Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic goods advertising and ASX announcements

Complying with the advertising rules for therapeutic goods while meeting continuous disclosure obligations

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TGA Health Safety Regulation

Contents

About this guidance

This guidance will assist companies involved in the therapeutic goods industry to understand and comply with the requirements for advertising therapeutic goods when making announcements to comply with their continuous disclosure obligations.

The focus of this guidance is to assist companies to understand how to make a disclosure without advertising therapeutic goods to the public. The guidance provides information about:

- activities that constitute advertising
- advertising compliance and enforcement.

Failing to have regard to the principles set out in this guidance may risk a disclosure being considered advertising and therefore subject to the requirements of the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Code).

For general information on advertising therapeutic goods, see:

- Advertising
- Advertising: Getting started
- How we manage advertising compliance
- Overview of supplying therapeutic goods in Australia.

Continuous disclosure obligations

Listed and unlisted companies have continuous disclosure obligations under the *Corporations Act 2001* to ensure market integrity and investor protection through timely and equal access to materially price sensitive information.

ASX Listing Rule 3.1 states:

> *'once an entity is or becomes aware of any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities, the entity must immediately tell ASX that information.'*

Listed companies are subject to the Australian Securities Exchange (ASX) Listing Rules. ASX market announcements must be released through ASX and the ASX Market Announcement Platform.

Unlisted companies are subject to guidance produced by the Australian Securities and Investments Commission (ASIC). In particular, the ASIC regulatory guidance ASIC RG198 requires information to be lodged with ASIC or published on the company's website.

While the ASX Listing rules (for listed companies) and ASIC guidance (for unlisted companies) are different, consistent principles apply for a company to meet continuous disclosure obligations while not breaching the therapeutic goods laws:

- The Corporations Act and ASX Listing Rules do not specify what information a disclosure should include but they do need to:
  - be accurate
  - be complete

  - not be misleading, and
  - put the information in appropriate context.
- Announcements must not be used for commercial purposes, including for the purposes of advertising a product.

Code of Best Practice for Reporting by Life Sciences Companies

ASX and AusBiotech, Australia's national industry organisation for the life sciences sector, strongly encourages companies in the life sciences sector to adopt best practice in reporting events to investors.

They have developed the Code of Best Practice for Reporting by Life Sciences Companies to guide public Australian life science companies in effective and informative communication to the market.

The Code is intended to be read in conjunction with ASX Listing Rule 3.1 to ensure that life science companies fulfill their obligations under that rule. The objectives of the Code are to:

- incorporate best practice in reporting to maintain and enhance the reputation, integrity and credibility of the Australian life science sector
- identify the key drivers of value for life science companies that may give rise to a disclosure, supporting more informed investment decisions.

Advertising prescription medicines and unapproved products to the public is prohibited

Particular care needs to be taken where the information in a disclosure relates to therapeutic goods that are prohibited from being advertised to the public. These include:

- prescription only medicines that include substances mentioned in schedule 4 or 8 of the Poisons Standard or would meet the criteria for mention in these schedules
- certain over-the-counter medicines that include substances mentioned in schedule 3 to the Poisons Standard or would meet the criteria for mention in this schedule
- therapeutic goods that are not yet included on the ARTG, such as those which are under development.

Announcement activities that may constitute advertising

'Advertise' is defined in the Act as:

> *'any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods.'*

The advertising requirements apply to any advertisement for therapeutic goods appearing in the public domain, even if the product advertised is not available for consumers to purchase or consumers are not the intended audience of the advertising. The perspective of the reasonable person viewing the material must be considered.

This means that if members of the public would reasonably consider that the information contained in a disclosure promotes the use or supply of the identified goods, then the TGA would likely consider it an advertisement. It must then meet the legislative requirements as set out in the Act and the Code.

The TGA acknowledges that the life science sector has specific areas of complexity that make communication with the market potentially challenging. These include the complexity of the science, long development lead times, significant ongoing capital requirements, regulatory processes and complex intellectual property issues.

The TGA also acknowledges that announcements may need to touch on matters regulated by the TGA. This may include matters such as:

- research and development, including the outcomes of clinical trial or testing results, regulatory and reimbursement matters
- naming specific medicines (or molecules) and medical devices
- disclosures relevant to the intended purpose and efficacy claims when applying to include a product on the ARTG.

Where this information is necessary to comply with continuous disclosure obligations, issuers should take care to ensure the material is not considered as advertising of the use or supply of the implicated therapeutic good(s).

Information posted on social media platforms is more likely to be considered advertising as these platforms are not an acceptable form for announcements under the Corporations Act, ASIC or ASX guidelines.

