

31 May 2018 EMA/353695/2018 Press Office

Start of community reviews

CHMP meeting of 18-31 May 2018

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

Name	INN	Type of procedure	Scope
Metamizole containing medicinal products	metamizole	Article 31 of Directive 2001/83/EC	Procedure triggered by Poland asking for an opinion on whether the scientific data regarding the maximum daily dose and contraindications concerning pregnancy and lactation are adequately presented in the product information of metamizole containing medicinal products

Table 2. Start of scientific review

Name	INN	Type of procedure	Scope
Norethisterone and ethinylestradiol	Norethisterone and ethinylestradiol	Article 5(3) of Regulation (EC) No 726/2004	Procedure triggered by the UK asking for a scientific opinion whether the zebrafish model is a reliable model for studying developmental effects and whether the effects seen with the Norethisterone and ethinylestradiol have clinical significance in case of foetal exposure during pregnancy.