EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2022
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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): dasatinib

Procedure No. EMEA/H/C/PSUSA/00000935/202106

Period covered by the PSUR: 27 June 2020 to 27 June 2021

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Scientific conclusions

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

In view of available data on chylothorax from clinical trial(s), the literature, spontaneous reports including in 13 cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between dasatinib and chylothorax is at least a reasonable possibility. The PRAC concluded that the product information of products containing dasatinib 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 dasatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dasatinib 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.