Information Exchange System

Alert No. 126

Contaminated Dextromethorpan Active Pharmaceutical Ingredient.

Increased vigilance is requested for batches of Dextromethorphan Active Pharmaceutical Ingredient produced by Konduskar Laboratories Private Limited, Kolhapur, Maharashtra India

On the 23rd November 2012, a serious incident occurred in Lahore, Pakistan which resulted in the death of approximately 20 persons and a number of other serious adverse reactions. All of those affected had consumed a cough syrup with the brand name Tyno, 120ml, locally produced by Reko Pharmacal with Dextromethorphan as the principal active pharmaceutical ingredient.

A second incident occurred on the 26/27 December 2012 when another 40 deaths occurred in Gujrunwala, (70kms North of Lahore), Pakistan. Again all of those affected had recently consumed a cough syrup with the name Dextromethorphan, 120ml, locally produced by Ethical Laboratories, Lahore.

All of the victims of both incidents had a history of drug abuse. Interviews with the survivors confirmed that they had been taking large quantities of the syrup exceeding therapeutic doses in conjunction with other narcotics for many years with no unexpected serious adverse reactions.

Investigations conducted with the manufacturers confirmed that they had both recently changed the source of their Dextromethorphan to Konduskar Laboratories Private Limited, Kolhapur, India and that the adverse reactions commenced immediately after following distribution of medicine produced with API from that source.

The Government of the Punjab took immediate steps to suspend the production and supply of both medicines and recalled large quantities of both products as well as unused Active Pharmaceutical Ingredient. They also requested assistance from the WHO and an International Laboratory to investigate the root cause of the deaths.

Samples of the medicine were tested in Pakistan and sent to a European regulatory agency for analysis. Those tests have revealed that both the API and syrups are contaminated with varying levels of Levomethorphan.

Levomethorphan is the enantiomer of Dextromethorphan and is a potent opioid analgesic which is internationally controlled under Schedule 1 of the Single Convention on Narcotic Drugs 1961.

All batches of the API imported into Pakistan have been traced and where available seized and samples submitted for analysis, including 100kgs held at Lahore airport awaiting customs clearance.
Communication with the Indian authorities is on-going to establish the quantity and distribution of other batches of Dextromethorphan by Konduskar Laboratories.

This Drug alert is issued as a precautionary announcement and a preventative measure in the event that batches of this API may have been widely exported and distributed. In addition, vigilance regarding quality of dextromethorphan as an active pharmaceutical ingredient in general is also recommended.

Further investigations are on-going. Updates will be issued as further information emerges.

If your Country has imported batches of Dextromethorphan active pharmaceutical ingredient manufactured by Konduskar Laboratories, Kolhapur, India, please ensure that it is tested and meets the recognised published specifications.

For any questions relating to this alert please contact Mr Michael Deats (deatsm@who.int) or Dr. Lembit Rago (ragol@who.int).