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Commonwealth Department of Health and Ageing

Sponsor Recall Package

GUIDANCE FOR SPONSORS WHO WISH TO VOLUNTARILY RECALL PRODUCTS THAT HAVE BEEN MANUFACTURED BY PAN PHARMACEUTICALS LIMITED

To assist sponsors in processing the large number of recalled products manufactured by Pan Pharmaceuticals Limited in the period since 1 May 2002 and supplied in Australia (and where the same goods are also exported from Australia), a streamlined process for the operation of the normal recall procedure has been developed.

NOTE: This streamlined process is only available to sponsors who advise the TGA by Close of Business Wednesday 30 April 2003 of their intent to voluntarily recall specified affected goods. Persons advising the TGA of such actions after this time may be required to meet the normal recall requirements.

The contents of this package summarises for sponsors their responsibilities and role in undertaking a recall in accordance with the Uniform Recall Procedure for Therapeutic Goods (URPTG). It also provides sponsors with a range of streamlined procedures to assist in the smooth running of the recall.

The URPTG remains the primary reference point for sponsors and should be referred to for detailed explanation of the recall process.

Elements of this package are: -

Background
Stages of the streamlined recall process
Attachment 1: Draft pro forma recall letter
Attachment 2: Recall Mailing Services
Attachment 3: Proposed advertisement pre-amble to inform consumers of the recall
Attachment 4: Pro forma advice letter to The Competition and Consumer Policy Division of The Treasury
Attachment 5: Interim reporting requirements pro forma
Attachment 6: Final reporting requirements pro forma

Should you require further assistance in the planning of the recall, please contact TGA Recalls Unit on 02 6232 8554

Background

Sponsors identified on the Australian Register of Therapeutic Goods (ARTG) as having products manufactured or possibly manufactured by Pan Pharmaceuticals Limited will have been contacted by the TGA advising them of the issues surrounding the suspension of Pan Pharmaceuticals Limited's manufacturing licence, and of a request for sponsors to voluntarily initiate a recall of any product manufactured by Pan Pharmaceuticals Limited since 1 May 2002.

The recall of therapeutic goods in Australia is required to be undertaken in accordance with the Uniform Recall Procedure for Therapeutic Goods (URPTG).

The URPTG defines a recall as the means to achieve the permanent removal of the therapeutic goods from supply or use for reasons relating to deficiencies in the quality, safety or efficacy of the goods.

This document is the result of an agreement between Commonwealth and State and Territory health authorities and the therapeutic goods industry in Australia. The Procedure is applicable to the recall of all types of therapeutic goods. A copy of this document can be found at the TGA website at http://www.tga.gov.au/docs/html/urptg.htm

When the need for a recall has been established, the sponsor of the affected goods assumes the responsibility for recovery of the goods while the TGA's Australian Recall Co-ordinator assists by advising the sponsor of the procedures, by notifying agreed third parties and by monitoring the overall action.

Most recalls are conducted on a voluntary basis. However, the Procedure is underpinned by the *Therapeutic Goods Act 1989* and the *Trade Practices Act 1974*. In terms of the *Therapeutic Goods Act 1989*, mandatory recall provisions can be applied in cases:

- when therapeutic goods are cancelled from the Australian Register of Therapeutic Goods; or
- where therapeutic goods are unlawfully supplied in Australia; or
- where therapeutic goods fail to comply with a standard (See Section L of the URPTG for further details).

The *Trade Practices Act 1974* contains provisions in relation to the safety-related recall of consumer goods. The relevant parts of this Act, which are administered by the Consumer Affairs Division (CAD) of the Department of Treasury, empower the Commonwealth Minister responsible for consumer affairs to take action when notification is not made of safety-related recalls, or where the recall has not been satisfactorily completed (see Section M of the URPTG for details).

Stages in the streamlined recall process (for products manufactured by Pan Pharmaceuticals Limited since 1 May 2002)

1. Problem identification

- In this case the TGA has identified problems associated with the manufacturer of the product, requiring sponsors to cease supply of all therapeutic goods manufactured by Pan Pharmaceuticals Limited since 1 May 2002. Sponsors are strongly recommended to voluntarily undertake a recall of these products down to consumer level because of significant safety and quality concerns.

2. Notification to the TGA Recalls Co-ordinator and Information Required to Assess Recall

- The TGA has written to sponsors seeking to specifically identify affected products. Your advice back to the TGA of the details of any implicated product will be forwarded to the Australian Recall Co-ordinator who will then contact you regarding the undertaking of the recall.

3. Assessment of Recall

- Based on the nature and type of failure linked to the manufacturer, the recall has already been classified as:
  - **URGENT MEDICINE RECALL**
  - The level of the recall is to **CONSUMER LEVEL**. The recall has been classified as **SAFETY RELATED.**
  - The recall is classified as **CLASS I** ie the products are potentially life-threatening or could cause a serious risk to health.

