



MAYNE PHARMA SETTLES US PATENT LITIGATION RELATING TO IMVEXXY® WITH SUN PHARMA

Key Points:

- Settlement reached with Sun Pharma resolving Paragraph IV litigation concerning IMVEXXY® FDA Orange Book patents
- Settlement includes an agreed market entry date of generic IMVEXXY® of 21 October 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

30 September 2026, Adelaide, Australia: Mayne Pharma Group Limited (Mayne Pharma or the Company) (ASX: MYX), today announces that Sun Pharmaceutical Industries Ltd (Sun Pharma) 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 Sun Pharma (commenced in July 2024) and provides an agreed pathway for potential future entry of a Sun Pharma generic product on 21 October 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 *“Resolving the Paragraph IV litigation with Sun Pharma is an important step in protecting the value of IMVEXXY®. The agreed pathway strengthens our longer term planning for IMVEXXY® within our menopause portfolio as part of our overall Women’s Health business. We will continue to actively manage and defend our IP estate and execute on access and patient support initiatives to maximise the product’s patent life and 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 one further ongoing Paragraph IV litigation matter for IMVEXXY®.

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

- ENDS -

Mayne Pharma Group Limited

ABN 76 115 832 963

[maynepharma.com](https://www.maynepharma.com)

1538 Main North Road, Salisbury South, SA 5106 Australia





For further information contact:

Dr Tom Duthy
Investor Relations
+61 402 493 727
ir@maynepharma.com

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.

