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Public statement

Hemoprostol

Withdrawal of the Article 58 scientific opinion

Linepharma International Limited has requested the European Medicine Agency (EMA) to withdraw its scientific opinion for Hemoprostol (misoprostol).

Hemoprostol was evaluated by EMA under the Article 58 provision[1], whereby EMA's Committee for Medicinal Products for Human Use (CHMP), in cooperation with the World Health organization (WHO), gives scientific opinions on medicines intended for use outside the European Union (EU).

The CHMP gave a positive opinion on Hemoprostol in January 2014.

The decision to request the withdrawal was based on commercial grounds, due to the fact that the company was unable to obtain national Marketing Authorisations or commercialise the product since the issuance of the CHMP scientific opinion.

Following the decision of Linepharma International Limited, the scientific opinion for Hemoprostol will no longer be updated and the CHMP will not make further recommendations on its conditions of use.

The Public Assessment Report (PAR) for Hemoprostol will be updated accordingly.

[1] Regulation (EC) No 726/2004

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