Tadalafil Lilly

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/2841/ 202210	Periodic Safety Update EU Single assessment - tadalafil	22/06/2023	23/08/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2841/202210.
IG/1620	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished	01/08/2023	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).

	product formulation - Change that does not affect the product information				
R/0008	Renewal of the marketing authorisation.	16/09/2021	12/11/2021	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Tadalafil Lilly in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/03/2021	12/11/2021	Labelling	
WS/1940	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/01/2021	12/11/2021	SmPC, Annex II, Labelling and PL	
PSUSA/2841/ 201910	Periodic Safety Update EU Single assessment - tadalafil	11/06/2020	n/a		PRAC Recommendation - maintenance
IG/1133	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	14/08/2019	n/a		
IG/0914	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	15/03/2018	n/a		

IB/0002	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/01/2018	n/a		
IB/0001/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/06/2017	31/05/2018	SmPC, Labelling and PL	