Ensuring an announcement is not advertising

The following information is designed to assist you to understand whether material included in an announcement is likely to be considered advertising.

If content is 'advertising', the advertising prohibitions and restrictions in the Act will apply. For further information, please see Complying with advertising requirements.

In general:

- an announcement is likely to be considered advertising if it includes promotional statements about a therapeutic good beyond what is required to satisfy continuous disclosure obligations
- an announcement is unlikely to be considered advertising if the material contains pertinent information about the company rather than a therapeutic good.

To ensure that information contained in ASX announcements (and other announcements) is not considered therapeutic goods advertising, issuers should:

✓ Ensure any information about therapeutic goods is necessary to disclose under continuous disclosure requirements.

✓ Follow the Listing Rules guidance produced by the ASX and ASIC which sets out that the information must be:

- ‘accurate, complete, fair and not misleading’
- ‘factual, relevant and expressed in an objective manner’, and
- must not contain ‘emotive, intemperate or vague language’.

✓ Ensure the content is purely informative and the language is, fair and balanced.

- Avoid:
  - focusing only on the positive qualities of a therapeutic good
  - omitting or downplaying the negative qualities such as possible side effects or limitations of use.

✓ Be cautious when reporting results of clinical trials.

- As advised by the Code of Best Practice for Reporting by Life Sciences Companies, companies are discouraged from prematurely announcing results on clinical trials or reporting on goods which have insufficiently validated evidence.

✓ Do not use content or language in an announcement that is promotional and overtly attempts to persuade the audience of the merits of the therapeutic good.

- Avoid the use of superlatives.
  - for example, ‘works fastest’, ‘the best’.
- Avoid the use of descriptive adjectives or statements that are emotive
  - for example, ‘life changing’.

Advertising compliance and enforcement

The TGA undertakes compliance and enforcement activity where there is a breach of the advertising requirements set out in the Act and the Code.

Some of the factors that inform our assessment of the risk associated with a breach of the advertising requirements include:

- the nature of the alleged breach
- the risk posed to the public
- the advertiser's attitude towards compliance, including their history of non-compliance in relation to advertising or other requirements.

Criminal and civil penalties may apply if you do not comply with your legal requirements under the Act and the Code.

For information on the types of actions we may take see Advertising enforcement and outcomes and Compliance actions and outcomes.

Examples

The following examples are intended to provide guidance on what the TGA may and may not consider to be advertising material.

These are fictional announcements, using fictional drugs and company names designed to demonstrate announcements that do and don't comply with therapeutic goods advertising requirements.

Please note, this is intended as guidance only and each announcement is assessed on its own merits as to whether the material is promoting the use or supply of a good.

Continuous disclosure announcement	Comment
Evidence from Phase II trial supports use of ProstaC3 in hormone refractory prostate cancer BeansPharma Ltd reports positive interim results for the prostate cancer cohort in its phase II clinical trial in patients with hormone refractory, Stage IV metastatic disease. ProstaC3 has been attributed to both relieve disease symptoms and reduce prostate size in 84% of trial patients who received the drug. The results contrasted to the control group where just 13% achieved the same result. These positive results demonstrate the potential for significant benefits of this drug to sufferers of the disease. ProstaC3 showed good tolerance when taken orally, however fewer side effects resulted when administrated intravenously. Mild side effects included nausea and vertigo. Rare severe side effects were seizure (one case) and blood clots (one case). Both patients made a full recovery. These results build upon testing in animal models (link here) where the rodent cure rate was at 79% with the control group 5% and a 1% mortality rate. Successful phase I trials tested dosage and treatment duration needed to obtain the lowest level of drug needed to achieve optimal patient results. Results can be found here. BeansPharma hopes to include in phase III trials our new vaccine TargaProst59 that targets metastatic prostate cells. When used as a combination therapy with ProstaC3 BeansPharma hope there could be greater benefit with increased remission rates. Ethics approval is underway with the trial expected to commence in early 2025.	✓ The statement provides fair and balanced information that is appropriate for disclosure purposes. ✓ This is considered balanced because it includes information on side effects as well as benefits and provides access to the trial results.

