



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Uniform Recall Procedure for Therapeutic Goods

2004 edition

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. The TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

Electronic Copies

An electronic copy of this booklet can be downloaded free of charge from the TGA website.

Additional forms for the reporting of recalls and medicine problem reports can also be downloaded from the TGA website.

<http://www.tga.gov.au>

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A. Preamble and definitions

Preamble

The *Uniform Recall Procedure for Therapeutic Goods* (the 'Procedure') is the result of an agreement between the therapeutic goods industry and Commonwealth and State/Territory health authorities. Its purpose is to define the action to be taken by health authorities and sponsors when therapeutic goods for use in humans, for reasons relating to their quality, safety or efficacy, are to be removed from supply or use, or subject to corrective action. It should be noted that in this document 'quality' means compliance with statutory or agreed standards rather than grade of materials and workmanship.

The Commonwealth, each State, the Northern Territory and the Australian Capital Territory health authorities each nominate an officer and a deputy through whom information relating to product recall will be channelled and co-ordinated. Overall responsibility for co-ordination of recalls lies with the Australian (Commonwealth) Recall Co-ordinator, who is an officer of the Therapeutic Goods Administration (TGA), Australian Department of Health and Ageing.

Each sponsor of therapeutic goods should advise the Australian Recall Co-ordinator of the names, after-hours addresses and telephone numbers of two persons in the sponsor company who have authority to discuss and, if necessary, implement a recall (see Appendix VI).

When the need for a recall has been established, the sponsor of the affected goods assumes the responsibility for recovery of the goods, or corrective action, while the 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 not mandated but are sponsor initiated. 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 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 for details.) The *Trade Practices Act 1974* contains provisions in relation to the safety-related recall of consumer goods. The relevant parts of the Act, which are administered by the **Product Safety Policy Unit, Australian Competition and Consumer Commission (ACCC)** 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 for details).

The Procedure is recognised by the ACCC as being appropriate to the specialised requirements for the recall of therapeutic goods. Its use is therefore, in effect, obligatory in relation to safety-related recalls of therapeutic goods.

Where recall is refused, or is not carried out satisfactorily, the Minister may order a mandatory recall. Failure to comply with such an order may result in substantial fines.

Relevant parts of the Procedure may also be used by sponsors for the purpose of disseminating emergency information on the safe use of therapeutic goods. This will normally be restricted to situations involving a significant safety factor and where distribution of the affected goods has been on a national scale.

Definitions

Recall is an action taken to resolve a problem with therapeutic goods for which there are established deficiencies in quality, efficacy or safety.

Two distinct types of recall are included in this Procedure:

- a. permanent removal of deficient goods from the market or from use; and
- b. correction, which may involve temporary removal from the market or from use.

These are designated **Recall** and **Recall for Product Correction** respectively.

Recall - means the permanent removal of therapeutic goods from supply or use for reasons relating to deficiencies in the quality, safety or efficacy of the goods.

It includes:

- requests to pharmacists, hospitals, pathology laboratories, fractionators, operating and research facilities, biomedical engineers or others to check and return goods found to be defective; and
- removal from supply or use of goods with inherent design or manufacturing defects.

It does not include:

- removal of time-expired goods; and
- removal of appropriate numbers of goods to determine whether there are deficiencies relating to quality, safety or efficacy.

Recall for Product Correction - means the repair, modification, adjustment or re-labelling of therapeutic goods for reasons relating to deficiencies in the quality, safety or efficacy of the goods. The corrective action may take place at the user's or the sponsor's premises or any other agreed location.

It includes:

- corrections involving a product's expiry date; and
- changes to any accessories, operating instructions or software, correcting deficiencies relating to the quality, safety or efficacy of the goods or outputs.
- Field corrections

It does not include:

- removal of individual goods for repair in the event of malfunction or failure as a result of normal wear and tear or for appropriate maintenance or due to lack of good maintenance; and
- removal of individual goods for modification due to technical improvements other than when these improvements overcome an inherent design or manufacturing defect.

Hazard Alert - means the issuing of precautionary information about an implanted device where it has been proven that there is no stock to be recalled and all affected devices are already implanted (this category only relates to implantable medical devices).

Sponsor - is the person, business or company that has the primary responsibility for the supply, including for clinical investigational use, of the product in Australia. The sponsor may also be the manufacturer of the goods.

Therapeutic Goods means goods:

1. that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - i. for therapeutic use; or
 - ii. for use as an ingredient or component in the manufacture of therapeutic goods; or
 - iii. for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
2. included in a class of goods the sole or principal use of which is, or ordinarily is a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes goods declared to be therapeutic goods under an order in force under section 7 of the *Therapeutic Goods Act 1989*, but does not include:

3. goods declared not to be therapeutic goods under an order in force under section 7 of the *Therapeutic Goods Act 1989*; or
4. goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or
5. goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

Therapeutic Use - means use in or in connection with:

1. preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
influencing, inhibiting or modifying a physiological process in persons or animals; or
testing the susceptibility of persons or animals to a disease or ailment; or
influencing, controlling or preventing conception in persons; or
testing for pregnancy in persons; or
the replacement or modification of parts of the anatomy in persons or animals.

Supply - includes:

1. supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and
2. supply, whether free of charge or otherwise, by way of sample or advertisement; and
3. supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons or animals; and
4. supply by way of administration to, or application in the treatment of, a person or animal.

Non-recall Actions

Safety Alert, Product Notification, Withdrawal and Recovery are four associated actions which are not recall actions, and are therefore not subject to this Procedure (Note: Hazard Alerts are considered to be recall actions which are subject to the Procedure). Where the sponsor is unsure of the appropriate action to be taken, and particularly in cases where patient safety may be a consideration, the issues involved should be discussed with the Australian Recall Co-ordinator.

Safety Alert - means advice regarding a specific situation with respect to a therapeutic good which, whilst performing to meet all specifications and therapeutic indications, might present an unreasonable risk of substantial harm if certain specified precautions in regard to its use are not observed.

Safety Alerts are intended only to provide information on safe use of therapeutic goods, as distinct from recall action which addresses product deficiencies. As patient safety is a factor in both, sponsors are encouraged to distribute Safety Alerts with a minimum of delay.

As mentioned in the Preamble, sponsors may, if they wish, use appropriate sections of the Procedure to assist in the dissemination of Safety Alert information. Copies of Safety Alerts should be forwarded to the Australian Recall Co-ordinator for distribution to the State/Territory health authorities for their information.

Product Notification - means the issue of precautionary information about a therapeutic good, in a situation that is unlikely to involve significant adverse health consequences.

Withdrawal - means a sponsor's removal from supply or use of therapeutic goods for reasons not related to their quality, safety or efficacy.

Recovery (for purposes of this document) - means a sponsor's removal of therapeutic goods from sale or supply that have not already been supplied by the sponsor.

B. Stages of recall procedure

The objective of the *Uniform Recall Procedure for Therapeutic Goods* is to facilitate recall when a deficiency in therapeutic goods is established and warrants such action.

The Procedure is divided into seven stages, which are set out below, with a reference to the Section in which detailed information is given.

