NFTHD #95: Australian vs. New Zealand - Shared Assets

In this Notes from the Help Desk, we explore the practical considerations involved in developing promotional materials intended for both Australian and New Zealand healthcare professionals.

At first glance, a shared asset may seem like an efficient way to save time, effort, and resources across two markets that are often grouped together, but are not the same. However, there are important compliance and regulatory risks that companies must carefully assess before pursuing this approach.

Are the indications the same?

It is well known that indications for the same medicine can differ across countries. Where indications vary, producing a shared asset can be problematic. Even when indications appear similar, small differences in the wording of Product Information (PI) documents can introduce significant risk. For example, if one PI specifies use only for severe cases of a condition while the other does not, the broader wording could inadvertently support promotion beyond the approved use in one country, which regulators may interpret as off-label promotion. Companies must ensure that no promotional material expands on the approved indication in either jurisdiction. An indication that is accepted in New Zealand but broader than the Australian approval cannot be promoted to Australian HCPs.

Including both indications or not

Including both indications in promotional material may be possible by clearly qualifying them as either the New Zealand or Australian indication. However, companies should be mindful that this approach carries some risk if the broader New Zealand indication is presented to Australian HCPs, as regulators could view this as extending beyond the approved Australian PI. The key consideration is how the information is framed: in proactive and promotional contexts, the potential for misinterpretation increases, particularly where materials are more complex. With careful design and clear differentiation, the risk can be managed, but it should be considered thoughtfully before proceeding.

A related issue arises when PBS listing details are broader than the approved PI. While there is a practical argument that HCPs should understand these differences, the TGA has advised that including PBS details in promotional material may carry a risk of breaching legislation if the PBS criteria extend beyond the PI. This is not an automatic or inevitable outcome but companies should carefully assess the context and exercise caution whenever considering proactive promotional communication that goes beyond the Australian PI (see Chapter 2 of this Promotional Claims Guidance for more detail).

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Cross-jurisdictional compliance

Although New Zealand and Australia share similar ethical principles and approaches to off-label promotion, there are key differences in our regulatory systems. What is compliant in one country does not always meet the requirements of the other. Shared assets must therefore comply with both legal frameworks and industry Codes, where even small details can make a significant difference.

While the Code allows companies to create dual-use promotional assets, careful consideration is required to ensure compliance. Companies must:

- Stay within approved indications in both jurisdictions.
- Ensure prescribing information is prominent and accessible.
- Avoid confusing or misleading presentation of differences between indications.
- Meet all relevant legal and industry Code requirements in both countries.

In short, efficiency should not come at the expense of compliance. A shared approach may be possible in some circumstances, but only if both sets of requirements are fully respected and carefully managed.

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