

NFTHD #91 - Compliance Check: Appropriate Use of PSP Data

In this week's NFTHD, we explore how data from Patient Support Programs (PSPs) can - and can't - be used, especially when it comes to communication with healthcare professionals and internal commercial strategies.

<u>Section 13(e)</u> of the Medicines Australia Code of Conduct is the starting point: PSP data must not be used for promotional purposes. This clause underpins a critical principle—that the objective of PSPs is to support patient care, not to influence prescribing decisions or drive sales outcomes.

Using PSP Data in HCP Materials: A Matter of Rigour

Companies can communicate the purpose and observed outcomes of PSPs—especially where there's evidence that the program enhances patient support or improves treatment adherence. <u>Section 13(d)</u> of the Code allows this, and when done appropriately, it can be a valuable part of HCP engagement.

For instance, if a PSP helps patients take their medicine as prescribed or reduces concerns about side effects, those are relevant and legitimate insights. These kinds of patient-centred outcomes do not amount to promotion of the medicine itself but rather highlight the supportive role a PSP can play in the overall treatment experience.

Companies may not make therapeutic claims based on PSP data. In general, PSPs are not designed or conducted with the level of scientific and statistical rigour required to support efficacy or safety claims about a product.

Where uncertainty exists, limit the use of PSP data to explaining the program's intent and any observed improvements in patient experience or adherence—rather than stepping into territory that could be interpreted as product promotion.

Exploring Enrolment Data: Operational Insight or Incentive Metric?

Enrolment figures can provide meaningful internal insights, such as assessing program reach and effectiveness. A recent query to the helpdesk raised the possibility of using enrolment numbers as a key performance indicator (KPI) and linking them to sales team incentives. This prompts an important question: what are the broader implications of using enrolment data in this way? Using enrolment figures as a basis for sales team incentives introduces a significantly higher level of risk.

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There are important considerations here:

- **Intent matters:** If enrolment targets become a proxy for sales targets, it undermines the PSP's patient-first intent.
- **Perceived promotion:** Encouraging sales teams to increase PSP uptake could be viewed as encouraging prescribing, particularly if it involves promoting the medicine via patient groups rather than through appropriate HCP channels.
- Public trust and compliance: It becomes increasingly difficult to demonstrate that the PSP exists to benefit patients and not simply to grow market share if the measure of success (patient enrolments) is linked to commercial rewards.

Don't get us wrong - commercial roles can communicate basic information about a PSP. These programs are designed to support patients, and there's no reason to hide them. However, we suggest that the way this information is shared matters. The focus should remain on the clinical value of the medicine, with the PSP clearly positioned as a secondary support tool -not as a primary driver of prescribing decisions. The balanced, evidence-based merits of the medicine - not the availability of a support program - should take centre stage in any promotional interaction.

Emphasising the importance of context, there may be specific circumstances where a PSP legitimately informs the prescribing decision - for example, where the program includes provision of a device or necessary patient training. In these cases, it's appropriate that the HCP is aware of the PSP as part of assessing the medicine's suitability. As always, a principles-based approach should guide how such information is communicated.

Put simply, while internal KPIs around PSP enrolments may be appropriate for operational monitoring, linking those metrics to sales incentives raises concerns. It introduces risk and makes it more difficult to demonstrate that the PSP is genuinely patient-focused, rather than commercially driven.

Key Takeaways

- **Context is everything:** Communicating PSP outcomes is allowed but only when it's clearly about patient support, not product promotion.
- **Rigour matters**: Without research-grade methodology, PSP data should never used to support therapeutic claims.
- Lead with clinical value: PSPs should complement not drive HCP prescribing decisions.
- **Be careful with incentives**: Internal PSP enrolment KPIs may be appropriate but using them to drive sales behaviours risks undermining ethical compliance and trust.

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