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Public statement

Zontivity

Withdrawal of the marketing authorisation in the European Union

On 23 June 2017 the European Commission withdrew the marketing authorisation for Zontivity (vorapaxar) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Merck Sharp & Dohme Limited, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Zontivity was granted marketing authorisation in the EU on 19 January 2015 for the reduction of atherothrombotic events in adult patients with a history of myocardial infarction.

The approved indication was subsequently extended to include adult patients with symptomatic peripheral arterial disease.

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Report (EPAR) for Zontivity will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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