

Centers for Disease Control and Prevention

August 22, 2005

Dear Colleague,

## RE: Availability of Bicillin® L-A for treatment of syphilis

Recently, CDC has received reports of difficulties in securing supplies of King's Bicillin<sub>®</sub> L-A (benzathine penicillin G). Benzathine penicillin G is the recommended treatment for syphilis and the only treatment option for pregnant women infected with or exposed to syphilis. This letter outlines procedures for securing supplies of King's Bicillin<sub>®</sub> L-A for the management of infectious syphilis in the United States.

Bicillin® L-A was previously produced by Wyeth for King (Monarch) Pharmaceuticals, the owner and distributor of the product. King is in the process of commissioning a new facility to manufacture Bicillin products. In anticipation of production interruption during the transition to its new facility, King has stockpiled adequate supplies of Bicillin and is continuing to distribute the drug from these supplies via its network of wholesalers. To ensure an equitable and managed distribution of Bicillin, King has restricted wholesalers from stockpiling locally. This, in combination with increasing demand, may have contributed to the recent difficulties experienced in accessing Bicillin® L-A.

CDC has been working with King and, more recently, the FDA Drug Shortage Program to monitor the situation. King Pharmaceuticals has been very responsive in ensuring that health departments experiencing delays receive their orders in a timely manner. In order to assist local sites in securing adequate supplies of Bicillin® L-A, we recommend the following steps:

- Plan ahead: Please review your stocks of Bicillin<sub>®</sub> L-A regularly. If you are likely to require a normal replenishment of stock, please contact your wholesale distributor so they can order supplies for you directly. Distributor supply is preferred because the mechanisms for transportation and storage of the drugs are already in place. It is a more secure and safe way of obtaining your drug.
- 2. If you are running dangerously low on supplies (i.e. depletion within a week), ask your local wholesaler to contact John Cole at King Pharmaceuticals at 423-990-8366 so that King can work with the wholesaler to have the supplies sent out immediately. Again, the wholesaler will take responsibility for handling and delivering the drug to you.
  - For legitimate, medical emergency situations where efforts to obtain product from your wholesaler have been unsuccessful, please contact John Cole at King directly. He will work with you to facilitate having the drug delivered directly to the practice/ institution.

Please circulate this guidance to others who are likely to be affected. It will require that for the foreseeable future, local stocks of Bicillin<sub>®</sub> L-A are regularly and proactively monitored.

Sincerely,

John M. Douglas Jr., MD

Director

Division of STD Prevention

National Center for HIV, STD, and TB Prevention

Randy Noonchester 423-990-8313 new contact 12/4/2006