European Medicines Agency
Evaluation of Medicines for Human Use

London, 22 October 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
ADCIRCA

International Nonproprietary Name (INN): ***tadalafil***

On 22 October 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend the variation to the terms of the marketing authorisation for the medicinal product Adcirca. The Marketing Authorisation Holder for this medicinal product is Eli Lilly Nederland B.V.

The CHMP adopted a new indication as follows:
"Adcirca is indicated for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity (see section 5.1).
Efficacy has been shown in idiopathic PAH (IPAH) and in PAH related to collagen vascular disease."

The CHMP also adopted the removal of an indication as follows:
"Treatment of erectile dysfunction.
In order for tadalafil to be effective, sexual stimulation is required.
Adcirca is not indicated for use by women."

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Adcirca will be as follows[***]:
"Adcirca is indicated for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity (see section 5.1).
Efficacy has been shown in idiopathic PAH (IPAH) and in PAH related to collagen vascular disease."

[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

[***] The text in bold represents the new or the amended indication.

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