

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

Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product(s) mentioned above, the scientific conclusions of CHMP are as follows:

The study results do not show an increase in the risk of death or cancer-specific death within the scope of the currently authorised therapeutic indication (third and later lines of therapy or in patients ineligible for any available systemic metastatic castration-resistant prostate cancer treatment). Therefore, in view of available data regarding the PASS final study report, the PRAC considered that removal of the condition of the marketing authorisation and respective changes to the Risk Management Plan were warranted.

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 the results of the study for the medicinal product(s) mentioned above, the CHMP is of the opinion that the benefit-risk balance of these medicinal product(s) is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation(s) of the medicinal product(s) mentioned above should be varied.