consumer Product Safety Division, and Executive General Manager of the Consumer and Fair Trading Division at the ACCC;

(d) the administration of this MOU are:

- Deputy Secretary, Health Products Regulation Group at the Department; and
- Chairperson of the ACCC;

(or such persons who, from time to time, hold or perform the functions of these positions).

10. Commencement, termination, variation and review

10.1. This MOU commences on the date it is signed by the Participants or the date the last Participant signs where the Participants do not sign the MOU on the same day.

10.2. This MOU remains in force until it is terminated by either Participant, giving 30 days' notice in writing.

10.3. Any variation to this MOU must be made in writing and be approved by authorised representatives of both Participants.

10.4. The Participants will review the operation of this MOU and consider the need for any variation to its terms after the MOU has been in effect for 12 months. The Participants will then agree on the next date for a review of the MOU.

11. Publication of MOU

11.1. This MOU communicates the administrative arrangements that operate between the Participants. To inform all stakeholders, this MOU may be made public.

Gina Cass-Gottlieb

Chairperson

Australian Competition and Consumer Commission

Date: 6 April 2023

Adj Prof John Skerritt

Deputy Secretary, Health Products Regulation Group

Department of Health and Aged Care

Date: 11/4/23

Schedule 1

Therapeutic Good Recalls and Other Safety Issues

1. Introduction

1.1. This Schedule 1 provides guidance on the respective roles of the TGA and the ACCC (**the Participants**) in relation to therapeutic good recalls and other safety issues.

1.2. The objective of the Participants is to establish practices, to the extent possible, to facilitate one point of contact for suppliers and consumers and avoid duplication of regulatory activity and contact. This includes:

(a) clarity of roles to minimise duplication of, or gaps in, regulatory oversight, and reduce the cost of compliance;

(b) simplicity and clarity for businesses whose activities are regulated by the Participants;

(c) consistent information for consumers which enables consumers to find the relevant safety information regardless of which Participant they first connect with;

(d) facilitation of consistent approaches and best regulatory practice; and

(e) sharing of information on compliance concerns and investigations, where lawful, to ensure consistency and efficiency of the Australian Government's response to investigations of non-compliance in relation to therapeutic goods.

2. Lead Participant

2.1. Subject to clauses 2.2 and 2.3 of this Schedule 1, the TGA is the Lead Participant for recalls and other safety issues for products that are 'therapeutic goods' as defined in section 3 of the TG Act.

Note: To support the operation of this Schedule 1 to the MOU, the TGA advises the ACCC as to whether the TGA considers that a good is a 'therapeutic good', particularly where an assessment is required as to whether conditions have been met. To assist this process, Attachment A to this Schedule 1 sets out a flow chart for determining if a good is a 'therapeutic good' although the Participants recognise that the Attachment will need to be revised over time.

2.2. The ACCC is the Lead Participant where the therapeutic good is also a 'consumer good' as defined in section 2 of the ACL and the safety issue arises from non-compliance with a safety standard or ban under Part 3-3 of the ACL or a safety information standard under Part 3-4 of the ACL.

2.3. On occasion, the Participants may need to consult each other to identify the Lead Participant – for example, where the:

(a) safety issue also involves misleading or unconscionable conduct in contravention of the ACL; or

(b) safety issue is best managed by reviewing an instrument made under section 7 or 7AA of the TG Act.

3. Lead Participant's functions

3.1. The Lead Participant's functions include:

(a) risk identification;

(b) risk assessment;

(c) risk management including risk communication;

(d) voluntary and compulsory recalls; and

(e) incident reports received.

The following clauses provide further guidance on these functions.

3.2. Risk identification – establishing processes to obtain information about potential safety risks.

3.3. Risk assessment:

(a) analysis and investigation to better comprehend the nature and characteristics of the identified safety risk, including where appropriate conducting a formal safety investigation;

(b) evaluating the risk against priority factors to determine whether to take action; and

(c) updating the risk assessment in light of new information.

3.4. Risk management – activity to control or reduce the safety risk such as:

(a) encouraging suppliers to take appropriate action such as a recall;

(b) risk communication e.g. issuing public warnings about potential safety risks;

(c) education and compliance strategies such as a consumer awareness campaign to change the way consumers use a product, or a supplier campaign to improve compliance with a safety obligation;

(d) enforcement strategies to enforce compliance with statutory obligations;

(e) regulatory strategies such as revising or making new subordinate legislation;

(f) compulsory recall;

(g) ongoing review of the effectiveness of the Lead Participant's risk management strategy; and

(h) issuing public guidelines and media releases, and responding to media requests.

