

CRISIS MANAGEMENT GUIDELINES

**For the management of actual, potential or threatened
tampering of medicines, complementary healthcare products
and medical devices**

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This document is not for general distribution

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CRISIS MANAGEMENT

1 INTRODUCTION

These Guidelines have been developed by the Australian Self Medication Industry (ASMI) in consultation with Medicines Australia (formerly the Australian Pharmaceutical Manufacturers Association (APMA), the Complementary Healthcare Council of Australia (CHC), the Medical Technology Association of Australia (MTAA) (formerly the Medical industry Association of Australia (MIAA), Consumers Health Forum (CHF), the Therapeutic Goods Administration (TGA), State and Territory Health Departments and the State and Territory Police Departments.¹

These Guidelines are presented as part of a three-tiered approach to Crisis Management to assist companies to meet their public health obligations and regulatory requirements and to manage effectively in times of crisis.

The three-tiered approach cascades as follows:

1. At the top level is a set of Ten Core Principles for the management of a crisis.
2. These industry Crisis Management Guidelines then expand on those principles
3. Individual company specific Crisis Management Plans flow from these Guidelines.

These industry Guidelines do not and cannot claim to adequately cover all possible circumstances. It is vital that each company develops its own Crisis Management Plan that reflects these Guidelines.

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

¹ These Guidelines are based on Crisis Management Guidelines developed for members of the ASMI in 1992 that are now superseded by these Guidelines. Special recognition is given to the Grocery Manufacturers Association (now the Australian Food and Grocery Council) whose draft Guidelines proved invaluable in producing the original document.

2 CRISIS MANAGEMENT

(page amended Sep 09, Ed 24)

A crisis can be defined as an unexpected set of circumstances, which represents an immediate and significant threat to a company, consumers of its products, employees and/or the community. This may include threats to products or services, damage to the public image/ reputation of a company or its products or disruption of the production process.

One such crisis is the actual, potential or threatened tampering with medicines, complementary healthcare products or medical devices.

The purpose of these Guidelines is to provide the framework that will enable a company to cope efficiently and effectively in times of crisis involving actual, potential or threatened tampering of its product(s).

Every crisis is different but shares to some extent the characteristics of surprise, insufficient information when it is most needed, intense scrutiny from outsiders and the disruption of regular decision-making processes. It will almost certainly affect short term planning and put important interests at stake and will be likely to attract media interest.

Companies should fully document a Crisis Management Plan based on these industry Crisis Management Guidelines and its more detailed supplement [Product Contamination & Extortion – A Protocol for the Therapeutic Goods Industry February 2004](#). The plan should outline the crisis management responsibilities, procedures and a communications policy. It should set out how decisions are made and by whom. It should refer to procedures for ongoing monitoring of emerging issues and to procedures for testing the plan and training staff on a regular basis, or when changes are made.

The Company Crisis Management Plan should set out tasks to be carried out before, during and after a crisis. At times of crisis, it is essential that individuals understand their specific tasks and areas of responsibility- while recognising that some flexibility is often necessary. The Crisis Management Team must drive any change in allocated tasks. It is each company's duty to ensure that relevant tasks are allocated well in advance and that individuals are trained in carrying them out. Crisis management should form a part of every manager's responsibility.

There are two essential elements to handling a crisis:

Policy	Action to fix the problem
Communications	Action to keep the public, media and stakeholders informed of what you are doing and why.

Companies should ensure that they have adequate and appropriate insurance coverage and the Crisis Management Plan should highlight the need to inform the insurance agency at the earliest indication of a problem.