4. Recall Letter/Recall Envelope/Paid press advertisement

- **The letter** - In accordance with Section G of the URPTG, the sponsor of each product should prepare a recall letter to be sent to all members of your distribution network (eg wholesalers, retailers and any direct sale customers). A pro forma letter suitable for use for this purpose is at Attachment 1.
- Actions required by sponsors are to either
  - use the pro forma letter with the text unaltered. In this case the letter may be dispatched immediately, with a copy of the correspondence to be supplied as in point 6 below

  or

  - use a different letter. In this case this correspondence will need to be submitted to the Australian Recall Co-Ordinator for approval before it is dispatched.

Please note:
- Information on the recall of multiple products can be included in a single letter.
- Decisions to provide any refunds is at your discretion.

- **The envelope** - Recall letters are required to be dispatched in "Urgent – Medicine Recall" envelopes as described in Section G of the URPTG. These letters can be sourced from the companies listed in Attachment 2; but as a large number of recalls are likely to be requiring their services you may wish to contact a local printing company. Where you are unable to

locate suitable envelopes for this purpose, it shall be considered sufficient compliance with the URPTG if the words URGENT MEDICINE RECALL are written in red characters of at least 1 centimetre height on the top left hand corner of the envelope.

- **The paid press advertisement** – In accordance with section G of the URPTG, for products subject to a consumer level recall, an advertisement paid by the sponsor is to be inserted in the daily print media of each State/Territory in which distribution has possibly taken place.
- Due to the large number of products subject to recall, this requirement will be suspended for sponsors who advise the TGA by Close of Business Wednesday 30 April 2003 of their intent to undertake a voluntary recall and relevant product details of goods to be recalled. Such information will be included in a single, all participating sponsor advertisement paid for by the Commonwealth, and is proposed to appear in daily print media on Tuesday 6 May 2003. The proposed pre-amble for this advertisement is at Attachment 3.
- Sponsors will receive confirmation from the Australian Recalls Co-Ordinator that this requirement will be suspended for their recalled products.

5. Notification to the Federal Minister Responsible for Consumer Affairs

- As these recalls have been classified as safety related, there is a legal requirement under the Commonwealth *Trade Practices Act 1974* to notify the Minister with responsibility for consumer affairs issues (via the Consumer Affairs Division of the Department of the Treasury) that you are undertaking the recall. Refer to Section M of the Uniform Recall Procedure for Therapeutic Goods for further explanation.
- A proforma for the provision of such advice is at Attachment 4.

6. Progress of Recall and Report

- Progress reports on the recalls are required to be submitted to the Australian Recall Co-ordinator at 2 weeks and 8 weeks after the commencement of the recall.
- A template for these reports, that can be used as is, are at Attachments 5 and 6.
- Further information may be requested at any time during the recall process.

7. Follow-up Action

- The effectiveness of the recall will be monitored by the Australian Recall Co-ordinator and the recall can be formally audited under the Commonwealth *Trades Practices Act 1974*.

Attachment 1

Draft pro forma recall letter

< Sponsors letterhead paper>

< Customer Name>
< Customer Address>

URGENT MEDICINE RECALL

PRODUCTS MANUFACTURED BY PAN PHARMACEUTICALS LTD FOR <SPONSOR or DISTRIBUTOR NAME>

<Company name> Pty Ltd, following serious concerns over the manufacturing processes involving the products listed below (or batches of product) and after consultation with the Therapeutic Goods Administration, is conducting a consumer level recall of these <products or batches of product>. No other batches or pack sizes of this product are affected by this recall. The batch numbers are displayed on the <position of batch numbers>.

Please inspect your stocks and quarantine all units from the above batch numbers, then complete the attached Facsimile Reply Form* and fax it to us so that we may arrange for your stock to be recovered. Please complete the Facsimile Reply Form even if you have no stock which is subject to recall, as we require this information to reconcile this process.

<a statement in relation to whether a refund is to be offered can be included here>

Please retain this letter in a prominent position for one month in case stock is in transit. <Company name> Pty Ltd sincerely regrets any inconvenience caused by this action.

<signature>

<relevant officer>
<Date>

*Please refer to the URPTG for an example of a Facsimile Reply Form

FACSIMILE REPLY FORM

To:	< Sponsor's name & address>
Attention:	< Sponsor's contact person>
Facsimile Number:	< Sponsor's facsimile number>
Postal Address:	< Sponsor's address>
	…….
Subject:	Recall of <product name/s>

From: *(Name of Institution)*	**…….**
Contact Person: *(please print)*	**……**
Telephone No:	**……**
Facsimile No:	**……**

- **We do/do not have stock which is subject to this recall.**
- **Stock received: <if multiple products, identify each product by batch>**

  Batch……..Qty…….

  Batch……..Qty…….

- **Unused stock subject to recall (currently in quarantine): <if multiple products, identify each product by batch>**

  Batch……..Qty…….

  Batch……..Qty…….

- **Any other relevant details: ……**

  ……

  Signature: ……..

  Date: ……..