3.5. Where a voluntary recall is proposed or notified:

(a) being the principal government liaison point for suppliers and other stakeholders (e.g. consumers, media and Ministerial enquiries, and other regulators);

(b) where the:

(i) TGA is the Lead Participant, coordinating notification of the recall to the ACCC if required under section 128 of the ACL;

(ii) ACCC is the Lead Participant, coordinating notification of the recall to the TGA if required under the TG Act or covered by the URPTG.

Note: Under section 128 of the ACL:

- a person is required to: notify the Commonwealth ACL Minister within 2 days of taking action to recall consumer goods for certain safety reasons; and notify any relevant overseas persons of the recall as soon as practicable, and give a copy of that notice to the Commonwealth ACL Minister within 10 days; and
- the ACCC receives these notices on behalf of the Commonwealth ACL Minister.

A recall does not need to be notified under section 128 of the ACL unless the consumer goods will/may cause injury or a relevant standard or ban applies under the ACL. In general, section 128 does not apply to class III recalls under the TGA's URPTG (as in operation from time to time) (class III recalls are situations in which use of, or exposure to, the deficient therapeutic good is not likely to cause adverse health consequences).

If a person submits a recall notice to a Participant that is not the Lead Participant (the Receiving Participant), the Receiving Participant will arrange for the Lead Participant to be notified of the recall.

To provide simplicity and clarity for stakeholders, the Lead Participant's recall guidelines apply to the recall, and not the other Participant's guidelines.[3] The Participants work together to ensure that suppliers meet the requirements of both regimes where applicable.

(c) negotiating the recall with the supplier;

(d) reviewing the supplier's recall strategy (including, where appropriate, risk assessment and method, frequency and content of communication with consumers and media strategy);

(e) publishing the recall notice on the Lead Participant's website;

Note: To address the problem of inconsistent websites, commencing in 2023, where the TGA is the Lead Participant, the recall notice will no longer also be published on the Product Safety Australia website.

However, at the request of the Lead Participant, the other Participant may share social media posts or publish on that Participant's website any safety alerts or media releases issued by the Lead Participant to assist the Lead Participant in raising public awareness of the safety risk.

(f) seeking alignment between the recall notice on the Lead Participant's website and other consumer communications where practicable;

(g) monitoring the progress and effectiveness of the recall, including by seeking regular progress reports on the recall from the supplier and other information related to the product or the recall (such as reports of death or serious injury or illness associated with the product, complaints by consumers or other suppliers in the supply chain, and information from experts and/or other Australian and international regulators);

(h) negotiating improvements to the voluntary recall where necessary or appropriate, and taking action where necessary or appropriate to improve recall effectiveness (e.g. negotiating additional steps with the supplier, issuing media releases);

(i) using compulsory information gathering powers to obtain information, documents and evidence relevant to a recall, where necessary or appropriate;

(j) addressing non-compliance with recall notification requirements through enforcement of the Lead Participant's legislation; and

(k) considering a compulsory recall as needed.

3.6. Where an incident report (including a mandatory report under section 131 or 132 of the ACL) is received:

(a) being the principal government liaison point for suppliers and other stakeholders (e.g. consumers, media and Ministerial enquiries, and other regulators);

Note: When a person contacts the wrong Participant, that Participant refers the person to the Lead Participant.

If a person provides a mandatory report to the ACCC in relation to a therapeutic good, the ACCC provides the report to the TGA provided the person has consented to disclosure of the report. The ACCC seeks consent if the person has not already provided it. If the person chooses not to consent, the ACCC may seek to disclose the report to the TGA under section 132A of the ACL.

(b) assessing the report and determining the appropriate risk management strategy; and

(c) where the report relates to a product that is subject to an existing voluntary recall, reviewing whether the report alters the original risk assessment and recall

[3] These guidelines (as in operation from time to time) are on the Participants' websites: TGA, Uniform Recall Procedure for Therapeutic Goods; and ACCC, Consumer Product Safety Recall Guidelines.

strategy and, if so, whether the published recall notice (and other consumer or related communications) should be updated, or other action taken.

4. Coordination & support

4.1. Staff from the TGA's Medical Devices and Product Quality Division, Medicines Regulation Division, Regulatory Practice and Support Division and the ACCC's Consumer Product Safety Division meet regularly at the project officer level to facilitate:

(a) an open exchange of information;

Note: Information exchange is subject to the applicable law in Australia including confidentiality and privacy.

(b) operational liaison including clarification of responsibilities in relation to a voluntary recall, mandatory recall, mandatory report, safety issue, or media or Ministerial request where necessary or appropriate;

(c) requests for support such as sharing social media posts or publishing any safety alerts or media releases issued by the Lead Participant, or facilitating contact with relevant State and Territory government networks;

(d) identification of any issues arising from a declaration under section 7 of the TG Act that a good is not a therapeutic good or a determination under section 7AA of the TG Act to exclude a good;

(e) updates in relation to public announcements, ministerial briefings, and legislative and administrative policy reviews and changes including any proposed changes to the definition of a 'therapeutic good' in the TG Act, instruments under section 7 or 7AA of the TG Act, or recall guidelines;

(f) consistency in approach to recalls and other product safety functions;

(g) opportunities for cooperative staff training and secondments; and

(h) sharing of information and cooperation on compliance concerns and investigations, where lawful, to ensure consistency and efficiency of the Australian Government's response to investigations of non-compliance in relation to therapeutic goods.