Recall Stage		See Section
1	<p>Notification to the Co-ordinator Crisis management</p> <p>This should be to the Australian Recall Co-ordinator.</p>	C
2	<p>Information Required to Assess Recall</p> <p>Information on product, problem and distribution is required, (see also - The Medicine Problem Report Form, Medical Device Incident Report Form and Human Blood and Tissues Report Form at Appendices I, II and III).</p>	E
3	<p>Assessment of Recall</p> <p>Liaison between sponsor and Australian Recall Co-ordinator to assess classification, level and strategy of recall.</p>	F
4	<p>Recall</p> <p>Letters and advertisements are submitted by the sponsor to the Australian Recall Co-ordinator for approval before despatch.</p>	G
5	<p>Notification to the Federal Minister Responsible for Consumer Affairs</p> <p>Where the recall is safety-related, there is a legal requirement to notify the <i>Minister via the Product Safety Policy Unit, Australian Competition and Consumer Commission (ACCC)</i>.</p>	M
6	<p>Progress of Recall and Report</p> <p>Progress reports are forwarded to the Australian Recall Co-ordinator.</p>	H
7	<p>Follow-up Action</p> <p>The effectiveness of the recall is monitored by the Australian Recall Co-ordinator.</p>	K

C. Notification/initiation of recall

Recall might be initiated as a result of reports referred to sponsors or co-ordinators from a variety of sources. The reports may be referred by manufacturers, wholesalers, retail and hospital pharmacists, blood banks, fractionators, pathology departments, tissue banks, operating and research facilities, medical practitioners, biomedical engineers, dentists and patients. Recall might also be initiated as a result of analysis and testing of samples of therapeutic goods by sponsors and by the Commonwealth and State/Territory testing laboratories; and as a result of advice received from the Australian Drug Evaluation Committee, the Adverse Drug Reaction Advisory Committee, the Medical Device Evaluation Committee, the Medicines Evaluation Committee, the Complementary Medicines Evaluation Committee and other bodies. Recall of goods manufactured overseas might be initiated by reports appearing in FDA Enforcement Reports and similar publications of health authorities, or from information received directly from such authorities.

Certain information is essential to permit the assessment of the validity of the report of a problem with therapeutic goods, the potential danger to consumers and the action appropriate to the situation. Copies of the Medicine Problem Report, Medical Device Incident Report and the Human Blood and Tissues Report Forms are provided at Appendices I, II and III respectively. These forms are used to report problems to the Therapeutic Goods Administration. Manufacturers, sponsors and distributors may also find the forms convenient for reporting problems.

Serious problems which may lead to recall should be reported directly to the TGA for investigation. Reports made to a State/Territory Recall Co-ordinator, with any opinions on toxicological or therapeutic hazards and the action proposed by the State/Territory should be referred on to the appropriate officers in the TGA. These are the Australian Recall Co-ordinator (medicine problems) and the Manager, Medical Device Incident Reporting Scheme (device problems).

When the need for recall has been established, additional information is required so that an appropriate recall strategy may be devised. A summary of the information required is provided in Section E.

Special Note on Radiopharmaceuticals

A special procedure is used for the initiation of recalls for short-lived radiopharmaceuticals, some of which are distributed before all quality control tests are completed. If such a product is shown not to comply with relevant specifications or if, for some other reason, doubt exists as to the product's quality, safety or efficacy, the head of the distributing organisation's radioactive products section or a nominated deputy must take immediate action to prevent its use by informing users accordingly by telephone or facsimile and seeking acknowledgment. The Australian Recall Co-ordinator should also be advised immediately.

In the case of telephone advice to users of radiopharmaceuticals or when incomplete facsimile advice has been given initially, a facsimile or medicine recall letter giving full details in accordance with Section G, as appropriate, is to be sent to users. The text of the communication is to be approved by the Australian Recall Co-ordinator.

D. Crisis management (including tampering of therapeutic goods)

A crisis is an unprecedented set of circumstances which represents an immediate and significant threat to a company, consumers of its products, employees and/or the community. This may include threats to the product, damage to the public image/reputation of a company or its products or a disruption of the production process. Such events are likely to attract media interest.

“Crisis Management Guidelines” have been developed by the Australian Self Medication Industry (tel 02 9922 5111, fax 02 9959 3693, www.asmi.com.au) in consultation with Medicines Australia, the Complementary Healthcare Council of Australia, the Medical Industry Association of Australia, Consumers’ Health Forum, the Therapeutic Goods Administration, State and Territory Health Departments and Police Departments.

Companies are urged to implement these Guidelines as quickly as possible and to ensure that the appropriate personnel are trained in their operation.

Tampering of Therapeutic Goods - All threats of criminal tampering with a company’s products should be considered to be genuine and therefore serious and be immediately reported to the Australian Recall Co-ordinator. (There is also a legal obligation to report such matters-see Section K). The Australian Recall Co-ordinator will convene a Crisis Reference Group (CRG) which will co-ordinate the activities required to resolve the crisis.

For any tampering crisis, the CRG will comprise:

The Australian Recall Co-ordinator nominated in the *Uniform Recall Procedure for Therapeutic Goods*;

The State or Territory Health Department Recall Co-ordinator nominated in the *Uniform Recall Procedure for Therapeutic Goods*;

The appropriate State Police officers nominated for this purpose by the Police Ministerial Council; and the senior personnel of the company concerned.

E. Information required for assessment of recall

Prior to notification of a recall situation to the Australian Recall Co-ordinator or the State/Territory co-ordinator, the sponsor should gather all the relevant information on problem reports, the product and its distribution, and action proposed. Similarly, the Co-ordinator should make available to the sponsor all relevant information on hand. Some of the information (for example, batch size, distribution chains and quantities distributed) will only be known to the sponsor and it is important for it to be readily accessible for use in recall situations.

The type of information required may include:

Details of the Problem

- name, telephone and facsimile number of the person reporting the problem;
- date of report;
- physical location of problem;
- nature of the problem;
- number of similar reports received;
- results of tests and other investigations on suspect or other samples;
- availability for investigation of suspect sample or other samples; and
- other relevant factors

Details of the Product

- product name and description including dosage form, strength, ARTG number, pack size or type;
- batch, serial number(s), donation number(s) or tissue bank number(s);
- expiry date (if relevant);
- manufacturer/Australian sponsor and contact telephone and facsimile numbers;
- date manufactured;
- date released;
- quantity of the batch, date and amount released;
- local distribution;
- overseas distribution of product exported from Australia;
- number of complaints received;
- whether the product is meant to be sterile; and
- sponsor's product/part/order code.

Risk assessment and proposed action

- type of hazard, and assessment of risk to user;
- action proposed by sponsor;
- proposed recall classification;
- proposed recall level; and
- availability of alternative product

It is recognised that some of the information provided may be of a commercially sensitive or private nature and such information will be treated appropriately.

F. Assessment of recall (strategy, classification, and level)

Strategy

Each recall is a unique exercise. However, in tailoring an appropriate recall strategy, there are a number of factors common to all recalls that need to be considered. These include the nature of the deficiency in the product, the incidence of complaints, consumer safety, distribution networks, recovery procedures, resources for corrective action and availability of alternative products.

In discussing the recall strategy, the sponsor and Co-ordinator should consider the factors which may affect the duration of the recall action, and a completion date should be agreed.

The actual implementation of the recall includes use of the basic steps which are summarised in section B and these will be common to all strategies.

Even when the required information (Section E) is available to the sponsor and to the Co-ordinator, the appropriate strategy may not be obvious and further liaison will then be necessary in order to attain an agreed course of action.

Classification

Recalls are classified according to the European classification system:

- Class I recalls occur when products are potentially life-threatening or could cause a serious risk to health.

Examples of Class I Defects

- Wrong product (label and contents are different products)
- Correct product but wrong strength, with serious medical consequences
- Microbial contamination of sterile injectable or ophthalmic product
- Chemical contamination with serious medical consequences
- Mix up of some products (“rogues”) with more than one container involved
- Wrong active ingredient in a multi-component product with serious medical consequences

- Class II recalls occur when product defects could cause illness or mistreatment, but are not Class I.

Examples of Class II Defects

- Mislabelling e.g. wrong or missing text or figures
- Missing or incorrect information – leaflets or inserts
- Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
- Chemical/physical contamination (significant impurities, cross contamination, particulates)
- Mix up of products in containers (“rogues”)
- Non-compliance with specification (e.g. assay, stability, fill/weight).
- Insecure closure with serious medical consequences (e.g. cytotoxics, child resistant containers, potent products).

- Class III recalls occur when product defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

Examples of Class III Defects

- Faulty packaging e.g wrong or missing batch number or expiry date.
- Faulty closure
- Contamination – microbial spoilage, dirt or detritus, particulate matter.

