NFTHD #87: Product-specific media statements: Getting the balance right

Pharmaceutical companies play an important role in helping the public access reliable, up-to-date information about diseases, conditions, and the prescription medicines available in Australia. But there's a fine line between providing helpful information and promoting a product — and it's one companies must navigate carefully.

Respecting the Legal Framework

Under Australian law, specifically the Therapeutic Goods Act 1989 (Cth), it's an offence to advertise prescription medicines (those included in Schedules 4, or 8 of the Poisons Standard) directly to the general public. Advertising is defined very broadly — covering any statement, image, or design that, however made, directly or indirectly promotes the use or supply of a therapeutic good.

The Medicines Australia Code of Conduct reflects these legal requirements. It prohibits the promotion of prescription medicines to the public while recognising that people need access to clear, responsible information. The Code provides a framework for companies to deliver educational, non-promotional content that supports public understanding.

New Guardrails in Edition 20: Mandatory Elements for Media Statements

A key change introduced in Edition 20 of the Code is the reintroduction of "mandatory elements" that must be included in any media statement referring to a specific prescription medicine. These clear, prescriptive requirements, outlined in Section 10.1(e), are not entirely new — they reflect requirements set out in Edition 18 and earlier versions of the Code but which were not included in Edition 19. Edition 20 brings these requirements back into focus to provide greater clarity and structure, supporting companies in striking the right balance in their public communications. This is intended to give companies greater assurance and clearer guardrails when communicating about their products to a consumer-facing audience.

One of these mandatory elements is a summary of the product's side effect profile, precautions, warnings, contraindications, adverse reactions, and interactions. Companies are expected to exercise their judgment when preparing this summary — they are not required to include information on every subcategory. Instead, they should create an overall, balanced summary that highlights the most relevant and important points for the intended public audience. Consulting the Consumer Medicine Information (CMI) can assist in finding appropriate content and language to meet this standard.

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It is also important to tailor the level of detail in the summary to the context of the communication. A summary in a longer media release may be more detailed and comprehensive, while a summary in a short, targeted social media post should be more concise. Regardless of the format, the guiding principle remains the same: include enough information to ensure balance.

Applying the "Promotion Test"
The Therapeutic Goods Administration (TGA) applies an objective, "reasonable person" test when interpreting whether something is an advertisement under the Therapeutic Goods Act 1989 (Cth). Here's how it works: If a reasonable person, viewing the material in context, would understand it as intended (directly or indirectly) to promote the use or supply of a therapeutic good, it can be considered an advertisement.

Companies must be aware that if information published (in any media) about their products can be accessed by the general public, there is always a risk it could be considered promotional. This risk remains even if the content includes all the mandatory elements outlined in Section 10.1(e).

In other words, good intentions and simple compliance with checklist requirements are not enough — companies should objectively assess how their information is likely to be interpreted by the public.

Managing Quotes from Third Parties
Another important area is transparency around third-party voices. Any quotes from healthcare professionals or members of the general public used in a company media statement must comply with the Code.

Companies should include a clear disclosure statement outlining any relationship with the healthcare professional spokesperson. This aligns with Overarching Principle 2 and reinforces our commitment to transparency in our interactions with healthcare professionals. For example: *"Dr. X has served on advisory boards and been involved in clinical trials sponsored by [Company Name] for which compensation was received. In relation to this [Company Name] media announcement, no compensation was provided to Dr X, and the opinions expressed are their own. Dr X has been briefed by [Company Name] on the approved use of this product."*

Keeping it on your corporate website
Following Complaint 1172, some companies took a very conservative approach by removing all product-specific media statements from their corporate websites. While this was a business decision made to manage perceived risk, it is important to be clear: there is nothing under the Code or the legislation that suggests housing a compliant, non-promotional, product-specific media statement in the media section of a corporate website is unethical or irresponsible.

If a media statement is compliant with the Code and maintains a balanced, educational, non-promotional tone — including the mandatory elements outlined in Section 10.1(e) — there is no reason why it cannot be accessible. Also, retaining the media statement on the corporate website should not be interpreted as issuing it more than 'once' (Code Section 10.1 c)). The key consideration is not where the information is housed, but how the information would be objectively assessed in terms of balance, educational value, and the absence of promotional messaging.

Keeping balance, context, and compliance front of mind is essential to managing risk while ensuring important information remains accessible to the public and media.

For educational purposes, we have attached an example to this NFTHD below, noting that the content is entirely fictitious and designed purely to illustrate how the principles of balance and compliance can be applied in practice.

Continued below

This is an educational example of a product-specific media release. It accompanies NFTHD #87, published May 2025 by Medicines Australia. The content is entirely fictitious and designed purely to illustrate how the principles of balance and compliance can be applied in practice.

*Note this is entirely fictitious. RPI is fictitious, the company is fictitious, the content is fictitious.

