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Start of union reviews

CHMP meeting of 21-24 June 2021

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

Name	INN	Type of procedure	Scope
Etifoxine-containing medicinal products	etifoxine	Article 31 of Directive 2001/83/EC	Procedure triggered by France asking to review the benefit/risk balance of etifoxine containing products, in light of the new results from the AMETIS study which failed to demonstrate any significant difference in terms of efficacy for etifoxine versus either placebo or the active comparator, lorazepam.