Class I or Class II recalls are considered to be urgent safety-related recalls. A safety related recall is defined under the Trade Practices Act 1974 as the recall of 'goods of a kind which will or may cause injury to any person'. Where the recall is safety-related, there is a legal requirement to notify the Minister (via the ACCC). See Section M for further details.

Class III recalls are considered to be routine non safety-related recalls

Note: Each recall is a unique exercise and there may be occasions when the scope of a recall can be narrowed to particular customer groups. For example, in some specific situations, hospital pharmacies might be excluded from a recall applying to retail pharmacies. The classification is determined by consultation between the sponsor, the Australian Recall Co-ordinator, and where appropriate, the State/Territory co-ordinator. Expert advice should be sought where the nature of the hazard or its significance is not clear.

Level

As with classification, the level (or depth) of a recall is to be determined by consultation between the sponsor, the Australian Recall Co-ordinator and, where appropriate the State/Territory co-ordinator. In determining the recall level, the principal factors to be considered are the significance of the hazard (if any), the channels by which the goods have been distributed, and the level to which distribution has taken place. Again, expert opinion may be necessary to determine the significance of the hazard.

In this procedure there are four levels of recall: wholesale, hospital, retail and consumer. One of these levels will be assigned to each recall.

Wholesale level

Includes:

- Medicine and device wholesalers
- State purchasing authorities etc.

Hospital level

Includes:

- nursing homes, hostels and other institutions;
- clinical investigators and the institutions in which clinical investigations are performed;
- hospital pharmacists, blood banks, pathology laboratories, operating facilities, fractionators, human tissue banks and personnel in other hospital departments; and
- wholesale level.

Retail level

Includes:

- retail pharmacists;
- medical, dental and other health care practitioners;
- other retail outlets, e.g. supermarkets and health food stores; and
- wholesale and hospital levels.

Consumer level

Includes:

- patients and other consumers; and
- wholesale, hospital and retail levels.

G. Recall letters, paid advertisements and media releases

Recall letters should include a factual statement of the reasons for the recall of the product, together with specific details that will allow the product to be easily identified

(See example letter at Appendix VIII).

The text of the recall letter is to be sent to the Australian Recall Co-ordinator for approval before being despatched. The letter, which may be sent by mail or facsimile or e-mail (and then also posted if sent by facsimile or e-mail), should be despatched within 48 hours of receiving the Co-ordinator's agreement. A signed copy of the recall letter (or facsimile) to customers is to be sent to the Australian Recall Co-ordinator at this time.

Medicine, Medical Device and Human Blood and Tissues* Recall Letters, Facsimiles or E-mails

[Use company letterhead; include date and name and title of signatory.]

Headings

If Class III:

'Medicine Recall' or 'Medical Device Recall' or 'Human Blood and Tissues Recall' or 'Recall for Product Correction' or 'Hazard Alert'

If Class I or II:

'Urgent Medicine Recall', or 'Urgent Medical Device Recall' or 'Urgent Human Blood and Tissues Recall' or 'Urgent Recall for Product Correction' or 'Hazard Alert'

Composition of Text

1. name of the product;
2. ARTG number (AUST L or AUST R) when this appears on the product;
3. unique identifying number(s) (Human Blood and Tissue products);
4. pack size;
5. dosage form or model;
6. batch or serial number;
7. expiry date (when this appears on the product);
8. other details necessary to allow absolute identification (eg. catalogue/ part/ order number as appropriate);
9. reason for recall;

10. necessity to identify and quarantine the product from further sale or supply;
11. the method of recovery (or disposal, if appropriate) or product correction which will be used;
12. a request to retain the letter in a prominent position for one month in case stock is in transit (where applicable); and
13. Contact telephone number and facsimile return numbers (preferably toll free).

If safety to the public is involved and distribution is limited, after discussion with the Australian Recall Co-ordinator, the information listed above may be given by telephone and then confirmed by the recall letter. This should happen in the case of **radiopharmaceuticals**, for which specific instructions for the packaging and return to the sponsor, or specific instructions for the disposal of the materials, are to be given.

Where recalled stock has been distributed to a limited number of hospitals and the recall letter is not to be sent to all hospitals in the respective State/Territory, the letter is to include the following statement or words to the effect of:

'If any of the recalled stock could have been transferred from your hospital to another, please immediately let that hospital know of the recall. It would be appreciated if you would then telephone - long distance callers reverse charge - the nearest company office indicated below so that we can make contact with the hospital supplied from your hospital.'

A business reply card or a facsimile reply form (see appendix VIII for an example) may be included with the recall letter where the sponsor considers this necessary.

*Recall letters for Human Blood and Tissue products must be sent by facsimile with a follow up phone call to hospitals. Sending letters is optional.

Envelopes for Dispatch of Recall Letters

A distinctive standard envelope is required to ensure that it is easily recognised among the large amount of mail usually received by professional people. The envelope is used for all classifications of recalls.

The envelope has been approved by Australia Post and measures about 220 x 110 millimetres and has a red border 2 - 3 millimetres wide along the top edge of the face.

The words '**Urgent - Medicine Recall**' or '**Urgent - Medical Device Recall**' or '**Urgent - Human Blood and Tissues Recall**' or '**Urgent - Product Correction**' or '**Hazard Alert**' are printed diagonally in bold red type at least one centimetre high in the top left hand corner and are underlined with three red bars of increasing thickness (See example envelopes at Appendix VII).

Full details of the design of the envelope and advice on commercial sources of supply may be obtained from the Australian Recall Co-ordinator.

Addressing of Recall Letters and Envelopes

i. Medicine Recalls

For hospitals, address to:

'Chief Pharmacist'.

In the case of a clinical investigational medicine, address to:

'Clinical Investigator' and 'Chief Pharmacist' (a copy of the letter to each) in the institutions in which the clinical investigations have been performed.

In the case of radiopharmaceuticals a copy of the letter should be sent to the head of each relevant department of nuclear medicine and pharmacy (e.g. 'Director of Nuclear Medicine').

ii. Medical Device Recalls

In the case of medical devices in a hospital, address to:

'Chief Executive Officer'

and marked to the attention of the head of the appropriate department. In the case of a clinical investigational device, address to:

'Clinical Investigator'

and if appropriate:

'Chief Biomedical Engineer'

and/or:

'Director of Nursing'.

iii. Human Blood and Tissues

'Senior Scientist and/or Pathologist'

and if appropriate, the Recipient's Surgeon.

Paid Advertisements

If the depth of recall is to consumer or retail level and the consumers or retail outlets cannot be identified (see Section H), advertisements paid by the sponsor are to be inserted in the daily print media of each State/Territory in which distribution has possibly taken place.

Description of Paid Advertisements

Choice of daily media - This should be made in consultation with the Australian Recall Co-ordinator or as described by the delegate in decisions relating to mandatory recalls. The Australian Recall Co-ordinator has available a list of the major media in each State and Territory. Consideration should also be given to the need to inform ethnic groups.

Size - Double column width by 10cm deep is the minimum size for advertisements, which should be enclosed in a diagonally hatched border.

Position - Advertisements are placed in one of the first five pages of each of the daily print media chosen.

Text - This is submitted to the Australian Recall Co-ordinator for confirmation before it is sent for publication.

Headings

If Class III: 'Medicine Recall' or 'Medical Device Recall' or 'Recall for Product Correction'.

If Class I or II: 'Urgent Medicine Recall' or 'Urgent Medical Device Recall' or 'Urgent Recall for Product Correction'.

Composition of Text

1. name of product;
2. ARTG number (AUST L or AUST R) where this appears on the label of the product;
3. pack size;
4. dosage form or model;
5. batch or serial number;

6. expiry date (where this appears on the label of the product);
7. other details necessary to allow absolute identification;
8. reason for recall;
9. a statement on the continued use or supply of the product;
10. the method of recovery (or disposal, if appropriate) and/or product correction which will be used;
11. if the hazard to the patient is serious, indications of clinical symptoms and advice to consult a medical practitioner, if desired; and
12. where the sponsor is unable to make a correction or offer replacement stock within a reasonable period, an indication of the likely time frame for correction or provision of replacement stock; and
13. Contact telephone number (preferably toll free).