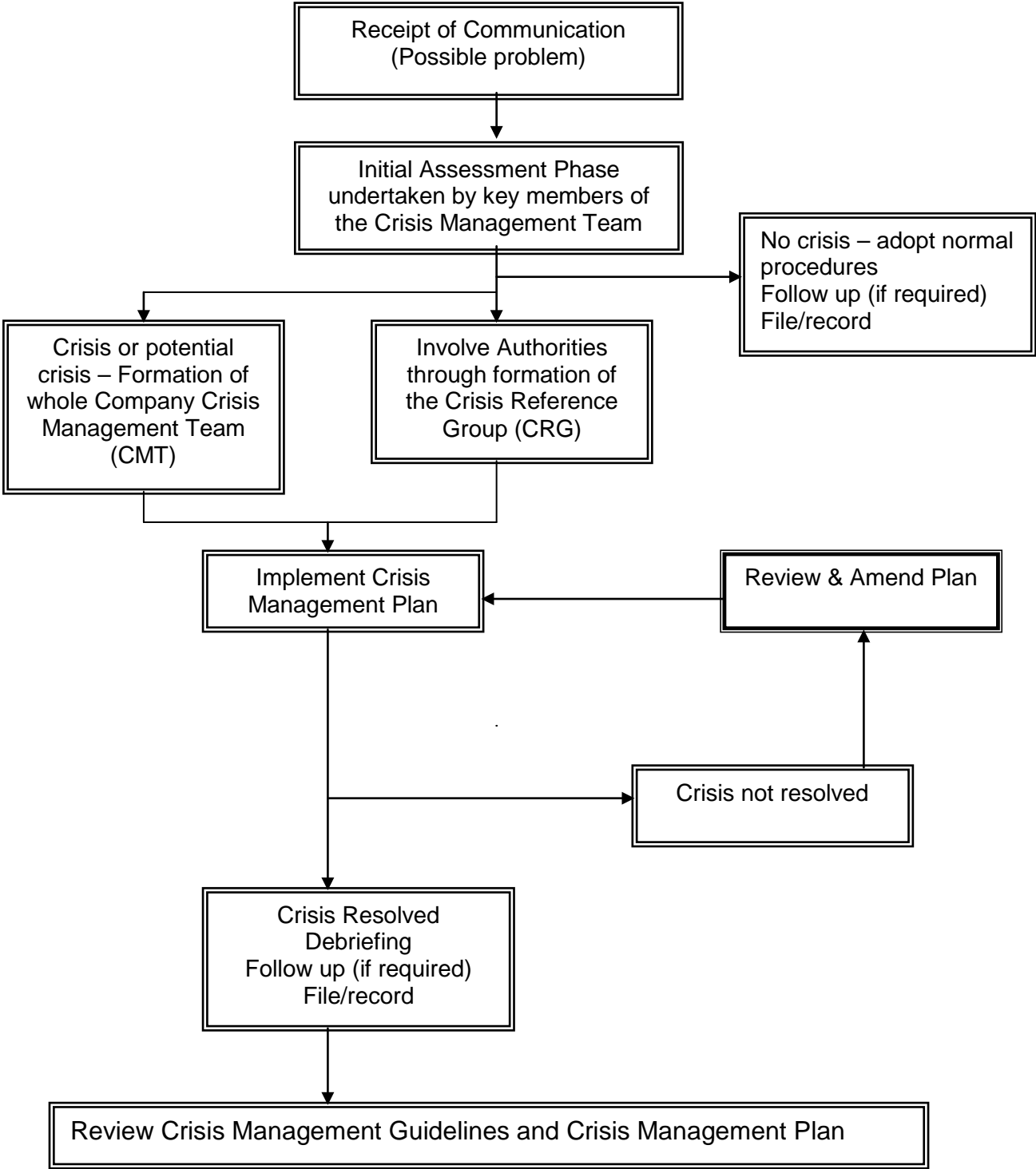
3 TEN CORE PRINCIPLES FOR MANAGING A TAMPERING CRISIS²

1. Company demonstration of organisational commitment to Crisis Management.
2. Establish an overall command and control structure to develop the strategy and framework for the management of and response to a crisis.
3. To manage a crisis, define clear policy and objectives which provide for;
 - a. the safety of people
 - consumers
 - public
 - employees;
 - b. protection of assets including reputation; and,
 - c. timely termination of the crisis
4. Ensure timely involvement of the appropriate authorities and stakeholders, including, but not limited to, the Police, Therapeutic Goods Administration and State Health Departments and insurance company.
5. Ensure timely and accurate information flow processes that support good decision making.
6. Coordinate appropriate skills to implement crisis management strategies.
7. Have in place robust plans (including incident management, media, recall and relaunch) and procedures that provide clarity of roles, responsibilities and actions.
8. Ensure regular education of staff, training of crisis management teams and key stakeholders, and validation of Crisis Management plans in preparation for the management of a crisis.
9. Fulfil legal and regulatory requirements
10. Develop effective stakeholder relations (pre, during & post the crisis).

² A special thanks to Control Risks Group Pty Limited for their assistance in the review of these Guidelines and in the development of the 10 Core Principles.

4 CRISIS MANAGEMENT FLOW CHART

(page amended Sep 09, Ed 24)



5 MANAGEMENT STRUCTURE

5.1 CRISIS MANAGEMENT TEAM (CMT)

Companies should establish an internal Crisis Management Team (CMT). Membership should be limited to the smallest number of senior personnel necessary to manage the incident. The CMT should have immediate access to communications, security, legal, marketing, operations, finance, technical, regulatory, medical and human resources functions. Functional expertise, including private risk management services that specialise in advice on contamination, tampering and extortion issues, should be called in as necessary.

