EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PROVENGE

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/10065	Periodic Safety Update EU Single assessment - AUTOLOGOUS PERIPHERAL BLOOD MONONUCLEAR CELLS ACTIVATED WITH PAP-GM-CSF (SIPULEUCEL-T)	07/05/2015	n/a		PRAC Recommendation - maintenance
IB/0005	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	07/01/2015	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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IB/0006	B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	17/12/2014	n/a		
IB/0004	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	09/12/2014	n/a		
PSUV/0001	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance
IA/0002	C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	18/06/2014	n/a		