Media Release

In the case of Class I or II consumer level recalls, it may be necessary to issue a media release. The text of the media release is developed by the sponsor, in consultation with the Australian Recall Co-ordinator. Expert advice may also be required.

The media release must contain sufficient detail to uniquely define the product, together with a clear outline of the problem (without causing unnecessary alarm) and must state the appropriate response by the consumer. A telephone number of the sponsor, to allow 24-hour access to further information, should be give

H. Responsibilities of sponsors

Sponsors, and persons with responsibilities for the supply of Human Blood and Tissues products, have responsibilities in relation to recall of therapeutic goods in two general areas:

1. in maintaining records and establishing procedures which will assist in facilitating recall should such action become necessary; and
2. in taking the prime responsibility for implementing recall in the situation where it is necessary.

Records

In accordance with the requirements of the relevant Manufacturing Principles and the Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the *Therapeutic Goods Act 1989*, sponsors should maintain records for the products manufactured by them in accordance with the following:

1. A system should be in operation whereby the complete and up-to-date histories of all batches of products from the starting materials (in the case of a medical device, all components) to the finished products are progressively recorded.
2. The system should allow the determination of utilisation and disposal of all starting materials (in the case of a medical device, all components) and bulk products.
3. For products having an expiry period, the complete records pertaining to manufacture should be retained for at least one year after the expiry date of the batch; otherwise, the complete records pertaining to the batch should be retained for at least six years after the date of its manufacture noting that other legislature requirements may impose much greater periods.

All sponsors should maintain records of problem reports received about each product. Problem reports should be evaluated by competent personnel and appropriate action taken. The evaluation of each report and the action taken should be shown in the records.

It is a requirement of the *Therapeutic Goods Act 1989* for sponsors to retain records of the distribution of registered/listed goods for a period of five years.

All records should be readily available and easy to follow so as to expedite recall whenever necessary.

The *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* sets out appropriate procedures for wholesaler distributors so that there is effective, efficient and safe handling, storage and distribution of such products. It is in the sponsor's interest to encourage their wholesalers to follow this Code

Sponsor Recall Procedure

As mentioned in Section B, sponsors should prepare procedures for recall action which are consistent with this Procedure and which are applicable to their own operations.

All senior personnel should be familiar with their responsibilities in connection with the procedure and of the records system for products.

Pre-Recall

Where evaluation of a problem report concerning therapeutic goods indicates that recall may be necessary, the report must be conveyed with the least possible delay to the Australian Recall Co-ordinator, including goods that have been exported – only and not supplied in Australia. Any batch of a formulated product that has been distributed, or any batch of a starting material that is found not to comply with the approved sponsor's specifications or a relevant standard of the Commonwealth *Therapeutic Goods Act 1989* (or complementary State/Territory legislation), must also be reported if it has been used in a distributed product.

Recall

The sponsor has the prime responsibility for implementing recall action, and for ensuring compliance with the recall procedure at its various stages (Section B). However, no recall, regardless of level, should be undertaken without consultation with the Australian Co-ordinator and without agreement on the recall strategy.

In cases of significant hazard to consumers, company personnel may be utilised to immediately disseminate information on the recall. This includes telephone advice to quarantine stock pending recall or possible recall. This advice should be based on the agreed text of the recall letter or facsimile, which must always be sent as confirmation of oral advice.

Company representatives (medical detailers and sales representatives) may be utilised to recover stock which is the subject of recall, providing the provisions of State/Territory and any applicable Commonwealth regulations are observed in relation to unauthorised possession of certain stock, e.g. medicines of addiction and restricted substances, and suitable recall letters in compliance with Section G are despatched.

For recall in which distribution to outlets such as supermarkets, health food stores and family planning clinics has taken place, the sponsor is to insert, as quickly as possible, paid and approved advertisements in the daily print media of each State/Territory in which distribution may have occurred (Section G), unless complete and accurate distribution lists are available.

For consumer level recall action, the sponsor is to insert, as quickly as possible, paid and approved advertisements in the daily print media of each State/Territory in which distribution may have occurred (Section G). The sponsor is to prepare a recall letter (Section G) for distribution to wholesalers and retailers upon approval of the text by the Australian Recall Co-ordinator.

Sponsors may also be required to notify overseas recipients of recall actions that affect them (Section M).

Sponsors should keep relevant wholesalers advised of the recall. The recall can involve wholesalers in considerable time and expense in issuing credit notes, handling returned stock and forwarding replacements.

Sponsors should be aware that the Commonwealth Minister responsible for Consumer Affairs may, under section 65F of the *Trade Practices Act 1974*, order suppliers to recall goods if it appears the supplier has not taken satisfactory action to prevent the goods causing injury to any person. This power applies not only to situations where the supplier has not taken any action to reduce risk to the public, but also where a supplier has taken action which is considered inadequate. As section 65F of the *Trade Practices Act 1974* empowers the Minister to order recalls for product correction, the power also applies to recalls for correction which are considered to be inadequate.

Post Recall

At two and six weeks after the implementation of recall, or at other agreed times, the sponsor is to provide the Australian Recalls Co-ordinator with an interim and a final report on the recall. The reports are to contain the following information (however, sponsors are not required to repeat information in the final report that has already been given in the interim report, unless there is a change to that information):

1. the circumstances leading to the recall;
2. the consequent action taken by the sponsor;
3. the extent of distribution of the relevant batch in Australia and overseas;
4. the result of the recall - quantity of stock returned, corrected, outstanding, etc;
5. confirmation, where practicable, (eg. hospitals, specialist clinicians) that customers have received the recall letter;
6. the method of destruction or disposal of recalled goods; and
7. the action proposed to be implemented in future to prevent a recurrence of the problem.

These reports establish the effectiveness of the recall and form the basis of reports to the ACCC Product Safety Policy Unit (safety-related recalls) and to the National Co-ordinating Committee on Therapeutic Goods. Unless satisfactory reports are received, further recall action may have to be considered.

I. Responsibilities of Australian recall co-ordinator

In connection with recall of therapeutic goods, using the Procedure, the responsibilities of the Australian Recall Co-ordinator are:

1. A list of current recall co-ordinators for sponsor companies is to be maintained.
2. The Uniform Recall Procedure for Therapeutic Goods is to be maintained for currency and available on the TGA Website (<http://www.tga.gov.au>) for downloading free of charge.
3. Copies of the Uniform Recall Procedure for Therapeutic Goods are to be available to all sponsors of therapeutic goods and others on request.
4. The Australian Recall Co-ordinator will advise the sponsor immediately of problem reports with therapeutic goods which may necessitate recall. All available information is to be provided in order to facilitate investigation by the sponsor.
5. Where there may be a hazard to the user, expert advice on the classification and level of recalls may be sought by the Australian Recall Co-ordinator.
6. The Australian Recall Co-ordinator will liaise with the sponsor on recall and provide advice and assistance in relation to letters, advertisements and recall strategies. Sponsors will be informed of actions being taken by the Australian Recall Co-ordinator in advising third parties.
7. Where applicable, the Australian Recall Co-ordinator will liaise with State and Territory Recall Co-ordinators in assessing the strategy for recall.
8. In patient or consumer level recalls, where the consumer hazard warrants, the Australian Recall Co-ordinator will liaise with experts within the Therapeutic Goods Administration and with the sponsor to prepare a statement for immediate use by the media (including the major ethnic media). These statements are intended to bring the problem to consumers' attention as quickly as possible as there may be a delay of several days in publication of paid advertisements.
9. Where necessary, the co-ordinator is to liaise with officers of the ACCC on safety-related recall actions.
10. The Australian Recall Co-ordinator will forward for each recall a report in writing (by facsimile and/or email) to the relevant parties listed in Appendix V. Such reports will include identification of the goods for which recall action is being taken, the nature of the problem, an assessment of consumer hazard, the distribution of the goods and the action proposed. For urgent recall action, notification is to be by telephone with confirmation in writing.
11. Where therapeutic goods have been exported to other countries, and are subject to safety related recall, the Co-ordinator will liaise with the sponsor in order to determine:
12. the sponsor's recall strategy for the exported goods; and
 - i. the form of the TGA advice of the recall to the authorities in the other countries.

