Review of the Uniform Recall Procedure for Therapeutic Goods

May 2004
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Executive Summary

In order to maintain the efficiency and effectiveness of the recall system and manage the greatly increased workload in the Recalls Section, a decision to review the Uniform Recall Procedure for Therapeutic Goods (URPTG) was made by the National Coordinating Committee for Therapeutic Goods (NCCTG). The review objectives are to:

“...undertake a review of recall processes for therapeutic goods undertaken in accordance with the Uniform Recall Procedure for Therapeutic Goods (URPTG) to ensure that:

- The URPTG is effective in defining the action to be taken by health authorities and sponsors when therapeutic goods for use in humans, for reasons relating to their quality, safety and efficacy, or for any other reason are removed from supply or use, or subject to corrective action.

- The actions and processes defined or utilised under the URPTG and the Therapeutic Goods Act 1989 are effective and appropriate for Australia in the context of:
  - being comprehensive, streamlined, timely and effective from the public health and safety and cost perspective;
  - facilitating the cooperation of all parties who are involved in recalls e.g. sponsors, retailers and health care professionals; and
  - being compatible with the proposed trans-Tasman harmonisation of the regulation of therapeutic goods.

The review is of the whole sector, including wholesalers. It is required to recommend improvements, including performance indicators and benchmarking against international practice, consider the place of blood and tissues in the recall system, and the adequacy of the powers of the Therapeutic Goods Act and its relationship to the Trade Practices Act.

As well as reviewing the Australian and international publications (which are scant) and TGA recall data, visits were made to each Australian capital city and to Wellington and Auckland, New Zealand in March 2003, to interview TGA staff, Medsafe staff, NCCTG members, as well as the relevant industry bodies that are affected by recalls, e.g. wholesalers and others. A summary of the issues was discussed with the NCCTG in April, 2003. Following the events surrounding the Pan recall, further interviews and email communications were initiated to pick up some of the major lessons from that process, and to cross check the earlier findings and recommendations. Those consultations reported that the Pan recall went well, but areas for improvement were identified, e.g. in the form the initial recall information was released, and the need to further consider the regulation of wholesalers under the Therapeutic Goods Act, rather than relying on State and Territory laws.

Overall, the review found that the recall system is effective, even under the stress of a recall as large as the Pan recall. The efforts of the Recalls Section in TGA are greatly appreciated by industry and the other stakeholders, e.g. the States and Territories. The recommendations for change are mostly at the margin.

The effectiveness of retail and consumer level recalls may not be as high as one might wish. There are several things that have been identified that can be done to address this, including increasing the awareness of the recall system and reducing barriers to compliance.

The lack of uniformity of the States’ and Territories’ responses to retail and consumer level recalls (in particular) is discussed and changes are proposed to make their actions more streamlined and uniform, and related to need, i.e. without duplicating the actions of others, while ensuring necessary infrastructure is in place.
Consideration is given to minor issues such as the style and appearance of recall notifications and the language used in them. Some changes are proposed to improve clarity, understanding, receipt by the right persons in the target organisations, and international consistency. Consideration is also given to consumer needs in relation to consumer-level recalls.

It is proposed that documentation be enhanced to more clearly outline the risk analysis approach. While this seems obvious there appear to be no similar guidelines internationally, so it is not a trivial task, and would be a world first. The aim of the guidelines would be to support the risk assessment and management processes and second to ensure the use of the language of risk in a clear and unambiguous manner.

The legislative framework for recalls in the *Therapeutic Goods Act* is discussed. While voluntary recalls will remain the mainstay of the recall process, there is a need to strengthen the powers to recall therapeutic goods in the legislation. This will also require some new approaches in the URPTG, including a quarantine arrangement. The double requirement for notification under the *Trade Practices Act* as well as the *Therapeutic Goods Act* is identified as adding no value and in need of reform. If notified pursuant to one a recall should be exempt from the notification requirements of the other.

The recall system in New Zealand was examined and some important differences were identified. These include the issue of recall of medicines when the recalled product is the only one that Pharmac subsidises; differences in thresholds and level of action taken; some differences in content and style of recall letters; and some pragmatic problems related to postal and telephone/fax services etc, as well as concerns that local issues may be overlooked.

Blood recalls were considered in relation to what may be reported monthly and what needs to be reported event by event. A proposal for a recalls system that treats blood recalls under the same risk framework as other recalls (Class 1 to 3) is made. The review also found major differences in the management of cellular product recalls between New Zealand and Australia. New Zealand should be involved in the discussions over what to report and how.

The review examined the international obligations of the TGA and found, on the basis of the papers provided, that the TGA fully complies with its obligations.

The review found that the workload of the Recalls Section has increased very substantially. Once the issue of managing recalls of cellular blood products is resolved, the section should manage much better, but there is a significant, real increase visible in the recall notification data, apart from blood recalls. Some process improvements need to be made. Ideally the SIME project would address the information systems in use in the Recalls Section in the near future, as that would help efficiency and effectiveness.

No detailed workload assessment of the Recalls Section was made but it is clear that it has no excess capacity to deal with emergencies. This then necessitates involvement of the TGA staff more broadly. An MOU is proposed in that regard. Even in ‘normal’ periods staffing appears to be tight and unless the workload is diminished (e.g. by better management of blood recalls) staffing would have to increase. It is difficult to measure performance of a section whose workload is driven almost entirely by external demands. The section’s job is to respond, rather than being highly proactive. However, some new performance indicators are proposed for the section, including the possibility of a survey of sponsors’ experiences when they have recently undertaken recalls.

The need for codifying the crisis management processes that the TGA follows is identified.
List of Recommendations

1. The Therapeutic Goods Administration should engage in discussions with the pharmaceutical profession and other retail groups as appropriate on the:
   - possibility of incorporating responsiveness to recalls into the Quality Care Pharmacy Program;
   - potential liability of individuals/organisations who fail to take appropriate action when provided with recall information;
   - provision of feedback to pharmacists and other retail groups about recalls, including the participation rate of the pharmacies or other groups.

2. An explanatory brochure about the Uniform Recall Procedure for Therapeutic Goods should be developed for dissemination to all who may be required to respond to recall notices.

3. The States and Territories should commit to a uniform recall system without duplication of the activities of the sponsors, and committing to undertake whatever specific national action is agreed in the event of a threat to health that requires their involvement.

4. States and Territories should maintain an appropriate process within their jurisdictions, enabling timely dissemination of information (typically the recall letter) in the event of a threat to health, as agreed with the Australian Recalls Coordinator.

5. Recall activity in the field other than that specifically requested of the States and Territories should be left to sponsors, who should be advised that they can approach the jurisdictions in exceptional circumstances if they want help from one or more of them.

6. If, in a particular instance, a jurisdiction sees a need to take action on any recall beyond that requested of them, they should advise the Australian Recalls Coordinator what they are doing and why, so that other jurisdictions can be advised and decide whether or not to follow suit. When this happens, the action undertaken and the reasons for it, should be discussed at the next meeting of the NCCTG.

7. The term Urgent should be applied to Class I and Class II recalls, and not to Class III recalls.

8. Consideration be given to removing the word ‘voluntary’ from recall letters, possibly using of some other form of words, such as ‘sponsor-initiated’, as appropriate.

9. The risk assessment framework for recalls that is followed customarily in the TGA should be written up as a formal guideline for internal use.
List of Recommendations (continued)

10. Recommendations
The cooperative nature of the recall system be maintained wherever possible, but supported by comprehensive legislative powers in the event of inability or unwillingness of a sponsor to undertake a recall. Amendments should be sought to provide this comprehensive set of arrangements. Areas for improvement include:

- ensuring the process of recall of therapeutic goods is quite separate from the process of registration and deregistration;
- clarifying that following the URPTG in the case of a mandatory recall is not ultra vires;
- providing for powers to order suspension of registration or listing on the ARTG and quarantine, for all therapeutic goods, and corresponding changes to the URPTG for a voluntary quarantine arrangement of therapeutic goods whose sale has been suspended voluntarily;
- consideration of the need to regulate wholesalers of therapeutic goods under the Therapeutic Goods Act;
- exempting therapeutic goods from the notification and possibly other provisions of the Trade Practices Act, as is the case in New Zealand, unless the relevant Minister declares that particular therapeutic goods are not to be exempted;
- enabling the TGA to order a previous sponsor, or a current sponsor if the previous sponsor cannot be identified or is insolvent, to undertake a recall of therapeutic goods if the previous sponsor was the sponsor at the time of the distribution of the goods;
- the Therapeutic Goods Administration having, as a last resort, a specific power to undertake a recall and recover costs from any party that registered or was involved in the sale or supply of the therapeutic goods, as appropriate. Consideration should be given to the debt ranking in front of other debt (but after employee entitlements) in the event that the relevant company is insolvent.

11. A Memorandum of Understanding should be developed between the Office of Devices, Blood and Tissues and the Regulators and other key sections in the TGA as to their roles and responsibilities in relation to the management of particularly complex or numerous recalls, and the resources and assistance to be provided in certain circumstances.

12. Performance indicators for the Recalls Section and the recalls process should be developed including: the time to initiate recalls; assessment of the level of response by such means as are available; and an occasional survey of sponsors that have undertaken recalls assessing the recall process and the Recall Section’s role.
Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>AD(JR) Act</td>
<td>Administrative Decisions (Judicial Review) Act</td>
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<td>ARCBS</td>
<td>Australian Red Cross Blood Service</td>
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<td>BRISC</td>
<td>Blood Review Implementation Steering Committee</td>
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<td>CEO</td>
<td>Chief Executive Officer</td>
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<td>CGMP</td>
<td>Code of Good Manufacturing Practice</td>
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<td>CGWP</td>
<td>Code of Good Wholesaling Practice</td>
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<td>EU</td>
<td>European Union</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>MDA</td>
<td>Medical Devices Authority (United Kingdom)</td>
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<td>MIAA</td>
<td>Medical industry Association of Australia</td>
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<td>MOU</td>
<td>Memorandum of Understanding</td>
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<td>MPA</td>
<td>Medicines Partnership of Australia</td>
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<tr>
<td>MRA</td>
<td>Mutual Recognition Agreement</td>
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<td>NCCTG</td>
<td>National Coordinating Committee on Therapeutic Goods</td>
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<td>NZBS</td>
<td>New Zealand Blood Service</td>
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<td>NZFSA</td>
<td>New Zealand Food Safety Authority</td>
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<tr>
<td>PI</td>
<td>Performance Indicator</td>
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<tr>
<td>PICS</td>
<td>Pharmaceutical Inspection Convention Scheme</td>
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<td>QCPP</td>
<td>Quality Care Pharmacy Program</td>
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<tr>
<td>QMS</td>
<td>Quality Management System</td>
</tr>
<tr>
<td>SIMe</td>
<td>Strategic Information Management Environment (project)</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<tr>
<td>TOR</td>
<td>Terms of Reference</td>
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<tr>
<td>URPTG</td>
<td>Uniform Recall Procedure for Therapeutic Goods</td>
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<tr>
<td>US</td>
<td>United States of America</td>
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Acknowledgements

The staff of the Recalls Section have been extremely helpful throughout this review and we wish to acknowledge their help and thank them for it. We also wish to thank all those who gave up time to be interviewed, provided data, or assisted in other ways.
1 Introduction

Late in 2002 the Therapeutic Goods Administration (TGA) sought tenders for a review of the Uniform Recall Procedure for Therapeutic Goods (URPTG). This action followed consideration of some issues relating to the URPTG by the National Coordinating Committee for Therapeutic Goods (NCCTG). The TGA advised the NCCTG to concerns of sponsors and other stakeholders about response rates received to recall letters and other actions taken by third parties in implementing a recall. Response rates from retailers, pharmacies and hospitals to recall letters are sometimes low; and sponsors may need to contact customers a number of times to achieve acceptable reconciliation rates for recalls. The NCCTG endorsed the Terms of Reference for the review and agreed to act as a reference point for it.

1.1 Background

The control of medicines, devices and blood and other biological products is becoming more rigorous and complex, e.g. in relation to prion-related disease. The capacity of the legislation to cover the widening range of products and the adequacy of traditional communication linkages within and beyond the medical and pharmaceutical professions, are examples of the stresses that continue to develop.

Recalls are a particular example of the expanding range of new situations that the TGA faces, with blood and tissue product recalls a relatively new requirement, and product tampering (not strictly a recall but closely related) a new sociological phenomenon, which impacts substantially on the TGA. Societal changes not only result in new situations, such as tampering, but also impact on stakeholders’ response to them. What was once done as a professional service may now require greater ‘marketing’, or a formal duty (e.g. as part of a Code of Ethical Behaviour), or direct remuneration, to obtain the outcome that has been achievable historically.

Significant organisational changes are also occurring that warrant review of the recalls process, not least the possibility of a joint agency with New Zealand, as well as the increasing use of mutual recognition agreements with other countries. This makes an internationally harmonised approach desirable and this has already commenced, e.g. in moving to three classes of recall, like the European system.

1.2 Review objectives

The objectives of the review are to “…undertake a review of recall processes for therapeutic goods undertaken in accordance with the Uniform Recall Procedure for Therapeutic Goods (URPTG) to ensure that:

- The URPTG is effective in defining the action to be taken by health authorities and sponsors when therapeutic goods for use in humans, for reasons relating to their quality, safety and efficacy, or for any other reason are removed from supply or use, or subject to corrective action.
The actions and processes defined or utilised under the URPTG and the Therapeutic Goods Act 1989 are effective and appropriate for Australia in the context of:

- being comprehensive, streamlined, timely and effective from the public health and safety and cost perspective;
- facilitating the cooperation of all parties who are involved in recalls e.g. sponsors, retailers and health care professionals; and
- being compatible with the proposed trans-Tasman harmonisation of the regulation of therapeutic goods.

