20 July 2023
EMA/355994/2023
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): tozinameran (COMIRNATY), tozinameran/riltozinameran (COMIRNATY Original/Omicron BA.1), tozinameran/famtozinameran (COMIRNATY Original/Omicron BA.4-5)

Procedure No. EMEA/H/C/PSUSA/00010898/202212

Period covered by the PSUR: 17 June 2022 To: 17 December 2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for tozinameran (COMIRNATY), tozinameran/riltozinameran (COMIRNATY Original/Omicron BA.1), tozinameran/famtozinameran (COMIRNATY Original/Omicron BA.4-5), the scientific conclusions of CHMP are as follows:

In view of available data on myocarditis and pericarditis from the literature and spontaneous reports, the PRAC considers that the current warning on this risk should be amended to reflect the clinical course and outcome (including very rare fatal outcome) of Comirnaty associated myocarditis/pericarditis. The PRAC concluded that the product information of products containing tozinameran, tozinameran/riltozinameran, tozinameran/famtozinameran 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 tozinameran (COMIRNATY), tozinameran/riltozinameran (COMIRNATY Original/Omicron BA.1), tozinameran/famtozinameran (COMIRNATY Original/Omicron BA.4-5) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tozinameran (COMIRNATY), tozinameran/riltozinameran (COMIRNATY Original/Omicron BA.1), tozinameran/famtozinameran (COMIRNATY Original/Omicron BA.4-5) 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.