The Australian Recall Co-ordinator will forward copies of sponsors' final recall reports and related papers to the Australian Competition and Consumer Commission, Product Safety Policy Section where the recall is safety-related.

The Australian Recall Co-ordinator will maintain detailed records of individual recalls and a register in which summaries of recalls are entered.

The Australian Recall Co-ordinator will prepare summarised reports of all recalls for review at meetings of the National Co-ordinating Committee on Therapeutic Goods.

The Australian Recall Co-ordinator may accompany personnel from the ACCC, Product Safety Policy Section, on audits of sponsors' records of safety-related recalls.

The Australian Recall Co-ordinator is responsible for the preparation of safety-related recall summaries for publication in the Bulletin of Australian Recalls and Cancellations published by the Therapeutic Goods Administration.

J. Responsibilities of state and territory co-ordinators

State/Territory Recall Co-ordinators have responsibilities in:

1. Passing on product problem reports and recall action information to the Australian Recall Co-ordinator:
 - Any problem which has been reported to a State/ Territory Recall Co-ordinator is to be notified to the Australian Recall Co-ordinator without delay. Advice from sponsors should be referred to the Australian Recall Co-ordinator.
 - Failures of goods found by State/Territory health authorities in testing for State Government tenders are to be notified to the Australian Recall Co-ordinator.
 - State/Territory Recall Co-ordinators are to provide details of recalls to other relevant organisations in the State/Territory.

Maintaining a current Rapid Alert System to communicate in an emergency, urgent safety related information to all public and private hospitals.

Assist in the timely provision of critical recalls information to pharmacists and other professional groups.

K. Follow-up action

The follow-up action consists of a check on the effectiveness of the recall and an investigation of the reason for the recall and remedial action taken to prevent a recurrence of the problem.

Check on Effectiveness of Recall Action

The Australian Recall Co-ordinator examines the reports received from the sponsor and an assessment made of the effectiveness of recall action. Recall records may be inspected by TGA and in some cases the records may be audited by the ACCC in the company of TGA.

Investigation of the Reasons for Recall and Initiation of Remedial Action

On completion of a recall, the sponsor is requested to provide details of the remedial action proposed to prevent a recurrence of the problem which gave rise to the recall (Section H). Where the nature of the problem and appropriate remedial action are not apparent, investigation and in some cases Good Manufacturing Practice audits may be necessary.

It is required under the *Therapeutic Goods Act 1989* that therapeutic goods made overseas for supply in Australia shall be subject to levels of good manufacturing practice equivalent to those expected for similar products manufactured in Australia.

Appropriate follow-up action will be taken by the Therapeutic Goods Administration where indicated; this might include, for example, review of the product by the relevant Product Regulator of the Therapeutic Goods Administration.

Where a recall is initiated following a report submitted by a party from outside the Commonwealth or the State/Territory health authorities, the reporter is to be provided, on request, with an outline of the results of investigations and a summary of the recall.

L. Commonwealth *Therapeutic Goods Act* 1989 Requirements

The *Therapeutic Goods Act 1989* (the Act) was amended in May 2003 to include new recall provisions for therapeutic goods which are regulated under Chapter 3 of the Act. The amendments ensure that similar recall provisions apply under Chapter 3 (relating to medicines, therapeutic devices covered by transitional arrangements and exempt goods) and Chapter 4 (relating to medical devices).

1. Introduction

The Act contains separate but similar recall provisions for therapeutic goods regulated under Chapter 3 and therapeutic goods regulated under Chapter 4.

Therapeutic goods regulated under Chapter 3 include medicines, therapeutic devices covered by transitional arrangements and exempt goods. The recovery provisions for these goods are set out in section 30EA of the Act.

Therapeutic goods regulated under Chapter 4 are medical devices. The recovery provisions for medical devices are set out in section 41KA of the Act.

The Act also contains recovery provisions for therapeutic goods that have been, or could possibly be, subject to actual or potential tampering. These provisions are set out in section 42V of the Act.

2. Recovery of goods regulated under Chapter 3

Section 30EA of the Act provides for public notification and recovery of therapeutic goods to which Chapter 3 applies (medicines and other therapeutic goods that are not medical devices). The powers in section 30EA of the Act are similar to the provisions contained in section 41KA of the Act for medical devices.

In short, section 30EA allows the Secretary to take action where:

- Therapeutic goods do not conform with applicable standards, or the relevant manufacturing principles have not been complied with;

Therapeutic goods have been supplied in contravention of:

- subsection 20(1) of the Act (ie a person imports, exports, manufactures or supplies therapeutic goods that are not registered or listed, or are not exempt under section 18 or 18A or are not the subject of an approval or authority under section 19 or section 19A); or
- subsection 42E(1) of the Act (ie a person manufactures or supplies in Australia, or imports into or exports from Australia therapeutic goods that are counterfeit and the person knows that fact or is reckless as to whether that fact exists);
- The manufacturer is unlicensed; or
- The registration or listing of the goods has been cancelled.

Depending on the circumstances, either the person supplying the goods or the person in relation to whom the goods are included in the Register may be required by the Secretary to take action in relation to the goods.

The person on whom the Secretary imposes requirements can be required to do one or more of the following:

- Take specified steps in a specified manner and within the reasonable period specified to recover goods that have been distributed;
- Inform the public or a specified class of persons what has happened;
- Publish specified information relating to the manufacture or distribution of the goods.

Recall and associated actions may be limited to specified batches of therapeutic goods. 30 EA (4) recall requirements do not apply to goods that cannot be recovered because they have been administered to, or applied in the treatment of, a person.

Imposition of requirements under section 30EA of the Act does not affect the Secretary's power to cancel the registration or listing of the goods.

When the Secretary takes action under section 30EA of the Act, the Secretary must cause to be published in the *Gazette* a notice setting out the particulars of the requirements imposed.

Non-compliance with requirements imposed under section 30EA of the Act constitutes an offence punishable on conviction by a maximum penalty of 60 penalty units.

3. Recovery of goods regulated under Chapter 4

Section 41KA provides for the public notification and recovery of medical devices.

The Secretary may take action in relation to medical devices where:

- The goods are included in the Register but do not comply with the essential principles, or the conformity assessment procedures have not been applied to medical devices of that kind;
- The goods supplied are exempt devices, or there is an approval under section 41HB (exemptions for special and experimental uses) relating to devices of that kind, or there is an authority under section 41HC (exemptions for medical practitioners) relating to devices of that kind, but medical devices of that kind do not comply with the essential principles, or the conformity assessment procedures have not been applied to medical devices of that kind;
- The goods supplied are not included in the Register and are not an exempt device, and there is no approval under section 41HB relating to devices of that kind, and there is no authority under section 41HC relating to devices of that kind;
 - The goods have been suspended from the Register; or
 - The goods have been cancelled from the Register.

Depending on the circumstances, either the person supplying the goods or the person in relation to whom the goods are included in the Register may be required by the Secretary to take action in relation to the goods.

The person on whom the Secretary imposes requirements can be required to do one or more of the following:

- Take specified steps in a specified manner and within the reasonable period specified to recover medical devices that have been distributed;
- Inform the public or a specified class of persons what has happened.

The imposition of requirements to recover medical devices may be limited to those medical devices of the kind to which the specific circumstances apply.

Recall requirements do not apply to a medical device that cannot be recovered because it has been administered to, or applied in the treatment of, a person.

Imposition of requirements under section 41KA of the Act does not affect the Secretary's powers of suspension and cancellation.

When the Secretary takes action under section 41KA of the Act, the Secretary must cause to be published in the *Gazette* a notice setting out the particulars of the requirements imposed.

Non-compliance with requirements imposed under section 41KA of the Act constitutes an offence punishable on conviction by a maximum penalty of 60 penalty units.

