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
ANGIOX

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

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 Angiox. The Marketing Authorisation Holder for this medicinal product is The Medicines Company UK Ltd.

The CHMP adopted a new indication as follows:
"Angiox is indicated as an anticoagulant in adult patients undergoing percutaneous coronary intervention (PCI), including patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI."

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 Angiox will be as follows[***]:

Angiox is indicated as an anticoagulant in **adult** patients undergoing percutaneous coronary intervention (PCI), **including patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI.**

Angiox is also indicated for the treatment of adult patients with unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) planned for urgent or early intervention.

Angiox should be administered with aspirin and clopidogrel.

[*] 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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