The review is also required to recommend improvements, including performance indicators and benchmarking against international practice.

Specific issues that need to be considered include the place of blood and tissues in the general recall system, and the adequacy of the powers of the Therapeutic Goods Act 1989 and its inter-relationship with the Trade Practices Act 1974.

2 Methodology

The requirement for the project brief required the consultant to;

1. Examine the current operation of the Uniform Recall Procedure for Therapeutic Goods in Australia and its effectiveness:

- as a procedure for defining the actions to be taken by health authorities and sponsors when therapeutic goods for use in humans, for reasons relating to their quality, safety and efficacy, or for any other reason are to be removed from supply of use, or subject to corrective action; and
- in producing appropriate recall action for therapeutic goods in Australia and in Australia meeting its obligations under international mutual recognition arrangements.

2. Consult with stakeholder groups, including

- representatives of sponsors of therapeutic goods and industries affected by recalls, consumer and professional associations and government agencies in Australia;
- in the context of Trans-Tasman harmonisation, with relevant New Zealand stakeholders; and
- NCCTG members.

3. Canvass options and recommend improvements to the current recalls procedure including legislative provisions that meet the objectives set out above and mechanisms for improving the response of retailers, pharmacies and hospitals to recall advice.

An outline of the methodology is given in Figure 1.
Visits were made to every Australian capital city and to Wellington and Auckland, New Zealand during March 2003, to interview TGA staff, Medsafe staff, NCCTG members, as well as industry associations and consumers. Appendix 1 provides a list of the persons interviewed.

A summary of the issues was discussed with the NCCTG in Alice Springs on April 10, 2003.

Soon after the draft report was presented to the TGA, the recall of all products manufactured by Pan Laboratories was initiated. This delayed consideration of the draft report and gave rise to the need to re-consider the report itself, consider issues that had arisen from the activity that was associated with the recall, and revise the report accordingly. The report was substantially completed in July 2003 but was further revised in the light of feedback received at the October 2003 meeting of NCCTG.
3 Findings

The most important finding of this review is that, on the whole, the URPTG works well, even under the severe stress generated by a recall as large as the Pan recall. At the time of that recall the TGA was fortunate in having a highly experienced team leading the organisation who, together, had managed other critical situations and who command great respect and commitment from the staff of the organisation. The review found this to be the most valuable asset of the TGA as the Pan recall unfolded, and this was also recognised by industry and the States.

Industry found the URPTG to be clear and easy to follow. It also reported that the TGA is very helpful when undertaking recalls. Proposed changes in this report are mostly at the margin, attempting to improve efficiency, rather than to the core of the recall process. Of course no recall process will be perfect all of the time – it can only reduce, not remove, risk.

3.1 Patterns of recalls

The number of recalls has accelerated rapidly in recent years (see Figure 2).

**Figure 2 The pattern of increase in number of recalls 1997-2002**

Much of this increase, but by no means all, is due to recall of cellular blood products, which commenced in 2001. There is also an increase not due to blood products.

Analysis of 2002 recalls (not including cellular blood products) yielded the following information:

- 93 sponsors had one product recalled
- 26 had two products recalled
- 12 had three products recalled
- 14 had four products recalled
- 4 had five products recalled
2 had six products recalled
4 companies had seven, eight, nine and ten products recalled, respectively.
A further 4 companies had more than ten products recalled (12, 14, 24 and 37).
Those that had many recalls tended to be organisations that sold instruments and devices that are therapeutic goods. They are, by and large, low risk goods.

3.2 Recall effectiveness issues
There are several issues that relate to the effectiveness of recalls that extend to pharmacy or retail level, or that need to be managed expeditiously and in a targetted way to avoid a consumer level recall, with its inherent costs (not just financial costs). These are discussed below, with proposals as to how they can best be addressed.

3.2.1 Pharmacy responsiveness
One issue that has given rise to this review is the reported low response rate from pharmacies to recall letters. Presumably when they do not have stock on hand they see no need to reply. This poor response rate has been confirmed in discussions with industry. It is in contrast to New Zealand which has a much better response rate from its pharmacies.

The prevailing view is that pharmacies that have stock do respond, as they need to get the refund, so the public health concern is minimal. But, although this explanation is likely, there is no evidence that this is the case. One cannot be sure that if 4,000 pharmacies have not responded there may not be perhaps 40 of them that have not even checked the stock.

This lack of response stems, in all probability, from several simple issues that can be addressed:

- Pharmacists are seeing more and more recalls but have no understanding of the overall process and never get any feedback on what happens;
- Pharmacists may not feel kindly towards the process as a result of occasional consumer level recalls where they are ‘the last to know’ (i.e. a customer found out first) and they had money tied up awaiting credits for stock, much of which was probably not even bought through their (or any other) pharmacy;
- Pharmacists do not appreciate that the response rate is monitored to measure the success of the recall, and so see no need to respond, even if it is no effort to do so;
- Some pharmacists will not respond if they have to spend money on a long distance fax call to do so, especially when the see no need – i.e. it is perceived to be ‘just to keep the bureaucracy happy’;
- It is not part of the overall quality management system for the pharmacy if they have one.

A number of actions to address these issues are possible, some of which relate to other initiatives. These are:
- Link the recall process, and the response from the pharmacy, to the Quality Care Pharmacy Program (QCPP), which is funded by the Commonwealth through the pharmacy organisations and covers Guild and non-Guild pharmacies.\(^1\)

Inclusion in a quality program would require some way to easily assess compliance. One way would be to include a panel like the one below in all recall letters, and the accreditation standard could require pharmacies to hold all letters on file for e.g. 12 months. These could then be audited to see if they have been actioned. This panel may be a good guide to, and reminder of, the steps in an efficient process in any case.

<table>
<thead>
<tr>
<th>Qty on Hand</th>
<th>Signature</th>
<th>Date</th>
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<tr>
<td>Stock checked</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advised others where goods on-sold</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reply fax sent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock returned (if stock on hand)</td>
<td></td>
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- Provide a greater level of feedback to pharmacists on how well/not so well pharmacies do, recall by recall, and why it is important to provide nil responses.

- Provide general information on what the URPTG is and does, and what role people have in ensuring it works well and public safety is protected. This information could be disseminated with recall letters in the first instance. An A4 brochure folded twice readily fits in the DL envelope in which recall notices are sent, and inclusion with recall notices would be an effective means of distribution.

- Reduce barriers to responding – by requesting sponsors of pharmacy/retail level recalls to provide toll-free fax numbers. While the cost of sending a fax may seem a small barrier, if the perceived need is low, compliance will be low and even a small barrier may reduce it further. TGA should strongly encourage this.

The Pan recall presented particular problems of pharmacists as well as other retailers, generated by the number of products involved and the fact that the initial information was released by the Australian Listing Number (AustL) only. Pharmacies and other retailers cannot readily identify affected stock by this means. So while it provided a quick way for the consumer to check, it was very difficult for the sellers of these goods. If it is ever necessary to release preliminary information in this fashion again, it would be as well to provide retailers with alternatives as soon as possible after the event, e.g. by inclusion of an Excel spreadsheet on the TGA website, with AustL/AustR number and more complete description of the goods (name(s), strength, etc). The retailers or their representatives could then sort the data into whatever order is preferred. Even if there were duplicates in the other data it could be used to indicate which goods might be linked to that AustL number. There are good reasons why more information was not immediately available, but the focus on consumer-oriented

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\(^1\) QCPP is an set of performance standards and supporting materials setting out business and professional standards developed by the Guild and the Pharmaceutical Society of Australia with other major industry stakeholders. The standards that includes a section on Professional Services. This consists of seven standards that deal with the sale of Pharmacist Only and Pharmacy Medicines and 17 Professional Practice standards, developed by the Pharmaceutical Society of Australia.
information initially, may have led to the retailers having a more difficult time as a result.

TGA should engage in discussions with the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia as to the possibility of incorporating responsiveness to recalls into the Quality Care Pharmacy Program. TGA could also discuss with Pharmaceutical Defence Limited and the Insurance Council of Australia the potential for liability of individuals/organisations who fail to take appropriate action when provided with recall information, with a view to developing a reminder to persons who are involved in a recall of any potential for liability if they fail to act appropriately.

3.2.2 Wholesalers’ obligations in a recall and the Code of Good Wholesaling Practice

One industry association involved has indicated that wholesalers for its industry have occasionally failed to provide the level of cooperation that is desirable, and this has led to slower or less complete recalls. The association sought to have the application of the URPTG tightened, as it felt there is no formal obligation for a wholesaler to do anything in relation to a recall. Looking only at the URPTG itself, that appears to be true, but most jurisdictions include a condition on the licence of wholesalers of scheduled medicines, requiring compliance with the Code of Good Wholesaling Practice (CGWP), and in one jurisdiction this requirement is by Regulation.

The Code of Good Wholesaling Practice (clause 640) requires that:

*There should be a written procedure detailing the action to be taken in recalling goods on behalf of their manufacturer or sponsor, subject to any amendment necessary in specific circumstances. This procedure should be consistent with the “Uniform Recall Procedure for Therapeutic Goods” issued by the Department of Health, Housing and Community Services. The wholesaler should be able to facilitate a recall procedure relative to the area to which goods have been supplied. Recalls carried out should be documented and records of all recalled goods received into the warehouse should be kept.*

Thus at least the wholesalers of scheduled medicines have some obligation to play an appropriate role. Sponsors of devices are often in a better position than pharmaceutical sponsors as they have relatively few large clients (e.g. hospitals) and have often distributed directly to them rather than through a wholesaler.

Notwithstanding these arrangements, some experiences of the Pan recall did show some gaps in wholesaler performance, and these need to be addressed.

The National Pharmaceutical Services Association, which represents the major pharmaceutical wholesalers, indicated that they are willing to do whatever sponsors require to facilitate a recall, and work with the sponsors on recalls. There may be a process of cost recovery associated with that activity.

It is not clear whether the events that led to the concern by the industry group were one-off events or were more systematic. The Pan experience may suggest the latter. There is an avenue of recourse through almost all State health agencies that either have Regulations or conditions on a wholesaler’s licence to sell poisons that require them to comply with the CGWP. As we have seen the CGWP requires wholesalers to
respond. A timely complaint from a sponsor to the State or Territory health agency should result in the State health agency investigating the complaint, and if it is an urgent recall, it is highly likely that the investigation and its findings would be implemented very quickly.

Nevertheless, as stated above, events of the recent Pan recall have shown that some wholesalers do not always have the capacity to fully comply with the requirements of the URPTG in such a complex recall. The best way to address this may be to include a requirement in the Therapeutic Goods Act, which is not linked to scheduled medicines. This will be further discussed in section 3.8.

Tracking distribution by batch at the wholesaler level

Sponsors would also like to be able to track batches through wholesalers. Clearly sponsors may be able to avoid a retail level recall if a recently distributed good can be tracked though the wholesaler and the specific points to which supply has been made dealt with on a one-on-one basis. The size of the ‘problem’ (occasional additional retail level recalls) however, hardly warrants all wholesalers tracking goods outwards to batch level. Based on the cost of doing so using today’s technology, there would have to be large safety benefits, and these are hard to identify.

Wholesalers are not likely to warm to idea of tracking to batch level without the technology to support it – i.e. bar coding with batch and expiry included. At present bar codes in Australia do not carry this level of information. Bar codes that can are too large for some packs and industry (at both manufacturer and wholesaler level) would have significant printing, packaging, process and equipment costs to enable the change to be made. It would require a long lead time, perhaps up to a decade, to implement.

Some wholesalers, e.g. of dental equipment, are never likely to be able to comply due to the large number of small items they handle. These are low risk goods in any case. Any requirement should be risk based, e.g. initially implantable and other electromedical devices and scheduled medicines.

The CGWP is being reviewed by the Therapeutic Goods Committee in near future. The industry association that feels the CGWP should be strengthened to require tracking outward goods to batch level will no doubt make its case, Until the Pan recall it was hard to see justification for such a measure. However, the performance of some wholesalers over the Pan recall suggests better systems are required, and the State laws may not be sufficient to provide the impetus for the systems development.

In the relatively near future technology will advance, and the wholesalers and others should be encouraged to start thinking about tracking at least high risk goods to batch level. TGA should ask wholesalers for their advice on the impact of a requirement to track high risk goods such as scheduled medicines to batch level, and how and when it will be feasible at reasonable cost. TGA should then provide that advice to the NCCTG and the CGWP Review, which should be then asked to provide advice as to why the Therapeutic Goods Act should not make the CGWP mandatory, at least for high risk goods.
3.2.3 Retail level recalls other than through pharmacies

Retail level recalls of unscheduled medicines obviously affect more than just pharmacies. In Australia today the retail stores fall into two distinct groups: the national supermarkets, and a large number of very small stores that are difficult to reach but sell goods that are of low hazard and sell relatively low volumes of them. Thus the risk of harm from goods sold in the small stores is low, unless it is a tampering incident where the hazard could be high due to a highly toxic foreign substance.

Special efforts should be made to communicate retail level recalls to these small stores despite the fact the risk may not be high. While the statistical probability is low due to low sales, an adverse event can still occur. However, it has to be accepted that despite best efforts, some will be missed.

In the case of consumer level recalls, small retailers have two additional sources of information as well as information specifically directed at them. They are likely to see the consumer advertisements and even if they miss them, they may be approached by consumers. So a consumer level recall should reach a substantial proportion of small retailers, even if the information specifically directed at them misses its mark.

