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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): rotavirus vaccine pentavalent (live, oral)

Procedure No. EMEA/H/C/PSUSA/00002666/201911

Period covered by the PSUR: 28/11/2018 To: 27/11/2019

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for rotavirus vaccine pentavalent (live, oral), the scientific conclusions of CHMP are as follows:

In view of sparse information that a recommendation of deferring live vaccines if exposed to a biologic in the third trimester was not always observed, and in line with the PRAC decision from January 2019 considering the statement in the SmPC that the "Administration of [RV] to infants who have known or suspected immunodeficiency, including in utero exposure to an immunosuppressive treatment, should be based on careful consideration of potential benefits and risks" it is recommended that that the product information of products containing Rotavirus vaccine (live) 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 rotavirus vaccine pentavalent (live, oral) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rotavirus vaccine pentavalent (live, oral) 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.