10 January 2013
EMA/6929/2013
EMEA/H/A-107i/1352

Review of tetrazepam-containing medicines started

The European Medicines Agency (EMA) has started a review of tetrazepam-containing medicines because of concerns over serious skin reactions with these medicines.

Tetrazepam belongs to a group of medicines called benzodiazepines. It is used by mouth to treat painful muscle spasms (cramps) mainly in patients with rheumatological diseases (conditions characterised by inflammation, swelling and pain in the joints and muscles).

Following several reports of serious skin reactions in France, the French medicines agency performed a review of data on all side effects, especially skin reactions, recorded in the French National Pharmacovigilance database. The review showed that side effects affecting the skin occurred at a high rate in comparison with other benzodiazepines. In addition, concern was raised about the seriousness of some reported cases which include Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), erythema multiforme and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome.

The European Medicines Agency will review all available data on the safety of tetrazepam-containing medicines in particular skin reactions in order to assess any impact on the benefit-risk balance of these medicines.

The Agency invites all stakeholders (e.g. healthcare professionals, patients' organisations, the general public) to submit data relevant to this procedure. Full details are available under the 'data submission' tab.

More about the medicine

Tetrazepam-containing medicines have been approved via national procedures in several EU Member States (Austria, Belgium, Bulgaria, Czech Republic, France, Germany, Latvia, Lithuania, Luxembourg, Poland, Romania, Slovakia and Spain), and are available on prescription under various trade names and as generics. In France, tetrazepam-containing medicines have been authorised since 1967 and are among the most commonly used benzodiazepines.

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More about the procedure

The review of tetrazepam-containing medicines has been initiated at the request of France, under Article 107i of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As tetrazepam-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a regulatory body that represents national medicines regulatory authorities of the EU Member States.