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Press Office

Start of union reviews

CHMP meeting of 24-27 February 2020

Table 1. Start of review for centrally authorised medicines

Name	INN	Type of procedure	Scope
Yondelis	trabectedin	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of Yondelis. The review started after a clinical trial investigating the use of Yondelis in patients with ovarian cancer was stopped due to lack of survival superiority. Differences are noted in the design and conduct of this trial compared to the one supporting the initial marketing authorisation, however some patients included belong to the broader patient population with ovarian cancer for whom Yondelis is indicated.

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Name	INN	Type of procedure	Scope
			Therefore, the impact of these findings on the benefit-risk balance of Yondelis in the ovarian cancer indication needs to be assessed.

Table 2. Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
Medicinal products which have been authorised or are pending approval based on clinical trials performed at Panexcell Clinical Laboratories Priv. Ltd	Various	Article 31 of Directive 2001/83/EC	Procedure triggered by Germany asking for an opinion on the benefit-risk balance of medicinal products which have been authorized in the EU as well as for pending procedures, based on clinical trials performed by Panexcell Clinical Laboratory Priv. Ldt., Navi Mumbai 400 701, India. This follows an inspection by the Austrian and German authorities which raised serious concerns in relation to the suitability of the quality management system and about the overall reliability of data generated by this CRO.