SUBACAP® EUROPEAN MARKETING APPROVAL APPLICATION UPDATE

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15 December 2011, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) announces that following discussions with the UK Medicines and Healthcare products Regulatory Agency (MHRA) the Company will be required to respond to questions raised following a review of the SUBACAP® dossier by the UK's Commission for Human Medicines. This will delay the approval of SUBACAP® beyond 30th June 2012 as further clinical work may be required.

The MHRA has advised the Company that while clinical data presented in the dossier showed superiority over placebo, no conclusions on the non-inferiority of SUBACAP® compared to the reference drug can be made as the reference drug did not show superiority over placebo.

The Company will complete a review of the questions raised once formally received from the Commission for Human Medicines. Following the review, the Company will either supplement its Marketing Authorisation Application (MAA) with further information or withdraw its MAA and complete further clinical work.

Mayne Pharma's CEO Dr Roger Aston said, "We are obviously surprised with these recent developments given the previous feedback we have had and we remain absolutely committed to gaining marketing approval for SUBACAP® in Europe and the US. The Company will utilise the advice received from the MHRA as we continue to finalise the details of a Phase III clinical trial which will be presented to the US FDA in 2012."

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Mayne Pharma Profile:
Mayne Pharma Group Limited (Mayne Pharma) is an Australian specialist pharmaceutical company with an intellectual property portfolio built around the optimisation and delivery of oral dosage form drugs.

Mayne Pharma has a long and successful history of developing and commercializing improved pharmaceuticals and has launched and marketed numerous products through partnerships with licensees in various countries around the world. Mayne Pharma focuses on delivering to patients improved versions of existing drugs in order to advance safety, efficacy or ease of administration.

A technology driven company, Mayne Pharma has a significant product portfolio and pipeline, global reach through distribution partners in Australia, USA, Europe and Asia and a manufacturing facility based in Salisbury, South Australia that employs over 150 people on a 32 acre site. The facility also undertakes the manufacture of products under contract for third parties to TGA, FDA and EU regulatory guidelines.