

31 January 2019 EMA/65306/2019 Press Office

Start of union reviews

CHMP meeting of 28-31 January 2019

Table 1. Start of reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Lartruvo	olaratumab	Article 20 of Regulation (EC) No 726/2004	Procedure triggered by the European Commission asking to CHMP to assess the results of the ANNOUNCE (JGDJ) study and its impact on the benefit-risk balance of Lartruvo.

Table 2. Start of scientific review

Name	INN	Type of procedure	Scope
Direct oral anticoagulants (DOACs)	apixaban, dabigatran etexilate, rivaroxaban	Article 5(3) of Regulation (EC) No 726/2004	Procedure triggered by EMA asking for a scientific opinion on the results of a study with the direct oral anticoagulants Eliquis (apixaban), Pradaxa (dabigatran etexilate) and Xarelto (rivaroxaban). Results from this study show differences in the risk of major bleedings between these medicines and concerns about the adherence in clinical practice to restrictions, special warnings and precautions about the medicines.