EMA/66011/2021

Ulipristal Acetate Gedeon Richter

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
A31/0002	Pursuant to Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data, on 5 March 2020, the European Commission requested the European Medicines Agency to assess the risk of severe liver injury and their impact on the benefit-	12/11/2020	11/01/2021	SmPC, Annex II, Labelling and PL	Please refer to the CHMP scientific conclusions and PRAC assessment report: Ulipristal acetate 5mg: EMEA/H/A-31/1496

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	risk balance of ulipristal acetate 5mg and to give its opinion, on whether the marketing authorisations for ulipristal acetate 5mg medicinal products should be maintained, varied, suspended or revoked. As the request results from the evaluation of data resulting from pharmacovigilance activities, the CHMP opinion was adopted on the basis of an assessment by the Pharmacovigilance Risk Assessment Committee.				
PSUSA/9325/ 201902	Periodic Safety Update EU Single assessment - ulipristal acetate (treatment of moderate to severe symptoms of uterine fibroids)	05/09/2019	n/a		PRAC Recommendation - maintenance