

22 April 2022 EMA/226804/2022 Press Office

## Start of union reviews

CHMP meeting of 19-22 April 2022

Table 1. Start of reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Rubraca	Rucaparib	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking to CHMP to review the detrimental effect in terms of overall survival seen in a clinical study aiming to confirm the efficacy and safety of Rubraca in the approved '3rd line or more treatment' indication, in the context of all available data, and assess their potential impact on the benefit/risk of Rubraca in that indication. In addition, the EC requested the CHMP to give its opinion, as soon as possible, as to whether temporary

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			measures are necessary to ensure the safe and effective use of this medicinal product.