Some of the problems experienced by retailers in the context of the Pan recall are discussed under section 3.2.1. The issue of advertising and its effectiveness in notification of information is discussed in section 3.7.

Recommendations

1. The Therapeutic Goods Administration should engage in discussions with the pharmaceutical profession and other retail groups as appropriate on the:

   - possibility of incorporating responsiveness to recalls into the Quality Care Pharmacy Program;
   - potential liability of individuals/organisations who fail to take appropriate action when provided with recall information;
   - provision of feedback to pharmacists and other retail groups about recalls, including the participation rate of the pharmacies or other groups.

2. An explanatory brochure about the Uniform Recall Procedure for Therapeutic Goods should be developed for dissemination to all who may be required to respond to recall notices.
3.2.4 Deliberately ignoring recalls and failure to return goods
Problems have been identified with occasional deliberate non-responses (e.g. if identical replacement stock not immediately available). This applies to wholesalers, retailers (including pharmacists) and hospitals.

In essence what happens is that, a further “risk assessment” is done by the staff when a recall is received. As we all live in “a sea of risk” and we underestimate familiar risks, the risk from the faulty goods may seem low to those that are familiar with them. People may be dismissive of the recall, often vicariously; e.g. a nurse may retain catheters that have been recalled because they cannot get identical replacements immediately, and so makes a decision to use the goods on behalf of those in whom the catheters are inserted. This approach may be reasonable if the lack of the goods leads to a real threat to wellbeing, but that judgement should have been made at the time of the initial recall decision. It is undesirable to have people making a subsequent risk analysis and deciding the recall is not really necessary in these particular circumstances. At least, any decision to use a recalled item would require informed consent.

Sponsors are concerned about this ‘second guessing’ and feel highly accountable – but they identify hospital staff and others who are not so concerned. One device sponsor indicated that they are lucky to get response rates of 30% from a device recall.

The actions already recommended concerning advice on liability and more information about the recall process, may help address this issue. The TGA may also wish to raise it with the Council on Quality and Safety in Health Care, with a few examples, as a quality issue that needs to be addressed.

3.2.5 Hospital responses to recalls
The efficiency/effectiveness of different hospitals in handling product faults for devices reported to the TGA is said to vary widely. Much depends on how effective their internal quality management systems (QMS) are. This variation in quality is likely to be just as common when handling recalls.

Not all hospitals have a QMS and so may not handle recalls well. For those hospitals without a QMS or who are in the process of developing one, a Draft SOP could be made available that hospitals could use if they did not have one of their own. It would need separate Draft SOPs for medicines, devices, and perhaps even types of devices (e.g. electromedical and implantable versus others). These would need to be developed in collaboration with the relevant industry associations (e.g. Society of Hospital Pharmacists, the MIAA, etc) and the Council of Quality and Safety in Health Care.

This is not a responsibility of the TGA. However, NCCTG could lead the development of Model Standard Operating Procedures (SOPs) for the conduct of recalls in hospitals, or an outline of the essential elements thereof, to encourage SOP development, or to guide action when there is no SOP in place at present.
3.3 Issues relating to States and Territories

Part J of the URPTG establishes two areas of responsibility for State and Territory recall coordinators. These are, in summary:

- To advise TGA of problems with therapeutic goods that come to their notice.
- To respond when a local response is necessary to ameliorate a significant threat to health (usually two circumstances – specific jurisdictional issue or require local knowledge/networks to maximise awareness of a serious risk to health).

In doing so the URPTG requests States and Territories to take particular responsibility for communicating urgent safety related information to public and private hospitals; and assist in the provision of timely information to pharmacists and other professional groups.

States and Territories generally recognise and accept their two roles but there are considerable differences in the level of effort put into the recall process. Some jurisdictions do a lot, some do little. A ‘belts and braces’ approach drives the smaller jurisdictions. Recalls are more likely to get media attention in small communities and the health agencies like to be seen to have done everything possible, even though it may duplicate the activities of the sponsor.

Smaller jurisdictions have good capacity to send faxes to pharmacies and hospitals whereas larger jurisdictions may have little capacity, due to complexity of the task of setting up and maintaining a database that is used so rarely as to be unwarranted. Thus the larger jurisdictions do not have robust infrastructure for this purpose other than the general emergency response mechanisms, and tend to leave it to the sponsors. In the case of community pharmacy, one could subcontract the Guild, but it only reaches about 75% of pharmacies by fax (not all pharmacies are Guild members and not all of those that are have fax machines).

Queensland undertakes a significant level of activity and it has SOPs for the management of recalls. Recalls to retail and consumer level are notified to each Area Coordinator and they take action that supplements the action of the sponsor. No other jurisdiction takes this approach. Some small jurisdictions will fax the initial recall notice to their pharmacies when the recall is ‘significant’ in order that the pharmacies do not have to wait for a letter to be received, but this is ad hoc and there is no parallel to the SOP and regionalised approach that Queensland has. Most States other than Queensland take action only when the TGA specifically requests assistance, or there is a publicity concern, or the State has a particular interest for other reasons.

This review has reached the conclusion that the mechanisms for contacting pharmacies should be left to the sponsors and industry associations to address, but with the general support of the TGA. States and Territories should not become involved unless there is an agreed national plan for them to do so.

It is worth noting that a member of the devices industry complained about States that undertake a lot of activity. A sponsor may have been able to run a highly targeted recall and then a State health agency alerts e.g. its hospitals that have either not had stock or it has been retrieved already, This can cause concern for no added benefit. All jurisdictions are willing (indeed concerned) to be involved when there is a serious threat to health or particular local/national political aspect, but all or nearly all are
content to leave management to TGA, and know they will hear from the TGA if there is something they need to know or do. Most jurisdictions were clear that they only want information on a need-to-know basis and were very satisfied with the TGA’s judgement on what they need to know and what they did not.

Some jurisdictions emphasised that they have decreasing capacity and resources to respond to recalls due to declining involvement with therapeutic goods regulation, as a result of the steadily increasing scope of TGA’s activity. Also some State health agency recall officers pointed out that they have very little involvement even with the State hospitals any more, due to organisational separation between the central office and the providers.

In relation to the Pan recall, States and Territories were asked to audit the effectiveness of the recall. The capacity of the States and Territories to do this readily was linked to the access to an inspectorate that is capable of doing so. All have some capacity in this regard but the ease of doing so varies widely. Queensland, for example, has a structure that facilitates such action whereas some others do not. While it can be carried out it is more difficult to mobilise resources in these jurisdictions.

This declining capacity of States and Territories to respond needs to be borne in mind and if it gets to a critical level and NCCTG cannot address it satisfactorily, there may need to be consideration of the matter by AHMAC. At this stage, the matter only requires monitoring as events like the Pan recall occur very rarely indeed.

As the URPTG is supposed to be a Uniform Recall Procedure, some effort needs to be made to keep jurisdictional responses uniform. Given that the two largest States do very little unless there is a particular request for help from the TGA, and this seems to make no difference to recall outcomes, most of the time it is hard to make an argument for more than a lowest common denominator approach. Ultimately it is the sponsors’ responsibility and they take the responsibility very seriously. It is hard to see why States and Territories should duplicate sponsors’ activity. This may mean some jurisdictions doing less.

There will be occasions when the States and Territories health agencies’ input is sought, particularly when there is criminal activity or when there is a very serious health recall, but these are quite exceptional. It may be better to ensure a substantial effort on these and spend less time spent on the more routine recalls.

States and Territories need to maintain a contact list for major public and private hospitals within their jurisdictions. Ideally it would have different emergency contacts for differing events. In practice, the contact list should be as specific as possible, e.g. for both Emergency Departments as well as a general list to Chief Executive Officers. The appropriate information for dissemination is typically the sponsor’s recall letter.

Recall information that TGA provides to States and Territories should be distributed by email only, except for recalls that require State and Territory action, or Class 1 recalls, or consumer level recalls, which should be sent by fax as well.

**Possible approach of a Trans Tasman agency**

It is instructive to consider what role the States and Territories may play if/when a joint agency is established with New Zealand and what will the State and Territory roles will be vis-à-vis the New Zealand Ministry of Health role. The joint agency will
be expected to ensure the sponsor undertakes the recall action appropriately on both sides of the Tasman. It is not expected that the New Zealand Ministry will undertake any action, except where there is a major public health threat, i.e. the model outlined above for the States and Territories. It is unlikely that the new arrangements would ask of a State or Territory something that was not similarly asked of the New Zealand Ministry of Health, or vice versa, except for jurisdictionally specific issues.

It is assumed that the Australian legislation for the joint agency will ‘cover the field’ using the Commonwealth’s foreign affairs powers. Recalls for an unincorporated body trading within a State etc, will then be covered by the joint agency’s recalls legislation, without States needing to have complementary legislation.

**Blood recalls at the jurisdictional level**

Jurisdictions were of the view that receiving the blood recall notices is mainly a nuisance and provided no added value. The information may be of value to the persons in health agencies that manage the relationships with ARCBS. Consultations were undertaken with a few of these people who indicated that they had no interest in receiving hundreds of emails or faxes about minor blood recalls, e.g. due to post donation illness. Blood recalls should no longer be distributed to State and Territory Recall Coordinators. A paper should be prepared for the Blood Review Implementation Steering Committee (BRISC), possibly for further referral to the Government Blood Committee or the Quality and Safety Committee (both subcommittees of BRISC), seeking identification of the best person in each State and Territory is to receive the recall information, if they want to get it at all. If they do wish to receive the recall information, they need to determine what the desired level of aggregation of that information is.

**Recommendations**

3. The States and Territories should commit to a uniform recall system without duplication of the activities of the sponsors, and committing to undertake whatever specific national action is agreed in the event of a threat to health that requires their involvement.

4. States and Territories should maintain an appropriate process within their jurisdictions, enabling timely dissemination of information (typically the recall letter) in the event of a threat to health, as agreed with the Australian Recalls Coordinator.

5. Recall activity in the field other than that specifically requested of the States and Territories should be left to sponsors, who should be advised that they can approach the jurisdictions in exceptional circumstances if they want help from one or more of them.

6. If, in a particular instance, a jurisdiction sees a need to take action on any recall beyond that requested of them, they should advise the Australian Recalls Coordinator what they are doing and why, so that other jurisdictions can be advised and decide whether or not to follow suit. When this happens, the action undertaken and the reasons for it, should be discussed at the next meeting of the NCCTG.
3.4 Complexity of the recall system and communicating about it

The URPTG has a number of dimensions that can be applied to a recall. They may be Class 1 (highest level of risk), Class 2 or Class 3 (lowest level of risk), they may be urgent (most safety recalls) or routine (generally related to quality rather than safety), they may be labelled Voluntary (or not) and the level of recall has to be determined (wholesale, retail, consumer, etc).

This classification is complex and means that in practice nearly all recalls are labelled urgent (sometimes after long periods of negotiation). The Class is put on the fax that goes to States and Territories but no-one really uses it. Its main use is international – to describe the level of the recall to others. The same system is used by the EU and nearly the same by the US, so it is widely understood overseas. The EU classifications are outlined in Appendix 2.

There is, arguably, one too many dimensions in the categories. If there are Class I to III recalls it is hard to see why they also need to be described as urgent or routine independently. A decision should be made to label only either Class I, or Class I and II recalls, Urgent. If the former, the term Urgent will be preserved only for those that truly are, and if the latter option is used the coverage is better but the word risks being over-used. The alternative is to label all safety related recalls Urgent. This means that the term is not aligned with Class, as at present. This was the preference expressed by NCCTG members when they were consulted in session in April 2003.

Consultations suggested that there is a preference to risk over-using the word Urgent, rather than conserving its use. Therefore, it is proposed that Urgent be used on Class I and II recalls and not on Class III recalls. This departs from present practice, i.e. use on all safety-related recalls, notwithstanding the view of the NCCTG that this should remain. The number of examples where the two approaches will result in a different outcome is likely to be small. As the rest of the western world uses Class as its guide to seriousness of the recall, to use something else departs from any semblance of international harmonisation.

One difficulty with widespread use of Urgent is that sometimes the negotiations with the sponsor have gone on for some time before the recall, and then suddenly it is Urgent. Some feel this is then an inappropriate use of the word. New Zealand tends to use Urgent less and Voluntary not at all, contending that voluntary has an implication that the recall is optional, i.e. you can do it or not as you wish. This argument has some merit and will need to be resolved if a joint agency is progressed.

Recommendations

7. The term Urgent should be applied to Class I and Class II recalls, and not to Class III recalls.

8. Consideration be given to removing the word ‘voluntary’ from recall letters, possibly using of some other form of words, such as ‘sponsor-initiated’, as appropriate.

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3 This classification is the reverse order in relation to risk to the classification of devices in the new Therapeutic Goods (Medical Devices) Regulations 2002, which also uses Class 1 (lowest level of risk), Class 2 and Class 3 (higher level of risk).
3.5 **Perceived difficulties in the execution of recalls by those involved**

A number of perceived difficulties with the standard practices in regard to recalls were commented on during the course of the review.

**Uncertainty about the process**

Some persons consulted indicated that many participants are not sure about their role in the greater scheme of things. They know too little about the Recall Procedure to be sure what, if anything, is expected of them. It was suggested that awareness of the URPTG and its application among hospital staff, pharmacists and other professionals needs to be higher. They need to know what they have to do and how to do it. This would addressed by implementing Recommendation 2.

