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Public statement

Clopidogrel Teva Generics B.V.

Cessation of validity of the marketing authorisation in the European Union

On 28 October 2010 the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Clopidogrel Teva Generics B.V. (clopidogrel hydrochloride), indicated for the prevention of atherothrombotic events in patients with myocardial infarction and acute coronary syndrome. It was also authorised for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation.

Clopidogrel Teva Generics B.V. has not been marketed in Europe since this initial marketing authorisation. In accordance with article 14(4) of Regulation (EC) No 726/2004 ('sunset clause')[1], the marketing authorisation of a medicinal product lapses if the product has never been marketed in one of the Member States within three years of its initial authorisation.

Because of this, the marketing authorisation for Clopidogrel Teva Generics B.V. is no longer valid.

Clopidogrel Teva Generics B.V. is a generic medicine of Plavix. There are other generic medicinal products of Plavix authorised and marketed in the EU.

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for Clopidogrel Teva Generics B.V. will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

[1] Article 14(4) of Regulation (EC) No 726/2004 ('sunset clause')

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