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Questions and answers on Prevora (chlorhexidine diacetate, 100 mg/ml dental solution)

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 Prevora. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Prevora outweigh its risks, and the marketing authorisation granted in Ireland can be recognised in other Member States of the EU.

What is Prevora?

Prevora is a dental solution used to reduce dental caries (tooth decay) in permanent teeth of adolescents and adults. The active substance in Prevora, chlorhexidine, is an antiseptic. It works by disrupting the membrane of bacteria, fungi and other organisms, blocking their growth.

Prevora is applied to the surface of permanent teeth by a dental professional in two stages. First a chlorhexidine coating solution is applied followed immediately by an inert sealant coating.

Why was Prevora reviewed?

CHX Technologies Europe Limited submitted Prevora for mutual recognition on the basis of the initial authorisation granted by Ireland on 5 May 2006. The company wanted the authorisation to be recognised in United Kingdom (the 'concerned Member State').

However, the Member States were not able to reach an agreement and the Irish medicines regulatory agency referred the matter to the CHMP for arbitration on 26 November 2009.

The grounds for the referral were that the United Kingdom could not approve the proposed indication, prevention of root caries in adult patients at high-risk of dental caries. The United Kingdom had concerns that the results from the main study with Prevora were not sufficient to support the proposed indication, and that another study was needed to confirm the results seen to date with the medicine.

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What are the conclusions of the CHMP?

Based on evaluation of the newly available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Prevora outweigh its risks in the prevention of coronal and root caries in adult patients at high-risk of dental caries. Therefore the marketing authorisation for Prevora should be granted in the United Kingdom.

The amended information to healthcare professionals and patients is available here.

The European Commission issued a decision on 03 December 2010

Rapporteur:	Patrick Salmon (Ireland)
Co-rapporteur(s):	Ian Hudson (United Kingdom)
Procedure start date:	26 November 2009
Company responses provided on:	28 July 2010, 15 September 2010
Opinion date:	23 September 2010