Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising guidance for businesses involved with intravenous (IV) vitamin and related therapies

Complying with therapeutic goods advertising requirements

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Contents

About this IV drips guidance

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care and is responsible for administering the regulation of therapeutic goods.

This guidance relates to the advertising of Intravenous (IV) drip products in Australia. IV drips are therapeutic goods that involve inserting a needle into a vein to deliver therapeutic substances into the body such as vitamins and minerals. IV drip products can also be referred to as drips, infusions, cannulas, fluids, etc. IV therapy is the combination of a health service that provides an IV infusion and the product itself. In this guidance we refer to 'IV drips and related therapies' as just 'IV drips' for simplicity.

The advertising and supply of therapeutic goods, such as IV drips, must comply with the:

- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods Regulations 1990* (the Regulations)
- *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (the Code).

This guidance assists providers of IV drips to understand how to comply with the therapeutic goods advertising requirements.

Failure to comply with the therapeutic goods advertising requirements can result in fines and criminal and civil prosecution.

What are therapeutic goods?

Therapeutic goods are defined in the Act as goods that are represented to be, or are likely to be taken to be, for therapeutic use.

Therapeutic use means:

- use in, or in connection with, preventing, diagnosing, curing, or alleviating a disease, ailment, defect or injury in a person
- use in, or in connection with, influencing, inhibiting or modifying a physiological process in a person.

Therapeutic goods pose a higher risk to consumers than ordinary consumer goods and are regulated by the TGA. In general, they must be entered in the Australian Register of Therapeutic Goods (ARTG) to ensure a level of safety, quality and efficacy. When therapeutic goods are supplied outside of the regulatory framework, there are no such assurances which poses an unacceptable risk to consumer health.

IV drips are therapeutic goods and are regulated by the TGA because of a number of factors, including: the ingredients they contain, how they are administered and how they are presented for supply, including the claims that are made.

IV drips must be entered in the ARTG, unless exempt

IV drips must be entered in the ARTG unless they are specifically exempt from this requirement or are otherwise authorised by the TGA.

In Australia, if not entered in the ARTG and no exemptions apply, these products cannot be:

- advertised
- imported
- exported
- manufactured, or
- supplied / sold.

Extemporaneously compounded IV drips

An **extemporaneously compounded** medicine is one that is prepared for, and administered to, a particular person for treatment or application to that person. It is generally prescribed by a suitably qualified and trained health professional.

Extemporaneously compounded goods must be prepared by a licenced pharmacist and meet the definitions and conditions set out in the Regulations. See TGA guidance on good manufacturing practice of compounded medicines.

Extemporaneously compounded IV drip products may be exempt from the requirement to be entered in the ARTG. However, advertisements of these products must still comply with the advertising requirements outlined below.

Advertising requirements for IV drip health services

Under the Act, **advertise** in relation to therapeutic goods includes:

> *any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:*
>
> *(a) is on the label of the goods; or*
> *(b) is on the package in which the goods are contained; or*
> *(c) is on any material included with the package in which the goods are contained.*

Whether information is intended to promote the use or supply of IV drips is determined not by what the person responsible for the content intends, but by what a reasonable consumer would understand the intent of the content to be.

This means that if members of the public would reasonably consider that information has been intended to promote the use or supply of therapeutic goods, then the TGA would likely consider it to be an advertisement. For more information see Activities that represent advertising.

Advertising is not limited to a specific type, or types of media and includes promotional materials on websites, through social media (such as Instagram, Facebook, YouTube and TikTok) and within patient brochures. You could also be considered responsible for advertising through social media comments and third-party review sites (like Google reviews).

See Activities that represent advertising for more information.

We see a spectrum of potentially non-compliant behaviour in relation to IV drips, businesses or health services. Common examples are provided below.

These examples are not exhaustive, and businesses involved with IV drips must assess their individual materials carefully.

Prescription medicines are prohibited from being advertised to the public

It is prohibited to advertise a substance (any ingredient of a medicine), or a good containing a substance, classified in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) as a pharmacist only medicine (Schedule 3) unless in Appendix H, prescription only medicine (Schedule 4) or controlled drug (Schedule 8).

Glutathione, when used in IV drips, is a Schedule 4 medication that is only available with a prescription.

It is therefore prohibited to advertise IV drips or injections that contain glutathione.

TGA permission is required for restricted and prohibited representations

Advertising (including product labels) must not refer to restricted or prohibited representations without prior permission or approval from the TGA.

Restricted representations are representations that refer to serious forms of diseases, conditions, ailments, or defects which require a suitably qualified health professional to diagnose and/or treat them.

Prohibited representations include:

- references to specific serious conditions, such as cancer, sexually transmitted diseases and mental illness.
- representations that vitamin or mineral supplements are a substitute for good nutrition or a balanced diet, or superior to or more beneficial in any way than dietary nutrients.

Advertisements must not claim government endorsement

Advertising must not state or imply that the goods are recommended, or otherwise endorsed by a government agency, such as the TGA. This includes, for example, statements such as ‘TGA approved’.

For more information, including what can be included in an advertisement, see: The claim 'TGA approved' must not be used in advertising.

Advertisements must comply with the Advertising Code

Where a product can be advertised to the public, advertisements are required to comply with the advertising requirements set out in the Code.

Guidance on applying the Advertising Code rules can be found on the TGA website.

Some of the basic advertising rules require an advertisement to:

- be accurate, balanced and substantiated
- not mislead consumers
- not claim that a product is safe, without side-effects, effective in all cases, magical or miraculous
- only use testimonials and endorsements that comply with the Code. Guidance on testimonials and endorsements in advertising can be found on the TGA Website.

The TGA can pursue compliance actions for each instance of non-compliance. This could result in multiple sanctions or penalties for a single advertisement/ against an advertiser.

Advertising health services that supply or prescribe IV drips

IV drip therapy involves a health service and a related therapeutic good. The regulation of health practitioners and the promotion of health services is not within the TGA's jurisdiction. However, if an advertisement for a health service also advertises therapeutic goods the advertiser must comply with the requirements of the Act.

If you only intend on advertising a health service, ensure the advertisement does not:

- refer to any therapeutic goods used in the delivery of the health service
- promote the use or supply of therapeutic goods directly or indirectly.

See the TGA guidance on Advertising for health services for more information.

Consequences of unlawful advertising of IV drips

The TGA will take appropriate regulatory action when:

- advertising does not comply with therapeutic goods advertising requirements
- therapeutic goods that are required to be entered in the ARTG are imported or supplied in Australia without being entered in the ARTG.

The TGA may pursue sanctions and penalties against those who do not comply with the advertising and other applicable regulatory requirements consistent with the TGA's Regulation Compliance Framework.

Advertisers and suppliers who are unsure of their regulatory obligations are encouraged to seek independent legal advice or the assistance of a regulatory affairs consultant.

More information on the compliance and enforcement powers provided for under the Act is available, see Compliance actions and outcomes.

Further information

- Advertising for health services
- Regulatory affairs consultants
- Advertising hub
- Activities that represent advertising
- How to advertise
- Advertising guidance
- Social media guidance

Version history

Version	Description of change	Author	Effective date
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