It is important that roles and responsibilities should be defined for each of the CMT members.

The CMT should be responsible to the CEO or CEO's representative, properly assess a threat or crisis and fulfil the following objectives:

- involve authorities as soon as it is established that there is an actual or potential crisis, always taking into account legal and regulatory obligations to report an incident;
- manage the crisis so as to minimise or eliminate any danger or risk to the public;
- Manage the crisis so as to minimise or eliminate any risk to the employees, assets, reputation and goodwill of the company;
- make all decisions needed to achieve these objectives after consultation with relevant authorities and other bodies as appropriate;
- communicate all necessary information accurately and truthfully to all relevant parties including company employees in a timely, efficient and orderly manner (refer to section 11 on communication);
- bring the crisis to a timely closure by reintegrating the management of remaining matters into the normal flow of business and preparing an internal post-incident report.

All decisions made by the CMT must relate back to these objectives.

All CMT members must:

- know crisis management procedures;
- understand their roles and responsibilities and be trained to carry them out;
- have timely access to all relevant documentation, eg. company policy documents and position papers
- understand and be able to act on the company's legal obligations
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(page amended Sep 09, Ed 24)

- be able to identify, equip, and use an appropriate incident room where a crisis can be managed privately;
- have access to the names and telephone numbers of current contacts in police forces, other relevant government agencies, TGA, State Departments of Health, wholesalers, pharmacists, other retailers and the media.
- take responsibility to ensure that the company's Crisis Management Plan is up-to-date and that relevant staff are trained.

During a crisis, the CMT must be able to concentrate solely on managing the crisis – other executives must be designated to run the day to day issues of the business. Further detailed management protocols are provided in the Industry Protocol – *Product Contamination and Extortion – A Protocol for the Therapeutic Goods Industry February 2004*.

5.2 CRISIS REFERENCE GROUP (CRG)

Managing a crisis requires the involvement of stakeholders such as the TGA, State or Territory Health Departments and Police to efficiently achieve the desired outcome with public health and safety the paramount objective. This involves a thorough assessment of the risk to public safety. The Police representative should lead this assessment. Effective management of a crisis may also involve a decision about the need for, or scope of a product recall.

While the responsibility for managing the crisis lies with the company, the CRG is convened to coordinate the activities to resolve the crisis. Either the Commonwealth or relevant State or Territory Recall Coordinating Officer convenes the CRG. (Appendix 1 lists the phone number of Coordinating Officers.)

While a member of the company CMT, or another person designated by the company, chairs the CRG the group will comprise:

- the Commonwealth Coordinating Officer nominated in the Uniform Recall Procedure for Therapeutic Goods;
- State or Territory Health Department Coordinating Officers nominated in the Uniform Procedure for Therapeutic Goods;
- the appropriate state police officers; and
- the senior personnel of the company concerned. These executives should also be members of the CMT.
- members of previous CRGs (optional) from the TGA and if possible, the police, State or Territory health departments and companies with experience managing these types of crises.

The CRG numbers should be kept to the minimum required for efficient and effective operation: usually one or two representatives from the company, the TGA, State or Territory Health and the Police.

The CRG is in constant contact during the crisis and meets in person as often as daily during the peak of the crisis. This is considered essential to effectively manage the crisis.

5.3 INVOLVING THE POLICE

The notification of the police in the formation of the CRG or prior to the formation of the CRG is extremely important since the police may have knowledge of other tampering attempts, which may be related.

While police and sponsors both have the fundamental priority of eliminating risk to the public, beyond this point there can be some variation in priority –

- the police: to bring the perpetrators to justice
- the sponsor: to restore normal trading and production as quickly as possible, to minimise adverse publicity and to restore public confidence in the company, its products or services.

The legal obligation to contact the police may vary in detail from state to state. How urgently the police must be notified depends upon the nature of the threat and the relevant State or Territory requirements.

The Police must be involved early to advise on the handling of any evidence.

It is important that police contact be made at the appropriate level within each state police force. Contact should be made with the Regional Commanders (or equivalent) listed in Appendix 3 who will be aware of the provisions contained in these Guidelines.

No action should be taken by the Police, the State, Territory or Commonwealth Health authorities, or the sponsor without consultation with the other parties involved in the Crisis Reference Group. It is essential that any response is a coordinated one.

In a crisis, one member of the CMT should act as liaison between the company and the police, regularly reporting back to the CMT and subsequently through to the CRG.

