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Human Medicines Development and Evaluation

Public statement on Doribax

Withdrawal of the marketing authorisation in the European Union

On 25 July 2008, the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Doribax, which had been approved for the treatment of nosocomial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections.

The marketing authorisation holder (MAH) responsible for Doribax was Janssen-Cilag International N.V.

On 31 July 2014, the European Commission issued a decision to withdraw the marketing authorisation for Doribax, following its receipt of a letter dated 6 July 2014 notifying the Commission of the MAH's decision to voluntarily withdraw the marketing authorisation for this product for commercial reasons.

Doribax was marketed in the following European countries: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Liechtenstein, Lithuania, Luxemburg, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden and United Kingdom.

Pursuant to this decision, the European public assessment report for Doribax will be updated to reflect that the marketing authorisation is no longer valid.

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