4. Recall of therapeutic goods that have been or could possibly be, subject to actual or potential tampering

Part 5-3 of the Act concerns product tampering and applies both to Chapter 3 and Chapter 4 therapeutic goods.

Section 42T imposes an obligation on any person who supplies, manufactures or sponsors therapeutic goods to notify the Secretary to the Department for Health and Ageing or the National Manager of the Therapeutic Goods Administration within 24 hours of becoming aware of a tampering or a substantial risk of actual or potential tampering to those therapeutic goods, or receiving information or a demand relating to actual or potential tampering with the goods.

Failure to notify the Secretary or the National Manager of the Therapeutic Goods Administration is an offence punishable on conviction by a maximum penalty of 400 penalty units.

Section 42V allows the Secretary, if satisfied that there has been actual or potential tampering, to require a person who supplies or has supplied the therapeutic goods, or a particular batch or kind of therapeutic goods, to take action to recover the goods that have been, or could possibly be, subject to tampering. The Secretary can also require the person to inform the public or other specified persons of the actual or potential tampering.

The Secretary may impose these requirements whether or not a notification has been made under section 42T.

Where the Secretary takes action under section 42V, the Secretary must cause to be published in the *Gazette* a notice setting out particulars of the requirements imposed.

Recovery requirements do not apply to a therapeutic good that cannot be recovered because it has been administered to, or applied in the treatment of, a person.

Non-compliance with requirements imposed under section 42V of the Act constitutes an offence punishable on conviction by a maximum penalty of 240 penalty units.

Section 42W of the Act makes it an offence to supply goods in Australia or export goods from Australia that are subject to recovery requirements imposed under Section 42V, unless the Secretary has given written consent and exceptional circumstances exist (maximum penalty: 240 penalty units).

M. Commonwealth *Trade Practices Act 1974* Requirements

Where a recall is safety-related, (i.e. there is risk of injury or harm to patients), there is a legal requirement under the Commonwealth *Trade Practices Act 1974* (the Act) for the sponsor to notify the Commonwealth Minister via the ACCC, within two days of taking recall action.

Three points should be noted in connection with this requirement:

2. Where the word 'recall' is used in the Act, it refers to both permanent removal of goods from the market (recall) and to temporary removal, correction and return to the market or use (recall for product correction).
3. The requirement is for notification only; the Procedure as set out in this document is to be used for the actual recall.
4. The requirement for notification applies only to safety-related recalls and not to purely quality-related recalls (minor labelling deficiencies, marginal sub-potencies etc.). Where the hazard is not clearly assessable, medical or other expert opinion should be sought.

The relevant provisions of the Act can be summarised as follows:

Under Section 65R of the Act, the sponsor of a product being recalled because the goods will or may cause injury to any persons must notify in writing the responsible Minister (via the ACCC) of the recall within two days of taking that action.

Notification must:

1. state that the goods are subject to recall; and
2. set out the nature of the defect in, or dangerous characteristic of, the goods.

Address:

Recall Co-ordinator

Product Safety Policy Section

Australian Competition and Consumer Commission

PO Box 1199

Dickson ACT 2602

E-mail: recalls@recalls.gov.au

Facsimile: (02) 6243 1171

Under Section 65F (7) of the Act, where goods which have been exported are recalled, a company is required to notify in writing, as soon as practicable, overseas recipients of the recalled stock.

Notification must:

1. state that the goods are subject to recall; and
2. if the goods contain a defect, have a dangerous characteristic or do not comply with a prescribed consumer product safety standard, set out the nature of the problem or in the latter case, the nature of non-compliance.

The company must provide a copy of the overseas notification letter(s) or facsimile(s) to the Minister (via the ACCC) within 10 days of sending such notification.

Failure to notify the Minister of a safety related recall within two days of taking that action, or failure to provide the Minister within ten days with a copy of notice sent to an overseas client advising of recall, have penalties of up to \$15,000 for a corporation or a fine up to \$3,000 for an individual.

Suppliers should also note that the Act empowers the Minister responsible to impose a mandatory recall if a supplier has not taken satisfactory action to remove the hazard created by the goods. Section 65L of the Act allows the Minister to order an immediate recall of goods if the goods create an imminent risk of death, serious illness, or serious injury. This power has been used to order recall of therapeutic goods. A corporation convicted of a failure to comply with a mandatory recall may be fined up to \$200,000 and an individual in a contravention up to \$40,000.

In order to advise the Minister that recalls have been completed satisfactorily, the Product Safety Policy Section of the Australian Competition and Consumer Commission, in consultation with the Therapeutic Goods Administration, Department of Health and Ageing, may conduct product recall audits. Suppliers should therefore ensure that adequate documentary evidence and other written records are maintained in respect of safety-related recalls.

Appendix I: Medicine problem report form

Electronic copies of the form are available from <http://www.tga.gov.au/safety/problem-medicine-forms-deficiency.htm>

Appendix II: Medical device incident report forms

Electronic copies of the forms are available from <http://www.tga.gov.au/safety/problem-device.htm>

Appendix III: Human blood and tissues recall reporting form

Electronic copies of the form are available from <http://www.tga.gov.au/safety/problem-report-bt-recall.htm>

Appendix IV: Recall co-ordinators

Recall co-ordinators – March 2012

Nominees for Medicines and their contact details

Commonwealth Mr Mick O'Connor	Bh 02 6232 8197 Mobile 0421 583 361 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Joshan Joy	Bh 02 6232 8636 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Peter Holian	Bh 02 6232 8178 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Ms Virginia Deigan	Bh 02 6232 8178 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
New South Wales Mr Bruce Battye	Bh 02 9879 3214 Mobile 0401 712 050 Fax 02 9859 5165 E-mail bruce.battye@doh.health.nsw.gov.au
Ms Judith Mackson	Bh 02 9879 3214 Mobile 0411 145 562 Fax 02 9859 5165 E-mail jmack@doh.health.nsw.gov.au
Victoria Ms Megan L Smith	Bh 03 9096 5355 Bh 1300 364 545 Mobile 0408 598 663 Fax 1300 360 830 E-mail megan.l.smith@health.vic.gov.au
Mr Matthew McCrone	Bh 03 9096 5066 Bh 1300 364 545 Mobile 0408 581 312 Fax 1300 360 830 E-mail matthew.mccrone@health.vic.gov.au
South Australia Ms Elizabeth Hender	Bh 08 8204 1942 Mobile 0418 747 833 Fax 08 8463 5540 E-mail elizabeth.hender@health.sa.gov.au

Mr Steve Morris	Bh 08 8204 1940 Mobile 0431 657 090 Fax 08 8463 5540 E-mail steve.morris@health.sa.gov.au
Queensland Mr Chris J Healey	Bh 07 3328 9310 Mobile 0403 053 090 Fax 07 3328 9354 E-mail chris_healey@health.qld.gov.au
Mr Andrew Hawkins	Bh 07 3328 9310 Mobile 0400522994 Fax 07 3228 9354 E-mail andrew_hawkins@health.qld.gov.au
Tasmania Ms Mary Sharpe	Bh 03 6233 3766 Moblle 0400516885 Fax 03 6233 3904 E-mail mary.sharpe@dhhs.tas.gov.au
Mr James Galloway	Bh 03 6233 2064 Ah 03 6223 7074 Fax 03 6233 3904 E-mail james.galloway@dhhs.tas.gov.au
Australian Capital Territory Mr Michael Conroy	Bh 02 6207 3974 Mobile 0418 182 375 Fax 02 6205 0997 E-mail pharmaceuticalservices@act.gov.au MichaelJ.Conroy@act.gov.au
Northern Territory Ms Helgi Stone	Bh 08 8922 7035 Mobile 0429 091 636 Fax 08 8922 7200 E-mail Helgi.stone@nt.gov.au
Northern Territory - Alternate Mr Tyronne DeZilva	Bh 08 8922 7340 Mobile 0415 285 065 Fax 08 8922 7200 E-mail tyronne.dezilva@nt.gov.au
Western Australia Mr Neil Keen	Bh 08 9222 6883 Mobile 0419 944 801 Fax 08 9222 2463 E-mail neil.keen@health.wa.gov.au poisons@health.wa.gov.au

