Viagra

Procedural steps taken and scientific information after the authorisation*

*Due to Agency`s update of its procedure management systems, an additional document, capturing the historical lifecycle may be available in the 'Assessment history' section. For the complete lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I.11 Introduction of, or change(s) to, the	28/08/2024	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).

EMA/VR/0000183094	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.a Implementation of wording agreed by the competent authority - Accepted To update the RMP following assessment as part of EMEA/H/C/PSUSA/00002699/202112 and EMEA/H/C/000202/X/0115.				
Article 61(3) / EMA/N/0000224658	- Notification acc. Article 61(3) - Update of the package leaflet with revised contact details of local representatives. Additionally, the MAH took the opportunity to introduce a minor linguistic amendment to the Italian translation.	21/08/2024		PL	