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EMA/493380/2023
Press Office

Start of union reviews

CHMP meeting of 6-9 November 2023

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

Name	INN	Type of procedure	Scope
Azithromycin	azithromycin	Article 31 of Directive 2001/83/EC	Procedure triggered by Germany asking the CHMP for an opinion to re-evaluate the benefit-risk balance of the azithromycin-containing products for systemic use in their approved indications considering the current scientific knowledge including increasing antimicrobial resistance, high consumption in the EU and data suggesting overuse, as well as different and broad indications in EU Member States. The CHMP will review all available information on the benefits and risks of azithromycin and will consider whether any changes are required to its approved uses across EU Member States.

