Zynquista (SRD)

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/10766 /202104	Periodic Safety Update EU Single assessment - sotagliflozin	02/12/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10766 /202010	Periodic Safety Update EU Single assessment - sotagliflozin	10/06/2021	n/a		PRAC Recommendation - maintenance

[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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PSUSA/10766 /202004	Periodic Safety Update EU Single assessment - sotagliflozin	26/11/2020	n/a		PRAC Recommendation - maintenance
IAIN/0005	A.1 - Administrative change - Change in the name and/or address of the MAH	24/09/2020	24/01/2022	SmPC, Labelling and PL	
PSUSA/10766 /201910	Periodic Safety Update EU Single assessment - sotagliflozin	14/05/2020	n/a		PRAC Recommendation - maintenance
T/0002	Transfer of Marketing Authorisation	18/12/2019	23/01/2020	SmPC, Labelling and PL	
IB/0001	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	05/08/2019	n/a		