Schedule 1 Attachment A: TGA-ACCC regulatory interface

Declarations: Is the good subject to an order made under section 7 of the TG Act declaring that the good is **not** a therapeutic good? (may depend on how the good is used/advertised/presented)

Therapeutic Goods (Declared Goods) Order 2019 Sch 2 e.g. (when presented in a particular way) certain deodorants, depilatory preparations, non-prescription spectacles, apparel, soaps & detergents, spa water or natural mineral water, drinking water purification substances, and unmedicated dental chewing gum

No – there is no section 7 order declaring that the good is not a therapeutic good

Yes – there is a section 7 order declaring that the good is not a therapeutic good

Is the good a 'consumer good' as defined in ACL?

Yes

Lead Participant: ACCC (but see MOU Sch 1 cl 2.3)

No

Not covered by TG Act or ACL

Excluded goods: Is the good subject to a determination under section 7AA(1) (excluded goods) or section 7AA(2) (excluded goods if goods advertised/used/presented in a specified way) of the TG Act excluding the product from being considered a therapeutic good?[4]

Therapeutic Goods (Excluded Goods) Determination 2018 e.g.:

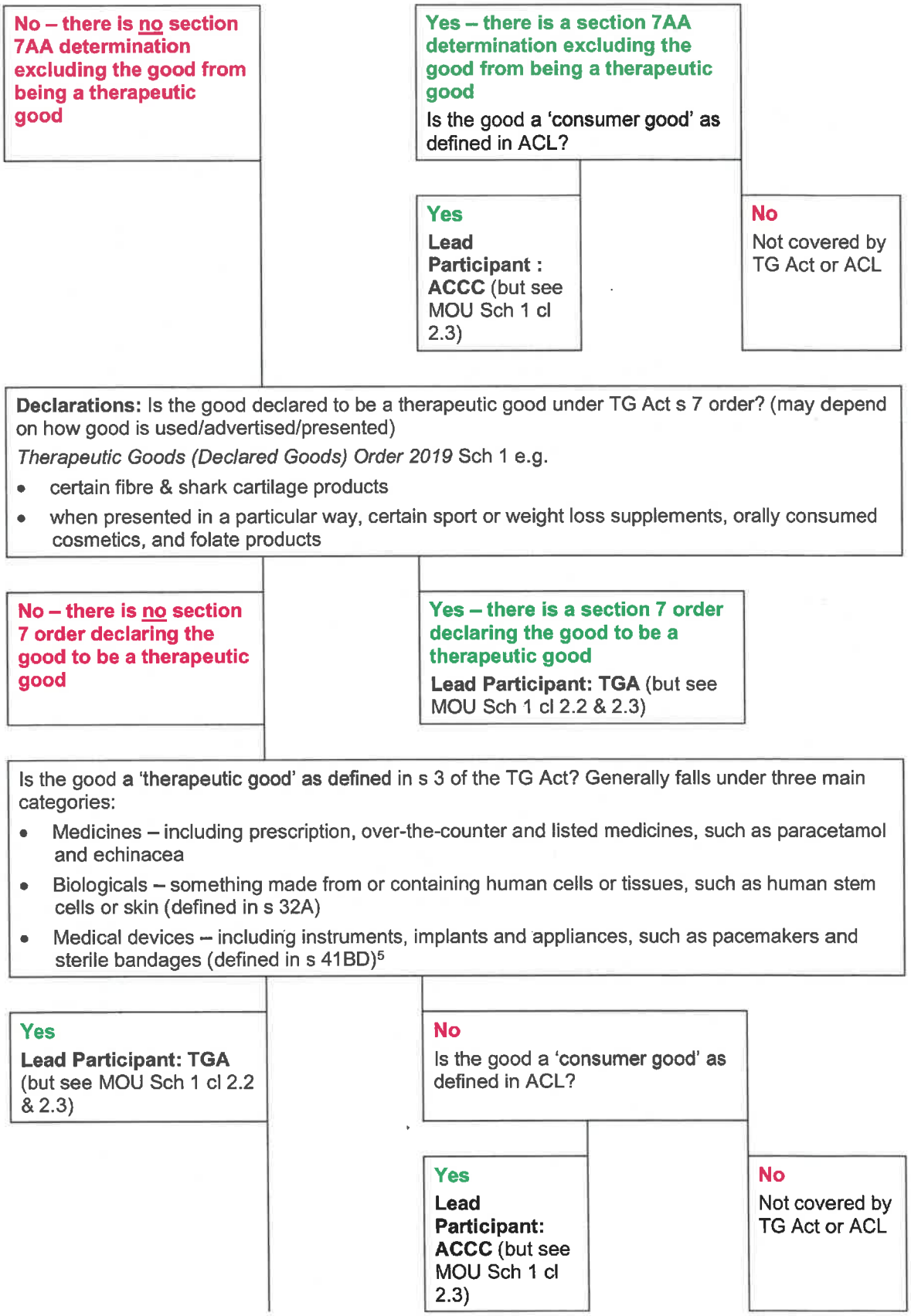
- certain antiperspirant preparations, non-sterile personal protective equipment (e.g. shin-guards for sport), dental bleaches & whiteners, detergents & soaps, blood alcohol testers, drinking water purification, ear candles, hair dyes, incontinence & menstrual pads, mouthguards, and software and vaping devices
- conditional exclusions: certain anti-acne skin care products, anti-dandruff hair care, moisturising skin care products with sunscreen, and oral hygiene products
- autologous human cells and tissue products if they meet the following criteria
    - collected from a patient who is under the clinical care of a medical or dental practitioner registered under a law of a State or an internal Territory
    - manufactured by that medical or dental practitioner, or by a person or persons under the professional supervision of that medical or dental practitioner in a hospital (except storage and testing), for that patient who must be a patient of that hospital, and
    - not advertised directly to consumers.

Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020

[4] Products may be excluded where regulation by the TGA is considered inappropriate or the products do not meet the legislative definition but are excluded for clarity. Excluded products:

- are not required to be included in the Australia Register of Therapeutic Goods (ARTG) or to be assessed in any way by the TGA before they are made available in Australia; and
- are not subject to the Therapeutic Goods Advertising Code or any post-market monitoring for ongoing safety by the TGA.

Suppliers of excluded good are not required to report adverse events and the TGA is unable to take regulatory action such as a recall or issuing a hazard alert if there is a problem with the product.



[5] A product can be specified to be a medical device under s 41BD(2A) & (2B) or declared not to be a medical device under s 41BD(3). E.g. *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020.*

Exemptions: Note that, although product is a therapeutic good, it may be exempt from certain TG Act requirements. E.g. for medical devices:

- **Unconditional exempt devices**: These devices are not required to be included in the Australian Register of Therapeutic Goods (ARTG). *Therapeutic Goods (Medical Devices) Regulations 2002* Sch 4 Part 1 includes:
    - devices imported for use by importer or immediate family
    - devices exported for non-commercial reasons
    - importation of samples of devices for particular purposes
    - medical devices manufactured by a healthcare practitioner from products specified to be medical devices
    - medical devices imported for purpose of being exported again.
- **Conditional exempt devices**: These devices are not required to be included in the ARTG subject to conditions. *Therapeutic Goods (Medical Devices) Regulations 2002* Sch 4 Part 2 includes:
    - Patient-matched medical devices produced in volumes of five or less a year
    - Clinical decision support software
    - Custom made medical devices
    - Special Access Scheme approvals or notifications
    - Authorised Prescriber Scheme approvals
    - Clinical trial notifications and approvals

Exempted medical devices do not have to be included in the ARTG but are still subject to some aspects of regulatory oversight by the TGA including requirements on sponsors to:

- comply with the relevant requirements for safety and performance
- report adverse events to the TGA, and
- comply with the Therapeutic Goods Advertising Code.

Schedule 5 to the *Therapeutic Good Regulations 1990* sets out certain goods which are not subject to Part 3-2 of the TG Act (requirements for registration and listing of therapeutic goods). Examples include:

- Tampons (but must comply with the specified Australian Standard).
- Disinfectants without specific claims are exempt but must comply with the relevant Standard.
- The following goods, unless the goods are for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect:
    - Unmedicated anti-acne preparations having only a cleaning action or purpose.
    - Medicated insect repellents for dermal use if the medication consists solely of an antiseptic having a secondary role in the formulation, except those that are included in a Schedule to the Poisons Standard.
- Unmedicated preparations for topical use for protecting against, or providing relief from, nappy rash symptoms by acting only as a barrier for the skin (whether or not the preparations also have a moisturising action).

Schedule 2

Request for information template

This template may be used by the ACCC or TGA when submitting a request for information.

REQUEST FOR INFORMATION	
1. **Information Request Reference Number:**	
2. **Request submitted to:**	
3. **Date request submitted:**	
4. **ACCC/TGA contact for this request:**	Name Work contact number Work email
5. **Is this request routine or urgent?**	
6. **Description of the specific information that is requested:**	
7. **How does the request relate to the work and mandate of the ACCC/TGA?**	
8. **Date information required by:**	