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Public statement

Angiox

Withdrawal of the marketing authorisation in the European Union

On 21 June 2018, the European Commission withdrew the marketing authorisation for Angiox (bivalirudin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, The Medicines Company UK Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Angiox was granted marketing authorisation in the EU on 20 September 2004 and was 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 was 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 was to be administered with acetylsalicylic acid and clopidogrel.

The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2009. It was then granted unlimited validity in 2014.

The European Public Assessment Report (EPAR) for Angiox will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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