Boostrix (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed) – New indication

- On October 7, 2022, the FDA announced the approval of GSK's Boostrix (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed), for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age.

- Boostrix is also approved for active booster immunization against tetanus, diphtheria, and pertussis in individuals aged 10 years and older.

- The approval of Boostrix for the new indication was based on a re-analysis of the Boostrix-relevant data from an observational case-control study of Tdap vaccine effectiveness. The FDA found these real-world data as providing real-world evidence to support this approval.

    - In this re-analysis, data from 108 cases of pertussis in infants younger than 2 months of age (including four cases whose mothers received Boostrix during the third trimester) and 183 control infants who did not have pertussis (including 18 whose mothers received Boostrix during the third trimester) resulted in a preliminary estimate of Boostrix as 78% effective in preventing pertussis among infants younger than 2 months of age, when administered during the third trimester of pregnancy.
    - This preliminary estimate of effectiveness was updated using data from published observational studies. These statistical analyses provided estimates of effectiveness that are consistent with the preliminary estimate of 78%.

- To prevent pertussis in infants younger than 2 months of age, Boostrix is administered as a 0.5 mL intramuscular injection to pregnant individuals during the third trimester of pregnancy.

- Refer to the Boostrix drug label for recommendations for active booster immunization.