

PAU Ref: 17648

CONSULTATION RESPONSE

Whether the TGA should publish that a prescription medicine is under evaluation

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About Perrigo Australia:

Orion Laboratories Pty Ltd. was founded in 1985 as a privately owned company. Orion grew rapidly into one of Australia's few pharmaceutical and medical device manufacturers and suppliers, particularly focused on hospitals. In March 2010 Perrigo acquired Orion. Perrigo, headquartered in Ireland, is one of the world's largest manufacturer of OTC pharmaceutical products for the Private Label market and an industry leader in pharmaceutical technologies. Perrigo provides "Quality Affordable Self-care Products" across a wide variety of product categories and geographies. Perrigo Australia markets in excess of one hundred quality affordable healthcare products throughout Australia, New Zealand and beyond. Our presence as a medical device manufacturer is primarily in the cost effective, low risk medical device market, with health care professionals and hospitals as our target consumers. The majority of these products manufactured in Australia and Perrigo Australia is proud of its ongoing commitment to Australian made products.

Perrigo Australia appreciates the opportunity to provide feedback on the Department of Health's Therapeutic Goods Administration (TGA) consultation on whether the TGA should publish that a prescription medicine is under evaluation.

Response to Consultation:

Perrigo Australia supports no change to the current TGA approach – OPTION 1.

This option provides the greatest protection of our commercial investment into product development, until such time as we are confident that the product will be registered, at which point we can then choose when to disclose this to the Health Care Sector and general public.

We feel that as per the case study provided in the consultation paper, the application Sponsor should be able to control what information, if any, is placed in the public domain and the timing around any such public announcement.

Perrigo Australia does not support any of the other options (with or without changes) provided in this consultation, we feel that changes in line with these options may devalue costly research and product development. They will also erase our right to commercial confidence with any application to the TGA.