

NFTHD #111 (b): Boxed Warnings – Understanding Another TGA Safety Mechanism

In [Notes from the Help Desk #111\(a\)](#), we explored the Therapeutic Goods Administration's (TGA's) Black Triangle Scheme. In this companion piece, we examine another important TGA safety mechanism: Boxed Warnings. While both seek to promote the safe use of medicines, they serve different purposes. In this Notes from the Help Desk, we explore what Boxed Warnings are, what the Code says about them, and some practical considerations when communicating Boxed Warning information.

What is a Boxed Warning?

A Boxed Warning is a TGA risk mitigation measure used to highlight important safety information in a medicine's Product Information (PI) and Consumer Medicine Information (CMI). According to the TGA's [guidance on the use of Boxed Warnings](#), they represent one of the most serious types of warning that can be mandated by a regulatory agency and are intended to draw attention to significant safety concerns that may affect the safe use of a medicine.

While both the Black Triangle Scheme and Boxed Warnings are TGA safety mechanisms, they serve different functions. The Black Triangle Scheme encourages the reporting of suspected adverse events for medicines subject to additional monitoring. By contrast, a Boxed Warning is used to highlight important known safety information and provide particular prominence to risks that may significantly affect the benefit-risk profile of a medicine.

Where a Boxed Warning appears in the PI, a corresponding prominent warning should generally also appear in the CMI, although the wording may differ to reflect the different audiences for those documents.

What does the Code say?

For prescription medicines that have a Boxed Warning included in their PI, the TGA requires all promotional material to either reproduce the Boxed Warning or include a prominent statement directing readers to it. This requirement is also reflected in the Code and is therefore not discretionary.

The Code recognises the importance of Boxed Warnings. Most notably, [Section 2.1](#) requires product-related promotional materials directed to healthcare professionals to include any Boxed Warnings required by the TGA. Boxed Warnings are therefore treated in the same way as other mandatory information required to support appropriate prescribing decisions.

These requirements align with the Code's broader expectation that information be presented in a comprehensive, balanced and fair manner, and that healthcare professionals have access to sufficient information to appropriately assess the risks and benefits of a medicine, as reflected in [Overarching Principles 3 and 7](#).

In this context, Boxed Warnings help ensure that significant safety information is given appropriate prominence alongside information relating to a medicine's benefits. The requirement reflects that information contained within a Boxed Warning is critical to the safe and appropriate use of the medicine. As such, omitting a required Boxed Warning may render material misleading by omission, as it presents an incomplete picture of the medicine's risk-benefit profile and may impair a healthcare professional's ability to form a balanced understanding of the product.

How should the information be presented?

Consistent with the Code's principles-based approach, there are no detailed requirements regarding the placement, size or formatting of Boxed Warnings in promotional materials. Presentation should be guided by the relevant TGA requirements and the company's judgement.

This extends to one of the more common practical questions: does a Boxed Warning need to appear in an actual box? The TGA guidance indicates that promotional materials should include either the Boxed Warning itself or a prominent statement drawing attention to the Boxed Warning. Companies should therefore consider not only whether the information has been included, but whether it has been presented in a way that effectively communicates its significance.

Several Help Desk enquiries have also explored the use of hyperlinks and QR codes to provide access to the PI. While the Code and supporting guidance permit the use of these tools, companies should be cautious about relying solely on a link to communicate important safety information such as a Boxed Warning. Consistent with the Code's emphasis on balance, healthcare professionals should have ready access to information that supports an appropriate assessment of both a medicine's benefits and risks.

For **product-related materials directed to healthcare professionals that do not contain promotional claims**, the appropriate approach will depend on the context. Companies should consider the purpose of the communication and whether reference to a Boxed Warning would assist healthcare professionals in appropriately assessing the risks and benefits associated with the medicine. As with many issues under the Code, the focus should be on whether important safety information is being appropriately communicated.

What about materials directed at patients and the general public?

The Consumer Medicine Information (CMI) has a particular role in communicating Boxed Warning information. TGA guidance indicates that where a Boxed Warning appears in the PI, a corresponding prominent warning should generally also appear in the CMI. However, because the CMI is directed to patients and the general public, the warning may differ from the PI and should be written in language that is readily understood by its intended audience.

The Code is silent on whether or how Boxed Warning information should be included in other materials directed to patients, and the TGA guidance does not specifically address this issue either. In these circumstances, companies should consider the purpose of the communication and the information needs of the intended audience. Where the format and circumstances support the inclusion of product safety information, companies are encouraged to include Boxed Warning information, as its inclusion will assist patients in understanding significant risks associated with the medicine. The wording used in the CMI may provide a useful reference point, as it has been specifically developed for communication with patients.

When considering communications directed to the general public, such as media releases or social media posts, the inclusion of Boxed Warning information will depend on the context, purpose and format of the communication. Media releases generally provide greater scope to include product safety information and, in those circumstances, inclusion of Boxed Warning information is recommended as part of the overall safety messaging. Further guidance can be found in [NFTHD #111\(g\): The Black Triangle Scheme](#).

Final reflections

Boxed Warnings are fundamentally a TGA risk mitigation mechanism, and TGA requirements remain the primary reference point when considering their use. Their prominence in the PI and CMI reflects the importance of ensuring that significant safety information is brought to the attention of healthcare professionals and patients.

Unlike the Black Triangle Scheme, the TGA specifically requires Boxed Warning information to be included in promotional materials directed to healthcare professionals. The Code reflects this approach and serves as a reminder that particularly important safety information should be given due prominence when communicating a balanced view of a medicine's benefits and risks.