Where there is a disagreement between a company and the police on the appropriateness of releasing information to the public, the Crisis Reference Group should assess the relevant issues, and after considering any conflicting interests, make a recommendation to the company as to whether information should be released publicly.

6 ACTUAL, POTENTIAL OR THREATENED TAMPERING

ALL threats of tampering with a company's products should be considered to be genuine and therefore serious, until otherwise determined by the CRG.

Any incident of tampering, suspected tampering or threat of tampering must be reported immediately to a Commonwealth Officer nominated in the Uniform Recall Procedure for Therapeutic Goods, who will immediately convene the CRG. (Appendix 1 lists the phone number of Coordinating Officer.)

Each company's Crisis Management Plan should identify who is responsible for these notification and reporting activities.

6.1. Handling of Evidence

It is extremely important that any material received with or in conjunction with a threat be treated as potential Police evidence. Handling of such material must be kept to a minimum and must not be sent to any other party without the full knowledge and consent of the Police. The Police must be involved early to advise on the appropriate handling of such material.

7 THREATS AND RESULTING COMPANY PROCEDURES

(page amended Sep 09, Ed 24)

A Company's initial response can greatly influence the outcome of a crisis. It is essential that, in addition to following a Crisis Management Plan, confidentiality be maintained. It is extremely important to assess how, when and to whom information is disseminated.

The first threat is most likely to be by one of the following means:

- Letter/facsimile or tape
- Telephone
- E-mail

Or may be via one or more of the following:

- Police
- Media
- Retailers
- Wholesalers
- Healthcare professionals
- Hospitals

7.1 Telephone threat

An internal company procedure should be developed to ensure that, where possible, the call goes to designated individuals as soon as possible.

The exact time, message content and telephone line on which the call was taken should be written down immediately. The accent and sex of the caller should be noted, together with anything unusual about the caller and any background noise.

The recipient should not terminate the call and should keep the call going for as long as possible, by taking time getting the details using the questions listed under Action 6 in Appendix 4.3 and record the call using FORM 1F – THREATENING CALLS – PHONE SHEET in the Industry protocol - *Product Contamination and Extortion – A Protocol for the Therapeutic Goods Industry Feb 2004*.

If the caller is not specific about a product or area of contamination then he/she should be asked for more details. It is important to obtain as much information as possible (see checklist in Appendix 4).

The caller should not be put on hold.

7.2 Letter/Facsimile or Tape threat

As soon as the recipient realises what information the letter/facsimile or tape contains, handling should be kept to a minimum, gloves should be worn for any handling, and the material should be isolated.

The Police may use this material as evidence. It is therefore extremely important that the Police be informed immediately to advise on appropriate handling of any evidence.

(page amended Sep 09, Ed 24)

Place any letter, facsimile, tape or other physical evidence in a manila folder or envelope to protect it from further handling. DO NOT USE PLASTIC BAGS OR PLASTIC FOLDERS and DO NOT SEAL the folder or envelope. Affix a Tracking Sheet to folder or envelope to record the date/time movements of the evidence and persons who handle them and reasons. (see Appendix 5, for evidence handling checklist and record the details using FORM 1G – RECEIPT OF EXTORTION THREAT – ADVICE BY LETTER OR AUDIO TAPE in the Industry Protocol - *Product Contamination and Extortion – A Protocol for the Therapeutic Goods Industry Feb 2004.*).

One person should take custody of the material and keep it in a secure location until it is presented to the police; this ensures continuity of control of the evidence. The person responsible for taking custody of such material should be identified in the company Crisis Management Plan.

Safety procedures for receiving toxic or dangerous substances or objects should also be outlined in the company Crisis Management Plan.

7.3 E-mail threat

As soon as the recipient realises what information the e-mail message contains, the exact time of receipt, time and date sent and address of both sender and recipient should be written down.

The message should be forwarded by email or in hard copy to a designated member of the CMT for assessment and action.

The message must not be deleted from the original recipients' computer and a copy of the message should be printed out.

7.4 Threat via police

In some instances, the police will make initial contact with the company. The head of the CMT should be informed immediately. Confidentiality must be maintained and all relevant information recorded.

7.5 Threat via the media

A procedure should be developed to ensure that all contacts from the media are directed to designated and media-trained members of the CMT immediately.

7.6 Threat via Pharmacy (including hospital pharmacy) and other retail outlets

Advice of potential tampering may come from a trading partner such as a wholesaler, retailer, health care professional / practitioner, pharmacy or hospital. Such contact should be referred immediately to the designated member of the CMT.

