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PRAC recommends withdrawal of oral almitrine-containing medicines

Recommendation by PRAC to be considered by CMDh for final position

During its May 2013 meeting, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) concluded that the benefits of oral almitrine-containing medicines no longer outweigh their risks and recommended that all marketing authorisations for these medicines should be withdrawn across the European Union (EU).

The PRAC recommendation will be considered by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), a regulatory body representing EU Member States, which will take a final position.

Why are oral almitrine-containing medicines being reviewed?

The review was requested by the French medicines agency, the National Agency for the Safety of Medicine and Health Products (ANSM). Almitrine, taken by mouth, has been authorised in some EU Member States since 1982 for chronic respiratory failure (inability of the lungs to take in oxygen and get rid of carbon dioxide properly) which is associated with hypoxaemia (lower than normal levels of oxygen in the blood). Respiratory failure can be serious and life threatening in patients with lung conditions known as chronic obstructive pulmonary disease (COPD), in which the airways and air sacs inside the lungs become damaged or blocked. However, ANSM was concerned that almitrine treatment can lead to side effects including marked weight loss and peripheral neuropathy (nerve damage in the hands and feet) in some patients. In addition, the French Agency considered that the available evidence does not support a role for almitrine as part of current management of COPD as its benefit is unclear and alternative treatments are available.

What are the PRAC conclusions?

The PRAC considered that there is a clear association of oral almitrine treatment with weight loss and potentially serious and long-lasting peripheral neuropathy, and cases have continued to be reported despite restrictions in the use of the medicine. Furthermore, almitrine is not one of the treatments that are now recommended for management of COPD; the benefits of almitrine are not well established, and the company indicated that it could not carry out further studies to clarify them. The PRAC therefore concluded that the risks of oral almitrine-containing medicines outweighed their benefits, and recommended that their marketing authorisations should be withdrawn across the EU.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

What will happen next?

The PRAC recommendation will now be considered by the CMDh which will adopt a final position on the marketing authorisations for these medicines across the EU. The final CMDh position, together with advice for patients and healthcare professionals, will be made public.

Patients and healthcare professionals should note that oral almitrine-containing medicines are not yet withdrawn and a final decision is still pending. Once the procedure is finalised, the final decision will be communicated and healthcare professionals prescribing or dispensing oral almitrine in the EU countries where it is marketed will receive a letter with detailed information on the appropriate actions to be taken. Patients who have any questions should speak to their doctor or pharmacist.

More about the medicine

Almitrine is a respiratory stimulant, a medicine that stimulates the part of the brain responsible for the breathing reflex. In the EU, it is authorised in France, Poland and Portugal as 50-mg tablets (Vectarion, Armanor).

More about the procedure

The review of oral almitrine-containing medicines was initiated in December 2012 at the request of France, under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. As almitrine-containing medicines are all authorised nationally, the PRAC recommendation will now be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position on whether the marketing authorisations should be maintained, changed, suspended or withdrawn. The CMDh is a medicines regulatory body representing the EU Member States.

If the CMDh position is agreed by consensus, the agreement will be directly implemented by the Member States where the medicines are authorised. Should the CMDh position be adopted by majority vote, the CMDh position will be sent to the European Commission, for the adoption of an EU-wide legally binding decision.