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): paclitaxel albumin

Procedure No. EMEA/H/C/PSUSA/00010123/201901

Period covered by the PSUR: 05 January 2016 To: 05 January 2019

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for paclitaxel albumin, the scientific conclusions of CHMP are as follows:

Following the analysis of case reports of scleroderma, published in literature during the reporting period, describing the temporal relationship with administration of the drug or reduction of the dose, a causal association for nab-paclitaxel is considered likely. Taking into account the seriousness of the event, as well as the fact that scleroderma is included in the SmPC of several solvent-based paclitaxel products, the MAH is requested to add scleroderma to section 4.8 of the SmPC with frequency not known. The PL should be updated accordingly.

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

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for paclitaxel albumin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing paclitaxel albumin is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.