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Press Office

Start of union reviews

CHMP meeting of 16-19 September 2019

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

Name	INN	Type of procedure	Scope
Ranitidine-containing medicinal products	ranitidine	Article 31 of Directive 2001/83/EC	Procedure triggered by the European Commission asking for an opinion on the benefit-risk balance of ranitidine containing medicinal products due to concerns over preliminary results showing the presence of N-Nitrosodimethylamine (NDMA) in some batches of drug substance and drug product and preliminary findings that NDMA could be generated under certain conditions in vivo.

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