Attachment 2

Recall Mailing Services

The following companies provide mailing services for the recall of therapeutic goods (mailings to hospitals, retail pharmacies, wholesalers, doctors, nursing homes etc.)

Pharmamail (Australian Pharmaceutical Publishing Company Ltd)
Suite F2
1-15 Barr Street
BALMAIN NSW 2041

Telephone (02) 9818 7800
Facsimile (02) 9818 7811

AMPCo (Australasian Medical Publishing Company)
Locked Bag 3030
STRAWBERRY HILLS NSW 2012

Telephone (02) 9562 6666
Facsimile (02) 9562 6662

Mail Marketing Works
2-6 Orion Rd
LANE COVE NSW 2066

Telephone (02) 9427 5063
Facsimile (02) 9418 7245

Attachment 3

Proposed press advertisement

URGENT MEDICINE RECALL

PRODUCTS MANUFACTURED BY PAN PHARMACEUTICALS LIMITED AND SUPPLIED BY VARIOUS SPONSORS AND DISTRIBUTORS

The Therapeutic Goods Administration, Australia's national regulator for medicines and other therapeutic goods, has in consultation with the sponsors (supplier or distributors) of the products identified below announced the immediate recall of the specified batches of these medicines.

These batches have been manufactured by Pan Pharmaceuticals Limited whose manufacturing licence has been suspended for a period of 6 months, with effect from 28 April 2003, due to serious quality and safety breaches in the manufacture of therapeutic goods by the company since 1 May 2002.

These recalls are being undertaken due to serious concerns that as the quality of the specific batches of medicines below cannot be assured, neither can their safety or effectiveness.

The list is organised by the AUST L* or AUST R* number followed by the product name.

If you have any of the specified batches of products on this list you should stop using them and safely dispose of any unused portions by returning to their local pharmacy. Questions of refunds will need to be addressed to the sponsor of the product. Anyone who is concerned in any way about the use of these medicines or availability of alternative products should consult their healthcare professional.

More information on this recall is available on the TGA website at www.tga.health.gov.au or from the toll-free Consumer Helpline on 1800 220 007 (8.30 am – 7 pm EST every day). Should further products be identified, this additional information will be available on the TGA website and the Recalls Australia Website

* The AUST L or AUST R can be located on the front panel of the label, usually in a lower corner. It is a 5 digit number prefixed by the letters AUST R or AUST L. As many product names are similar, it is important that this number is checked.

Attachment 4

Pro forma advice letter to The Competition and Consumer Policy Division of The Treasury

Required by s.65 of the Trade Practices Act 1974 for any safety-related recall.

- Company letterhead -

Senator the Hon. Ian Campbell
Parliamentary Secretary to the Treasurer
Competition and Consumer Policy Division
The Treasury
Langton Crescent
PARKES ACT 2600

Attention: Ms Gloria Hobbs Fax: (02) 6263 2830

Dear Minister

<Sponsor name> is recalling the therapeutic goods included in Schedule 1 to this letter due to serious concerns that as the quality of this/these medicine(s) cannot be confirmed, neither can the safety or effectiveness of this/these medicine(s) be assured.

The recall is being coordinated by the Therapeutic Goods Administration.

The Schedule also indicates where and to whom any affected product has been exported from Australia.

We have notified all parties to whom any recalled product has been exported and a copy of this advice to each party is attached.

Yours faithfully

[Signature]

Name:
Title:
Date:

Schedule 1

Sponsor Name: ……

Recall No*	Product Name	Batch/lot details	Exported Y/N	Export destination

*Sponsors will generate their own recall number by combining the following information
Prefix [SR] Sponsor enterprise number /AUST L or R number for the good.

Attachment 5

Interim reporting requirements pro forma
(information required two weeks after recall initiation for each product)

To : Australian Recall Co-ordinator
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Recall number: SR……/ ……. (to be generated by the sponsor by combining the following information Prefix [SR] Sponsor enterprise ID /AUST L or R number of the therapeutic good)

Product Name:……..

Quantity of product supplied in Australia:

Class of person advised of the recall:

Wholesaler	□
Retailer	□
Pharmacist	□
Direct sale consumer	□
Overseas importer	□

Attached is a signed copy (on company letterhead) of the recall letter

…….. signed

……/……/ 2003

Attachment 6

Final reporting requirements pro forma
(information required eight weeks after recall initiation for each product)

To : Australian Recall Co-ordinator
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Recall number: SR……/ ……. (to be generated by the sponsor by combining the following information Prefix [SR] Sponsor enterprise ID /AUST L or R number of the therapeutic good)

Product Name:……..

Quantity of product supplied in Australia:

Quantity of Australian supplied product returned:

Method of destruction or disposal of recalled medicines:

Remedial Action: Cancellation of product from the ARTG □

Removal of Pan Pharmaceuticals Limited from the list of approved manufacturers on the ARTG □

Nomination of a different manufacture on the ARTG □

…….. signed

……/……/ 2003