EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Duzallo

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
PSUSA/10704 /201912	Periodic Safety Update EU Single assessment - allopurinol / lesinurad	09/01/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10704 /201906	Periodic Safety Update EU Single assessment - allopurinol / lesinurad	16/01/2020	n/a		PRAC Recommendation - maintenance
IB/0003	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a	26/08/2019	n/a		

[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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	re-test period/storage period supported by real time data				
IB/0002/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	31/07/2019		SmPC, Labelling and PL	
PSUSA/10704 /201812	Periodic Safety Update EU Single assessment - allopurinol / lesinurad	11/04/2019	n/a		PRAC Recommendation - maintenance