**The recall fax**

Some minor aspects of the recall fax sent to States and Territories were not seen as optimal:

- The fax form is not sufficiently distinctive when it comes through – it did not look very different from other faxes. A distinctive logo – perhaps stripes like those used on the recall letter – would make the fax instantly recognisable.
- Some of the lines of the fax were redundant – e.g. the “From:” line was not necessary. This increases the reading time unnecessarily.
- Some lines of the fax were in the ‘Not for circulation’ part of the fax that some thought should be able to be circulated, in particular whether it is safety related or not.

The format of the fax form and the usual letter should be revised, with consideration being given to adopting the letter format used in New Zealand.

**Recall letters**

Some thought the letter could be better set out for easy reading and quickly grasping what needs to be done. The New Zealand Code and the recall letters published by the UK Medical Devices Authority (MDA) both use a format that has a very short introduction and then a panel of that outlines in dot point form the action required. This seems to have merit as a means of providing people that need to take action with very clear information about what action to take.

There are a number of other issues related to the recall letters that were identified during consultations that are not directly part of TGA business but are concerns of some stakeholders, notably financial aspects – what the credit arrangements are going to be, what if any compensation will there be for the time and trouble involved, etc. This is especially when the activity is on the scale of the Panadol® recall. Pharmacists want to know this information as part of or at the same time as the recall letter.

There is an assumption by pharmacists that every pharmacy will be notified. This may not always be the case e.g. where stock has only gone to a limited number of pharmacies and the sponsor elects to contact only those pharmacies. If there has been secondary distribution of the product the primary pharmacist may fail to notify those to whom stock has been sent.
Where there may have been secondary distribution of stock the pharmacists should not assume that a letter will have been sent to every pharmacist, and they must take responsibility to distribute the recall advice in such circumstances. This is something that could go into a brochure on the recall procedure (see Recommendation 1).

**Fax as a possible alternative to letters**

As noted above, not every pharmacy has a fax machine, although the great majority do. It seems likely that those that do not have their own could identify one that could be used to send them a recall notification in the case of an emergency. Where a fax number is completely unavailable, a telephone number would suffice. At least you can then ring and either get a fax number or alert the person verbally.

Maintaining a list of pharmacy faxes is not the core business of the TGA and the health agencies in large States and Territories have made it clear that they do not see it as core business either. It would be reasonable to ask the professional associations to pursue this, in collaboration with the pharmaceutical industry associations as they are the potential beneficiaries of such an arrangement.

The Medicines Partnership of Australia (MPA) is attempting something similar, in trying to establish a 24-hour contact point for all pharmacies. It is a somewhat more ambitious undertaking but a good start would be to ensure they have immediate contact/fax points for all pharmacies when they are open. The TGA should encourage this initiative if it may lead to a situation where all pharmacies can be faxed as a faster alternative to letters.

It is understood that the purpose of the MPA initiative is in relation to tampering. It may be that, if a fax database is available that could be used by sponsors for recalls (rather than letters) usage fees could pay for its maintenance, ensuring its effectiveness if/when another tampering incident occurs. The cost effectiveness of creating and maintaining a pharmacists’ contact database solely for tampering or other criminal incidents will be very poor if that is its only use.

**Issues relating to recall envelopes**

A number of persons raised the concern that the letters were addressed in accordance with the recall procedure, e.g. to the Chief Pharmacist, but the envelopes may not be. This alleged problem seems to have been largely fixed in the case of hospital pharmacists but it was also raised in relation to device recalls, with envelopes addressed to the CEO. There is a risk that letters so addressed may take a significant period of time before getting to the right hands and be acted upon in a large hospital.

The TGA has a list of mailing houses that it provides sponsors so they know where to start. It may be better to ask the pharmaceutical and device industries to work with interested mailing houses and for industry to produce appropriate lists of mailing house that are competent to undertake either device or medicines recalls or both.

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3 This group consists of the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, Medicines Australia, Australian Self Medication Industry and the National Pharmaceutical Services Association. The Guild acts as the secretariat.

4 The URPTG currently requires that letters also be sent if fax is used. That should be optional once a comprehensive fax list is available and people are aware that the information will not be followed up by letter.
In doing so, the industry association can then ensure that the mailing house has made reasonable efforts to include an appropriate title on the address, not just ‘CEO’. However, in some circumstances, e.g. a very large number of small centres, that might be as good as one can do and in these small centres it may not matter much. It is the very large centres where mail has the capacity to go astray and they are the ones where high risk goods, e.g. implantable devices, are most likely to be in routine use.

The list of ‘industry approved’ mailing houses could then be supplied directly by the relevant industry association, and the TGA could simply advise sponsors where they need to go to get it.

One device company pointed out that there is no standard letter format for Safety Alerts and it felt there is a need. They had developed a sticker for the envelopes that said Safety Alert – Please open immediately.

Stickers have the virtue of being able to be held on hand and used as necessary. This may be faster than having envelopes printed when trying to get the letters out as quickly as possible.

Several significant changes to present procedures could be made:

- TGA in collaboration with the device industry, consider the need for a distinctive envelope or a standard sticker for safety alerts, and whether the use of stickers rather than specially printed envelopes may speed up the process of mail outs in the case of recalls.

- TGA should encourage the Medicines Partnership of Australia to develop a database with fax number for every pharmacy, so that urgent recalls can be faxed and eventually the use of letters to pharmacies can cease.

- TGA should request the medicines and device industry associations to each produce a list of mailing houses that they believe are capable of producing lists of addresses that are appropriate for recalls in their industry, so that sponsors can be advised how to access suitable lists when necessary.
3.6 Risk analysis and threshold issues

The Recalls Secretariat Section (referred to hereafter as the Recalls Section or just the Section) has its process of risk assessment that is followed when a potential problem is identified and a recall is being considered but it is not set out formally, e.g. as a TGA guideline for internal use, although the risk management strategies (e.g. the various types of recovery action and the various levels of recall) are clear enough.

In the language of risk\(^5\), initially one has to assess:

- the hazard, e.g. is it an antacid tablet that is involved, or a product containing a highly potent alkaloid such as digoxin; or is it a urinary catheter or a pacemaker that is faulty and what is the nature of the fault);

- the level of exposure (in general use and encountered often, or used in very specialised situations e.g. a rare diagnostic test).

As risk = (hazard x exposure), a relatively low hazard and low exposure will result in a low risk, but still may require some recall action if safety is compromised. Making this judgement is the risk assessment. The management strategy is developed according to how the assessment rates the risks, but also takes other issues into account, e.g. feasibility, timing, etc. The risk assessment considers only the science whereas the risk management process is pragmatic.

This risk assessment process is one that the recall section and their advisers go through now. It may take two minutes and involve writing nothing down, or 5 minutes and some notes, or it may take days to elucidate e.g. the exposure, sufficiently to assess the risk.

It is proposed that documentation be enhanced to more clearly outline the risk analysis approach. While this seems obvious there appear to be no similar guidelines internationally, so it is not a trivial task, and would be a world first. The aim of the guidelines would be, first to support the risk assessment and management processes and second to ensure the use of the language of risk in a clear and unambiguous manner, e.g. not talking about risk when you mean hazard. This is very important when staff are new. TGA is fortunate in having had stable staffing in the Recalls Section, but that may not always be so.

The risk analysis framework should not become a mantra that must be chanted religiously, but it should be an aid to fall back on when the analysis is tricky or when transparency of the methodology is important. It should be a framework to help clear and logical thinking about the problem and its component parts.

A summary of the principles of risk analysis in the context of therapeutic goods, is given in Appendix 3 and a set of relevant principles in Appendix 4. Appendix 3 is based on the recent publication of the Department on assessing environmental risk and the other appendix is taken from it. These are not given as a prescription but as a starting point in developing a risk analysis framework for assessment of risks relating to the recall of therapeutic goods.

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\(^5\) Unfortunately the language of risk is not consistent, but the language used here is consistent with that used in *Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards*, published by Department of Health and Ageing: Canberra. 2002.
Another guide to risk assessment related specifically to recalls (although the framework that is included is not) is the US Consumer Product Safety Commission’s Information Quality Guidelines (see www.cpsc.gov/LIBRARY/infoguidelines.html). This also includes some other useful discussion on public recall information quality.

Threshold issues are a problem – at what point is the evidence enough evidence? Risk assessment will not suddenly make the decision whether to trigger a recall easier, but it should provide a framework for thinking it through, again important if new staff are undertaking the task. In the case of a voluntary recall (i.e. most of the time) it is the sponsor’s decision, but TGA often provides sponsors with guidance.

Occasionally, valuable time may slip by while looping through the risk assessment process – trying to get enough evidence to clearly identify the magnitude of the risk, and to then be able to say what the risk management process should be. One strategy that may assist the decision making in these circumstances is a quarantine arrangement in the recall procedure. This would reduce the severity of the action taken while evidence is gathered. Quarantine is further discussed under the section on Legislation.

A formal risk assessment framework and a quarantine arrangement should improve the clarity of the process when still trying to decide whether to recommend to the company that a recall be undertaken or not. Quarantine will also provide another, lesser option than a full recall while the risk is further elucidated.

**Recommendation**

9. **The risk assessment framework for recalls that is followed customarily in the TGA should be written up as a formal guideline for internal use.**

### 3.7 Consumer issues

It will always be true that consumer recalls need to generate greater awareness. You can never reach everybody. The current system works well if picked up by the media as a news item, but that is a hit-and-miss process, unrelated to actual risk. There are no data or research that this review has been able to identify as to how to do better, and no evidence-based guidance as to what works. The recall process, here and elsewhere, is only assessed by what was done (inputs) not what the outcomes are, as they are too hard to measure.

Consultations with consumers indicated their chief concern is to have accurate, balanced information available in a timely manner through different media (preferably not just newspapers) and that the message is consistent.

The practice of the TGA to usually only require advertisements in the major daily newspapers. The Pan recall notices were in the regional newspapers, but this was exceptional, and exceptionally expensive. It is, however, routine practice in New Zealand to advertise in regional newspapers.

It is hard to recommend advertisement in regional newspapers in the absence of any information one way or the other as to the effectiveness of present practices in terms of outcome rather than process. Given that it is in the order of ten times as
expensive to advertise in all the regional papers as well as the major papers, it is unlikely that this is necessary, affordable or cost effective, other than in very exceptional circumstances.

Consumers would also like to see:

- A Consumer Helpline – for all significant consumer level recalls – and monitoring/debrief on the questions that were asked so that can improve over time. If the TGA feels it is appropriate, a consumer helpline should be provided by the sponsor. Sometimes the recall is too small to warrant such a step and in that case the TGA could waive the requirement.

- Relevant consumers group be advised directly e.g. for a recall of respiratory inhalers, Asthma Australia would be advised. This could be done through Consumers’ Health Forum if the relevant groups were not obvious. This should be flagged with sponsors during recall negotiations and preparations.

### 3.8 Legislated recall powers and related issues

While voluntary recalls will remain the main type of recall, there will be times when that is not possible and so the legislative provisions need to be comprehensive. At present this is not the case. The events of the Pan recall also demonstrated some of the problems of relying on the general powers under the *Trade Practices Act* (different elements to prove, etc).

**Linkage of recalls to registration and de-registration**

At present the powers to undertake recalls are mostly in Chapter 3 of the *Therapeutic Goods Act*. This Chapter relates in particular to the process of registration of therapeutic goods and the general appeal framework for decisions made pursuant to that Chapter are appropriate to the consideration of registration or de-registration. The relevant sections of the Act are set out in Appendix 5.

With one recent and very notable exception (the Pan recalls), very few recalls are linked to registration. They generally relate to a problem with a particular batch and rarely threaten the actual registration of a product. This means that the appeal framework may not be appropriate for the type of activity that recalling goods generally involves. In fact the provisions can be used by sponsors to prevent the TGA taking prompt action to protect public safety.

It would be better if a framework that related to the particular circumstances that generally surround recalling goods, not registration, was applicable, especially in regard to appeal provisions, which must take account of the urgent nature of recalls and the possibility that the appeals process can be used vexatiously. The possibility of de-registration of a recalled product is often an after-the-event consideration, e.g. after completion of further investigation.

**Relevant consideration**

The legislation also needs to allow for a mandatory recall to be undertaken after following the process for a voluntary recall, or requiring a mandatory recall to follow the URPTG for the sake of consistency without one affecting the viability of the other.
In one Federal Court decision, a copy of which was provided to the review, it was observed that by taking matters into account from the URPTG, a delegate may be in breach of the AJ(DR) Act, section 5(2)(a). This says:

5 Applications for review of decisions
(1) A person who is aggrieved by a decision to which this Act applies that is made after the commencement of this Act may apply to the Federal Court or the Federal Magistrates Court for an order of review in respect of the decision on any one or more of the following grounds:

(e) that the making of the decision was an improper exercise of the power conferred by the enactment in pursuance of which it was purported to be made;

(2) The reference in paragraph (1)(e) to an improper exercise of a power shall be construed as including a reference to:

(a) taking an irrelevant consideration into account in the exercise of a power; ...

This is a standard principle of administrative law in any case.

Section L of the URPTG states that any Notice issued pursuant to section 30, 30A or 30B may require that the URPTG be used to recover the goods. It is not clear if this is sufficient to fully address the issue raised in the Federal Court decision – it probably is not.

It seems there is a risk that the time taken to try and persuade a sponsor to undertake a voluntary recall, and keeping the process in line with the URPTG, may count against the TGA in the event that the notice to recall ends up in dispute before the court. Processes that are completely in line with the requirements of administrative law should be established. This may require adoption of the URPTG under the Act.

