

Australian Government

Department of Health Therapeutic Goods Administration

<u>Therapeutic Goods Act 1989</u> <u>Approval under section 42DF for use of restricted representations by</u> <u>Ego Pharmaceuticals Pty Ltd</u>

I, Leanne McCauley, Delegate of the Secretary to the Department of Health, on receipt of an application from Ego Pharmaceuticals Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (**the Act**) the restricted representations described in paragraph (A) below for use in advertisements directed to consumers, for the product identified in paragraph (B), provided the condition identified in paragraph (C) is met:

(A)

- i. Treatment of Papulopustular Rosacea
- ii. Anti-bacterial lotion for Papulopustular Rosacea
- iii. Anti-bacterial lotion for the treatment of Papulopustular Rosacea
- iv. For Papulopustular Rosacea
- v. Suitable for Papulopustular Rosacea
- vi. Papulopustular rosacea requires a diagnosis, please see your doctor before using this product
- **(B)** "Azclear Action Medicated Lotion" (AUST R 71006) (the Medicine)
- **(C)** When the Medicine is advertised together with other products, including other products under the Azclear range, it must be clear to consumers that the references to the restricted representation *'Papulopustular Rosacea'* (other than on the label) are clearly linked to the Medicine, "Azclear Action Medicated Lotion" AUST R 71006.

Dated this 24th day of June 2019

Signed electronically

Leanne McCauley Delegate of the Secretary to the Department of Health Advertising Compliance Section Regulatory Education and Compliance Branch

