European Medicines Agency

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Questions and answers on the referral for Betavert N tablets containing betahistine dihydrochloride (8 or 16 mg)

The European Medicines Agency (EMEA) has completed an arbitration procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Betavert N. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Betavert N outweigh its risks, and the marketing authorisation granted in Germany can be recognised in other Member States of the European Union.

What is Betavert N?
Betavert N is used to treat patients with Menière's disease. Menière's disease is a disease where an accumulation of fluid in the inner ear causes a build-up of pressure. Patients with Menière's disease have vertigo (a spinning sensation), often associated with feeling sick or vomiting, tinnitus (ringing in the ear) and hearing loss.

The active substance in Betavert N, betahistine, is an analogue of histamine, a naturally-occurring substance in the body that is involved in many processes. In Menière's disease, betahistine is thought to attach to some receptors to which histamine normally attaches. This allows a dilation of the blood vessels in the inner ear, thus helping the pressure to drop and relieving the symptoms of the disease.

Betavert N is a 'generic medicine'. This means that Betavert N is similar to a 'reference medicine' already authorised in the European Union (EU) called Betaserc 8.

Why was Betavert N reviewed?
Hennig Arzneimittel GmbH & Co. KG submitted Betavert N for mutual recognition on the basis of the initial authorisation granted by Germany on 18 April 2007. The company wanted the authorisation to be recognised in Austria, Bulgaria, the Czech Republic, Hungary, Poland, Romania and Slovakia (the concerned Member States).

However, the member states were not able to reach an agreement and the German medicines regulatory agency referred the matter to the CHMP for arbitration on 30 October 2008.

The grounds for the referral were concerns expressed by the Czech Republic that Betavert N had not been shown to be bioequivalent to Betaserc 8. Medicines are bioequivalent when they produce the same levels of active substance in the body.

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What are the conclusions of the CHMP?
Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP was of the opinion that bioequivalence between Betavert N and Betaserc 8 had been demonstrated. The CHMP therefore concluded that Betavert N could be considered a generic medicine of Betaserc 8, and the marketing authorisation for Betavert N should be granted in all concerned Member States.

The European Commission issued a decision on 2 June 2009.

Rapporteur:	Dr. Karl Broich (Germany)
Co-rapporteur:	Dr. Ondřej Slanař (Czech Republic)
Referral start date:	20 November 2008
Company responses provided on:	11 February 2009
Opinion date:	19 March 2009