European Medicines Agency

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Questions and answers on the referral for Myderison

tablets containing tolperisone hydrochloride 50 and 150 mg

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 Myderison. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Myderison do not outweigh its risks, and the marketing authorisation granted in Hungary cannot be recognised in other Member States of the EU. The marketing authorisation in Hungary should also be revocated.
The review was carried out under an 'Article 29' referral[1].

What is Myderison?
Myderison is a medicine that is used to treat skeletal muscle spasticity (stiffness of voluntary muscles). The active substance in Myderison, tolperisone, is a centrally acting muscle relaxant. The exact way tolperisone works is not known, but it is thought to act in the brain and spinal cord to reduce the nerve impulses that make the muscles contract and become rigid. By reducing these impulses, tolperisone is expected to reduce muscle contraction, helping to relieve the stiffness.

Why was Myderison reviewed?
Meditop Pharmaceutical Co. Ltd submitted Myderison for mutual recognition on the basis of the initial authorisation granted by Hungary on 28 March 2006. The company wanted the authorisation to be recognised in the Czech Republic, Germany, Lithuania, Poland and Slovakia (the concerned Member States). However, the Member States were not able to reach an agreement and the Hungarian medicines regulatory agency referred the matter to the CHMP for arbitration on 20 December 2008. The grounds for the referral were that the medicine did not meet the 'well established use' criteria. These are criteria a company can use to obtain access to the market for medicines where the active substance has been in used for a number of years, and the company can rely on published literature to support their application for marketing authorisation. In this instance, the concerns were that:

- efficacy and safety had not been sufficiently demonstrated;
- the company had not presented sufficient information on the way the medicine is dealt with by the body (pharmacokinetics);
- the dosing recommended in the prescribing information had not been adequately documented nor justified;
- interactions with other medicines had not been adequately evaluated in pre-clinical and clinical studies.

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 Myderison do not outweigh its risks, and therefore the marketing authorisation should not be granted in the concerned Member States. In addition the

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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Committee also required that the marketing authorisation for Myderison in Hungary should be revocated.

The European Commission issued a decision on 09 August 2010.

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