Nominees for Medical Devices and their contact details

Commonwealth Mr Mick O'Connor	Bh 02 6232 8197 Mobile 0421 583 361 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Joshan Joy	Bh 02 6232 8636 FAX 02 6203 1451 E-mail recalls@tga.gov.au
Mr Peter Holian	Bh 02 6232 8178 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Ms Virginia Deigan	Bh 02 6232 8178 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
New South Wales Mr Bruce Battye	Bh 02 9879 3214 Mobile 0401 712 050 Fax 02 9859 5165 E-mail bruce.battye@doh.health.nsw.gov.au
Victoria Dr Michael Ackland	Bh 03 9096 5186 Mobile 0411 239 133 Fax 03 9096 9166 E-mail michael.ackland@health.vic.gov.au
Ms Megan L.Smith	Bh 03 9096 5355 Bh 1300 364 545 Mobile 0408 598 663 Fax 1300 360 830 E-mail megan.l.smith@health.vic.gov.au
South Australia Professor Paddy Phillips	Bh 08 8226 2578 Mobile 0417 863 858 Fax 08 8226 9837 E-mail Paddy.Phillips@health.sa.gov.au
Ms Anita Chambers	Bh 08 8226 6305 Mobile 0401 123850 Fax 08 8226 0725 E-mail anita.chambers@health.sa.gov.au

Queensland Mr Chris J Healey	Bh 07 3328 9310 Mobile: 0403 053 090 Fax 07 3328 9354 E-mail chris_healey@health.qld.gov.au
Mr Hasmukh Patel	Bh 07 3406 8008 Mobile 0409 582 915 Fax 07 3406 8035 E-mail Hasmukh_Patel@health.qld.gov.au
Tasmania Dr Craig White	Bh 03 6233 3297 Mobile 0410 312 194 Fax 03 6233 6392 E-mail craig.white@dhhs.tas.gov.au E-mail karen.foster@dhhs.tas.gov.au
Australian Capital Territory Mr Michael Conroy	Bh 02 6207 3974 Mobile 0418 182 375 Fax 02 6205 0997 E-mail pharmaceuticalservices@act.gov.au MichaelJ.Conroy@act.gov.au
Northern Territory Ms Helgi Stone	Bh 08 8922 7035 Mobile 0429 091 636 Fax 08 8922 7200 E-mail Helgi.stone@nt.gov.au
Northern Territory - Alternate Mr Tyrrone DeZilva	Bh 08 8922 7340 Mobile 0415 285 065 Fax 08 8922 7200 E-mail tyronne.dezilva@nt.gov.au
Western Australia Mr Neil Keen	Bh 08 9222 6883 Mobile 0419 944 801 Fax 08 9222 2463 E-mail neil.keen@health.wa.gov.au poisons@health.wa.gov.au

Appendix V: Parties advised of recalls by the Australian co-ordinator

Addresses and facsimile numbers:**Group 1 (for all recall actions)**

Mr G Stefanoff (02) 6205 0997
 Pharmaceutical Services
 ACT Health & Community Care
 Locked Bag 5
 Weston Creek ACT 2611

Mr C Healey (07)32341480
 Drugs & Poisons
 Queensland Department of Health
 GPO Box 48
 Brisbane QLD 4001

Mr J Lumby (02)98595165
 Pharmaceutical Services Branch
 Department of Health, NSW
 PO Box 103
 Gladesville NSW 1675

Mr K Moyle 1300 360 830
 Drugs & Poisons Unit
 Department of Human Services
 GPO Box 1670N
 Melbourne VIC 3001

Mr J Galloway (03)62333904
 Pharmaceutical Services Branch
 Department of Health & Human Services
 PO Box 191B
 Hobart TAS 7001

Mr W.B Dollman (08)82266959
 Public & Environment Health Division
 South Australian Health Commission
 PO Box 65
 Rundle Mall SA 5000

Mr M Patterson (08)93884988
 Pharmaceutical Services
 Health Department of WA
 PO Box 8172
 Perth Business Centre
 Perth WA 6849

Chief Pharmacist (02)6266 3784
 Department of Defence DHSB
 CP2-7-6
 Campbell Park ACT 2600

Assistant Secretary (02)62894727
 Community-based Health Care
 PO Box 21
 Woden ACT 2606

Ms H Stone (08)89227200
 Pharmacy and Poisons
 Territory Health Services
 PO Box 40596
 Casuarina NT 0811

Recall Co-ordinator (02)62431171
 Product Safety Policy Section
 Australian Competition & Consumer
 Commission Dickson ACT 2602

Director (03)62323310
 Antarctic Division
 DASETT
 Channel Highway
 Kingston TAS 7050

Mr A D Ferguson(02) 98435031
 National Pharmaceutical Services Association
 (Medicine Recalls Only)
 P O Box 123
 Wentworthville NSW 2145

Manager PBS (02)6124 6888
 Health Insurance Commission
 (Medicine Recalls Only)
 Reed St
 Tuggeranong ACT 2900

Health Insurance Commission Offices:

Sydney (02)98953324
 Melbourne (03)96057982
 Brisbane (07)30045407
 Adelaide (08)82749380
 Perth (08)92148336
 Hobart (03)62155640

New Zealand Ministry of Health
 0015 64 4 4962229
 Mr D Fitzgerald (medicines) or
 Dr T Nisbet (devices)
 Director-General of Health
 Ministry of Health
 Wellington, New Zealand

Group 2 (for devices only)

Mr D F Mines (07)34068035
Biomedical Engineering & Health
Technology Services
450 Gregory Terrace
Fortitude Valley
QLD 4006

Mr A Wilkins (03)62332909
Senior Executive Officer
Medical Equipment
Dept. Health & Human Services
P.O. Box 125B
Hobart TAS 7001

Group 3 (for consumer level recalls only)

President (02) 6285 2869
Pharmaceutical Society of Australia
Deakin ACT 2600

Editor (02) 95773355
Choice Magazine
Marrickville NSW 2204

Executive Director (02) 62701800
The Pharmacy Guild of Australia
Deakin ACT 2600

Group 4 (for radiopharmaceuticals only)

Director (03) 94321835
ARPANSA
Yallambie VIC 3085

Group 5 (for blood and blood products only)

Dr Rod Givney (08)8226 7187
Department of Health
P.O. Box 65
Rundle Mall SA 5000

Dr Anne McDonald (02) 6244 2892
The Canberra Hospital
Garran ACT 2605

Mr Michael Furey (03) 9616 7764
Acute Health Division
Dept Victoria Health Services

Mr D Fitzgerald 0015 64 4 496 2229
Medsafe New Zealand

Group 6 (for overseas recall notifications)

Health authorities, direct or via the
Australian embassy, in countries to which
goods were exported (see Section I(j)).

Group 7 (for recalls where poisoning is possible)

Poison Information Centres:

Queensland	(07) 32521903
ACT	(02) 62443334
Victoria	(03) 93491261
South Australia	(08)82046049
Western Australia	(09) 93463493
Northern Territory	(08) 8922 8499
New South Wales	(02) 98453597
Tasmania	(03) 62228029

Group 8 (for recalls of non-scheduled medicines and medical devices sold by grocery retailers)

Policy Director (02) 9299 7154
Australian Retail Association (supermarkets)
Level 2, 20 York Street
Sydney NSW 2000

Metcash(02) 9741 3008
IGA Distributors
4 Newton Road
Silverwater NSW 2128

Group 9 (for recalls of implanted orthopaedic joints)

Australian Orthopaedic Association National
Joint Replacement Registry
(03) 9342 8780
Dept. of Orthopaedic Surgery
Royal Melbourne Hospital
Grattan Street
Parkville VIC 3050

Appendix VI: Authorised persons form

Message to the Managing Director

The **Uniform Recall Procedure for Therapeutic Goods** requires all Australian sponsors of therapeutic goods to nominate two personnel who are authorised to implement a recall.

