

## NEWS

# German evaluation says new drug for alcohol dependence is no better than old one

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Germany's scientific institute for evaluating the effectiveness of medicines has concluded that studies of the alcohol dependence drug nalmefene offers no additional benefits to naltrexone, an older and less costly comparator therapy.

The assessment, by the Institute for Quality and Efficiency in Health Care, widely known as IQWiG, is in contrast to an assessment issued in October by the UK's National Institute for Health and Care Excellence (NICE), which recommended nalmefene as a "possible treatment" for alcohol dependence.<sup>1</sup> With 28 nalmefene tablets—one month's worth—costing £84.84 (€108; \$132), the NICE recommendation was criticised by some.<sup>2</sup>

The IQWiG assessment that an added benefit of nalmefene over naltrexone has not yet been proved will be forwarded to Germany's Federal Joint Committee (G-BA),<sup>3</sup> which determine coverage guidelines for nalmefene within Germany's public health insurance system and an acceptable price level.

Nalmefene, an opioid receptor modulator marketed under the trade name Selincro by the Danish firm H Lundbeck A/S, was given a "positive opinion" in December 2012 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).<sup>4</sup> At the time, Lundbeck issued a press release announcing the committee's positive opinion.<sup>5</sup>

The EMA accepted the positive opinion and granted European market authorisation in February 2013 for nalmefene to be used as a prescription drug in conjunction with psychological support to help alcohol dependent adults reduce consumption.<sup>6</sup> The EMA decision was criticised by some, including Glasgow general practitioner Des Spence writing in *The BMJ*.<sup>7</sup>

For its assessment, IQWiG analysed studies and material submitted by Lundbeck and was not convinced that nalmefene has added benefit when compared with naltrexone, which has been used since the 1990s to treat alcohol dependence.

Of the 11 studies cited by Lundbeck, IQWiG said four investigated the effect of nalmefene in comparison with placebo in alcohol dependent people who still consumed alcohol with the goal to reduce consumption. The remaining seven studies investigated the effect of naltrexone in comparison with placebo. In six of those seven naltrexone studies, the treatment goals were not reduced alcohol consumption as in the four nalmefene studies, but rather abstinence and prevention of relapse of people who already had quit drinking for at least "several days," according to IQWiG.<sup>8</sup>

"A comparison with nalmefene patients with a current high level of alcohol consumption with naltrexone patients who are already abstinent cannot be interpreted in a meaningful way also with regard to outcomes like change in drinking behaviour," IQWiG said. "Hence these studies provide no suitable data for the indirect comparison of nalmefene and naltrexone."

Alain Braillon, a public health doctor in Amiens, France, who in a March 2014 letter to *The BMJ*<sup>9</sup> criticised the EMA's approval of nalmefene, applauded the new IQWiG assessment. He told *The BMJ*: "IQWiG has made a fine and wise assessment using just simple common sense."

Niamh Fitzgerald, a trained pharmacist and now a lecturer in alcohol studies at the University of Stirling in Scotland, agreed with IQWiG's assessment of nalmefene. She said, "To my knowledge no trials have been conducted directly comparing the two drugs and indirect comparison is hampered by the variation in studies and the highly specific patient group in whom nalmefene is licensed for use. I have not seen any evidence that nalmefene has superior efficacy to naltrexone."

**thebmj.com** From the Frontline: Bad medicine: nalmefene in alcohol misuse. *BMJ* 2014;348:g1531.

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