

NFTHD #32: PBS statement – in the box or not?

In this Notes from the Help Desk, we answer a few questions relating to the PBS Box – specifically, do companies still need to state the PBS details in a black box with black writing on a white background?

The PBS Box has undergone significant evolution over its 20-year history, originating from the Galbally Review and the subsequent push to reduce PBS expenditure. Despite these changes, its core purpose remains the same: to provide a clear and prominent statement that draws attention to the PBS status of the advertised product.

In early iterations, the Code prescribed numerous statements that addressed different types of products, listings and sub-listings, differences in formulations, and restrictions. This was to be displayed in black text of a specific font size, on a white background, housed in a neat black box. It was to be prominently located - unmissable by the reader.

Over the years, however, the utility of the PBS Box has been impacted by two things: PBS listing becoming more complex; and the PBS Yellow Book being digitised. As products have increasingly more complicated indications and listings, these PBS boxes were becoming more difficult to write and even more difficult to understand. Companies sought a simplified way of describing their listing status. This request was enhanced by the yellow book moving online, rather than a hard copy resource, allowing for a direct link to the most current information on the product. These two factors now enable us to use simplified statements and links to external sources.

So, what does the Code say? In Section 2.1, the Code requires “A statement indicating the public funding or reimbursement status of the product, with or without details of listing, or a direction to where the relevant information is available” for all promotional material. There is no requirement specified for this information to be in a 'box'. There are many ways this can be represented.

A minimal but compliant approach is “PBS listed: Refer to www.pbs.gov.au for full authority information”.

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Just because we can break out of the box and present PBS information in different ways doesn't negate our responsibility to provide prescribing information that is balanced and accessible. Companies need to ensure that healthcare professionals have access to sufficient prescribing information for them to appropriately prescribe the product for a person consistent with its approved use, and the PBS status of that product is relevant and necessary information in any such context. This is supported by Overarching Principle 7, requiring companies to clearly communicate relevant information in their materials. In this case, we would emphasise the approach to be clear and upfront. Keep the PBS statement clearly visible, and don't shift it to the fine print.

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