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- **Allergic Reactions Associated with Sanofi Pasteur Product (Tubersol® Lot # C2316AA)**

FROM:

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Introduction

There has been a cluster of allergic reactions following tuberculin skin testing with TUBERSOL® (Purified Protein Derivative [Mantoux]), Lot # C2316AA reported recently to Health Canada and Sanofi Pasteur. Reactions that have been reported range from a localized rash to anaphylaxis.

Local Distribution

This situation is under investigation by Sanofi Pasteur and Health Canada. Peel Public Health has confirmed that Lot # C2316AA of TUBERSOL® has been distributed to physicians in Peel Region. Until the results of the investigation are known, the Ministry of Health and Long-Term Care is recommending that as physicians you:

- Check your vaccine supply and set aside all TUBERSOL® Lot # 2316AA until further notice
- **DO NOT** return any TUBERSOL® Lot # C2316AA to Peel Public Health. Instead, please keep it stored under appropriate cold chain conditions in your office until further notice is given. It may be helpful to place the product in a bag marked "DO NOT use until further notice".

- To order more TUBERSOL® please call the vaccine order desk at **(905) 791-7800 ext. 6404** and you will be given TUBERSOL® from a different lot number
- Keep Epinephrine Hydrochloride Solution (1:1000) and other appropriate agents available for immediate use in case an anaphylactic or other acute hypersensitivity reaction occurs
- Monitor all patients for immediate reactions for a period of at least 15 minutes after inoculation
- Report all reactions to Peel Public Health at (905) 799-7700

For any other inquiries, please contact Peel Public Health at **(905) 799-7700**.