



Renfrew County and District Health Unit  
"Optimal Health for All in Renfrew County and District"

## Memorandum

**Date:** July 30, 2018  
**To:** Health Care Providers: Primary Care, Hospitals, ERMS  
**From:** Clinical Services  
**Subject:** **Vaccine Recall in China**

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Two batches of DTaP vaccine were recalled by China Food and Drug Administration (CFDA) on October 29, 2017 after failing potency testing

- Batch 201605014-01 produced by Changchun Biotechnology Co. was distributed to Shandong province in China
- Batch 201607050-2 produced by Wuhan Institute of Biological Products was distributed to Chongqing and Hebei provinces in China.

These lots were released between March 2017 and May 2017 and were recalled by CFDA at the end of October, 2017. Therefore, these products could have been available for use in these areas between March and October 2017. The issue is one of vaccine potency, and not vaccine safety. These vaccines have not been distributed in Canada.

China CDC identified all children who received substandard DTaP vaccines through their Children Immunization Information Management System, and is in the process of revaccinating those identified.

Please consider children who received vaccines with recalled DTaP lot numbers, or in the absence of a lot number, **in China from March to October 2017** in Hebei, Shandong, or Chongqing provinces, to be invalid. These children should be revaccinated after consideration of the child's current age, and the number of previous doses of DTaP received, according to Ontario's Catch-Up Immunization Schedule ([http://www.health.gov.on.ca/en/pro/programs/immunization/docs/immunization\\_schedule.pdf](http://www.health.gov.on.ca/en/pro/programs/immunization/docs/immunization_schedule.pdf)) and the Canadian Immunization Guide. It is likely that the only cohort of children impacted would be those between approximately 3 months and 24 months of age at the time they were immunized in China, given their vaccine schedule and allowing for late administration.

In addition to the DTaP recall, on July 15, 2018, Changchun Biotechnology Co. was found to have falsified production records of rabies vaccines in an unannounced inspection by the CFDA. There is limited information on the specifics of vaccines associated with this July 2018 recall, however, we will send an update as it becomes available.

For more information:

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