8 COMMUNICATIONS

Good communication allows a company to:

- address concerns of the public
- keep its employees and other stakeholders informed
- initiate contact with or respond to the media
- control the escalation factor
- avoid confusion
- ensure the company is seen to be taking appropriate action
- provide valid and timely guidance on what affected persons should do.

In the case of tampering, it is generally accepted that the premature release of information to the media can be prejudicial to the police investigation and not in the interest of public health and safety. Information should only be released publicly after the company, the police and any other relevant authorities have agreed and should take into consideration:

- public safety;
- protection of the victim/s;
- the need to discourage further tampering attempts;
- the need to discourage copycat crimes, the risk of which is considerable;
and
- the potential impact on the company, its employees, suppliers and customers.

8.1 Communication - Before a Crisis

Each crisis must be handled as the circumstance demands. Nevertheless, a range of easily accessible contingency statements for media and employees should be prepared as far in advance as possible. The objective remains the same: to ensure the communication of timely, accurate, consistent information.

Company spokespersons must be identified and trained. Managing contact with the media is a skilled task that requires knowledge, experience and sensitivity. ***To avoid the potential for any confusion it is essential that contact people are specifically identified and trained. They should be available to speak to the media in a controlled and timely manner.*** For matters of an industry nature, no information concerning any tampering incident should be passed to media without prior consultation with the CRG and the relevant industry association.

Have plans in place to call upon the services of specialist crisis management consultants and specialist media consultants.

News of a crisis may well be received via the media, possibly outside normal company hours. Relevant home telephone numbers must be made available to key personnel and members of the CMT must be able to contact each other at any time.

8.2 Communication - During a Crisis

Ensure the switchboard is alerted and informed as to where incoming calls should be transferred.

Once the level of the crisis has been established and objectively assessed, the range of actions to be undertaken will be dictated by the circumstances in each case. Such actions will include some or all of the following:

- advise relevant company personnel;
- brief company spokespersons, external advisers, switchboard security;
- issue media and employee statements where appropriate;
- establish appropriate liaison with wholesalers, pharmacies, retailers, and other trade customers;
- arrange press briefings/conferences as necessary;
- ensure the press office is properly manned, equipped and serviced at all times with dedicated phone lines if necessary;
- record all action/events/communications; and
- monitor all media coverage.

Remember the following key points of effective media communication.

- You are the expert.
- Take your time.
- Keep your promise.
- Be factual – do not speculate.
- Limit sources of information.
- Nothing is “off the record”.
- Resist combative instincts.
- Be sincere and honest.
- Show concern for the public, customers and employees.
- Ensure that messages from the company, TGA, State Health Departments and Police are consistent and coordinated by the CRG.
- Ensure that company, TGA, State Health Departments and Police nominate a spokesperson and make comment relating only to their own areas of responsibility.

Journalists will demand to know answers to the following questions: What? Who? When? Where? Why? How? Responses must be dictated by the circumstances but it is important that the spokesperson maintains control of the situation and is not bullied into answering the questions before the facts are available and properly prepared. When preparing for an interview, it is also valuable to have in mind three “must get across” points.

8.3 Communication - After a Crisis

The following actions should be taken after a crisis:

- Victims and staff should be debriefed and the need for individual support assessed;
- relevant government officials should be debriefed;
- other audiences such as customers, shareholders and industry associations, should be advised, as appropriate; and
- a post-incident report should be prepared for the company’s records.

These actions should continue to be coordinated through the CRG.

9 NOTIFICATION TO TRADING PARTNERS

(page amended Sep 09, Ed 24)

It is important to provide accurate and timely information to wholesalers and retailers, hospitals, pharmacies and other healthcare professionals. Each company should have in place procedures for contacting ALL of their trading partners. These may include grocery, pharmacy, hospital, route trade and/or export markets (inter company and international traders) and other retail outlets.

The responsibility for notifying trading partners should be defined in each company's Crisis Management Plan.

The procedures set out in the Uniform Recall Procedure for Therapeutic Goods must be implemented, as appropriate. The TGA representative(s) on the CRG assist the company in implementing these procedures, including the notification to the Consumer Affairs Division of the Department of Treasury and the notification of government agencies in export markets.

It is critically important that sponsors, wholesalers, pharmacists, healthcare professionals and retailers actively cooperate in managing any crisis so that public safety is assured and public confidence and trust in both sponsor and retailer is quickly re-established.