Suspension of the registration or listing of medicines
The Therapeutic Goods Act does not provide a power to suspend registration of medicines. This has now been included for devices (see Division 3 of Part 4.4 the Act).

The public have shown, in the support for the actions of the TGA over Pan Laboratories, that they want a conservative regulatory stance taken where medicines may cause unanticipated harm. It is therefore necessary that when the TGA has a prima facie case to believe that harm may occur, they have the power to act quickly. This could include, as an interim action, suspension of the goods for a period while further information is gathered, in line with the arrangement for devices.

If a sponsor is unwilling to undertake a recall, the present legislative requirements are not necessarily consistent with prompt action, unless the specific goods have been shown to be faulty in some way, not just that there is a strong prima facie case that they are faulty. If a large number of products are involved, testing cannot be done in a short period of time, and the statistical chance of detecting every faulty batch through random testing is essentially zero. In such circumstances, to be truly effective there also needs to be a reverse onus of proof, i.e. the sponsor has to show the prima facie case is not valid, rather than the TGA having to show the medicines are unsafe.
Safeguards could be built around this, e.g. the prima facie case that is the basis for the goods being suspended may have to meet certain tests.

The new section 30EA has widened the scope of the recall arrangements but still seems to require a high level of proof.

**Quarantine of therapeutic goods**

Given that a device registration may be suspended now, there is then a need for a power to quarantine therapeutic goods as once suspended under present arrangements they will have to be recalled. Suspension means that eventually the goods may be put back into use, i.e. they are being held up until further matters have been addressed. Recall is not appropriate in this circumstance.

There is no power to quarantine therapeutic goods in the legislation and no reference to quarantining goods in the URPTG. These both need to be addressed, and the arrangements need to apply to all forms of therapeutic goods. This option, linked to the power to suspend goods, would go a long way to addressing some of the ‘threshold’ issues that are inherent in the system at present.

It was pointed out during early consultations that the Therapeutic Goods Act also lacked the power to order the recall of exempt therapeutic goods, and (it was said by some) to order the recall of counterfeit therapeutic goods (although these are unregistered therapeutic goods and may therefore fall under section 30A). These deficiencies have been addressed by the very recent amendments to the Act. The amendments are included in the extracts of the relevant portions of the Act in Appendix 5.

**Two separate sets of notification requirements**

Representation was also made to the review about the double regulation of recall notification with requirements under the Trade Practices Act as well. These powers appear to add nothing to the recall process except additional paperwork. For organisations that undertake numerous recalls, such as those relating to cellular blood products, it generates a substantial amount of additional work.

In New Zealand, it was reported that recalls undertaken under the supervision of Medsafe do not have to be notified to the Commerce Commission as well. It is desirable that a recall executed pursuant to the Therapeutic Goods Act or the URPTG does not have to be notified again to the Competition and Consumer Policy Division of Treasury.

Organisations like the Australian Red Cross Blood Service and commercial sponsors that undertake many recalls experience a lot of work and cost for no health gains as a result of this double requirement. TGA could provide the information on all their recalls to Treasury for statistical purposes, which seems to be the only purpose that it serves.

**Persons or enterprises that have ceased to be sponsors or are no longer solvent**

There also needs to be a power to do a recall first and find the sponsor of the goods and recover the costs later. TGA needs to be able to do this when it believes health and safety are threatened and the sponsor is, for example, bankrupt or is (at least temporarily) beyond the reach of the law, e.g. overseas or missing. The recall itself
may send a company into liquidation and so there may be a case to give some priority to recovery of expenses incurred by the TGA in undertaking the recall.

This power to do a recall first and find the sponsor of the goods and recover the costs later has also been signalled in the Trans Tasman discussion in relation to goods associated with advertising that is false or misleading.

There needs to be a similar power to order a recall when the sponsor has changed. Even though the current sponsor may not have sold the goods there needs to be the power to order either the previous sponsor or the current one to undertake a recall, as the TGA sees fit.

**Auditing of recalls**

There is a lack of power to audit recalls. There is both a lack of power to audit statutory recalls and no arrangements under URPTG for non-statutory recall audits. Ideally there would be a power to audit any recall, whether mandatory or undertaken voluntarily, if necessary. In the case of voluntary recalls the power could be linked to any recall notified to the TGA. Not notifying a recall should also be an offence.

**Appeals**

Clearly, all of these provisions require relevant appeal mechanisms, but the mechanisms need to be consistent with the need to act as quickly as possible. A formal process leading up to a mandatory recall could be set out in the legislation which would add certainty for both the sponsors and the TGA.

**Inability of some parties to comply with requirements**

Consultations following the recent Pan recall have suggested that some intermediate parties, in particular some wholesalers, may not have the capacity to fully comply with the URPTG. In the event that a mandatory recall or (one day) quarantine order is issued, the sponsor may not be able to gain compliance of these intermediate parties, and there is no legal obligation on them to do so.

The recall orders may have to be more inclusive of parties beyond just sponsors. Obviously a voluntary arrangement would be preferable, but some of the small wholesalers may not be members of industry associations, and the capacity to make a voluntary arrangement work is then diminished. TGA needs to consider a power to cover wholesalers by licensing or other means. In section 3.2.2 the potential need to track high risk goods such as scheduled medicines to batch level was outlined. TGA should take both of these matters to the wholesalers for discussion and, either through the CGWP Review or outside of it, consider the need for legislation to cover wholesale activities.
Recommendation

10. The cooperative nature of the recall system be maintained wherever possible, but supported by comprehensive legislative powers in the event of inability or unwillingness of a sponsor to undertake a recall. Amendments should be sought to provide this comprehensive set of arrangements. Areas for improvement include:

- ensuring the process of recall of therapeutic goods is quite separate from the process of registration and deregistration;
- clarifying that following the URPTG in the case of a mandatory recall is not *ultra vires*;
- providing for powers to order suspension of registration or listing on the ARTG and quarantine, for all therapeutic goods, and corresponding changes to the URPTG for a voluntary quarantine arrangement of therapeutic goods whose sale has been suspended voluntarily;
- consideration of the need to regulate wholesalers of therapeutic goods under the *Therapeutic Goods Act*;
- exempting therapeutic goods from the notification and possibly other provisions of the *Trade Practices Act*, as is the case in New Zealand, unless the relevant Minister declares that particular therapeutic goods are not to be exempted;
- enabling the TGA to order a previous sponsor, or a current sponsor if the previous sponsor cannot be identified or is insolvent, to undertake a recall of therapeutic goods if the previous sponsor was the sponsor at the time of the distribution of the goods;
- the Therapeutic Goods Administration having, as a last resort, a specific power to undertake a recall and recover costs from any party that registered or was involved in the sale or supply of the therapeutic goods, as appropriate. Consideration should be given to the debt ranking in front of other debt (but after employee entitlements) in the event that the relevant company is insolvent.
3.9 Trans Tasman issues

As well as meeting the Trans Tasman group in Australia, two days were spent in New Zealand, consulting with Medsafe, the pharmaceutical associations and industry in both Wellington and Auckland, to look at differences that may need to be taken into account in the event of a joint agency, and to learn from what New Zealand is doing differently and possibly better than Australia. Some important differences were found.

For some categories of product, there is a less vigorous approach in initiating recall action compared to the TGA. Recalls were either less likely to be initiated, or if initiated were less likely to reach as far, e.g. maybe only to wholesale level rather than retail level. In essence, the risk assessment may be the same but the risk management strategy appeared to take into account the impact of a recall in the market, while remaining safety focussed.

By contrast, New Zealand has a rigorous approach to recalls once initiated, including:

- Relatively more newspapers (typically 23 overall, including regional papers).
- A demand for (and compliance with) a much higher response rate from pharmacies and others.
- Sponsors meet patients’ and other costs, e.g. couriers, etc. Thus if recall required another visit to the medical practitioner this was typically paid for by the sponsor.
- Recall letters have a more structured format, with inclusion of a list of actions in dot point form very early in the text of the letter that explains exactly what to do.
- A toll free number is strongly encouraged for ease of reply to when required.

With the exception of sponsors of devices (as they are not registered in New Zealand) linkages to the distribution chain seem stronger than in Australia.

The arrangements that New Zealand has in relation to Pharmac (the New Zealand equivalent of the Australian Pharmaceutical Benefits Scheme) affect some recall processes. Pharmac typically lists only one brand, so if that brand is withdrawn (as happened recently with filodipine) there may be no alternative immediately available, and even if one is, Pharmac will only pay the price of the withdrawn product. When a medicine is withdrawn completely from the market, this has to be taken into account in developing the risk management strategy for New Zealand. The Pharmacy Guild of New Zealand is particularly concerned about this aspect after the experience with filodipine.

Consultations revealed that the New Zealand Fair Trading Act exempts recalls from reporting when Medsafe manage them, although the precise legislation was not sighted and the Commerce Commission was not visited, so no detailed understanding of the mechanism for this exemption was obtained. The arrangement saved double reporting of recalls, and is a model to emulate in Australia if possible.
The control of recalls of cellular blood products is managed completely differently in New Zealand. There are essentially no recalls of cellular products that Medsafe are involved in. The New Zealand Blood Service is also the provider of the blood service *within* many of the larger hospitals and so the criterion of leaving control of the sponsor is at a much later point. Apart from that, there was a different relationship between the NZBS and the regulator, with NZBS advising Medsafe and the Ministry of Health if there was a problem that it regarded as serious (on a need-to-know basis).

**New Zealand Concerns**

Certain concerns were expressed about the recall arrangements in New Zealand under a joint agency. These included:

- That there would not be a sufficient understanding of the social climate and values in New Zealand. For example, the higher level of media interest may not be understood and taken into account to a sufficient extent.
- There is concern that a more risk averse, less flexible approach, may cause a loss of the positive relationship with industry. This concern was expressed within Medsafe at least as much as it was by industry. The Recall Procedure itself is seen as being more prescriptive than New Zealand’s (although this is not universally the case, e.g. New Zealand is more specific about the reply form than Australia).

Medsafe expressed the view that there is a need for a process where two the agencies (Medsafe and TGA) synchronise approaches used in recalls – carefully elucidating the differences and finding a way forward on them, e.g. the format and use of some words – New Zealand consistently removes the word ‘voluntary’ from draft recall letters.

There are also some pragmatic considerations that need to be taken into account. For example:

- There needs to be New Zealand not Australian telephone numbers to contact.
- Postal services across the Tasman can be quite slow. Recall letters for New Zealand must be posted in New Zealand.
- Access to alternative products/further supplies (see Pharmac discussion, above).
- New Zealand fax numbers where fax back is required.

This review has not undertaken sufficient consultation to be sure of having identified *all* of the issues that need to be addressed in relation to recalls under a joint agency. It is understood that New Zealand has the task of working the issues through, and to that end a draft paper has been prepared, though not circulated. That process needs to continue and the Trans Tasman group need to consult Pharmac about any concerns that it may have. There was discussion about a de-briefing on the issues of filodipine, which had not happened at the time of consultation. If held, it may be useful for the Australian recalls staff to be involved in that process, as it will give them an understanding of the particular issues that the Pharmac arrangements create.

Further work needs to be done by Therapeutic Goods Administration and Medsafe to identify outstanding issues and describe in detail the process of operation of recalls if/when the joint agency is established.
3.10 Blood recalls

Since 2000 the TGA has more closely regulated cellular blood products. This has led to a massive escalation in the number of recalls (see Figure 2), and the associated workload. In 2002 over 1,000 blood recalls were undertaken. The ARCBS also has to notify the Consumer Safety Unit of Treasury, and this generates considerable work for the ARCBS with no obvious benefit.

Typically the cellular blood product recalls involve one donation and a very small number of products, and are resolved quickly and simply. Some are not, however, and they are also important as an indicator of the quality of the ARCBS’ processes.

The TGA wishes to rationalise the workload from large numbers of ‘minor’ recalls, but at the same time the GMP assessors in particular wish to be able to monitor the performance of the ARCBS on a continuous basis. There have been proposals to reduce recall workload by moving to monthly reporting in the case of e.g. those that are due to mild post-donation illness (colds, gastroenteritis, etc). The resolution of that matter has been delayed, in part by this review.

The ARCBS divides recalls into Donor Triggered Recalls and Process Recalls. The proposed classification for the monthly report that the ARCBS is proposing is given in Table 1.

<table>
<thead>
<tr>
<th>Table 1 Proposed Categories to be used for Cellular Blood Product Recalls</th>
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<tbody>
<tr>
<td><strong>Donor Triggered Recalls</strong></td>
</tr>
<tr>
<td>1.0 Donor Triggered Illness</td>
</tr>
<tr>
<td>2.0 Donor Triggered Notification - Travel</td>
</tr>
<tr>
<td>3.0 Donor Triggered Notification - Other</td>
</tr>
<tr>
<td><strong>Process Related Recalls</strong></td>
</tr>
<tr>
<td>4.0 Processing</td>
</tr>
<tr>
<td>5.0 Labelling</td>
</tr>
<tr>
<td>6.0 Mandatory Testing</td>
</tr>
<tr>
<td>7.0 Other Testing</td>
</tr>
<tr>
<td>8.0 Positive Micro</td>
</tr>
<tr>
<td>9.0 Interview (i.e. incomplete questionnaire, donor was accepted outside of Guidelines)</td>
</tr>
<tr>
<td>10.0 Recipient Reaction</td>
</tr>
<tr>
<td>11.0 Other</td>
</tr>
</tbody>
</table>

It is not clear to this review what value the concept of ‘donor triggered’ recalls adds to this classification. Only post-donation illness is completely unavoidable. Discussions within the TGA and with the ARCBS did not fully elucidate these issues, because different people want different outcomes.
A conservative approach would, therefore, be to allow reporting of only post donation illness of a monthly basis, and report all others as they happen. This may not be sufficient to stem the flow of recalls, and so the TGA may wish to go further and may be able to do so with little or no additional risk. Unfortunately, the recall data as provided to the TGA (and thus to this review) is not conducive to analysis by type of recall (this being a descriptive field not a coded one), thereby preventing estimates of impact on the number of recalls that particular changes might make.

