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): vismodegib

Procedure No. EMEA/H/C/PSUSA/00010140/201601

Period covered by the PSUR: 30 July 2015 – 29 January 2016

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for vismodegib, the scientific conclusions of the CHMP are as follows:

Following recent enquiries from pharmacists and prescribers received in the past months regarding prescribing and dispensing restrictions for women of childbearing potential (WCBP), it came to the PRAC's attention that the current warning in the Erivedge SmPC is not clear. The current warning in the SmPC outlines that the initial prescription and dispensing of Erivedge should occur within 7 days of a negative pregnancy test. However, the PRAC considered unclear if the day of negative pregnancy test is counted as day 0 or as day 1. Considering that it is currently a matter of interpretation if the period is actually 8 days (with the day of the negative pregnancy test counted as day 0) or 7 days (with the day of the negative pregnancy test counted as day 1), the PRAC recommended to clarify the current warning in the SmPC by specifying that the day of the negative pregnancy test should be counted as day 1.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information and conditions of the marketing authorisation of medicinal products containing vismodegib were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for vismodegib, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing vismodegib is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.