Approval Date: November 6, 2019

Product: KINRIX

Proper Name: Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine

Manufacturer: GlaxoSmithKline Biologicals

Indication: Active immunization against diphtheria, tetanus, pertussis, and poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series in children 4 through 6 years of age whose previous DTaP vaccine doses have been with INFANRIX® and/or PEDIARIX® for the first three doses and INFANRIX® for the fourth dose.

Description: KINRIX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine) is a noninfectious, sterile vaccine for intramuscular administration.

BLA: BL 125260

Regulatory Milestone:

On 24 June 2008, GSK Biologicals' diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine, KINRIX [DTaP-IPV], was licensed in the US as a single booster dose for children 4-6 years of age.

PDUFA Goal Date: July 28, 2014

Package Insert: Package Insert - KINRIX

Summary Basis for Regulatory Approval: July 01, 2014 Summary Basis for Regulatory Action - KINRIX

European Public Assessment Report: No results found

Advisory Committee:

The application was not referred to the Vaccines and Related Biological Products Advisory Committee because the review of information submitted in this supplement did not raise concerns or controversial issues which would have benefited from an advisory committee discussion.

Safety:

The analyses for safety were a secondary endpoint of the study and were performed on the Total Vaccinated Cohort (TVC). An updated version of the Pharmacovigilance plan was submitted in the original amendment to this file to include the results from this co-administration study. No additional pharmacovigilance is planned as a result of this study. As per FDA guidance ("Guidance for Industry Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment"-March 2005), for a product without safety risks identified pre- or post-approval and for which at-risk populations are thought to have been adequately studied, routine spontaneous reporting will be sufficient for post-marketing surveillance. Post-marketing adverse events will be collected in the usual manner for a licensed product.

NCT Numbers:

- NCT00871117
- NCT02447978
- NCT01621802
- NCT01651247

EudraCT Numbers:

- 2011-002946-11

Publications:

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- Martins, R., Camacho, L. A., Marcovistz, R., Noronha, T. G., Maia, M., dos Santos, E. M., Barbosa, G. G., Silva, A. M., Souza, P. C., Lemos, M. C., & Homma, A. (2008). Immunogenicity, reactogenicity and consistency of production of a Brazilian combined vaccine against diphtheria, tetanus, pertussis and Haemophilus influenzae type b. *Memorias do Instituto Oswaldo Cruz*, *103*(7), 711–718. https://doi.org/10.1590/s0074-02762008000700014
- Espinoza, F., Tregnaghi, M., Gentile, A., Abarca, K., Casellas, J., Collard, A., Lefevre, I., & Jacquet, J. M. (2010). Primary and booster vaccination in Latin American children with a DTPw-HBV/Hib combination: a randomized controlled trial. *BMC infectious diseases*, *10*, 297. https://doi.org/10.1186/1471-2334-10-297
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- Munoz, F. M., Bond, N. H., Maccato, M., Pinell, P., Hammill, H. A., Swamy, G. K., Walter, E. B., Jackson, L. A., Englund, J. A., Edwards, M. S., Healy, C. M., Petrie, C. R., Ferreira, J., Goll, J. B., & Baker, C. J. (2014). Safety and immunogenicity of tetanus diphtheria and acellular pertussis (Tdap) immunization during pregnancy in mothers and infants: a randomized clinical trial. *JAMA*, *311*(17), 1760–1769. https://doi.org/10.1001/jama.2014.3633

- Dalvi, S., Kulkarni, P. S., Phadke, M. A., More, S. S., Lalwani, S. K., Jain, D., Manglani, M., Garg, B. S., Doibale, M. K., Deshmukh, C. T., & SIIL DTwP + HepB Hib Author

Group (2015). A comparative clinical study to assess safety and reactogenicity of a DTwP-HepB+Hib vaccine. *Human vaccines & immunotherapeutics*, *11*(4), 901–907. https://doi.org/10.1080/21645515.2015.1010953

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- Kovac, M., Rathi, N., Kuriyakose, S., Hardt, K., & Schwarz, T. F. (2015). Immunogenicity and reactogenicity of a decennial booster dose of a combined reduced-antigen-content diphtheria-tetanus-acellular pertussis and inactivated poliovirus booster vaccine (dTpa-IPV) in healthy adults. *Vaccine*, *33*(22), 2594–2601. https://doi.org/10.1016/j.vaccine.2015.03.104