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): rotavirus vaccine monovalent (live, oral)

Procedure No. EMEA/H/C/PSUSA/00002665/201607

Period covered by the PSUR: 12.07.2015-11.07.2016

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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:

No new important risks have been identified during the reporting period of this periodic safety update report (PSUR). However, regarding the risk of intussusception, data of a study (Stowe et al., 2016), performed in England, has shown increased risk of intussusception in a European setting, mostly for the 1–7 day period after the first dose of Rotarix. In this study, the relative incidence was higher (i.e. RI=13.81; 95%CI 6.44-28.32) for the period 1-7 days post-dose 1, than observed in other similar studies. The attributable risk was 1.68 per 100,000 doses for the same period.

It is essential to ensure the continuous communication to inform both parents and health care professionals (HCPs) correctly on the risks and benefits of rotavirus vaccination, and more importantly on the first signs and symptoms of intussusception which should be recognised as soon as possible to allow the essential rapid medical care, ensuring the best prognosis for the infant.

The PRAC agreed to reflect the results of the above study in section 4.8 of the Summary of Product Characteristics for Rotarix and agreed on the relevance to reinforce the message in the Package Leaflet for the parents to rapidly seek medical care if symptoms of intussusception develop.

In summary it is important to keep in mind that:

- parents must systematically be informed that intussusception may occur very rarely within the month following vaccination but that this medical problem can be solved with immediate medical care;

- parents must systematically be informed that a doctor/HCP should be contacted right away if their child experiences one of the signs suggestive of intussusception (severe stomach/belly pain, persistent vomiting, blood in stools, a swollen belly and/or high fever);

- doctor/HCPs must follow-up on any symptoms indicative of intussusception (severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever) occurring in children vaccinated against rotavirus within the previous month;

- the vaccination course should systematically be completed by the age of 24 weeks.

Moreover, as the risk of intussusception is common to both Rotarix and Rotateq (i.e. rotavirus) vaccines, the PRAC is of the opinion that the update of the Product Information and the possibility of a communication at national level should be considered for both vaccines.

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.