EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

# Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): talimogene laherparepvec

Procedure No. EMEA/H/C/PSUSA/00010459/201710

Period covered by the PSUR: 27 April 2017 to 26 October 2017

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**Scientific conclusions and grounds for variation to the terms of the marketing authorisations**

'Accidental exposure of health care provider (HCP)' is an important identified risk and 'Transmission of Talimogene Laherparepvec from patient to close contacts or HCPs via direct contact with injected lesions or body fluids resulting in symptomatic infection (primary or reactivation)' is an important potential risk for the use of talimogene laherparepvec. In view of suspected herpetic infection events as well as quantitative PCR-confirmed infections, the PRAC considered that the overall monitoring of herpetic infections should be improved. Therefore, additional wording regarding the possibility of qPCR-testing for talimogene laherparepvec should be included in section 4.4 of the SmPC through the amendment of the existing warning regarding accidental exposure to Imlygic, and section 2 of the Package Leaflet in order to improve the screening for transmission of talimogene laherparepvec.