Pan Pharmaceuticals Limited - Regulatory action and product recall information

http://www.tga.health.gov.au/recalls/pan.htm

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- **Urgent medicine recall - Products manufactured by Pan Pharmaceuticals Limited and supplied by various sponsors and distributors advertised for consumer level recall** (Lists of recalled products as at 12 November 2003)
- Pan Pharmaceuticals Limited manufactured products for immediate recall (28 April 2003)
- Sponsors that do NOT use Pan Pharmaceuticals Limited as a manufacturer for any of their products

The Therapeutic Goods Administration (TGA) has suspended the licence held by Pan Pharmaceuticals Limited of Sydney to manufacture medicines, for a period of six months with effect 28 April 2003, because of serious concerns about the quality and safety of products manufactured by the company.

The suspension follows audits of the company's manufacturing premises, which revealed widespread and serious deficiencies and failures in the company's manufacturing and quality control procedures, including the systematic and deliberate manipulation of quality control test data. The licence has been suspended in order to urgently address the safety and quality concerns posed by the multiple manufacturing breaches. Where the quality of a medicine cannot be certain, neither can the safety or effectiveness of that medicine.

Due to the serious and widespread nature of the manufacturing problems identified and following expert advice regarding potential risks, the TGA has taken the decision to recall all batches of medicines manufactured by Pan Pharmaceuticals Ltd since 1 May 2002 and that are being supplied on the Australian market.

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219 products manufactured and supplied in Australia by Pan Pharmaceuticals Limited have been identified for immediate recall. These products have been cancelled from the Australian Register of Therapeutic Goods for quality and safety reasons. The company has also had its approval to supply its range of export products (approximately 1650) cancelled.

In addition, a further, larger recall of products manufactured by Pan Pharmaceuticals Limited under contract for other sponsors is underway. The TGA has been working with the sponsors of these products to identify those for recall. Lists of these products have been published in the newspapers and details are also available on this website.

A single batch of the antidepressant medicine, Allegron 25 mg is being recalled as part of the recall of medicines manufactured by Pan Pharmaceutical Limited. The recall applies only to this prescription medicine, and only to 178 packs of a single batch of Allegron that was released to pharmacists in parts of NSW and Queensland. Details of the batch number and action required by patients who have had medicines prescribed from this batch are available at http://www.tga.gov.au/docs/html/mediarel/mrpan6.htm.

No safety problems have been identified with any other prescription medicines available in Australia. Australians may continue to take their prescription medicines.

Recall information on this website will be updated regularly.

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Further information

Media releases

- TGA reminds Australians of the potential danger of Pan Pharmaceuticals
  (TGA Media Statement 24 August 2003)
- More names added to TGA recall list
  (TGA Media Release 5 May 2003)
- Consumers still have access to most trusted medicines
  (Australian Self-Medication Industry Media Release 4 May 2003)
- Women Should Keep Taking Folate
  (The Hon Trish Worth - Media Release 3 May 2003)
- Pregnant women frightened unnecessarily
  (TGA Media Release 3 May 2003)
- Allegron 25MG Subject to PAN Pharmaceutical Recall
  (TGA Media Release 2 May 2003)
- Pan recall list to be published in regional newspapers
  (The Hon Trish Worth - Media Release 2 May 2003)
- TGA issues final list of Pan products
  (TGA Media Release 1 May 2003)
- Extra 449 products added to recall
  (TGA Media Release 30 April 2003)
- Pan Pharmaceuticals Limited Recall Update
  (TGA Media Release 29 April 2003)
- National Medicines Regulator Suspends Drug Company's Manufacturing Licence
  (TGA Media Release 28 April 2003)
- Federal Government To Strengthen Pharmaceutical Laws
  (The Hon Trish Worth - Media Release 28 April 2003)

TGA reminds Australians of the potential danger of Pan Pharmaceuticals

Media release

- Printable version of *TGA reminds Australians of the potential danger of Pan Pharmaceuticals* media release

24 August 2003

The Australian public should not forget how bad the manufacturing practices were at Pan Pharmaceuticals which prompted what may be the world's biggest medicines recall.

The Therapeutic Goods Administration (TGA), in responding to a forthcoming television program about Pan Pharmaceutical's boss, Jim Selim, reminded Australians that audits of Pan found substitution of ingredients, manipulation of test results and substandard manufacturing processes.