Liaison in product removal and other aspects of dealing with tampering or extortion at retail level are complex management issues, and will need to be carried out in consultation with the Therapeutic Goods Administration. Important matters to be addressed include:

- coordination of withdrawal of product from sale including;
 - who will be responsible for the recalled product,
 - the security of the recalled product,
 - collection procedures from shelf and warehouse,
- establishment of procedures for consumers to return goods already purchased;
- agreement on the announcement of these details in the media;
- what to do with product when it is removed including;
 - transportation,
 - storage,
 - examination,
 - disposal,
- financial considerations including;
 - compensation,
 - refunds to members of the public,
 - who will be meeting the costs,
- confidentiality of tampering details;
- procedures for dealing with incidents such as hoaxes and copycats during a tampering incident and
- communication channels for tampering details as the issue develops;

10 NOTIFICATION TO THE PUBLIC AND CONSUMERS

A crisis may well result in the need to communicate directly to individual members of the public. Inquiries from the public can be either direct to the company or, frequently indirect via the police, health/enforcement authorities, pharmacy or retailer where the purchase was made, or the media.

As far as possible, pre-emptive action should be taken with these important groups and a direct communication with the public should be managed separately from the media information process. Where appropriate, a 1800 number or company web page should be established to handle public enquiries or provide the latest information. Any public warning must be conveyed as quickly as possible. This should be supported by communication to relevant groups that the public are likely to turn to for more information, reassurance and advice. These groups may include pharmacists, drug information services, retailers, hospitals and/or doctors, other healthcare professionals and relevant consumer organisations.

Messages to the public should be clear and simple and repeated through a range of media to ensure they reach all who need to hear them.

11 OTHER IMPORTANT AUDIENCES

During any crisis, support for the company is likely to come from any or all of the following:

- Department of Health and Aging
- State and Territory Health Departments
- Attorneys General, Federal and State
- Consumer Affairs Division of the Department of Treasury
- Trade customers (wholesalers, retailers)
- Local Government Authorities
- Australian Self-Medication Industry
- Medicines Australia (previously Australian Pharmaceutical Manufacturers Association)
- Complementary Healthcare Council of Australia
- Medical Technology Association of Australia (previously Medical Industry Association of Australia)
- The Pharmaceutical Society of Australia
- The Pharmacy Guild of Australia
- Australian Food and Grocery Council
- National Pharmaceutical Services Association of Australia (previously National Pharmaceutical Distributors Association)
- Environment Protection Authority
- Relevant consumer organisations

It is important for the company to establish and maintain a dialogue with some or all of the above and to acquaint them with the company and business operations well in advance of a crisis.

During a crisis, each of these organisations may well be an audience whose information needs must be addressed individually.

The key guideline for communication is to provide accurate, consistent and timely information directly to these audiences.

12 CLOSURE AND EVALUATION

Effective management of a crisis will bring the crisis to an end as soon as possible. The CMT has a responsibility to integrate the management of the after effects of the crisis into the normal flow of business.

Preparation of a post-incident report helps to identify areas that could have been managed more efficiently or effectively and provides a basis on which to review both the company Crisis Management Plan, the industry Crisis Management Guidelines and CRG operation.

APPENDIX 1 – MEDICINES CONTACT LIST – May 2013

**NOMINATED COMMONWEALTH & STATE MEDICINES
RECALL COORDINATING OFFICERS**

Commonwealth Mr Mick O'Connor	Bh 02 6232 8197 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Joshan Joy	Bh 02 6232 8636 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Simon Waters	Bh 02 6232 8178 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
New South Wales Mr Bruce Battye	Bh 02 9391 9944 Mobile 0401 712 050 Fax 02 9424 5860 E-mail bbatt@doh.health.nsw.gov.au
Ms Judith Mackson	Bh 02 9391 9944 Mobile 0411 145 562 Fax 02 9424 5860 E-mail jmack@doh.health.nsw.gov.au
Victoria Ms Megan L Smith	Bh 03 9096 5355 Bh 1300 364 545 Mobile 0408 598 663 Fax 1300 360 830 E-mail megan.l.smith@health.vic.gov.au
Mr Matthew McCrone	Bh 03 9096 5066 Bh 1300 364 545 Mobile 0408 581 312 Fax 1300 360 830 E-mail matthew.mccrone@health.vic.gov.au
South Australia Ms Elizabeth Hender	Bh 08 8204 1942 Mobile 0418 747 833 Fax 08 8463 5540 E-mail elizabeth.hender@health.sa.gov.au
Ms Naomi Burgess	Bh 08 8226 7080 Mobile 0417 216 833 Fax 08 8463 5540 E-mail naomi.burgess@health.sa.gov.au
Queensland Mr Bill Loveday	Bh 07 3328 9890 Fax 07 3328 9821 E-mail MRQ@health.qld.gov.au

