**To:** Vermont Health Care Providers and Facilities

**Date:** July 25, 2025

From: Daniel Daltry, Infectious Disease Program Manager

# Recall and Shortage of Bicillin® L-A

### **Background**

On July 10, 2025, Pfizer issued a <u>voluntary recall</u> of multiple lot numbers of Bicillin<sup>®</sup> L-A (penicillin G benzathine injectable suspension) due to particulates identified during visual inspection. The recall includes both 1.2 million units/2 mL and 2.4 million units/4 mL prefilled syringes distributed between December 11, 2023, and June 24, 2025. At this time, no adverse events or concerns about drug potency have been reported related to the use of the recalled product.

On July 14, 2025, the FDA updated its <u>Drug Shortage Alert</u> to reflect this issue and to provide information on alternative formulations. The FDA has approved two temporary alternative formulations for use during the shortage: <u>Lentocilin</u><sup>©</sup> and <u>Extencilline</u>. Review the prescribing and administration information before using these products.

Prepare for a potential prolonged national shortage of Bicillin<sup>®</sup> L-A, and prioritize Bicillin<sup>®</sup> L-A for pregnant people and infants, given the critical need in these populations. Please consult the <u>CDC congenital syphilis treatment guidelines</u> for clinical management considerations.

The Health Department has a limited supply of Bicillin® L-A that may be provided for pregnant people when clinically appropriate. To support accurate staging and appropriate treatment of syphilis, the Health Department can assist with case review and, if needed, coordinate consultation with infectious disease specialists. Clinicians are encouraged to refer to the <a href="CDC">CDC</a> 2021 STI Treatment Guidelines and may seek additional guidance from a University of Vermont Health Network infectious disease clinician, a Health Department STI expert (802-863-7240), or the NNPTC's STD Clinical Consultation Network.

#### **Requested Actions**

#### 1. Assess inventory:

- If you have any of the affected lots, discontinue use.
- Follow the instruction letter from Pfizer to return affected lots.

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- 2. **Use other appropriate antimicrobials for infections that do not require benzathine penicillin G specifically.** Alternatives are not appropriate for pregnant people or infants exposed to syphilis. For non-pregnant adults with syphilis:
  - Doxycycline as an alternative for early syphilis (100 mg orally twice daily for 14 days).
  - For late latent syphilis or syphilis of unknown duration, extend doxycycline treatment to 28 days.
- 3. Reserve and prioritize Bicillin® L-A for:
  - Pregnant patients diagnosed with syphilis at any stage.
  - Infants with confirmed or suspected congenital syphilis.

#### **Additional Resources**

- FDA Healthcare Provider Letter for Extencilline
- FDA Healthcare Provider Letter for Lentocilin<sup>©</sup>
- CDC STI Treatment Guidelines

If you have any questions, please contact Daniel Daltry at: <a href="mailto:Daniel.Daltry@vermont.gov">Daniel.Daltry@vermont.gov</a>

To have your information updated please email the Vermont HAN Coordinator at: <a href="mailto:vthan@vermont.gov">vthan@vermont.gov</a>

## **HAN Message Type Definitions**

**Health Alert:** Conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** Provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** Provides updated information regarding an incident or situation; unlikely to require immediate action.

**Info Service Message:** Provides general correspondence from the Vermont Department of Health, which is not necessarily considered to be of an emergent nature.

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