

QSM/MC/IEA.125

03 February 2012

## **Information Exchange System**

### **Alert No. 125**

#### **Contaminated Isotab® (isosorbide mononitrate) incident in Lahore Pakistan**

**Increased vigilance is requested for batch/lot number J093 of Isotab® 20 mg (isosorbide mononitrate) labeled as being manufactured by Efroze, Karachi, Pakistan.**

A serious incident occurred in Lahore (Punjab, Pakistan) involving the deaths of 107 patients with serious adverse reactions in more than 450 patients. The incident is currently being investigated.

At the request of the Department of Health Government Punjab, samples of the suspected tainted medicines were sent to different laboratories for testing in Pakistan and abroad, including two European laboratories of national regulatory authorities.

The results of those tests are being communicated, both to the Punjab Health Authority and to WHO. The analysis from the first of those tests are now available. The Punjab Health Authority and WHO have been informed that one of the medicines tested, an antianginal medicine (isosorbide mononitrate) contained pyrimethamine in quantities large enough to cause a substantial overdose. The effects caused by the overdose of this medicine are consistent with some of the symptoms exhibited by the patients who have been admitted to hospital in Lahore.

The product concerned is Isotab® (isosorbide mononitrate 20 mg) which contained a significant amount of the pyrimethamine. From the information available to date, the contamination has only been found in the production batch **J093** of Isotab labelled as being manufactured by Efroze, Karachi, Pakistan. Samples of the same medicine tested from other batches have not shown any contamination with pyrimethamine to date.

The Department of Health Government Punjab has taken steps to contain the supply of the suspected medicines and according to the Pakistan authorities, the medicines concerned have only been delivered to The Punjab Institute of Cardiology in Lahore.

However, this alert is issued as a precautionary announcement, and a preventive measure, in the event that this batch of medicine has been more widely distributed.

Further investigations are ongoing. Updates will be issued in case further enquiries reveal that other batches and/or other medicines are involved.

If this specific batch of medicine has been imported, distributed or dispensed in your country please notify Mr Michael Deats (deatsm@who.int) and Dr Lembit Rägo (ragol@who.int)