Tasmania Ms Mary Sharpe	Bh 03 6233 3766 Moblie 0400516885 Fax 03 6233 3904 E-mail mary.sharpe@dhhs.tas.gov.au
Mr James Galloway	Bh 03 6233 2064 Ah 03 6223 7074 Fax 03 6233 3904 E-mail james.galloway@dhhs.tas.gov.au
Australian Capital Territory Ms Cathy Beckhouse	Bh 02 6207 3974 Mobile 0402 916 644 Fax 02 6205 0997 E-mail pharmaceuticalservices@act.gov.au Cathy.Beckhouse@act.gov.au
Vivian Beven	Bh 02 6205 0998 Mobile 0419 516 399 Fax 02 6205 0997 Email Pharmaceuticalservices@act.gov.au Vivian.Beven@act.gov.au
Northern Territory Ms Helgi Stone	Bh 08 8922 7035 Mobile 0429 091 636 Fax 08 8922 7200 E-mail Helgi.stone@nt.gov.au
Northern Territory - Alternate Peter Kern	Bh 08 8922 7340 Mobile 0414 327 884 Fax 08 8922 7200 E-mail Peter.Kern@nt.gov.au
Western Australia Mr Neil Keen	Bh 08 9222 6883 Mobile 0419 944 801 Fax 08 9222 2463 E-mail neil.keen@health.wa.gov.au poisons@health.wa.gov.au

APPENDIX 2 – MEDICAL DEVICES CONTACT LIST – May 2013

NOMINATED COMMONWEALTH & STATE MEDICAL DEVICES RECALL COORDINATING OFFICERS

Commonwealth Mr Mick O'Connor	Bh 02 6232 8197 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Joshan Joy	Bh 02 6232 8636 Mobile 0412 205 568 FAX 02 6203 1451 E-mail recalls@tga.gov.au
Mr Simon Waters	Bh 02 6232 8178 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
New South Wales Mr Bruce Batty	Bh 02 9391 9944 Mobile 0401 712 050 Fax 02 9424 5860 E-mail bbatt@doh.health.nsw.gov.au
Victoria Dr Michael Ackland	Bh 03 9096 5186 Mobile 0411 239 113 Fax 03 9096 9166 E-mail michael.ackland@health.vic.gov.au
Ms Megan L. Smith	Bh 03 9096 5355 Bh 1300 364 545 Mobile 0408 598 663 Fax 1300 360 830 E-mail megan.l.smith@health.vic.gov.au
South Australia Professor Paddy Phillips	Bh 08 8226 2578 Mobile 0417 863 858 Fax 08 8226 9837 E-mail Paddy.Phillips@health.sa.gov.au
Ms Anita Chambers	Bh 08 8226 6035 Mobile 0401 123850 Fax 08 8226 0725 E-mail anita.chambers@health.sa.gov.au
Queensland Mr Bill Loveday	Bh 07 3328 9890 Fax 07 3328 9821 E-mail MRQ@health.qld.gov.au
Mr Has Mukh Patel	Bh 07 3406 8008 Mobile 0409 582 915 Fax 07 3406 8035 E-mail Hasmukh_Patel@health.qld.gov.au

Tasmania Dr Craig White	Bh 03 6233 3297 Mobile 0410 312 194 Fax 03 6233 6392 E-mail craig.white@dhhs.tas.gov.au E-mail karen.foster@dhhs.tas.gov.au
Australian Capital Territory Ms Cathy Beckhouse	Bh 02 6207 3974 Mobile 0402 916 644 Fax 02 6205 0997 E-mail pharmaceuticalservices@act.gov.au Cathy.Beckhouse@act.gov.au
Vivian Beven	Bh 02 6205 0998 Mobile 0419 516 399 Fax 02 6205 0997 Email Pharmaceuticalservices@act.gov.au Vivian.Beven@act.gov.au
Northern Territory Ms Helgi Stone	Bh 08 8922 7035 Mobile 0429 091 636 Fax 08 8922 7200 E-mail Helgi.stone@nt.gov.au
Northern Territory - Alternate Peter Kern	Bh 08 8922 7340 Mobile 0414 327 884 Fax 08 8922 7200 E-mail Peter.Kern@nt.gov.au
Western Australia Mr Neil Keen	Bh 08 9222 6883 Mobile 0419 944 801 Fax 08 9222 2463 E-mail neil.keen@health.wa.gov.au poisons@health.wa.gov.au

APPENDIX 3 – BLOOD & BLOOD PRODUCTS CONTACT LIST – May 2013*(appendix introduced May 13, Ed 31)***NOMINATED COMMONWEALTH & STATE BLOOD & BLOOD PRODUCTS RECALL COORDINATING OFFICERS**

