Approval Date: August 27, 2020

Product: Afluria Quadrivalent

Proper Name: Influenza Vaccine

Manufacturer: Seqirus Pty Ltd.

Indication: For active immunization of person ages 18 years and older against influenza disease caused by influenza virus subtype A and type B present in the vaccine.

Description: AFLURIA QUADRIVALENT, Influenza Vaccine for intramuscular injection, is a sterile, clear, colorless to slightly opalescent suspension with some sediment that resuspends upon shaking to form a homogeneous suspension.

BLA: BL 125254

Regulatory Milestone:

Afluria TIV, developed by CSL Biotherapies (renamed as bioCSL in 2014), was granted accelerated approval for immunization of persons 18 years of age and older on September 28, 2007 (STN 125254/0). On November 10, 2009, accelerated approval was extended to include children 6 months to 18 years of age in response to the 2009 H1N1 influenza pandemic. On December 2, 2011, traditional approval was granted for individuals 18 years of age and older, based on a clinical endpoint efficacy, safety and immunogenicity study in adults 18 to 65 years of age, and a non-inferiority immunogenicity and safety study in adults ≥ 65 years of age (STN 125254/259). . In July, 2015, bioCSL and the influenza vaccines business of Novartis merged to form Seqirus. On August 26, 2016, Afluria QIV was approved in adults 18 years of age and older (STN 125254/565).

In April 2010, Afluria TIV administered in the Southern Hemisphere, was associated with increased reports of pediatric fever and febrile seizures, predominantly in children less than 5 years of age. On October 31, 2017, Seqirus submitted a supplement to their Biologics License Application.

PDUFA Goal Date: December 1, 2018

Package Insert: Package Insert - AFLURIA QUADRIVALENT

Summary Basis for Regulatory Approval: October 3, 2018 Summary Basis for Regulatory Action - Afluria Quadrivalent

European Public Assessment Report: No data

Advisory Committee:

No issues were identified during the review of the supplement that would necessitate presentation before an advisory committee.

NCT Numbers: None

EudraCT Numbers:

- 2016-004753-33
- 2016-004133-25
- 2015-000175-27

Publications:

- Treanor, J. T., Albano, F. R., Sawlwin, D. C., Graves Jones, A., Airey, J., Formica, N., Matassa, V., & Leong, J. (2017). Immunogenicity and safety of a quadrivalent inactivated influenza vaccine compared with two trivalent inactivated influenza vaccines containing

alternate B strains in adults: A phase 3, randomized noninferiority study. *Vaccine*, *35*(15), 1856–1864. https://doi.org/10.1016/j.vaccine.2017.02.066

- Statler, V. A., Albano, F. R., Airey, J., Sawlwin, D. C., Graves Jones, A., Matassa, V., Heijnen, E., Edelman, J., & Marshall, G. S. (2019). Immunogenicity and safety of a quadrivalent inactivated influenza vaccine in children 6-59 months of age: A phase 3, randomized, noninferiority study. *Vaccine*, *37*(2), 343–351. https://doi.org/10.1016/j.vaccine.2018.07.036
- Forster, A. H., Witham, K., Depelsenaire, A., Veitch, M., Wells, J. W., Wheatley, A., Pryor, M., Lickliter, J. D., Francis, B., Rockman, S., Bodle, J., Treasure, P., Hickling, J., & Fernando, G. (2020). Safety, tolerability, and immunogenicity of influenza vaccination with a high-density microarray patch: Results from a randomized, controlled phase I clinical trial. *PLoS medicine*, *17*(3), e1003024. https://doi.org/10.1371/journal.pmed.1003024