25 April 2025
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): measles / mumps / rubella / varicella vaccines (live)

Procedure No. EMEA/H/C/PSUSA/00001936/202409

Period covered by the PSUR:
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Annex IV

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for measles / mumps / rubella / varicella vaccines (live), the scientific conclusions of PRAC are as follows:

In view of available data on the literature regarding congenital rubella syndrome in pregnancy, the PRAC concluded that the product information of ProQuad (measles / mumps / rubella / varicella vaccines (live)) 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 measles / mumps / rubella / varicella vaccines (live) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing measles / mumps / rubella / varicella vaccines (live) 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.