Approval Date: November 6, 2019

Product: PEDIARIX

Proper Name: Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined.

Manufacturer: GlaxoSmithKline Biologicals

Indication:

- PEDIARIX is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis, infection caused by all known subtypes of hepatitis B virus, and poliomyelitis.
- PEDIARIX is approved for use as a 3-dose series in infants born of hepatitis B surface antigen (HBsAg)-negative mothers.
- PEDIARIX may be given as early as 6 weeks of age through 6 years of age (prior to the 7th birthday).

Description: PEDIARIX [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine] is a noninfectious, sterile vaccine for intramuscular administration.

BLA: BL 103907

Regulatory Milestone:

GSK submitted the final study report for Study 217744/088 to the Pediarix IND (IND #(b)(4)) on June 29, 2007. In a Supplement to the Pediarix BLA (STN 103907/5227), submitted

September 26, 2007, GSK included the final study report for Study 217744/088 and an updated package insert to include results from this study. In addition, the format of the Pediarix package insert was revised to comply with FDA's final rule "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" published in the Federal Register in January 2006. On July 25, 2008, a Complete Response letter was issued to GSK Biologics requesting additional datasets and clarification of statistical analyses. On June 4, 2009 a complete response to the July 25, 2008, letter was received. On November 20, 2009, a major amendment was submitted in response to CBER's November 2, 2009 request for additional information regarding statistical analyses.

PDUFA Goal Date: March 5, 2010

Package Insert: Package Insert - PEDIARIX

Summary Basis for Regulatory Approval: Summary Basis for Regulatory Action - Pediarix

European Public Assessment Report: No data

Advisory Committee: There were no issues in this supplement that required input from an Advisory Committee.

Safety: There were no special concerns identified with this study.

NCT Numbers:

- NCT00146835
- NCT00129129
- NCT00289783
- NCT00614614
- NCT03207750
- NCT02096263
- NCT02447978
- NCT01978093
- NCT00133445
- NCT00611559
- NCT00879827
- NCT03621670
- NCT00345579
- NCT00334607
- NCT01000974
- NCT01651247

- NCT00322335
- NCT00373958
- NCT00804284
- NCT01129362
- NCT00345683
- NCT00359983
- NCT00505063
- NCT00474526

EudraCT Numbers:

- 2016-003210-27
- 2012-002401-22
- 2005-002352-18
- 2013-003459-39
- 2013-004194-27
- 2005-006066-34
- 2013-004304-19
- 2015-001530-25
- 2011-004638-32
- 2008-003688-38
- 2011-002946-11

Publications:

- Denoël, P. A., Goldblatt, D., de Vleeschauwer, I., Jacquet, J. M., Pichichero, M. E., & Poolman, J. T. (2007). Quality of the Haemophilus influenzae type b (Hib) antibody response induced by diphtheria-tetanus-acellular pertussis/Hib combination vaccines. Clinical and vaccine immunology: CVI, 14(10), 1362–1369. https://doi.org/10.1128/CVI.00154-07
- 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
- Dbaibo, G., El-Ayoubi, N., Ghanem, S., Hajar, F., Bianco, V., Miller, J. M., & Mesaros, N. (2013). Immunogenicity and safety of a quadrivalent meningococcal serogroups A, C, W-135 and Y tetanus toxoid conjugate vaccine (MenACWY-TT) administered to adults aged 56 Years and older: results of an open-label, randomized, controlled trial. Drugs & aging, 30(5), 309–319. https://doi.org/10.1007/s40266-013-0065-0
- 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

- Leonardi, M., Latiolais, T., Sarpong, K., Simon, M., Twiggs, J., Lei, P., Rinderknecht, S., Blatter, M., Bianco, V., Baine, Y., Friedland, L. R., & Miller, J. M. (2015). Quadrivalent meningococcal (MenACWY-TT) conjugate vaccine or a fourth dose of H. influenzae-N. meningitidis C/Y conjugate vaccine (HibMenCY-TT) is immunogenic in toddlers who previously received three doses of HibMenCY-TT in infancy. Vaccine, 33(7), 933–941. https://doi.org/10.1016/j.vaccine.2014.08.027
- Leonardi, M., Latiolais, T., Sarpong, K., Simon, M., Twiggs, J., Lei, P., Rinderknecht, S., Blatter, M., Bianco, V., Baine, Y., Friedland, L. R., Baccarini, C., & Miller, J. M. (2015). Immunogenicity and reactogenicity of Infanrix™ when co-administered with meningococcal MenACWY-TT conjugate vaccine in toddlers primed with MenHibrix™ and Pediarix™. Vaccine, 33(7), 924–932. https://doi.org/10.1016/j.vaccine.2014.09.064
- 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
- Pace, D., Khatami, A., McKenna, J., Campbell, D., Attard-Montalto, S., Birks, J., Voysey, M., White, C., Finn, A., Macloed, E., Faust, S. N., Kent, A. L., Heath, P. T., Borrow, R., Snape, M. D., & Pollard, A. J. (2015). Immunogenicity of reduced dose priming schedules of serogroup C meningococcal conjugate vaccine followed by booster at 12 months in infants: open label randomised controlled trial. BMJ (Clinical research ed.), 350, h1554. https://doi.org/10.1136/bmj.h1554
- 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
- Bona, G., Castiglia, P., Zoppi, G., de Martino, M., Tasciotti, A., D'Agostino, D., Han, L., & Smolenov, I. (2016). Safety and immunogenicity of a CRM or TT conjugated meningococcal vaccine in healthy toddlers. Vaccine, 34(29), 3363–3370. https://doi.org/10.1016/j.vaccine.2016.05.009
- Borja-Tabora, C., Peyrani, P., Webber, C., Van der Wielen, M., Cheuvart, B., De Schrevel, N., Bianco, V., Aris, E., Cutler, M., Li, P., & Perez, J. L. (2020). A phase 2b/3b MenACWY-TT study of long-term antibody persistence after primary vaccination and immunogenicity and safety of a booster dose in individuals aged 11 through 55 years. BMC infectious diseases, 20(1), 426. https://doi.org/10.1186/s12879-020-05104-5