Continuous disclosure announcement	Comment
BeansPharma Ltd has completed trials of CDZE-25 BeansPharma Ltd has completed a phase I/II trial of CDZE-25 which is being investigated as a new treatment option for patients with prostate, breast, ovarian and pancreatic cancer. Patients in the phase I/II trial were treated with up to 3 cycles of CDZE-25 with no steroid, antihistamine or anti-emetic pre-treatment. Patients experienced reduced side effects commonly associated with CDZE-25 such as bone marrow toxicity, anorexia and vomiting. There were no cases of hypersensitivity; no cases of hair-loss; no need for anti-nausea medications. The trial results can be found here (link). There were 20 patients. Phase III trials are set to begin in December to further evaluate its safety and repeatability of results in a larger and geographically diverse cohort.	✓ The statement provides fair and balanced information which is appropriate for disclosure purposes and objectively communicates details of clinical trials. ✓ It is clear the product is in trial phases and not available for use or supply.
Facebook post:  **BeansPharma Ltd have published an ASX announcement about promising trial results for our potential new prostate cancer treatment.** **Click here for more information** **www.urllinkingtoannouncement.com.au**	✓ This post is factual and avoids promotional language. The post is only intended to raise awareness of a new announcement without adding promotional content. ✓ The use of the adjective 'promising' to interpret the findings from the trial is appropriate for disclosure purposes as it conveys the significance of the results while also indicating further research is required. ✓ The mention of trial results indicates that it isn't an available product for use or supply because it is still being assessed for efficacy. ✓ In this example, the image is of the company CEO and the post does not contain promotional visual imagery.

Continuous disclosure announcement	Comment
Groundbreaking medicinal cannabis treatment to be marketed from January BeansPharma Ltd is developing a range of products of different strains of medicinal cannabis which are expected to be on the market by mid-January. These medicinal cannabis products will significantly enhance treatment for cancer patients. Cannabinoids found in medicinal cannabis products have a multitude of benefits for cancer patients including dramatically reducing pain and preventing the side effects of chemotherapy such as nausea and vomiting.	✘ The announcement could be considered misleading and not balanced as it relates to an unapproved product in Australia that is only available through the special access scheme or authorised prescriber scheme. ✘ The announcement includes promotional language that could reasonably be taken as encouragement to seek out the product in January. ✘ The inclusion of language such as 'dramatically reducing pain', is promotional in this context as it is not supported by evidence or where evidence can be found and not likely to be necessary under continuous disclosure requirements. ✘ The article is missing information such as the evidence that supports how the product could enhance treatment for cancer patients.

BeansPharma's MedXYZ stops influenza virus in its tracks BeansPharma Ltd announced new findings for it's breakthrough influenza treatment MedXYZ. The results indicate that MedXYZ is highly effective in inactivating and blocking influenza virus in the body, reduces viral load and thereby prevents or significantly reduces infection. MedXYZ provided high levels of protection against the seasonal influenza viruses, particularly the highly infectious variant FLU-2. FLU-2 is approximately 12 times more infectious than FLU-1 and studies show that MedXYZ is a highly protective and highly effective year-round preventative treatment. In the trial with 1200 animal participants, MedXYZ or control, was adminstered pre, during and post intentional exposure via intranasal spray of an animal model equivalent of the human seasonal flu virus. Viral load was measured by flock swab every 12 hours for 7 days. Animals treated with MedXYZ showed a 99% reduction in viral load compared to control, demonstrated in all test group animals. For Eurpean trial data please visit the www.medxyz.co website. MedXYZ is currently available in 20 countries and is awaiting regulatory approval in Australia. It is available for purchase from online marketplaces.	✘ Taken as a whole, the announcement has become promotional. ✘ The article contains overtly promotional language such as 'sensational', 'breakthrough' 'impressive', 'new era in the treatment', and 'highly protective and highly effective as a broad use preventative treatment that can be used all year' – these place unnecessary emphasis on the efficacy of the goods where a reasonable consumer would likely take these representations as encouraging them to seek out MedXYZ – this would be a prescription medicine for treatment of influenza however it has not been tested in human trials so promoting it in this way draws a reasonable consumer's mind to the product and encourages them to seek it out. This is inappropriate because it is not yet approved for human use. ✘ Use of the statement 'It is available for purchase from online marketplaces' draws attention to purchase (supply) of the product for importation. It is illegal to promote a product that is not in the ARTG for personal importation under subsection 42DLB (9) of the Therapeutic Goods Act 1989 and regulation 7 of the Therapeutic Goods Regulations 1990. **Note**: information about overseas regulatory approvals may be included in an announcement if it is clearly stated that the product is 'not available for purchase' or

Continuous disclosure announcement	Comment
	'approved for supply' in Australia (or words to that effect). Links to or advice on where the product can be purchased should not be included.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Compliance Branch	September 2022
V1.1	Minor editorial changes for consistency with the ASX Listing Rules. Additional information provided for the Code of Best Practice for Reporting by Life Sciences Companies. Updated examples to provide additional context and clarity,	Regulatory Compliance Branch	February 2022

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