21 March 2024
EMA/238395/2024
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): Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)

Procedure No. EMEA/H/C/PSUSA/00010119/202307

Period covered by the PSUR:
31/01/2023 To 31/07/2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara), the scientific conclusions of PRAC are as follows:

In view of available data on Facial paralysis / Bell's palsy from spontaneous reports with a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara) and Acute peripheral facial paralysis (Bell's palsy) is at least a reasonable possibility. Further, following the confirmation of the signal of "syncope / loss of consciousness", a special warning and precaution as common medical practice for injectable vaccines is endorsed. The PRAC concluded that the product information of products containing Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara) 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.