26 January 2023
EMA/29414/2023
Press Office

Start of union reviews

CHMP meeting of 23-26 January 2023

Table 1. Start of reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Adakveo	crizanlizumab	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of Adakveo. This follows information provided by the company (Novartis Europharm Limited) on the first interpretable results of a phase III A2301 study (STAND). It shows that neither the primary nor the key secondary endpoint (i.e. annualized rates of VOC leading to healthcare visit, or leading to healthcare visit and treated at home combined) with crizanlizumab were met. In light of the current emerging data,

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Name	INN	Type of procedure	Scope
			there is a need to review the findings in the context of all available data and assess their potential impact on the benefit-risk of Adakveo in its approved indication.

Table 2. Start of scientific review

Name	INN	Type of procedure	Scope
Colistimethate Sodium	Colistimethate	Article 5(3) of Regulation (EC) No 726/2004	Procedure triggered by EMA asking for a CHMP scientific opinion on the impact of different ratios for the colistimethate sodium subcomponents as established in the active substance *Ph. Eur.* Monograph, and the safe range for the composition profile in the finished product.