Harvoni

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to 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 /	This was an application for a group of	09/01/2026	N/A		To update the RMP by removing the 'Specific

[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/0000311080	variations. C.I.11 Introduction of, or change(s) to, the 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 C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) – To update the RMP by removing the 'Specific Adverse Reaction Follow up Questionnaires' (i.e. targeted questionnaires) for Bradyarrhythmia. C.I.11.a (Type IA_IN) – To update the RMP by removing the following Important Identified Risks (IIRs), both requested by PRAC during the last Harvoni Periodic Safety Update Report (PSUR) procedure EMA/PSUR/0000248480: (1) "Severe bradycardia and heart block when used with concomitant amiodarone" and (2) "HBV reactivation in HBV/HCV coinfected patients". In addition, the MAH took the opportunity to update the post-authorisation exposure data (Section SV.1.2).				Adverse Reaction Follow up Questionnaires' (i.e. targeted questionnaires) for Bradyarrhythmia. To update the RMP by removing the following Important Identified Risks (IIRs), both requested by PRAC during the last Harvoni Periodic Safety Update Report (PSUR) procedure EMA/PSUR/0000248480: (1) "Severe bradycardia and heart block when used with concomitant amiodarone" and (2) "HBV reactivation in HBV/HCV coinfected patients". In addition, the MAH took the opportunity to update the post-authorisation exposure data (Section SV.1.2).

PSUR / EMA/PSUR/0000248480	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the benefit-risk balance of medicinal products containing sofosbuvir / ledipasvir remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).