EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): dengue tetravalent vaccine (live, attenuated)

Procedure No. EMEA/H/C/PSUSA/00011034/202308

Period covered by the PSUR:
18/02/2023 To: 18/08/2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for dengue tetravalent vaccine (live, attenuated) [Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated / Dengue virus, serotype 2, live, attenuated.], the scientific conclusions of PRAC are as follows:

During the reporting period 2 cases had a positive laboratory dengue test: 1 case from Germany tested positive for dengue virus with PCR test, this case was likely vaccine viremia since Germany is no endemic country; 1 case from Indonesia tested positive for dengue virus with NS1 test, this case could be true positive considering the endemic country. Considering that interpretation of dengue diagnostic tests post vaccination is complex, healthcare professionals should be made aware that diagnostic tests can be positive after vaccination and are not able to distinguish between vaccine and wild type virus. It is proposed to add additional information to SmPC section 4.8 in the existing subsection on Vaccine viremia to make healthcare professionals aware of the possibility of positive dengue diagnostic tests after vaccination.

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 dengue tetravalent vaccine (live, attenuated) [Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated / Dengue virus, serotype 2, live, attenuated.] the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dengue tetravalent vaccine (live, attenuated) [Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated / Dengue virus, serotype 2, live, attenuated.] 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.