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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 monovalent (live, oral)

Procedure No. EMEA/H/C/PSUSA/00002665/201807

Period covered by the PSUR: 12 July 2017 - 11 July 2018

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

- Infants who have known or suspected immunodeficiency

Section 4.4 of the SmPC of Rotarix includes a warning on administration of Rotarix to infants who have known or suspected immunodeficiency. Besides, the SmPC of immunosuppressive therapies, such as adalimumab, infliximab, includes a recommendation to defer live vaccine administration in infants who were exposed in utero to these treatments. Bond et al. (2018) suggested some non-compliance to such recommendation in a recent conference abstract. In order to strengthen the current warning on administration of Rotarix to infants who have known or suspected immunodeficiency, it is recommended to update the current warning.

- Urticaria

Despite a low reporting rate of urticaria events (i.e. 0.013 cases per 100,000 doses distributed), some spontaneous cases suggested a possible association between Rotarix vaccination and urticaria. This was supported by a very short time-to-onset (from immediate onset to a few hours), the absence of co-administered vaccines or drugs, and the rapid resolution of the event, with or without treatment. These data are considered sufficient to support the inclusion of urticaria in section 4.8 of the SmPC with the frequency very rare, as the SmPC guideline recommends to list in section 4.8 all adverse reactions for which, after a thorough assessment, a causal relationship between the medicinal product and the adverse event is at least a reasonable possibility.

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 monovalent (live, oral) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rotavirus vaccine monovalent (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.