Nevertheless, testing of samples drawn at the successive time points was completed, and immunogenicity data were presented as listing for individual subjects only; information on the deviation to the study procedure for these 2 subjects was briefly presented in the Clinical Study Report (CSR).

Safety analyses

The 2 subjects were not included in the Safety Analysis Set (subjects who have received the study or control vaccine) as the information on the group allocation might have created a bias in the reporting of adverse events (AE) and reactions (AR). Moreover, considering that ruling out a subject from the safety analysis might be considered as removing AE or AR impacting the global safety profile, safety data for these 2 subjects were presented as individual listings.

In Summary, due to the unblinding of the 2 patients, the decision was to not use the data of the patients in the study analyses as recommended by the Inspectors.

CHMP comment:

The exclusion of immunogenicity and safety data of 2 subjects not only from the PP set but also the FAS as well as the safety analysis set, respectively, was requested by GCP inspectors due to improper unblinding of the 2 subjects. Although in the opinion of the CHMP this is disproportionate, it is accepted. From the individual immunogenicity results of the subjects it can be inferred that both subjects reached seroprotective antibody levels at post-dose 3 against Hexyon and Rotavirus antigens.

Issue has been solved.