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Press Office

**Press release**

# European Medicines Agency recommends suspension of marketing authorisations for meprobamate-containing medicines in the European Union

## Gradual withdrawal period of 15 months recommended

The European Medicines Agency has recommended the suspension of all marketing authorisations for meprobamate-containing medicines for oral use in the European Union, because their risks, particularly the risk of serious side effects affecting the nervous system, are greater than their benefits. To ensure prescribers have enough time to determine the most appropriate treatments for individual patients, the Committee has recommended that the withdrawal of the medicines from the market be carried out gradually, within 15 months of the European Commission decision.

Doctors should stop prescribing meprobamate-containing medicines over the next 15 months and consider alternative treatments in line with national recommendations for the condition being treated. Patients currently taking the medicines should discuss their treatment with their doctor at their next routine appointment.

Meprobamate is a sedative medicine used to treat the symptoms of anxiety and related conditions, including anxiety states, alcohol withdrawal, migraine attacks, digestive disorders, muscle tension or cramps, and insomnia.

The review of meprobamate-containing medicines was started because the French authorities announced in July 2011 their intention to suspend the marketing authorisations for oral meprobamate-containing medicines because of serious side effects seen with these medicines.

The Agency's Committee for Medicinal Products for Human Use (CHMP) reviewed all available data on the safety and efficacy of these medicines, including data from studies, post-marketing surveillance and the published literature, as well as from poison control centres on cases of poisoning with meprobamate.

The CHMP noted that there was a risk of serious and potentially fatal side effects, such as coma, in patients taking meprobamate-containing medicines under normal conditions of use. The Committee considered that these risks were increased due to the danger of unintentional overdose because of the small difference between the treating dose and the dose that can harm patients, including elderly

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people. The CHMP also noted that some patients can become addicted to the medicine, leading to serious and sometimes fatal side effects if they stop treatment abruptly after using it for a long time.

The Committee concluded that the benefits of meprobamate-containing medicines for oral use do not outweigh their risks.

## Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Meprobamate-containing medicines have been authorised in a number of EU Member States for several decades via national procedures. They are currently authorised in France, the Netherlands, Finland, Hungary, Italy, Romania, the United Kingdom, Iceland and Norway under the invented name Equanil and other trade names.
3. The review was carried out under Article 107 of Directive 2001/83/EC, as amended. This type of procedure is triggered when a Member State varies, suspends or revokes the marketing authorisation for a medicine in its territory because of a safety issue.
4. The Committee's opinion has been forwarded to the European Commission for the adoption of a decision.
5. All other opinions and documents adopted by the CHMP at its January 2012 plenary meeting will be published on Friday, 20 January 2012 at 12.00 noon UK time on a dedicated web page.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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