How much further it should go in granting concessions is a matter of balancing the needs of the GMP assessors on one hand and the workload in the recall section (how many recalls can they handle on an individual basis with the level of resources that they have available).

The details of any such an arrangement need to be agreed between and Recalls and GMP sections, the ARCBS and foreshadowed with the NZBS.

There are problems with the categories set out in the proposal from the ARCBS. The ARCBS pointed out to the TGA that it would also have the ‘Progesa code’ which allows further breakdown. This seems a clumsy way for the TGA to undertake its analysis, and would be an approach of last resort. A better alternative would be for the ARCBS to further subdivide the codes proposed above into the major subcategories required, e.g. 6.0 could be broken down further into 6.1 HIV, 6.2 Hepatitis C, etc. The further breakdown needs to be developed jointly by the ARCBS and TGA, after TGA has analysed what, in particular, it needs to know.

In summary, for cellular blood product recalls, TGA needs to undertake further work in defining what it needs to know immediately and what it needs to know monthly in summary form. When this is clear, agreement needs to be negotiated with the ARCBS (and foreshadowed with the NZBS) on the reporting format.

**Blood recalls at the State and Territory level**

The Recall Coordinators in the States and Territories made it quite clear that they see little value in the present arrangements for blood recalls. They took no action as a result of them and they simply made work filing them. It is desirable, however, to retain an information flow to the States and Territories. To that end, discussions were held with several people involved in cellular blood product supply in the jurisdictions seeking their advice as to what they wish to know. One (South Australian) had been involved in a trial of the information coming through to them, but it had been abandoned because there was a lot of it and it did not add any value.

It was suggested that the information is probably the province of the Quality and Safety Committee under BRISC, but it was also noted that not all jurisdictions are represented on that subcommittee. The consensus view was, therefore, that a paper should go to BRISC on the issue, and it could determine whether it should go to the Quality and Safety Committee or the Government Blood Committee for consideration. It was considered unlikely that any jurisdiction would want unaggregated data – they would want a report not the individual notifications unless there was a threat to the blood supply or some other need-to-know issue was involved.

For the present, providing routine blood recall advice to State and Territory Recall Coordinators should cease, and the above paper should be prepared for the Blood Review Implementation Steering Committee.
Cellular blood products – Trans Tasman issues

As outlined above there are essentially no recalls of cellular blood products in New Zealand. At the time of consultation it was still being debated as to whether a joint agency would regulate blood in New Zealand, but since then it has been agreed that cellular blood products will be included. It is, therefore, important that whatever arrangements are made with ARCBS are also discussed with the NZBS.

It also needs to be clear that Progesa codes, if used in reporting, are the same in Australia and New Zealand. If not the reporting mechanisms may need to differ.

Given the impending Trans Tasman arrangements, whatever the Therapeutic Goods Administration refers to the Australian Red Cross Blood Service for consideration that is of general application should also be referred to the New Zealand Blood Service.

3.11 International obligations

A number of bilateral agreements exist between Australia and overseas regulators including the EU, US, Canada and Singapore. In addition there is an arrangement whereby New Zealand, at a minimum, gets everything that the State and Territory recall coordinators get whether or not the goods have been distributed into New Zealand. Each of the arrangements seems to require different (and sometimes undefined) things.

The ‘Cooperative Arrangement’ with the US FDA requires the TGA to

“…endeavor to provide the FDA with prompt notification of … particular products which may constitute a potential hazard to health… This may include the exchange of recall information… deemed appropriate by the TGA. ”

The EU Mutual Recognition Agreement (MRA) states, in relation to medicines:

“Alert System: Contact points will be agreed between the Parties to permit competent authorities and manufacturers to inform the authorities of the other party with the appropriate speed in the case of a quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch...”

In relation to devices the EU MRA states:

“Exchange of information: The parties agree to inform each other of incidents in the context of medical device vigilance procedure, or with regard to matters concerning product safety, and shall establish contact points for this purpose.”

In the case of Singapore the MRA states:

Contact points shall be agreed between the Parties to permit Regulatory Authorities and manufacturers of one Party to inform the regulatory authorities of the other Party with appropriate speed in the case of a quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed.”
There is also a two way alert system in place with Canada. The details of this agreement were not sighted, other than the contact points between the two countries. Negotiations are understood to be continuing to establish an MRA.

The more general Pharmaceutical Inspection Convention Scheme (PICS) has an SOP for handling rapid alerts and recalls arising from quality (presumably including safety) defects. The PICS rapid alert document proposes that competent authorities notify other competent authorities of Class 2 recalls when the goods have been distributed to the other country and all Class 1 recalls all the time. It is to be noted, however, that the PICS is a voluntary scheme without the legal basis that a relationship with another country provides, unless adopted specifically. On the basis of the documents seen, it is not clear that there is an enforceable obligation to provide information under PICS outside, e.g. the EU MRA. PICS simply provides a framework to do so.

Section 61 of the Therapeutic Goods Act provides extensive information on the ability to provide information to the head of national regulatory authorities in other countries relating to, among other things, withdrawal of supply of therapeutic goods. In any case, the recall information is by its very nature public, and is published fortnightly in the Recalls Bulletin, to which anyone can subscribe.

In summary, the MRAs with Singapore and the EU establish obligations to notify the medicines or device regulatory agencies in these jurisdictions. The US Consultative Arrangement appears to establish nearly the same level of obligation. PICS proposes notification of all Class 1 recalls but any international requirement to do so on the basis of PICS alone is not clear. There is no impediment to providing recall information to the head of another international regulatory agency – there is a clear power to do so in the Act.

3.12 Radiopharmaceuticals

Radiopharmaceuticals are mentioned particularly in the URPTG, in relation to the early release of them when they have very short half lives. No detailed investigation of radiopharmaceuticals was carried out beyond ascertaining that recalls are very rare. No short lived radiopharmaceuticals were recalled in 2002 or so far in 2003.
3.13 The Recalls Section itself

The work of the Recalls Section is greatly appreciated by industry, who found the staff knowledgeable, cooperative and helpful in the recall process. Even before the Pan recall occurred, there were comments from the field that the section is under pressure. While the commentators did not necessarily know about the issue of burgeoning blood recalls, the change they reported was contemporaneous with the commencement of cellular blood regulation. Clearly the system for managing blood recalls needs to be streamlined, as do other activities – e.g. fewer faxes.

Of course since the Pan recall the Section has been completely inundated, along with others in the TGA, and that will be discussed further below.

Even cursory examination of the staffing of the section indicates that for a section that is there to react to external events it is, at best, staffed only to the level of the routine workload and the peaks have to be managed by other means. Ideally there would be some standing capacity, which can mean idle time when there is a gap in demand. It must be said that there is no evidence of idle time at present, because the workload is high, even before the Pan recall occurred.

If one compares the section with some other groups that have a reactive role – e.g. firemen, armed services, etc – they have substantial standing capacity, as they have enough staff to respond to peak demand, meaning a lot of time is available to spend training and preparing. This contrasts sharply with the recall section in TGA.

No detailed study of the section’s operation and workload has been undertaken no specific recommendation can be made as to staffing levels, though they are clearly stretched, even before the events of the Pan recall.

The need to respond to periods of exceptional demand, including occasional crises, means the section either has to have substantial standing capacity (not likely) or have an arrangement that allows the broader resources of the TGA to be brought in at short notice, dropping everything else if necessary. This is what happens now but it is informal, and so other sections may not see it as part of their role and it may take precious time to negotiate the efficient and effective re-assignment of resources.

It would be helpful if a Memorandum of Understanding (MOU) with product regulators in the TGA underpinned the actions of the Recalls Section in emergency/crisis situations. This would put in place formal arrangements to quickly and efficiently call up the wider organisational resources when needed. The other sections would then formally acknowledge the nature of the recalls section as a clearing house, not as the section that takes full responsibility for recall management when recalls are particularly numerous or complex. They would also be clear about their responsibilities in the event of a recall of goods that are managed by their area or about which they have some special expertise or role. The MOU would need to make clear the involvement, roles and responsibilities of those that have legislative delegations in each of the Branches (the Regulators) in the event of a recall of goods in their area. It could clarify the sign off arrangements for recalls by the regulators, which are a concern to some in the organisation. This MOU is also necessary in the implementation of a quality system in the section.
In the light of the Pan recall, it was also suggested to the review that the recalls section should be amalgamated with other post-marketing areas of the TGA into a new Branch/Office. This is outside the terms of reference of the review which are mainly focussed on the procedures. In any case, it would be our view that structure is less important than function – making what you have work well is often the most important focus. The present structure is adequate, and there is never a perfect one.

**Quality Systems in the Recalls Section**

Other sections in the Office of Devices, Blood and Tissues mostly have formal quality systems in place. The Recalls Section is an exception (although this does not mean that what they do is not of high quality). The work practices, SOPs, and other elements of the work of the section will require re-thinking if the findings of this review are addressed. It will, therefore, be timely to take the additional step of moving to a formal quality system approach if the change management can be resourced. This may involve some training as well as time to think through and document improved processes and systems.

One issue in this regard is the place of the recalls system in the queue for reform under SIME. It is not near the top of the list, and that has an impact on other factors, e.g. linking a company’s recall information to its GMP file.

The review observed first hand that even simple statistical and other data can be hard to obtain. The information available to this review was limited and took some effort by the Recall Section’s staff to obtain because of the older information systems. Implementing SIME would make a significant difference in this regard, and its present priority for this area should be reviewed.

**Performance Indicators**

It is difficult to measure performance of a section whose workload is driven almost entirely by external demands. The section’s job is to respond, rather than being highly proactive. The issues this raises have been discussed above.

The section collects statistics on types of recall and data are included in the database of the underlying cause. In the form provided to the review, the data did not allow ready analysis. It is noted in the Quarterly Reports that recalls of medicines and devices are broken down by cause. This is being addressed for blood, through the ARCBS arrangements for monthly reporting. This would allow easy analysis when the same cause occurs over and over again, as it does in blood recalls.

Any set of performance indicators (PIs) must start with the absolute number of recalls in each period (month, year) and broken down into meaningful types. But this has severe limitations as a workload measure because the section is demand driven. The work is intrinsically reactive rather than proactive, and so cannot be measured by outputs that are irregular in both frequency and size. Numerically they may be up one month and down the next and the section has no control over this. The smaller number may also represent more work, although such variations even out in the long run.

Nevertheless, it is possible to measure parameters that would assist the monitoring of the efficiency of the section and/or the effectiveness of the recall process.
The time taken from the point of initial notification of a potential problem to the decision to recall is worth monitoring. There is no ‘right’ time, and some will inevitably take much longer than others, but a shorter time is preferable. By measuring the time and then choosing an end point e.g. the time of the 50th percentile (the median), or the 75th percentile or the 90th percentile, one would have a measure of the trend over time. Since the sooner a recall is triggered the better, this provides a basis to monitor whether it is taking longer to make a decision, or is the time stable, or getting shorter. Establishing the baseline is the first step towards improving performance in this area.

It is desired to measure the level of response in the field to a recall notification, but is quite hard to do across the board. One parameter that is available as a PI of the recall process is the percentage of replies received when a fax-back recall notice is sent out. If the proportion faxed back is steadily increasing, that would show a healthy trend. If not one would want to know why not. Perhaps one would intervene to improve it. There may be other similar items that demonstrate responsiveness, which could be routinely requested from sponsors and the data collated from the recall reports. If so these could be used in addition to or instead of the reply rates. It should be noted that only businesses such as pharmacies allow the relative efficiency to be calculated as the registration of the businesses provides a denominator to calculate the fraction that responded. This could not be done for e.g. supermarkets and general stores.

Another way to assess responsiveness in the field is to do a survey. A particularly well informed observer of the recall system is a person who has recently undertaken one and experienced it first hand. It is therefore proposed that from time to time a small survey of randomly selected sponsors that have been involved in a recall in the preceding 12 months be undertaken by an independent surveyor by telephone or written questionnaire. This would demonstrate the level of satisfaction with the recall process and areas that need improvement. Such a survey could be done less often if cost was an issue, e.g. every second year. It would test both the recall procedure and the performance of the Section and it would provide a basis for continuous quality improvement of both. The survey should include a set of questions that are the same, year-in-year-out, to provide a comparison over time with a few questions that address one-off issues in the preceding period. It would be necessary to pilot test the year-in-year-out questions before committing to them indefinitely.

Finally, the audit of recalls is a good measure of effectiveness. Once there is a power to audit, the PIs should require that a certain number of audits are performed each year and the results of a certain percentage (initially say 60% of those firms audited) need to be of an acceptable standard with no major shortcomings. Of course, the audits will demand resources and there is no point in setting the PI unless there will be the resources to undertake them.

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6 Once you have collected the data it is easy to measure any or all of these and then choose the one that seems to do the job best.
Comparison of the recalls process with other countries

No information could be obtained that allowed the practice and performance of the TGA Recalls Section to be compared with any other recalls section in any meaningful way, other than as discussed earlier in this report in relation to New Zealand.

