



PALLA PHARMA

# ASX ANNOUNCEMENT

Thursday 3 December 2020

## Marketing Authorisations Approval Process Update

As previously announced by Palla Pharma Limited ("PAL") on 6 November 2020, the Medicines and Healthcare Products Regulatory Agency (MHRA), the UK pharmaceutical industry regulator, informed PAL that it had accepted its application to add the PAL Norwegian production site (Kragero) as an approved manufacturer of Co-Codamol under its own Marketing Authorisation (MA).

Further to this application, PAL has now received a request for additional information from the MHRA. The nature of the information requested is typical for an application of this type. The information has been prepared and uploaded to the MHRA Common European Submission Portal (CESP) as of 1 December 2020, as requested.

As a result of this request for additional information, upon successful review of its application, PAL can now expect to be able to start manufacturing and selling products under its own MAs early in the first quarter of 2021.

In the interim, the Norwegian FDF (Finished Dosage Formulation) capacity will be fully deployed manufacturing Co-Codamol for the Norwegian market under an agreed contract with Karo and producing Co-Codamol for the UK market for Wockhardt.

PAL will continue to update the market with progress on the approval process of its own branded MAs.

This announcement has been authorised for release by the Board of Palla Pharma Limited.

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### About Palla Pharma Limited:

Palla Pharma Limited (ASX:PAL) is a vertically integrated opiate manufacturer from poppy straw growing through to tableting production. Palla Pharma has developed an innovative, efficient and environmentally sustainable opiate manufacturing process based on a novel water-based extraction technology. The company is one of six licensed opiate producers globally, and one of three fully integrated suppliers from opiate extraction through to tableting production delivering on its strategy to secure access to regulated downstream narcotics markets by leveraging its production cost advantage.

#### Palla Pharma Limited

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