Please complete the names and telephone numbers of these two personnel below then transmit a copy of this form by facsimile to the number given below.

Please retain a copy of this form to notify the TGA of any changes in Authorised Personnel.

Note: After hours numbers are used in urgent recall situations only and will be kept confidential.

FACSIMILIE MESSAGE

To:

Australian Recall Co-ordinator
Recalls and Secretariat Section
Therapeutic Goods Administration

Fax: (02) 6232 8687

Two Personnel authorised to perform recalls:

1. Title:

First Name:

Surname:

Business telephone number: ()

After hours telephone number: ()

2. Title:

First Name:

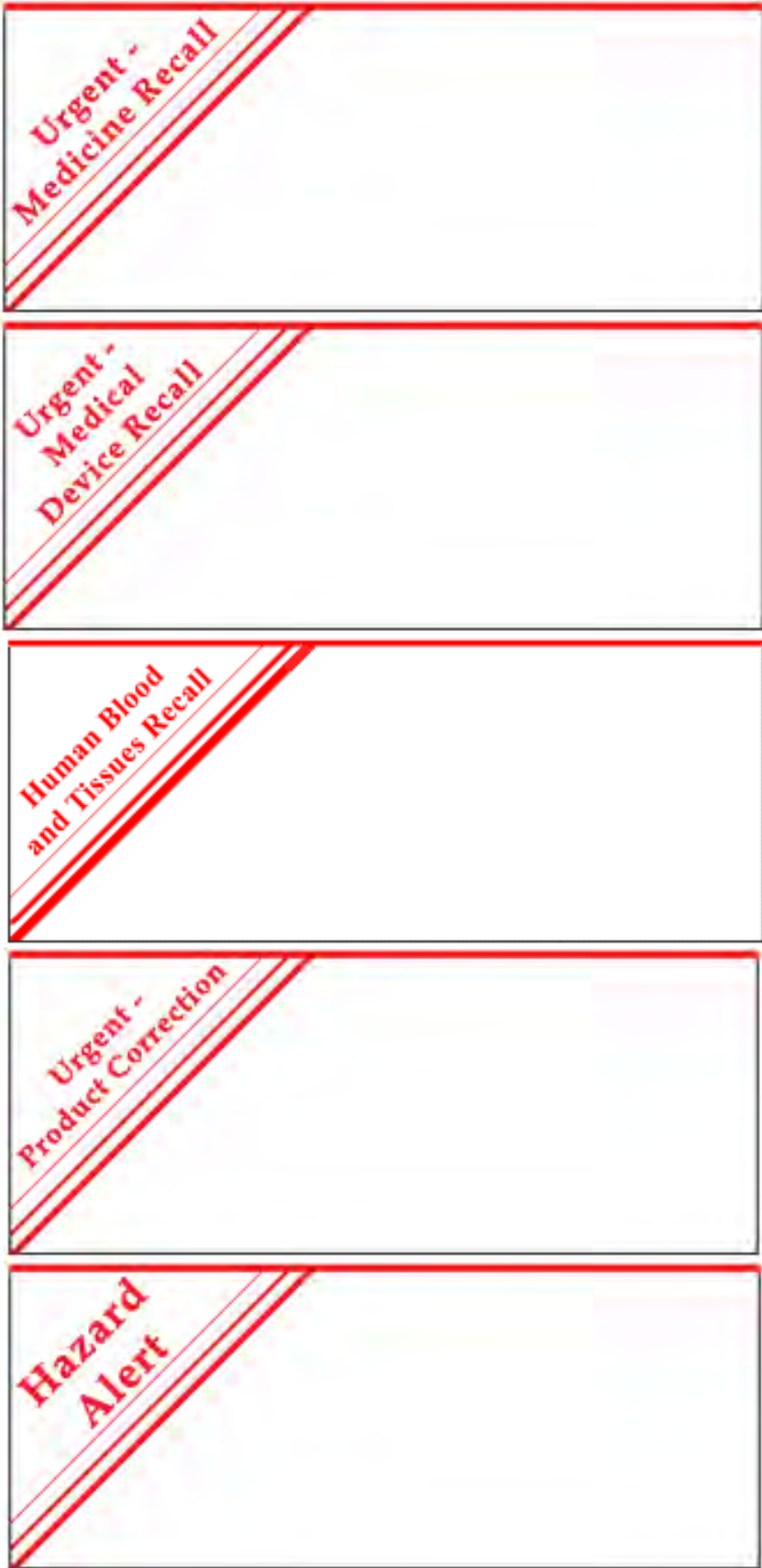
Surname:

Business telephone number: ()

After hours telephone number: ()

From:

Appendix VII: Recall envelopes diagram



Appendix VIII: Example of a recall letter and facsimile reply form

Example of a recall letter for a hospital level recall (similar letters, with appropriate amendments, would be required for retail or wholesale level recall letters to physicians)

< Sponsors letterhead paper >

Chief Executive Officer

< Hospital Address >

Attention: 1. Stores Manager
 2. Director of Nursing

URGENT MEDICAL DEVICE RECALL

<PRODUCT NAME> 10cm SQUARE SURGICAL DRESSINGS, PACKS OF 2

Catalogue number: 46783

Batch numbers: 123, 124, 125, 126 & 128

Order code: 0001884-9873

AUST L xxxxx

<Company name> Pty Ltd, following advice that these batches may not be sterile and after consultation with the Therapeutic Goods Administration, is recalling the above batches of <product name> 10cm Square Surgical Dressings. No other batches or pack sizes of this product are affected by this recall. The batch numbers are displayed on the bottom right hand corner on the front of the packs.

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 and replacement stock , or a credit note, issued. 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.

If any of the recalled stock could have been transferred from your hospital to another, please immediately let that hospital know of the recall. It would be appreciated if you would then telephone (long distance callers, reverse charge) us so that we can make contact with the hospital supplied from your hospital.

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 to your hospital.

<signature>

Joe Bloggs

Manager

<Date>

Facsimile Reply Form

TO: <Company name> Pty Ltd

ATTENTION: Joe Bloggs, Manager

FACSIMILE NUMBER: (02) xxxx xxxx

POSTAL ADDRESS: PO Box 4, Upper Graft, NSW 2999

SUBJECT: Recall of <product name> 10cm square surgical dressings,
packs of 2, Batch numbers: 123, 124, 125, 126 & 128

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:

Batch _____ Qty _____

Batch _____ Qty _____

. Unused stock subject to recall (currently in quarantine):

Batch _____ Qty _____

Batch _____ Qty _____

. Any other relevant details: _____

Signature: _____

Date: _____

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Appendix IX: Example of a consumer level print media advertisement



URGENT MEDICINE RECALL

<PRODUCT NAME> ELIXIR

120mg paracetamol per 5mL
100mL bottle

Batch number XXXXX, Expiry date: Dec 2003
AUST R XXXXX

<Company> Pty Ltd, Following consultation with the Therapeutic Goods Administration, is recalling batch XXXXX of <Product Name> (which is an analgesic used to treat aches, pains and feverish conditions) because eucalyptus oil has been found in some bottles of this batch. No other batches of <Product name> Elixir are affected by this recall.

If you have a bottle of <Product name>Elixir from batch XXXXX, do not use it. Return it to the place of purchase for a refund or call our customer service line to arrange the return of affected product and refund.

CUSTOMER SERVICE 1800 XXX XXX

Ingestion of eucalyptus oil (other than in small amounts as in throat lozenges and inhalations etc.) may be harmful. As little as a few millilitres of eucalyptus oil may cause nausea, vomiting, dizziness, muscular weakness, delirium and convulsions. Anyone who is concerned in any way about the use of this product should consult their doctor.

<Company name> Pty Ltd sincerely regrets any inconvenience to their customers.

Therapeutic Goods Administration

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www.tga.gov.au

Reference/Publication #