While the practice of managing recalls seems similar, the differences are also sharp. For example the Canadian recall procedure is superficially similar to the URPTG but is much less detailed and more generic than the URPTG i.e. it applies to more than just therapeutic goods.

It is also clear that the investment of public funds is sometimes much greater in other countries and this distorts comparisons. For example the UK has publicly funded implant registers, which would greatly facilitate a recall/look back process if there is a problem with a particular implantable device.

These differences were assessed as being so great as to render comparisons invalid except for other reasons, i.e. in the case of New Zealand.

Recommendations

11. A Memorandum of Understanding should be developed between the Office of Devices, Blood and Tissues and the Regulators and other key sections in the TGA as to their roles and responsibilities in relation to the management of particularly complex or numerous recalls, and the resources and assistance to be provided in certain circumstances.

12. Performance indicators for the Recalls Section and the recalls process should be developed including: the time to initiate recalls; assessment of the level of response by such means as are available; and an occasional survey of sponsors that have undertaken recalls assessing the recall process and the Recall Section’s role.

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7 The Canadian recall procedure applied to products, defined thus: …any domestic or imported food, drug, cosmetic, device, radiation emitting device, and any advertisement thereof,
3.14 The management of therapeutic goods crises more broadly

There is widespread agreement from industry and from the State recall coordinators that the Pan recall was very well handled by the TGA. It is clear that it was a very difficult time and that everyone in the TGA has worked extremely hard to protect public health. As stated already the TGA is very fortunate to have a mature executive team that have worked together on other major public health incidents, and who have a highly supportive staff. This made possible the high quality response to the crisis.

While the TGA successfully managed the Pan recall, there is, as always, potential to improve the arrangements. A generic crisis management approach could be more clearly elaborated, which would assist a less experienced team if it was at the helm.

A tampering incident in the past gave rise to a crisis management plan developed jointly by TGA and industry and the establishment of a joint committee in such events. The Pan incident, however, demonstrates that tampering is not the only possible source of crises, and one can think of other potential crisis areas, e.g. a sudden series of serious adverse reactions in Australia or elsewhere, or further TSE-like diseases, in addition to the things that already have such as tampering or a manufacturing disaster threatening public health and supplies of medicines.

While the TGA has a mature executive team in place, it should develop a formal plan outlining processes and procedures to be used in the event of any crisis. This would reduce the level of stress in the event of less experienced individuals having to manage a crisis in the first few hours of it occurring, when planning time is scarce.
Appendix 1 Persons consulted in the course of the Review of the Uniform recall procedure for Therapeutic Goods

<table>
<thead>
<tr>
<th>Date</th>
<th>Person</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Various</td>
<td>Phil Harrison, Trevor Byrne</td>
<td>TGA</td>
</tr>
<tr>
<td>5 Feb</td>
<td>Bob Tribe</td>
<td>TGA</td>
</tr>
<tr>
<td>5 Feb</td>
<td>Graham Peachey, Gary Lacey</td>
<td>TGA</td>
</tr>
<tr>
<td>5 Feb</td>
<td>Jim Ramsay</td>
<td>ARCBS</td>
</tr>
<tr>
<td>5 Feb</td>
<td>John McEwen</td>
<td>TGA</td>
</tr>
<tr>
<td>5 Feb</td>
<td>Jorge Garcia, Pam Carter</td>
<td>TGA</td>
</tr>
<tr>
<td>5 Feb</td>
<td>Leonie Hunt</td>
<td>TGA</td>
</tr>
<tr>
<td>5 Feb, 18 Mar</td>
<td>Rita MacLachlan*</td>
<td>TGA</td>
</tr>
<tr>
<td>5 Feb</td>
<td>Eric McIntosh</td>
<td>TGA</td>
</tr>
<tr>
<td>7 Feb</td>
<td>Sharon McGregor</td>
<td>TGA</td>
</tr>
<tr>
<td>24 Feb</td>
<td>Vee Armstrong</td>
<td>ARCBS</td>
</tr>
<tr>
<td>26 Feb</td>
<td>Murray Patterson*</td>
<td>Dept of Health WA</td>
</tr>
<tr>
<td>28 Feb</td>
<td>Peter Gray (telephone)</td>
<td>3M</td>
</tr>
<tr>
<td>3 Mar</td>
<td>Helgi Stone*</td>
<td>Territory Health Services</td>
</tr>
<tr>
<td>5 Mar</td>
<td>Bill Dollman*</td>
<td>Dept Human Services SA</td>
</tr>
<tr>
<td>6 Mar</td>
<td>Keith Moyle*, Richard Bell</td>
<td>Dept Human Services Vic.</td>
</tr>
<tr>
<td>11 Mar</td>
<td>John Galloway*, Mary Sharpe</td>
<td>Department Health Tas.</td>
</tr>
<tr>
<td>12/13 Mar</td>
<td>Chris Healey, Andrew Hawkins, David Jones,</td>
<td>Queensland Health</td>
</tr>
<tr>
<td></td>
<td>Andrew Petrie*</td>
<td></td>
</tr>
<tr>
<td>16 Mar</td>
<td>Penny Adams, Maria Chambers, Cathy Tinsley,</td>
<td>MIAA</td>
</tr>
<tr>
<td></td>
<td>Nerida Hunt</td>
<td></td>
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<tr>
<td>17 Mar</td>
<td>Susan Parker, Jonathon Breach</td>
<td>ASMI</td>
</tr>
<tr>
<td>17 Mar</td>
<td>John Lumby*</td>
<td>NSW Health</td>
</tr>
<tr>
<td>18 Mar</td>
<td>Graeme Harris, Martin Devitt</td>
<td>TGA</td>
</tr>
<tr>
<td>18 Mar</td>
<td>Merryn Hagan</td>
<td>TGA</td>
</tr>
<tr>
<td>19 Mar</td>
<td>Steven Armstrong</td>
<td>Pharmacy Guild Aust</td>
</tr>
<tr>
<td>20 Mar</td>
<td>Allan Crosswhaite</td>
<td>CHC</td>
</tr>
<tr>
<td>20 Mar</td>
<td>Guy Wilmington, Deborah Monk</td>
<td>Medicines Australia</td>
</tr>
<tr>
<td>20 Mar</td>
<td>George Stefanoff*, Jane Strang</td>
<td>Health &amp; Comm. Care ACT</td>
</tr>
<tr>
<td>21 Mar</td>
<td>Peter Williams</td>
<td>Consumer Safety Unit, Treasury</td>
</tr>
<tr>
<td>21 Mar</td>
<td>Mark Salter, Craig Jamieson</td>
<td>Food Standards Australia</td>
</tr>
<tr>
<td>21 Mar</td>
<td>Helen Hopkins</td>
<td>Consumers Health Forum</td>
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<tr>
<td>21 Mar</td>
<td>Steven Howells</td>
<td>TGA</td>
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<tr>
<td>24 Mar</td>
<td>Peter Pratt, Donna Jennings, Barbara Cavanagh, Trevor Nisbett</td>
<td>Medsafe New Zealand</td>
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<tr>
<td>24 Mar</td>
<td>Mike Thompson</td>
<td>Researched Medicines Industry</td>
</tr>
<tr>
<td>24 Mar</td>
<td>Christine Mandeno, Meena Vallabh</td>
<td>Pharmacy Guild New Zealand</td>
</tr>
<tr>
<td>25 Mar</td>
<td>Peter Flanagan, R Scott, N Smith</td>
<td>New Zealand Blood Service</td>
</tr>
<tr>
<td>25 Mar</td>
<td>Faye Sumner</td>
<td>MIA New Zealand</td>
</tr>
<tr>
<td>25 Mar</td>
<td>Roger Smart</td>
<td>Douglas Pharmaceuticals for SMI NZ</td>
</tr>
<tr>
<td>Date</td>
<td>Name</td>
<td>Organization</td>
</tr>
<tr>
<td>----------</td>
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</tr>
<tr>
<td>25 March</td>
<td>Roger Sanderson</td>
<td>Thompsons (representing complementary medicines NZ)</td>
</tr>
<tr>
<td>3 April</td>
<td>Wendy Phillips</td>
<td>Medicines Partnership of Australia (Secretariat, Pharmacy Guild of Australia)</td>
</tr>
<tr>
<td>3 April</td>
<td>Lyn Lewis</td>
<td>Secretary, TGC, TGA</td>
</tr>
<tr>
<td>14 April</td>
<td>Joan Bedford (telephone)</td>
<td>WA Department of Health</td>
</tr>
<tr>
<td>15 April</td>
<td>Doug Ferguson (telephone)</td>
<td>National Pharmaceutical Services Association</td>
</tr>
<tr>
<td>16 April</td>
<td>Bill Heiler, Sue Ireland (telephone)</td>
<td>NSW Health/ SA Department of Human Services</td>
</tr>
<tr>
<td>26 May</td>
<td>Carole Isbister</td>
<td>New Zealand Food Safety Authority</td>
</tr>
<tr>
<td>7 June</td>
<td>Pio Cesarin</td>
<td>Non-Prescription Medicines Branch, TGA</td>
</tr>
<tr>
<td>9 June</td>
<td>Michael Wiseman</td>
<td>Non-Prescription Medicines Branch, TGA</td>
</tr>
</tbody>
</table>

* Denotes NCCTG members.
Appendix 2  EU criteria for Batch Recalls for Quality Defects

Class 1: Defects, which are potentially life-threatening or could cause serious risk to health.

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

Class 2: Defects, which could cause illness or mistreatment but are not Class 1.

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

Class 3: Defects which may not pose a significant hazard to health but where a recall has been initiated (perhaps not required by the competent authority) for other reasons, but are not Class 1 or 2.

Examples:
3.1: Faulty packaging: e.g. wrong or missing batch number or expiry date.
3.2: Faulty closure
3.3: Contamination
   - microbial spoilage
   - dirt or detritus
   - particulate matter
Appendix 3 A risk assessment methodology when considering recalls

Determining whether or not to initiate a recall almost always involves the analysis of risk. At present this is an informal process, which is fine but can lead to different processes being used in different parts of the TGA and differences in language leading to misunderstanding.

Risk Analysis – can be used to describe the whole process of:

- Hazard identification – realising and establishing that a hazard exists;
- Risk Assessment – including e.g. hazard assessment; exposure assessment (number exposed and where/how); level of certainty;
- Risk Management – how to manage the hazard, e.g. do nothing, quarantine, recall, etc;
- Risk communication – accurately communicating the risk to health to the relevant audience.

In conducting a risk assessment when a company or person has reported a problem that might or might not give rise to a recall, the process of risk assessment will often (but not always) be necessary.

Risk analysis will not be necessary, for example, when the decision is already made (e.g. an international company has initiated a world wide recall) or the goods are not on the ARTG, or the problem is very simple and the action self evident.

In some cases the sponsor will already have conducted a risk assessment in having reached its own decision that a recall is necessary (though perhaps not thinking of it as such). The first step should then be to ask the company for all the data it has and what its assessment of the problem is.

The Recalls Section is well set up to coordinate recalls but the risk assessment may be conducted by nearly anyone in the TGA, and at present the process is relatively informal.

There is the possibility of a (successful) appeal to the AAT in the case of a statutory recall, the risks from which is minimised if there is a formal risk assessment process, but in any case a more formal approach is desirable and in keeping with contemporary practice, whether the recall is statutory or voluntary, unless as stated above there are circumstances where the decision is self evident.

The necessary steps include:

- Gathering all the known data on the hazard:
  - What has caused the concern?
  - What is giving rise to the hazard and what is known about it?
  - Is any disease/condition/injury evident in one or more persons?
- Undertaking a risk assessment – will consider a variety of factors including:
  - How serious is the anticipated health impact?
  - What is the best estimate of the frequency of occurrence of the adverse event?
What is the size of the population that could be exposed and in what manner?
Thus, how many people are likely to be affected over a given time?
Are there special subpopulations that need to be considered, e.g. immunosuppressed patients, children?
What are the consequences/outcomes likely to be.

- Reaching a conclusion about possible alternative actions and why the recommended action was chosen over the other alternatives.

The Key Principles outlined in the Guidelines for Assessing Human health Risk from Environmental Hazards should be followed. These are given in Appendix 4.

This risk assessment process may be a five minute desktop process, or it may take days and involve considerable resources, depending on the nature of the events, the level of evidence and the relative impact of recall action versus no action on the public as well as the sponsor. For more substantial risk assessments, there should be a document that summarises each step with attachments where any step has required further work.

- Risk management – involves taking the action that is required to control the risk. This action will be determined in part by the risk assessment but will also take into account other issues such as feasibility, timeliness, impact on wider issues (e.g. ongoing access to something that is equivalent) and cost.
- Risk communication the appropriate publicity about that action. Risk communication should also address problems of risk perception. These are adequately described in the present SOPs and the URPTG itself, and require no further elaboration at his point.


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8 One particular risk perception issue is that successive recipients of product recall information (progressively closer to the user) tend to be more and more accepting of risk (often vicariously, i.e. on someone else’s behalf). This is because the perceived risk is low. Ideally actual, estimated and perceived risk would be close to each other, but this is often not the case. Thus, e.g. hospitals do not return recalled goods because they cannot be replaced like with like at the time of the recall, and staff are unwilling to change to another product, preferring to ‘take the risk’ with the goods on hand.
Appendix 4 Key Principles in Environmental Health Risk Assessment


There are a number of key principles for environmental health risk characterisation (EPA NSW, 1998; US EPA, 1995):

1. Actions should always adequately protect public health and the environment, putting these responsibilities before all other considerations.

2. Risk assessments should be transparent. The nature and use of default values and methods, assumptions and policy judgements in the risk assessment should be clearly identified. Conclusions drawn from the evidence should be separated from policy judgements.

