

Therapeutic Goods Administration  
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## **Draft guidance for therapeutic goods advertising and ASX announcements**

AusBiotech welcomes the opportunity to review the updated *Draft guidance for therapeutic goods advertising and ASX announcements*. The recommendations noted below aims to provide clarity and consistency in language between the two guidances (ASX and the TGA) so as to enable and support industry in meeting their respective requirements when undertaking compliance activities.

AusBiotech is the Australian representative body for one of Australia's most innovative industries with a well-connected network of over 3,000 members in the life sciences industry, which includes biotherapeutics, medical technology (devices and diagnostics), and agricultural biotechnology sectors. This response has been developed together with the AusBiotech's members who are actively engaged in delivering social and economic benefits to Australia through the commercialisation of biotechnologies and medical technologies.

1. The draft guidance regularly references the need for language in announcements (ASX and otherwise) to be "neutral", whereas the guidance from the ASX is "fair and balanced", "accurate", and/or "complete. AusBiotech recommends this is updated for consistency and continuity with existing and familiar ASX language and expectations.

The ASX's use of these phrases is intentional as ASX announcements are intended to include information in a manner that conveys the importance and significance of the information, whether positive or negative, and this is not possible if it were to be mandated that the language must be neutral. Some description must be provided to convey the importance of the information, but it is accepted that the description must not rise to the level of being emotive or promotional, which is consistent with the ASX's listing rules.

2. In relation to prematurely announcing clinical trial results, the draft guidance references the [Code of Best Practice for Reporting by Life Sciences Companies](#). AusBiotech appreciates the additional reference, however, the Code is under review and may change imminently. AusBiotech also recommends reframing the reference to ensure its context is retained.

Whilst it currently highlights one message included within the Code, it does not appropriately frame the guidance within its broader purpose. It is recommended that an additional section is included in the beginning of the guidance, and draft text has been included below for your consideration:

### **Code of Best Practice for Reporting by Life Sciences Companies**

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

A resource has been developed to provide a reference tool to guide public Australian life science companies in effective and informative communication to the market, according to a guidance framework; to incorporate international best practice in reporting, and thus maintain and enhance the reputation, integrity and credibility of the Australian life science sector; and to provide information to investors about the disclosure framework that identifies the key drivers of value for life science companies, supporting more informed investment decisions.

There are specific areas of complexity in the life science sector that make communication with the market potentially challenging, including the complexity of the science, long development lead times, significant ongoing capital requirements, regulatory hurdles and complex intellectual property issues.

Read the Code [here](#).

3. It is noted in the final continuous disclosure announcement example that:

*Use of the statement 'it is available for purchase from online marketplaces' draws attention to a consumer to purchase the product and import it. It is illegal to promote a product that is not in the ARTG for personal importation under section 42DLB(9) of the Therapeutic Goods Act 1989 and regulation 7 of the Therapeutic Goods Regulations 1990.*

The audience of ASX announcements is global and includes existing and prospective shareholders, market participants (e.g., brokers, analysts, and fund managers), and other stakeholders relevant to companies (e.g., existing or potential commercial partners).

As Australia is a smaller end-market for many home-grown biotech companies, having a product being available to purchase can be a relevant statement of fact to investors of that company. Therefore, in addition to the existing example, it would be valuable to include a second example utilising acceptable wording for where a company has a product approved in other major markets and countries but is not approved in Australia.

4. The inclusion of a social media example within the guidance is welcomed. It would be further bolstered by inclusion of some appropriate adjectives demonstrating the significance and relevance of the trial results, such as 'positive', 'promising' or 'encouraging', that will support the interpretation of the findings. This aligns with best corporate governance practice, as well as the ASX's need to include information in a manner that conveys the importance and significance of the information (see #1).