When public health information is kept private

Jesse McLean

Toronto Star
3) Supplier Corrective Action Request (SCAR) # 717 was initiated on 20 August 2007 to have the vial supplier investigate vials described as “dirty vials”, “white film on vials”, & “tacky substance adhering to the exterior walls of the vials”. The plan was to have 4 vials sent to the supplier for testing but this action was never performed.

4) WinRho Liquid lot # (b)(4) was released 03 October 2007 and shipped to the U.S. on 09 October 2007 prior to closure of the Deviation # 5615.

OBSERVATION 1

Failure to report promptly to the IRB all unanticipated problems involving risk to human subjects or others.

Specifically,

A) You failed to report three (3) serious adverse events (SAEs) to the IRB/Ethics Board:

Protocol M02-404:

- Subject 21007 inpatient hospitalized
- Subject 21011 inpatient hospitalized
- Subject 21014 inpatient hospitalized
>STAR INVESTIGATION

COMPANIES KNEW DRUGS THEY SOLD WERE DEFECTIVE

U.S. Food and Drug Administration reports reveal Canadian pharmaceutical firms changed and destroyed test data showing products were tainted and Health Canada kept inspection details secret, potentially putting health of patients at risk

David Brulé and Jesse McLean

North American patients have been put at risk by pharmaceutical drugs that Canadian companies knew to be defective, a Star investigation has found. After warnings by the U.S. Food and Drug Administration, some Canadian companies destroyed test data, changed test results and breached confidentiality agreements with U.S. regulators, according to documents released to the Star under Freedom of Information Act requests.

Health Canada officials and the Star’s own investigation revealed that the department failed to disclose vital information to the U.S. regulator or other Canadian authorities.

The documents, which were gathered through the Star’s Freedom of Information Act requests, show that Canadian companies had been warned by the U.S. regulator for months that test results for their drugs were not accurate. In some cases, the companies were asked to recall their products. Health Canada, however, did not alert other Canadian regulatory bodies.

The documents reveal that Health Canada was aware of the problems but chose not to act.

The Star has learned that some of the drugs, which were manufactured in India, were used in Canada.

> STAR INVESTIGATION

Blind spot in drug ingredient testing

Hundreds of pharmaceutical plants that export to Canada haven’t been inspected by regulators

Jesse McLean and David Brulé

Health Canada allows drug ingredients to enter the country from hundreds of pharmaceutical facilities that have not been inspected by a regulator, an ongoing Star investigation has found.

Instead, nearly 100 foreign drug facilities have been inspected only by themselves or hired consultants.

Drug ingredients made overseas are then imported and used to make medications sold in Canada. Poorly made drug ingredients have been linked to side effects and deaths, Health Canada has said.

The regulatory blind spot means a swath of the pharmaceutical industry is in charge of policing the quality of its own products.
How things have changed

Find the latest results from Canada’s drug and health product inspections. Search by company, location, rating, inspection date and other options.

- Search the drug inspection results »
- Search the clinical trial inspection results »
- Search the medical device inspections results »
- Search the pharmacovigilance practices (GVP) inspections »
- Search the cells, tissues and organs (CTO) inspections »
- Search the blood inspections »
<table>
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<tr>
<th>Reference number</th>
<th>Establishment name</th>
<th>Site</th>
<th>Inspection start date</th>
<th>Rating</th>
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<th>Terms and conditions</th>
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<td>502088</td>
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<td>504926</td>
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<td>Source of Information under review</td>
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| **Anuha Pharma Ltd**        | • Canadian importer(s) contacted by Health Canada for information  
• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)  
• No medically necessary products identified at this time | • Regulatory Partner(s)              | • General GMP observations                  |
| E-17/3 & E 17/4 M.I.D.C. Tarapur, Taluka Palghar, District Thane, India-401 506 Boisar, Maharashtra |                                                                                                                                                                                                             |                                      |                                             |
| **Cadila Pharmaceuticals Limited.** | 294, G.I.D.C. Industrial Estate, Ankleshwar, India  
• Canadian importer(s) contacted by Health Canada for information  
• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)  
• No medically necessary products identified at this time  
• No critical risks identified to date | • Regulatory Partner(s)              | • General GMP observations                  |
| **Dr. Reddy’s Laboratories** | • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)  
• No medically necessary products identified at this time  
• Requested voluntary quarantine  
• Voluntary quarantine in place  
• Issued terms and conditions to Canadian Importer(s)  
Related recalls and alerts:  
• Health products quarantined from two sites in India as Health Canada assesses data integrity concerns | • Regulatory Partner(s)              | • Data integrity  
• General GMP observations                  |
jmclean@thestar.ca

416-869-4147

PGP: tinyurl.com/glxrtuq