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Press Office

Press release

European Medicines Agency recommends approval of medicine for reduction of alcohol consumption

Selincro offers treatment in conjunction with psychosocial support

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the granting of a marketing authorisation for Selincro, a medicinal product intended for the reduction of alcohol consumption in adults with alcohol dependence.

Selincro is indicated to help lower alcohol consumption in adults with alcohol dependence who have a high drinking risk level (consumption of more than 60 g of alcohol per day for males, and more than 40 g of alcohol per day for females), who do not have physical withdrawal symptoms and who do not require immediate detoxification.

The Committee also recommended that Selincro should be prescribed in conjunction with continuous psychosocial support that focuses on treatment adherence and reducing alcohol consumption. The medicine should only be prescribed to patients who continue to have a high drinking risk level two weeks after initial assessment.

The active substance of Selincro is nalmefene. Nalmefene is an opioid receptor antagonist, which means it blocks the action of certain receptors in the brain called 'opioid receptors', which are involved in the complex process of alcohol dependence.

Impact of harmful alcohol use on public health

Alcohol dependence is a psychiatric disorder with harmful physical, mental and social consequences. It is characterised by craving, tolerance, a preoccupation with alcohol and continued drinking in spite of harmful effects.

It is considered a major public-health problem. In Europe, the prevalence of alcohol dependence is estimated at 5-6% in men and 1-2% in women. Harmful use of alcohol is related to premature death and avoidable disease, and is a major avoidable risk factor for neuropsychiatric disorders, cardiovascular diseases, cirrhosis of the liver and cancer.

According to the Agency's 'Guideline on the development of medicinal products for the treatment of alcohol dependence', adopted by the CHMP in 2010, the ultimate treatment goal in alcohol-dependent

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patients is abstinence, reduction in frequency and severity of relapse, and improvement in health and psychosocial functioning.

The CHMP's opinion on Selincro will now be sent to the European Commission for the granting of a marketing authorisation.

Notes

1. This press release, together with all related documents, is available on the European Medicines Agency's website.
2. A bottle of wine (750 ml; 12% alcohol by volume) contains approximately 70 g alcohol and a bottle of beer (330 ml; 5% alcohol by volume) contains approximately 13 g alcohol.
3. Guideline on the development of medicinal products for the treatment of alcohol dependence: http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500074898&mid=WC0b01ac058009a3dc
4. The applicant for Selincro is Lundbeck.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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