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Start of union reviews

CHMP meeting of 16-19 June 2025

Table 1. Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
Sodium oxybate (in alcohol dependence)	sodium oxybate	Article 31 of Directive 2001/83/EC	Procedure triggered by France (ANSM) asking for an opinion on the benefit-risk balance of sodium oxybate-containing medicinal products in alcohol dependence as well as pending marketing authorisation applications in these indications due to concerns about efficacy and the risks of abuse and misuse.

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