

**News/Update: Ineffective DTaP Vaccines Manufactured and Distributed in China**

12 September 2018

Dear State Refugee Health Coordinator,

We are providing the following guidance regarding ineffective DTaP vaccines manufactured and distributed in China. The guidance primarily affects immigrants coming from China, rather than refugees. Because clinicians seeing refugees also may see immigrant populations, we are providing this information for your situational awareness.

This guidance is for U.S. health care providers who see children who may have received DTaP vaccine in China in 2017. Specifically, the guidance applies to any child who received DTaP vaccine from one of two Chinese vaccine manufacturers from March through November 2017. Three lots of DTaP vaccine were recalled from two companies because of potency issues, impacting four Chinese provinces.

**Guidance for identifying affected children**

- Review vaccine history of infants and children who have recently returned or arrived from China.
- Check whether they received one or more DTaP vaccine doses between March 2017 through November 2017 in Anhui, Shandong, Chongqing, or Hebei provinces from either Wuhan Biological Products Research (lot number: 201607050-2) or Changchun Changsheng Company (lot numbers: 201605014-01 and 201605014-02).
- Any DTaP doses that meet the above criteria should be considered invalid and these children need to be revaccinated. If the vaccine record does not include vaccine manufacturer or lot number information, but the vaccine dose was delivered in China from March through November 2017, it is still recommended you administer the appropriate number of valid dose(s).

**Background**

- On October 31, 2017, and August 13, 2018, China's Food and Drug Administration recalled approximately 900,000 doses of DTaP vaccine from two domestic, private-sector vaccine manufacturers because of potency concerns.
- The two companies are:
  - Wuhan Biological Products Research Institute Co., Ltd
    - Lot number: 201607050-2
    - Estimated 400,000 doses (recalled on Oct 31, 2017)
  - Changchun Changsheng Company
    - Lot number: 201605014-01
    - Estimated 250,000 doses (recalled on Oct 31, 2017)
    - Lot number : 201605014-02
    - Estimated 250,000 doses (recalled on Aug 13, 2018)

While the recall is not because of a safety issue, there is concern about inadequate protection due to the low potency of vaccine components:

- Pertussis potency was low in both companies' vaccines.
  - Tetanus toxoid potency was low in Changchun Changsheng's vaccine.
  - The diphtheria component met standards in both companies' recalled DTaP vaccines.
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- The three vaccine lots were distributed to Anhui, Shandong, Chongqing, and Hebei provinces from March 2017 through possibly as late as November 2017.
  - It is believed these 900,000 doses were administered to infants and children using the routine vaccination schedule of DTaP at 3, 4, 5, and 18 months of age. (There is a DT booster at 6 years of age.) Among children with known vaccination receipt, approximately 400,000 received 1 dose of the implicated vaccine; 80,000 received 2 doses; and 17,000 received 3 doses.
  - Because of the timing of vaccine distribution and the timing of recall (5 to 8 months), children could have received subpotent vaccine for the primary series or the 18-month booster dose, but not both.

If you have questions about this matter, please contact CDC at [nipinfo@cdc.gov](mailto:nipinfo@cdc.gov).

Please let us know if you have any questions.

Sincerely,



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