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): doxorubicin

Procedure No. EMEA/H/C/PSUSA/00001172/202211

Period covered by the PSUR: 12/11/2021 To: 12/11/2022



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**Scientific conclusions**

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

In view of available data on interstitial lung disease from the literature and spontaneous reports including in some cases a close temporal relationship, the PRAC considers a causal relationship between pegylated liposomal doxorubicin and interstitial lung disease is at least a reasonable possibility. The PRAC concluded that the product information of products containing pegylated liposomal doxorubicin should be amended 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 doxorubicin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing doxorubicin 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.