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3 Post-Authorization Safety Surveillance of a New Pentavalent Vaccine within a National Childhood Vaccination Program in Central America

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Background: The vaccine against diphtheria, tetanus, and pertussis (DTwP) has been administered since the 1940's. In the 1990's WHO endorsed the incorporation of hepatitis B vaccine (HBV) and in 1998 of *Haemophilus influenzae* type B (Hib) into national Expanded Programs on Immunization (EPI). Subsequently, combination vaccines were developed to reduce the number of injections and logistical requirements, and to increase parental compliance. These combination vaccines have been incorporated into EPI, also in emerging and developing countries. The fully liquid DTP-HepB-Hib combination vaccine Quinvaxem™ developed by Crucell Berna Biotech Korea and Novartis Vaccines is based on licensed HBV (Hepavax-Gene®) and DTwPHib (Quattvaxem®). Prequalified by WHO in September 2006 this pentavalent vaccine is licensed in several countries world-wide.

Objective: No new or unknown specific risks emerged from the randomized clinical trials assessing safety of Quinvaxem™, or from trials of the single components. However, following licensure, when the new vaccine is under conditions of routine use and introduced into EPI, monitoring safety is of utmost importance to preserve the integrity of immunization programs and protect public health.

The objective of this observational post-licensure surveillance study (PLS) is to investigate the incidence of important safety outcomes in infants vaccinated with Quinvaxem™ according to the EPI schedule in Guatemala in their first year of life.

Methods: The method of active prospective PLS was considered adequate to ascertain the number of clinically relevant and serious AEs with follow-up and outcome information. 3000 infants eligible for the local EPI schedule are recruited over 1.5 years at public health clinics from the Institute of Social Security (ISS) in Guatemala City and followed-up over 5 months. The parents / legal guardians are asked to observe their infant, and will be instructed to contact the health care professional (HCP) if the infant experiences any symptoms they perceive as serious. HCP questions about any AEs during the clinic visits for the 2nd and 3rd vaccination. All AEs are documented. The infant's parents / legal guardian are contacted by telephone 2 weeks after each vaccination and 4 weeks after the 3rd vaccination to collect information on any AEs observed.

Results: The feasibility and methods of performing an active prospective, observational PLS in a Central American country within ISS is discussed.

Conclusion: This model is a feasible approach to demonstrate safety and tolerability in emerging and developing countries, and thus to overcome the limitations of passive surveillance and spontaneous reporting of AEFIs.

Conflicts of interest: Involved in the development and conduct of the surveillance study sponsored by Crucell, Berna Biotech Ltd