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Questions and answers on Clopidogrel Teva and associated names (clopidogrel 75 mg tablets)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Clopidogrel Teva and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Clopidogrel Teva outweigh its risks, and the marketing authorisation can be granted in Germany and in the following Member States of the EU: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden and the United Kingdom.

What is Clopidogrel Teva?

Clopidogrel Teva is a medicine that contains the active substance clopidogrel. It is used in adults to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) such as a heart attack or stroke.

The active substance, clopidogrel, is an inhibitor of platelet aggregation. This means that it helps to prevent blood clots from forming. When the blood clots, this is due to special cells in the blood called platelets aggregating (sticking together). Clopidogrel stops the platelets aggregating by blocking a substance called ADP from attaching to a special receptor on their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming and helping to prevent another heart attack or stroke.

Clopidogrel Teva is a generic medicine based on a 'reference medicine', Plavix which is authorised in the EU.

Why was Clopidogrel Teva reviewed?

Teva Pharma B.V. submitted Clopidogrel Teva to Germany for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Germany) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as

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in other Member States (the 'concerned Member States', in this instance Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden and the United Kingdom).

As, the Member States were not able to reach an agreement, the German medicines regulatory agency referred the matter to the CHMP for arbitration on 29 October 2009.

The grounds for the referral were concerns from Sweden that patients would be exposed to the antioxidant butylated hydroxyanisole (BHA) unnecessarily. The company had chosen to use 'clopidogrel base' as the form of the active substance in the medicine, and not a salt such as the 'hydrogen sulfate salt' used in Plavix. Clopidogrel base is less stable than the salt form, and BHA is included in the medicine to stabilise it.

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Clopidogrel Teva outweigh its risks and recommended that the marketing authorisation be granted in all the concerned Member States.

The European Commission issued a decision on 2 June 2010.

Rapporteur:	Dr Harald Enzmann (Germany)
Co-rapporteur(s):	Prof Pieter de Graeff (the Netherlands)
Referral start date:	19 November 2009
Company responses provided on:	18 January 2010
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