SAFETY AND REACTOGENICITY OF DTPA-HBV-IPV/HIB AND DTPA-IPV/HIB VACCINES IN A POST-MARKETING SURVEILLANCE SETTING

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Abstract. Combination vaccines have been shown to improve the timeliness of vaccination and vaccine coverage. Safety and reactogenicity of combined diphtheria-tetanus-acellular pertussis-inactivated poliovirus and *Haemophilus influenzae* type b vaccine (DTPa-IPV/Hib, *Infanrix*™ IPV+Hib, GlaxoSmithKline Biologicals) was assessed in two clinical studies. In Study A, 2,590 subjects received DTPa-IPV/Hib at 3, 4 and 5 months of age with a booster at 18 months. In Study B, 702 subjects received the same schedule but with DTPa-hepatitis B-IPV/Hib (DTPa-HBV-IPV/Hib, *Infanrix hexa*™, GlaxoSmithKline Biologicals) vaccine administered at 5 months of age. Reactogenicity was assessed for four days after each dose using diary cards. Serious adverse events (SAEs) were assessed until 24 months of age. The vaccines were well tolerated. After primary vaccination, irritability was the most frequently reported grade 3 general symptom (0.8% of doses in both studies). Fever (axillary) >39ºC was infrequent (0.3% of doses in Study A; 0.5% of doses in Study B). After the booster dose, the most frequently reported grade 3 symptom was redness (5%) in Study A and pain (0.5%) in Study B. An axillary temperature >39ºC was reported in 1.1% of subjects. Throughout the study period, 646 SAEs were reported, of which 6 SAEs were considered to be vaccination-related. The reactogenicity and safety profile of the combined DTPa-IPV/Hib vaccine was good when used for primary and booster vaccinations in over 3,000 Singaporean infants. Substitution of DTPa-IPV/Hib with DTPa-HBV-IPV/Hib at Month 5 reduced the number of injections required at this age by one.

Keywords: DTPa-HBV-IPV/Hib vaccine, DTPa-IPV/Hib vaccine, safety, reactogenicity

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