

NFTHD #36: Initiating a press release for an unregistered product?

In this Note from the Help Desk, we answer a query about the possibility of issuing a social media post or press release about an unregistered pipeline product that is publicly available on the TGA website.

The Code provides the ability for companies to proactively engage with media and other stakeholders, so long as the nature of the communication is strictly non-promotional, relevant to the Australian public, and not made with any intention to inform patient-level prescribing, or influence prescribing (Section 10).

The Code explicitly states that no statements or comments should be initiated by a company regarding any products that are not registered in Australia. Ask yourself how the information is relevant to the Australian public, if it is not on the ARTG? The Code's Overarching Principles reference TGA-approved medicines, and Section 10.1b) actively suggests some circumstances which are appropriate; unregistered pipeline products is not one of them.

Whilst the information might be publicly available on the TGA website, this does not justify initiating any communication on the matter. Information made available by one party (such as the TGA) can be understood as non-promotional. That very-same information could be replicated and delivered by another party (such as the sponsor company) and it could be understood to be promotional, because they will profit/benefit from that product. This is why context remains key.

Listed and unlisted companies have continuous disclosure obligations under the Corporations Act 2001 and the TGA has issued consistent principles that apply for a company to meet continuous disclosure obligations while not breaching the therapeutic goods laws. The Code recognises disclosure requirements in 10.1 h) and it might be that companies will need to proactively communicate about a pipeline product with their shareholders in order to meet those obligations. The TGA have "Guidance: Complying with advertising rules for therapeutic goods when making an ASX announcement" which is available on their [website here](#).

If you are thinking of telling the wider world about the listing of your sponsored approved product, you can, as long you heed Section 10.1. Non-registered pipeline products need to wait for registration for any company-initiated public announcement. Until then, pipeline products remain squarely in the realm of scientific exchange, as articulated in the Code at Section 7.

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