



MAYNE PHARMA RESPONDS TO SPECULATION ON FDA UNTITLED LETTER

14 May 2025, Adelaide, Australia: Mayne Pharma Group Limited (Mayne Pharma or the Company) (ASX: MYX), today provides an update in relation to market speculation following the recent publication of an 'untitled letter' from the U.S. Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP) received by Mayne Pharma on 28 April 2025 (US time) and made public on 12 May 2025 (US time) related to certain promotional claims used in a speaker presentation for NEXTSTELLIS® (drospirenone and estetrol tablets), a combined oral contraceptive (FDA Untitled Letter).

Mayne Pharma takes the views of the FDA seriously and will respond to the letter within the prescribed timeframe. Out of an abundance of caution, and as an initial and immediate action, Mayne Pharma voluntarily withdrew the speaker presentation referenced in the FDA Untitled Letter.

The FDA Untitled Letter does not impact Mayne Pharma's ability to continue to sell and distribute NEXTSTELLIS® in the United States. Mayne Pharma does not regard the receipt of the FDA Untitled Letter as materially price sensitive.

Mayne Pharma's intention is for the proposed Scheme of Arrangement with Cosette to continue to proceed in accordance with the timetable previously announced on 22 April 2025.

- ENDS -

Authorised for release to the ASX by the Board Chair

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel pharmaceuticals, offering patients better, safe and more accessible medicines. Mayne Pharma is a leader in dermatology and women's health in the United States and also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40-year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit [maynepharma.com](https://www.maynepharma.com).

NEXTSTELLIS® is a trademark of a third party.

Mayne Pharma Group Limited

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Important information

This announcement contains forward-looking statements that involve subjective judgement and analysis and are subject to significant uncertainties, risks and contingencies, many of which are outside the control of, and are unknown to the Company. These forward-looking statements use words such as 'potential', 'expect', 'anticipate', 'intend', 'plan', 'target' and 'may', and other words of similar meaning. No representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including the Company). Actual future events may vary materially from the forward-looking statements and the assumptions on which the forward-looking statements are based. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Subject to the Company's continuous disclosure obligations at law and under the listing rules of the Australian Securities Exchange, the Company disclaims any obligation to update or revise any forward-looking statements. The factors that may affect the Company's future performance include, among others: changes in economic conditions; changes in the legal and regulatory regimes in which the Company operates; litigation or government investigations; decisions by regulatory authorities including approval of our products as well as their decisions on label claims; competitive developments affecting our products; changes in behaviour of major customers, suppliers and competitors; interruptions to manufacturing or distribution; acquisitions and divestitures; the success of research and development activities and research collaborations and the Company's ability to protect its intellectual property.