European Medicines Agency

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QUESTIONS AND ANSWERS ON THE RECOMMENDATION TO SUSPEND THE MARKETING AUTHORISATIONS FOR CARISOPRODOL-CONTAINING MEDICINES

The European Medicines Agency (EMEA) has completed a review of the safety of carisoprodol. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of medicines containing carisoprodol no longer outweigh their risks, and that all marketing authorisations for these products should be suspended throughout Europe.

What is carisoprodol?
Carisoprodol is a medicine that is used for the treatment of pain, mainly acute (short-lived) lower back pain. It works within nerve cells in the brain and spinal cord, helping to reduce pain by causing muscles to relax.

Medicines containing carisoprodol have been available since 1959. They include tablets containing carisoprodol on its own, or in combination with paracetamol or other medicines. They are authorised in 12 Member States[1] under various trade names[2]. The medicines can only be obtained with a prescription.

Why was carisoprodol reviewed?
In March 2007, the Norwegian medicines regulatory authority completed a review of the benefits and risks of carisoprodol, after it had become aware of new information on an increased risk of abuse and addiction in Norwegian patients, as well as a risk of causing intoxication (affecting mental state) and psychomotor impairment (unusual thoughts and difficulty co-ordinating movements). On the basis of this new information, the Norwegian authority concluded that the risks of carisoprodol outweighed its benefits, and that the medicine should no longer be available on the Norwegian market.

Consequently, the Norwegian authority wrote to the company that markets carisoprodol in Norway asking it to withdraw its marketing authorisation for carisoprodol-containing medicines. On 29 March 2007, the company agreed to this withdrawal. The Norwegian authority plans to withdraw all marketing authorisations in Norway permanently from 1 May 2008.

As required by Article 107 of Directive 2001/83/EC as amended, the Norwegian authority informed the CHMP of its action so that the Committee could prepare an opinion on whether the marketing authorisations for all products containing carisoprodol should be maintained, changed, suspended or withdrawn across the European Union (EU).

Which data has the CHMP reviewed?
In the current review, the CHMP looked at all available information on the safety of carisoprodol, especially its potential for causing addiction, intoxication and psychomotor impairment. This information came from the companies that market carisoprodol-containing medicines in Europe. It also included reports of side effects in patients taking the medicine and one new study looking at levels of the medicine in the blood of volunteers taking it. It also included information from the published scientific literature.

[1] Carisoprodol-containing medicines are available in the Czech Republic, Denmark, Finland, Greece, Hungary, Iceland, Italy, Norway, Slovakia, Spain, Sweden and the United Kingdom.
[2] Carisoprodol-containing medicines include Somadril, Somadril comp, Carisoma, Soma Complex, Scutamil C, Relacton-C, Mio Relax and Relaxibys.

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What are the conclusions of the CHMP?
Based on the information provided, the CHMP has concluded that:

- there is a risk of abuse and addiction, intoxication and psychomotor impairment with carisoprodol;
- alternative medicines are available for the treatment of lower back pain. These seem to be as effective as carisoprodol and have a better safety profile.

The Committee also noted that blood levels of carisoprodol are often higher than expected, even when patients take the recommended dose of the medicine. This means that patients taking the medicine may inadvertently have levels of carisoprodol in the blood that could be unsafe. This may make it difficult for the medicine to be used safely.

In the light of these findings, the CHMP concluded that the risks of carisoprodol outweigh its benefits. Therefore, the Committee recommended that the marketing authorisations of medicines containing carisoprodol be suspended in all EU markets.

What are the recommendations for patients and prescribers?

- Patients who are currently taking carisoprodol should consult their doctor or pharmacist to discuss which other treatment they can use.
- Prescribers should not issue any new prescriptions for carisoprodol and should switch patients currently taking the medicine to an alternative treatment if necessary. Patients should not stop taking carisoprodol abruptly, but should seek advice from their doctor on other treatment options
- Patients who have any questions should speak to their doctor or pharmacist.

A European Commission Decision on this opinion will be issued in due course.