EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 March 2015
EMA/170904/2015
Committee for Medicinal Products for Human Use (CHMP)

CHMP assessment report for paediatric studies submitted in accordance with article 46 of regulation (EC) No1901/2006, as amended

Rotarix

rotavirus vaccine, live

Procedure No: EMEA/H/C/000639

P46 077

Assessment Report as adopted by the CHMP with all information of a commercially confidential nature deleted

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I. RECOMMENDATION

Based on the review of the data from study 10PN-PD-DIT-028 (Synflorix, COMPAS study) the Rapporteur considers that the benefit-risk balance for Rotarix remains unchanged. Please refer to the ongoing Synflorix variation application EMEA/H/C/973/II-52 for detailed information.

II. BACKGROUND

GlaxoSmithKline (GSK) Biologicals submitted the application for its live attenuated human rotavirus vaccine (HRV) to the European Medicines Agency (EMA) via the Centralised Procedure on 21 December 2004. Rotarix is indicated for the active immunisation of infants aged 6 to 24 weeks for prevention of gastro-enteritis due to rotavirus infection.

The study reports of 10PN-PD-DIT- 028, i.e. Interim Report Main, Report Main and Annex Report Main, are being submitted to comply with the requirements of Article 46 of the Paediatric Regulation (EC) No 190112006.

Study 10PN-PD-DIT-028 (=COMPAS study) was a phase III, randomized, controlled multicentre study conducted in healthy children in Argentina (42 centres), Panama (16 centres) and Colombia (3 centres) to evaluate Synflorix' efficacy against community acquired pneumonia (CAP) and acute otitis media (AOM).

Synflorix (10Pn-PD-DiT vaccine) is a 10-valent pneumococcal polysaccharide conjugate vaccine composed of Streptococcus pneumoniae polysaccharide serotypes 1,4, 5, 6B, 7F, 9V, 14, 23F conjugated to protein D, serotype 18C conjugated to tetanus toxoid and serotype 19F conjugated to diphtheria toxoid.

Rotarix was not specifically studied in this study. In Colombia, 2 doses of licensed Rotarix vaccine were offered to all subjects within the first six months of life to provide additional benefit.

According to Rotarix Product Information, Rotarix can be administered at the same time as other normally recommended vaccines, such as diphtheria, tetanus, pertussis, Haemophilus influenzae type b, oral or inactivated polio, hepatitis B vaccines as well as pneumococcal and meningococcal serogroup C conjugate vaccines.

III. SCIENTIFIC DISCUSSION

No immunogenicity results were generated for Rotarix in the COMPAS study. Since Rotarix was co-administered with other vaccines in the study, the safety analysis performed in the study does not relate to the administration of Rotarix alone. The overall safety conclusion from the study was that Synflorix was generally well tolerated when administered according to a 3+ I dose schedule in subjects aged between 6 and 16 weeks at the time of the first vaccination.

Assessor's note: for the study design as well as the aim of the different study reports, please refer to the ongoing Synflorix variation application EMEA/H/C/973/II-52 for detailed information.

IV. MAH'S OVERALL CONCLUSION

GlaxoSmithKline has reviewed the results of this study and has concluded that no changes to the Product Information are needed since no data specifically on Rotarix were obtained in this study.

V. RAPPORTEUR'S CONCLUSION

The MAH's overall conclusion is endorsed.

VI. REQUEST FOR SUPPLEMENTARY INFORMATION AND MODIFICATION OF THE SPC

None