Audits by the TGA on Pan Pharmaceuticals revealed a range of critical manufacturing deficiencies including test data being systematically and deliberately manipulated to give false results that product was within specification to enable its release into the market.

An Expert Advisory Committee, including five professors and Chaired by Dr Richard Whiting, Chairman of the Medicines Evaluation Committee, reviewed the audit reports and advised that the quality and safety concerns posed by the manufacturing breaches at Pan Pharmaceuticals needed to be urgently addressed.

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In their assessment of the risks posed by audit evidence of Pan Pharmaceuticals the Expert Committee found that the multiple failures of good manufacturing practice (GMP) identified in the auditors' report created risks of death, serious illness, and serious injury.

Other safety related irregularities found at audits by the TGA included:

- manipulation of the assay results of finished products in order to comply with specifications.
- fabrication of finished product assay results of a vitamin product for export in order to comply with specifications. In two instances the product was over-strength in the other two under-strength.
- several instances of the use of beef cartilage in place of shark cartilage and one instance of use of shark cartilage in place of beef cartilage.
- poor hygiene and sanitation, equipment that was not correctly calibrated, equipment design faults giving concerns for cross contamination between different products, documentation that was deficient and the company's internal inspection program was not effective.

The action by the TGA was designed to protect the health and safety of the Australian public and followed advice received from an expert advisory group convened to give an independent evaluation of the TGA findings.

Specifically, issues identified by the Expert Group included:

- Misidentification (mix-up) of raw materials, especially herbal materials, which could lead to severe organ damage, including renal and hepatic damage;
- Cross-contamination or substitution of ingredients due to inadequate operating procedures and poor compliance with existing procedures could lead to severe allergic reactions including anaphylaxis;
- Microbiological contamination through poor raw material sourcing and handling, poor cleaning practices, and inadequate operating procedures, could lead to infections.

The Expert Group concluded that the risk would increase over time and could be realised at any time.

Specific risks included:

- Substitution of shark cartilage for bovine cartilage which could cause severe allergic reactions, including anaphylaxis, in fish-protein sensitive individuals;
- Substitution of bovine cartilage for shark cartilage where the bovine cartilage has been sourced without any assurance that it is TSE-free, and the country of origin is unknown; and
- Bovine colostrum obtained from non-approved suppliers where the raw material could be sourced from a TSE 'at risk' country, and where the source is unknown.

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The Expert Group also noted a number of products described in the auditors' report for which there potentially could be safety concerns as a result of poor product quality. These included vitamin A products, pancreatic enzyme products, multiple herbal products, several OTC medicines and a prescription medicine.

The Expert Group stated it lacked confidence in the quality of any products manufactured by the company. The Group advised that poor quality products had an increased risk of failure in both safety and efficacy.

The Expert Group recommended that the company should be subject to significant remediation. The Group recommended that the company's manufacturing licence should be suspended immediately for the protection of the community's public health and safety.

Based on this report and to protect the health and safety of the Australian community, the TGA took the action to cancel the licence of Pan Pharmaceuticals and recall all products made by the company both under the Pan brand and other brands for which Pan Pharmaceuticals was the manufacturer.

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The TGA did not test all of the recalled products because the TGA was advised by the Expert Committee that the failures in manufacturing practices were so bad that they created immediate risks of death, serious injury or serious illness and no confidence could be placed in the quality any products manufactured by Pan Pharmaceuticals.

There was such widespread endemic deplorable practices by the company, particularly in basic hygiene such as cleaning equipment between batches that any product ingredient was considered a potential contaminant for any other product subsequently manufactured.

The TGA confirms that there are ongoing criminal investigations into Mr Jim Selim and the practices of Pan Pharmaceuticals.

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Mayne Health, a large health care company whom Pan supplied with health care products, stated that their company had regularly conducted their own rigorous testing of Pan's product and had not found a cause for concern. The TGA offered no explanation as to why an independent distributor of Pan's products could find no problem on testing when the regulator claimed there was a life-threatening problem.
Eve Hillary, TGA Skeletons, WHO Privatised the Regulator?
http://www.ciss.org.au/documents/Jul%2003%20TGA%20Skeletons.doc