3. Risk characterisations should include a summary of the key issues and conclusions of each of the other components of the risk assessment, as well as describing the likelihood of adverse health effects. The summary should include a description of the overall strengths and limitations (including uncertainties) of the assessment and conclusions.

4. Risk characterisations (and risk assessments) should be consistent in general format, but recognise the unique characteristics of each specific situation.

5. Health risk assessment must be undertaken with an appreciation that the health risk assessment is often part of a larger assessment that encompasses ecological risk assessment.

6. To protect public health and the environment an appropriate degree of conservatism must be adopted to guard against uncertainties.

7. Ensure that comparisons have been made against environmental health criteria that have been endorsed by the relevant Commonwealth, State or Territory environmental health agencies.

8. Where there are no Environmental Health Criteria for a particular agent refer to the administrative authority at the relevant Commonwealth, State or Territory level.

9. Ensure that human health risk assessments are undertaken, where necessary, according to methods in this document, or its revisions as published from time to time.

10. When deriving environmental health criteria use toxicological data or exposure criteria from agencies or organisations relevant to the State or Territory (e.g. local or Commonwealth health agencies such as NHMRC, or the enHealth Council) or to which Australia is party (e.g. World Health Organization). (See Toxicity Assessment Section 5.4)

11. Ensure that human health risk assessments are undertaken using national toxicological assessments (e.g. NHMRC) or WHO assessments or, where neither has been made, methods agreed to by the administrative authority for contaminated sites at the relevant Commonwealth, State or Territory level.
12. The risk assessor's knowledge of the peer-reviewed scientific literature relevant to risk assessment and the practical aspects of risk assessment should be up-to-date.

13. Variations in risk assessments as a result of particular statutory requirements, resource limitations, and other specific factors should be explained as part of the risk characterisation. For example, a reason will be required to explain why certain elements are incomplete.
Appendix 5 Key sections of the Therapeutic Goods Act that particularly relate to recalls (not including penalties etc)

Extract from Division 2—Registration and listing

30 Cancellation of registration or listing

(1) The Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a) it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury; or

(b) the goods become exempt goods; or

(c) the person requests in writing the cancellation of the registration or listing; or

(d) the goods contain substances that are prohibited imports for the purposes of the Customs Act 1901; or

(e) in the case of goods listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(a), (e) or (g) are incorrect or (if applicable) the requirements under subsection 26A(3) are not fulfilled; or

(f) both of the following apply:

(i) under the regulations, an authority constituted by or under the regulations gives a direction to, or makes a requirement of, the person in relation to an advertisement of the goods to ensure that advertising complies with the Therapeutic Goods Advertising Code;

(ii) the person does not comply with the direction or requirement.

(2) Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a) it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable; or

(b) the goods have changed so that they have become separate and distinct from the goods as so included; or

(ba) in the case of goods listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(b), (c), (d), (f) or (h) are incorrect; or

(c) the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is subject; or

(ca) the person has contravened subsection 29A(1) in relation to the goods; or

(d) the goods become required to be included in the other part of the Register; or

(e) the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable to the goods under the regulations; or

(f) the annual registration or listing charge is not paid within 28 days after it becomes payable.
(3) Where the Secretary proposes to cancel the registration or listing of goods in relation to a person under subsection (2) otherwise than as a result of a failure to pay the annual registration or listing charge, the Secretary must:
   (a) inform the person in writing that the Secretary proposes to cancel that registration or listing and set out the reasons for that proposed action; and
   (b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed action.

(4) Where a person makes submissions in accordance with paragraph (3)(b), the Secretary is not to make a decision relating to the cancellation until the Secretary has taken the submissions into account.

(4A) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration of the goods if the Secretary becomes aware that protected information was used when evaluating the goods for registration.

(5) Where the Secretary cancels the registration or listing of goods in relation to a person, the goods cease to be registered or listed:
   (a) if the cancellation is effected under subsection (1)—on the day on which the notice of cancellation is given to the person; or
   (b) in any other case—on such later day as is specified in the notice.

(6) Where the Secretary cancels the registration or listing of goods in relation to a person, the Secretary:
   (a) may, in writing, impose on the person one or both of the following requirements:
      (i) to inform the public, or a specified class of persons, in the specified manner and within such reasonable period as is specified, of the cancellation;
      (ii) to take steps to recover any of the goods that have been distributed; and
   (b) must cause to be published in the Gazette, as soon as practicable after the cancellation, a notice setting out particulars of the cancellation.

(7) A person who intentionally or recklessly refuses or fails to comply with a requirement under paragraph (6)(a) is guilty of an offence.

   Maximum penalty: 60 penalty units.

30A Recovery of wrongly supplied therapeutic goods

(1) This section applies if:
   (a) any person supplies therapeutic goods; and
   (b) the goods are not registered goods, listed goods, exempt goods, goods that are the subject of an approval or authority under section 19 or goods that are the subject of an approval under section 19A.

(2) The Secretary may, in writing, impose on the sponsor of the goods one or both of the following requirements:
   (a) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that the goods have been wrongly supplied;
   (b) to take steps to recover any of the goods that have been distributed.
(3) The Secretary must cause to be published in the Gazette, as soon as practicable after imposing such a requirement, a notice setting out particulars of the requirement.

(4) A person who intentionally or recklessly refuses or fails to comply with a requirement under subsection (2) is guilty of an offence.

Maximum penalty: 60 penalty units.

**30B Recovery etc. of registered or listed goods not conforming to standards**

(1) This section applies if:

(a) therapeutic goods of a particular kind are included in the Register in relation to a person; and
(b) any person supplies a batch of goods of that kind; and
(c) the Secretary is satisfied that the goods included in that batch do not conform to a standard applicable to goods of that kind; and
(d) the Secretary is not aware that any other goods of that kind supplied by the person within the previous 6 months have failed to conform to that standard or another standard applicable to goods of that kind.

(2) The Secretary may, in writing, impose on the sponsor of the goods one or both of the following requirements:

(a) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that the goods included in that batch do not conform to a standard applicable to goods of that kind; and
(b) to take steps to recover the goods included in that batch (except any of those goods that cannot be recovered because they have been administered to, or applied in the treatment of, a person or animal).

(3) The Secretary must cause to be published in the Gazette, as soon as practicable after imposing such a requirement, a notice setting out particulars of the requirement.

(4) A person who intentionally refuses or fails to comply with a requirement under subsection (2) is guilty of an offence.

Maximum penalty: 60 penalty units.

(5) This section does not prevent the Secretary from taking action under section 30.

**Extract from Division 2A—Public notification and recovery of therapeutic goods**

**30EA Public notification and recovery of therapeutic goods**

(1) The Secretary may, in writing, impose requirements, relating to therapeutic goods, on a person if:

(a) any of the circumstances referred to in the second column of an item in the following table occur in relation to the goods; and
(b) the person is referred to in the third column of that item.
### Circumstances in which requirements may be imposed

<table>
<thead>
<tr>
<th>Item</th>
<th>Circumstance relating to therapeutic goods</th>
<th>Person subject to requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The goods are supplied while they are registered goods or listed goods, but they do not conform with a standard applicable to the goods</td>
<td>The person in relation to whom the goods are included in the Register</td>
</tr>
<tr>
<td>2.</td>
<td>The goods are supplied while they are registered goods or listed goods, but the manufacturing principles have not been observed in the manufacture of the goods</td>
<td>The person in relation to whom the goods are included in the Register</td>
</tr>
<tr>
<td>3.</td>
<td>The goods are supplied while: (a) they are exempt goods; or (b) they are exempt under section 18A; or (c) they are the subject of an approval or authority under section 19; or (d) they are the subject of an approval under section 19A; but they do not conform with a standard applicable to the goods</td>
<td>The person supplying the goods</td>
</tr>
<tr>
<td>4.</td>
<td>The goods are supplied while: (a) they are exempt goods; or (b) they are exempt under section 18A; or (c) they are the subject of an approval or authority under section 19; or (d) they are the subject of an approval under section 19A; but the manufacturing principles have not been observed in the manufacture of the goods</td>
<td>The person supplying the goods</td>
</tr>
<tr>
<td>5.</td>
<td>The goods are supplied in contravention of subsection 20(1) or 42E(1)</td>
<td>The person supplying the goods</td>
</tr>
<tr>
<td>6.</td>
<td>The goods are supplied while they are registered goods or listed goods, but one or more steps in the manufacture of the goods has been carried out by a manufacturer while the manufacturer did not hold a licence that was in force</td>
<td>The person in relation to whom the goods are included in the Register</td>
</tr>
<tr>
<td>7.</td>
<td>The registration or listing of the goods has been cancelled under this Part</td>
<td>The person in relation to whom the goods were included in the Register</td>
</tr>
</tbody>
</table>

(2) The requirements may be one or more of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover therapeutic goods that have been distributed;

(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, to the effect that the circumstances referred to in paragraph (1)(a) have occurred in relation to therapeutic goods;

(c) to publish, in the specified manner and within such reasonable period as is specified, specified information, or information of a specified kind, relating to the manufacture or distribution of therapeutic goods.
(3) If the circumstances referred to in paragraph (1)(a) apply only to a batch of therapeutic goods, the Secretary may limit the imposition of the requirements to the therapeutic goods included in that batch.

(4) A requirement to recover therapeutic goods under this section does not apply to therapeutic goods that cannot be recovered because they have been administered to, or applied in the treatment of, a person.

30EB Publication of requirements

The Secretary must cause to be published in the *Gazette*, as soon as practicable after imposing a requirement under section 30EA, a notice setting out particulars of the requirement.

30EC Non-compliance with requirements

A person is guilty of an offence if:

(a) the person does an act, or omits to do an act; and

(b) the act or omission constitutes a contravention of a requirement imposed on the person under section 30EA.

Maximum penalty: 60 penalty units.

30ED Power of cancellation unaffected

Imposition of a requirement under section 30EA does not affect the Secretary’s power to cancel the registration or listing of therapeutic goods under this Part.

Extract from Part 5 3—Product tampering

42V Recovery of therapeutic goods because of actual or potential tampering

(1) The Secretary may, in writing, impose requirements under this section on a person if:

(a) the person supplies or has supplied therapeutic goods of a particular kind, or a particular batch of therapeutic goods of that kind; and

(b) the Secretary is satisfied that therapeutic goods of that kind, or included in that batch, are, have been or could possibly be, subject to actual or potential tampering.

(2) The requirements may be one or more of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover therapeutic goods of that kind, or included in that batch, that the person has supplied;

(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that therapeutic goods of that kind, or included in that batch, are, or have been, subject to actual or potential tampering;

(c) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that therapeutic goods of that kind, or included in that batch, could possibly be subject to actual or potential tampering.
(3) Requirements referred to in paragraph (2)(a) do not apply to therapeutic goods that cannot be recovered because they have been administered to, or applied in the treatment of, a person or animal.

(4) The Secretary must cause to be published in the Gazette, as soon as practicable after imposing such requirements, a notice setting out particulars of the requirements.

(5) The Secretary may impose requirements under this section whether or not the Secretary has been notified under section 42T.

(6) A person who intentionally refuses or fails to comply with a requirement under subsection (1) is guilty of an offence.

Maximum penalty: 240 penalty units.

(7) This section does not prevent the Secretary from taking action under section 30.

Extract from Chapter 7 Miscellaneous

60 Review of decisions

(1) In this section and section 60A:

*decision* has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

*initial decision* means a decision of the Secretary or of a delegate of the Secretary:
(a) under the definition of *therapeutic devices* in subsection 3(1) or under subsection 7(1); or
(b) refusing to grant a consent under section 14; or
(c) under Part 3 or 4.

*reviewable decision* means a decision of the Minister under subsection (3).

(2) A person whose interests are affected by an initial decision may, by notice in writing given to the Minister:
(a) in the case of a decision particulars of which are required to be notified in the Gazette—within 90 days after those particulars are so notified; or
(b) in any other case—within 90 days after the decision first comes to the person’s notice;
request the Minister to reconsider the decision.

(3) Subject to paragraph 60A(2)(b), the Minister must, as soon as practicable after receiving a request under subsection (2), reconsider the initial decision and, as a result of that reconsideration, may:
(a) confirm the initial decision; or
(b) revoke the initial decision, or revoke that decision and make a decision in substitution for the initial decision.

(4) Where a person who has made a request under subsection (2) does not receive notice of the decision of the Minister on reconsideration, or (if applicable) notice that the matter has been remitted under paragraph 60A(2)(b), within 60 days of
the making of the request, the Minister is to be taken to have confirmed the original decision.

(5) After reconsideration of an initial decision, the Minister must give the applicant a notice in writing stating the result of the reconsideration and that the applicant may, except where subsection 28(4) of the Administrative Appeals Tribunal Act 1975 applies, apply for a statement setting out the reasons for the decision on reconsideration and may, subject to that Act, make an application to the Administrative Appeals Tribunal for review of that decision.

(6) Where written notice of the making of an initial decision is given to a person whose interests are affected by the decision, the notice is to include a statement to the effect that a person whose interests are affected by the decision may:
   (a) seek a reconsideration of the decision under this section; and
   (b) subject to the Administrative Appeals Tribunal Act 1975, if the person is dissatisfied with the decision upon reconsideration, make an application to the Administrative Appeals Tribunal for review of that decision.

(7) Any failure to comply with the requirements of subsection (5) or (6) in relation to a decision does not affect the validity of the decision.

(8) An application may be made to the Administrative Appeals Tribunal for review of a reviewable decision.