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Questions and answers on Dexamed and associated names (dexamfetamine sulphate, 5 mg tablet)

Outcome of a procedure under Article 29(4) of Directive 2001/83/EC

On 22 May 2014, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Dexamed (dexamfetamine sulphate). The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Dexamed outweigh its risks, and the marketing authorisation can be granted in the United Kingdom and in the following countries: Denmark, Finland, Ireland, Luxembourg, the Netherlands, Norway, Spain and Sweden.

What is Dexamed?

Dexamed is a medicine that contains the active substance dexamfetamine sulphate. It is to be available as tablets (5 mg) for the treatment of children between 6 and 17 years of age who have attention deficit hyperactivity disorder (ADHD) and in whom methylphenidate (another medicine for ADHD) was not effective (second-line treatment). ADHD is a condition that mainly affects children, resulting in a persistent inability to concentrate, hyperactivity and impulsive behaviour.

Dexamfetamine belongs to a group of medicines called 'psychostimulants' and is thought to work by activating certain areas of the brain that control attention and concentration, thus helping to reduce impulsive behaviour.

Why was Dexamed reviewed?

Kohne Pharma GmbH submitted Dexamed to the UK medicines regulatory agency for a decentralised procedure. This is a procedure where one European country (the 'reference Member State', in this instance the United Kingdom) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other European countries (the 'concerned Member States', in this instance Denmark, Finland, Ireland, Luxembourg, the Netherlands, Norway, Spain, and Sweden).

However, the Member States were not able to reach an agreement and the UK medicines regulatory agency referred the matter to the CHMP for arbitration on 10 June 2013.

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The grounds for the referral were concerns raised by the Netherlands that Dexamed presents a higher risk for abuse and dependence compared with other ADHD treatments, and that the data submitted to support the application did not provide sufficient evidence to demonstrate its effectiveness as a second-line treatment for ADHD.

What are the conclusions of the CHMP?

Although the CHMP acknowledged that there is a risk of abuse and dependence with Dexamed, it concluded that the risk minimisation measures proposed to mitigate this risk are adequate. These conclusions were supported by a group of experts in childhood and adolescent behavioural problems consulted by the CHMP. The experts' group advised that while there is some evidence that medicines of the same type as Dexamed are more likely to induce dependence than other treatments for ADHD, based on clinical practice the risk of developing dependence in patients treated with dexamfetamine is considered to be low and could be adequately managed with appropriate risk minimisation measures.

These measures include starting and regularly monitoring treatment with Dexamed under the supervision of a doctor experienced in treating childhood and adolescent behaviour disorders. Educational material will be provided to doctors to help them decide if treatment with Dexamed is appropriate and to monitor patients receiving the medicine. Educational material will also be given to pharmacists, parents and carers to help them identify any potential abuse or improper use of Dexamed. Furthermore, the company that markets Dexamed will conduct additional studies on the risk of abuse for this medicine.

The CHMP also noted that evidence from studies and clinical practice is available to show that dexamfetamine is effective in ADHD, including in patients in whom other treatments have failed.

Therefore, based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Dexamed outweigh its risks for second-line treatment of ADHD and recommended that the marketing authorisation be granted in all concerned Member States.

The European Commission issued a decision on 06 August 2014.