21 July 2025

Australian Regulatory Path Confirmed for Initial Access to ED & Dysmenorrhoea Products

Multiple Prescription Access Pathways Confirmed for Australian Launch in 2025

- Final regulatory prerequisites now met for Libbo (ED) and Dyspro (dysmenorrhoea) under TGA medicines access pathways
- First commercial batch purchase order for Dyspro submitted, with national prescriber coverage in place via telehealth and GP clinics
- Commercial rollout in Australia expected to commence before end of 2025
- Export submission planned to support global market expansion and full Australian registration

EVE Health Group (ASX:EVE, EVE or the Company) is pleased to confirm that it has satisfied the regulatory requirements to enable prescription access to its lead products, Libbo and Dyspro, in Australia under the TGA medicines access pathways.

This milestone enables EVE to proceed with commercial launch in Australia ahead of its originally anticipated regulatory timeline, with first prescriptions expected before the end of calendar year 2025.

Both products have been developed by EVE using fast-acting oral dissolvable formats incorporating established active pharmaceutical ingredients. They target significant unmet needs in men's and women's health, respectively.

Product stability data has determined an expiry date minimum of 2 years for Libbo and 1 year for Dyspro respectively. EVE is committed to ongoing stability testing in accordance with pharmaceutical good manufacturing practices (GMP), providing further validation for broader regulatory submissions, including future application for TGA review for export markets. Following initial Australian market entry, the Company intends to apply to TGA Australian Register of Therapeutic Goods (**ARTG**) to facilitate international expansion.

Commercial Readiness and Timeline

With the regulatory foundation now in place, EVE has shifted focus to the operational and commercial activities required for launch. These include finalising product manufacture and packaging, appointing a national distribution partner, completing practitioner onboarding and prescribing and dispensing software integration, and preparing for pharmacy fulfilment.

These steps are expected to be completed progressively across CY Q3 and Q4 2025. First prescriptions of Libbo and Dyspro are targeted before the end of CY 2025.

Regulatory Access Pathways

Both Libbo (oral soluble film containing tadalafil) and Dyspro (cannabinoid-based pastille formulation) are classified as *unapproved medicines* under the Therapeutic Goods Act 1989, and may be legally prescribed in Australia through TGA authorised frameworks for supply on prescription to patients.

Commenting on the milestone, EVE Chief Operating Officer Ben Rohr said:

"Meeting the regulatory prerequisites for launch is a major achievement and clears the way for Libbo and Dyspro to become available to patients in Australia. This milestone reflects the quality of our team, the strength of our development and regulatory strategy, and our commitment to bringing innovative, fast-acting solutions to market."

Authorised for release by the Board of Directors.

— ENDS —

For more information, please contact:

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About EVE Health Group

EVE Health Group (ASX: EVE) is an Australian-based health company developing and commercialising evidence-based wellness and pharmaceutical products. Through its subsidiaries Meluka Australia and Nextract EVE delivers science-led innovations designed to support consumer and practitioner health across retail, pharmacy and clinical channels.

For further information, please visit www.evehealthgroup.com.au and follow us on LinkedIn.