



MAYNE PHARMA SETTLES US PATENT LITIGATION RELATING TO IMVEXXY® WITH TEVA PHARMACEUTICALS USA

Key Points:

- Settlement reached with Teva Pharmaceuticals USA resolving Paragraph IV litigation concerning IMVEXXY® FDA Orange Book patents
- Settlement includes an agreed market entry date of generic IMVEXXY® of 2 September 2032
- The settlement highlights the validity and enforceability of the IMVEXXY® patent portfolio
- Mayne Pharma continues to support IMVEXXY® and defence of its IP portfolio with the last expiring patent in February 2034

16 October 2026, Adelaide, Australia: Mayne Pharma Group Limited (Mayne Pharma or the Company) (ASX: MYX), today announces that Teva Pharmaceuticals USA Inc. (Teva Pharmaceuticals USA) has agreed to resolve the US Paragraph IV litigation relating to IMVEXXY® (estradiol vaginal inserts) and the associated FDA Orange Book-listed patents, brought by Mayne Pharma and TherapeuticsMD.

The settlement resolves ongoing patent litigation with Teva Pharmaceuticals USA (commenced in April 2020) and provides an agreed pathway for potential future entry of a Teva Pharmaceuticals USA generic product on 2 September 2032, or earlier under certain circumstances, subject to court approval of the settlement terms. The settlement does not include any financial payment or upfront monetary consideration between the parties.

Mr Aaron Gray, CEO of Mayne Pharma said *"Following our settlement with Sun Pharma announced on 30 September, today's agreement with Teva Pharmaceuticals USA resolves all outstanding Paragraph IV litigation relating to IMVEXXY®. Together, these settlements give us clarity on the generic entry landscape and remove the cost and uncertainty of ongoing litigation. This provides a firm foundation for our longer-term planning for IMVEXXY® within our menopause portfolio and broader Women's Health business. We will continue to defend our IP estate and invest in access, adherence and prescriber engagement to maximise the product's long-term contribution."*

IMVEXXY® is a locally administered estradiol vaginal insert used in the treatment of moderate to severe dyspareunia due to menopause. The product sits within Mayne Pharma's Women's Health franchise and is supported by ongoing commercial execution initiatives focused on access, adherence and prescriber engagement. In the 12 months to 30 June 2026, IMVEXXY® total prescriptions grew 6% over the prior corresponding period and net sales were up 8% to US\$29.3 million.

After the settlement announced today, the Company has no further ongoing Paragraph IV litigation matters for IMVEXXY®.

Click [here](#) to view the announcement on Investor Hub.

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Authorised for release to the ASX by the Board Chair.

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.

IMVEXXY® is a trademark of a third party.

About Paragraph IV litigation

In the United States, generic manufacturers can seek approval to market a generic version of a branded medicine by filing an abbreviated new drug application (ANDA) with the U.S. Food and Drug Administration (FDA) under the Hatch-Waxman framework. A Paragraph IV certification alleges that one or more Orange Book-listed patents for the branded product are invalid, unenforceable or not infringed, which may lead to patent litigation. If the brand company commences patent infringement proceedings within the statutory timeframe (commonly referred to as 45 days), this can trigger an automatic stay of FDA final approval of the ANDA for up to 30 months (subject to applicable circumstances) or until the dispute is resolved, including via settlement.