01 May 2025 | Canberra, Australia

Australian Adults with Regulatory Peptide Insufficiency (RPI) Receive PBS Access to Brand Name®

MyPharmaCompany, a leading biotechnology company, today joined medical experts and the patient community in welcoming Federal Government funding for the treatment of severe Regulatory Peptide Insufficiency (RPI) in adults. Already indicated and reimbursed for children with Regulatory Peptide Insufficiency (RPI), Brand Name®(AAN of active ingredient), will now be reimbursed for adults with the condition as of 1 May 2025.

Regulatory Peptide Insufficiency (RPI) is a progressive metabolic disorder where the body produces insufficient levels of certain regulatory peptides critical for maintaining cellular communication, immune balance, and tissue repair[1]. RPI is a rare condition, affecting approximately 1,200 adults in Australia[2]. Some individuals are diagnosed in childhood, while in others the deficiency develops later in life, referred to as adult-onset RPI.[3]

BRAND NAME® is indicated as an adjunct therapy to diet and exercise in patients with RPI.[4] The active ingredient in BRAND NAME® is designed to attach to cells and help them send the right signals, so the body can repair itself and keep the immune system balanced.[2]

Dr Marjorie Expert, Senior Specialist and Director of the Major Hospital Metabolic Centre, said: *"Until now, adults living with this debilitating condition who were prescribed BRAND NAME® as children often had to transition to an alternative reimbursed treatment to continue managing their condition. The listing of BRAND NAME® on the PBS for adults with RPI provides greater choice and*

10.1e) The product-specific media statement must contain all of the following:

- ✓ The product's brand name;
- ✓ The Australian Approved Name of the active ingredients in the product;
- ✓ Its approved indications, relevant to the product-specific media statement;
- ✓ Therapeutic class;
- ✓ Public funding status and restrictions, or a notation if the product is not publicly funded;
- ✓ A summary of the side effect profile, product's precautions, adverse effects, warnings, contraindications, and interactions; and
- ✓ A copy of, or a link to the product's Consumer Medicine Information.

10.1f) It may include a non-comparative description of the mechanism of action.

10.1g) Quotes from others can be included as long as they are not promotional or comparative in nature.

In this context, references are not mandatory; however, all company communications must be accurate and up to date. By including references, a company demonstrates how its information is sourced, which also supports transparency.

[1] Australian RPI Foundation. A Guide to Deficiency. Accessed May 2023: https://rpi.asn/Fact-Sheet-2023_Digital-Final.pdf
[2] Australian Government. Department of Health and Aged Care. The Pharmaceutical Benefits Scheme (PBS) [Online]. Available at: https://www.pbs.gov.au/. Accessed April 2025.
[3] BRAND NAME® Consumer Medicine Information. Available www.ebs.tga.gov.au/. Accessed April 2025
[4] BRAND NAME® Australian Approved Product Information. Available www.ebs.tga.gov.au Accessed April 2025.

means patients are no longer forced into making a transitional decision,".

"It is important for endocrinologists to have a range of medicines available to prescribe, because each patient has unique needs. Having another treatment option available on the PBS is good news for patients and doctors," Dr Expert said.

While referral to a treating clinician is not mandatory for product-specific media statements, it is considered appropriate in this context.

BRAND NAME® Consumer Medicine Information is available here. Treatment options should be discussed with a patient's clinician. BRAND NAME® is an Australian registered prescription medicine and can only be prescribed by a Doctor.

A summary of the side effect profile, product's precautions, adverse effects, warnings, contraindications, and interactions: Companies are expected to exercise their judgment when preparing this summary — they are not required to comment individually on every subcategory. Instead, they should create an overall, balanced summary that highlights the most relevant and important points for the intended public audience.

Side Effects[4]: All medicines can have side effects. Serious side effects of BRAND NAME® can include allergic reaction, decreased muscle mass and strength, and fatigue and decreased energy. **Precautions**[4]**:** Kidney function should be evaluated prior to starting of BRAND NAME® and periodically thereafter. Treatment with BRAND NAME® should be ceased prior to major surgery. **Interactions**[4]: Immunobalance therapy may inhibit response to BRAND NAME®

No compensation was provided to Dr Marjorie Expert for their involvement in this media activity, and the opinions expressed are their own.

Companies are expected to include a brief disclosure statement outlining any relationship between the company and the healthcare professional spokesperson, for transparency reasons.

Dr Marjorie Expert has received consultancy fees/honorarium for speaking engagements, was an Advisory Board member, and has received institutional research funding from MyPharmaCompany.

About MyPharmaCompany

MyPharmaCompany, a leading science and technology company, operates across life sciences and focuses on the discovery, development, and commercialisation of prescription medicines in Rare Diseases including Metabolism. Originally based in Germany, MyPharmaCompany innovative medicines are used by millions of patients worldwide. Please visit MyPharmaCompany.com.au for more information.

Companies can promote themselves; they cannot promote prescription medicines. All company activities, such as this one, needs to be clearly named as a company activity (Overarching Principle 10)

End