Commonwealth Mr Mick O'Connor	Bh 02 6232 8197 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Joshan Joy	Bh 02 6232 8636 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Mr Simon Waters	Bh 02 6232 8178 Mobile 0412 205 568 Fax 02 6203 1451 E-mail recalls@tga.gov.au
Western Australia Mr Neil Keen	Bh 08 9222 6883 Mobile 0419 944 801 Fax 08 9222 2463 E-mail neil.keen@health.wa.gov.au poisons@health.wa.gov.au
New South Wales Mr Bruce Battye	Bh 02 9391 9944 Mobile 0401 712 050 Fax 02 9242 5860 E-mail bbatt@doh.health.nsw.gov.au
Tasmania Ms Mary Sharpe	Bh 03 6233 3766 Mobile 0400 516 885 Fax 03 6233 3904 E-mail mary.sharpe@dhhs.tas.gov.au
Northern Territory Jane Darvall	Bh 08 8922 8027 Mobile 0410 781 272 Fax 08 8922 8048 Jane.darvall@nt.gov.au
Dinesh Arya	Bh 08 8999 2669 Fax 08 8999 2412 Dinesh.arya@nt.gov.au
South Australia Ms Susan Ireland	Fax 08 8463 5540 E-mail Susan.Ireland@health.sa.gov.au

APPENDIX 4 - AUSTRALIAN POLICE FORCES: CONTACT OFFICERS – May 2013

The Police officers responsible for the conducting of investigations into product tampering or extortion offences in each State (or for NSW, each Region) are set out below.

State	Branch	Region/City	Officer in Charge	Phone (P), Mobile (M) & Fax (F) , Email
ACT	Criminal Investigations	Australian Federal Police, Canberra	Det Supt Brett McCann	P 02 62649540 M 0423 022 167 F 02 62649580 E brett.mccann@afp.gov.au
	After Hours	Australian Federal Police, Canberra	ACT Policing Operations	P 02 6256 7777 F 02 6256 7755
NSW	State Crime Command	Sydney	Det Insp Mark Henney	P 02 8835 8578 M 0416 299 385 F 02 8835 8577 E henn1mar@police.nsw.gov.au
	After Hours	All Regions Surry Hills	Duty Operations Inspector, Communications Group	P 02 9265 4408 F 02 9265 4272
NT	Major Crime Division	Territory wide responsibility	Det Supt James O'Brien	P 08 8922 3552 M 0412 657 131 F 08 8922 3570 E james.obrien@pfes.nt.gov.au
	After Hours	Territory wide responsibility	Joint Emergency Services Communication Centre Supervisor	P 08 8922 1500 F 08 8922 3412
QLD	Organised Crime Group State Crime Operations Command	State wide responsibility	Detective Supt Darryl Charleson	P 07 3364 6597 M 0428 102 605 F 07 3364 6447 E Charleson.DarrylJ@police.qld.gov.au
	After Hours	Queensland Police Service	Duty Officer, Police Communications Centre	P 07 3364 3512 F 07 3236 2359
SA	Major Crime Investigation Branch	Adelaide	Det Supt Grant Moyle	P 08 8172 5480 F 08 8172 5441 E: grant.moyle@police.sa.gov.au
	After Hours	SA Police	Communications Branch Shift Manager, Communications Centre, Adelaide	P 08 8207 4455 F 08 8207 4525
TAS	Hobart Criminal Investigations Branch (Crime Unit)	Tasmania Police	Det Insp Glenn Lathey	P 03 6230 2622 M 0419 878 416 F 03 6230 2333 E Glenn.Lathey@police.tas.gov.au
VIC	Crime Department Tasking & Co-ordination Support Group	Victoria Police	Det. Inspector David Pike	P 03 9611 8547 M 0417 085 323 E David.Pike@police.vic.gov.au
	After Hours	Victoria Police	Duty Crime Officer Contact via Serious Crime Desk (24 hrs service)	P 03 9865 2727 E majorcrimedesk.crime@police.vic.gov.au
WA	Organised Crime Squad	Perth	Main Switch Det Inspector Andy Martin	P 08 9230 3558 M 0427 897 734 F 08 9223 3566 E Andy.Martin@police.wa.gov.au
	After Hours	WA Police	Organised Crime Squad On Call	P 0438 554 483

APPENDIX 5 – THREAT PROCEDURES

(appendix amended Sep 09, Ed 24)

5.1 CRISIS MANAGEMENT TEAM (CMT) REQUIREMENTS

Ideally, the CMT should have access to a designated room, equipped with fax machines, telephones (including a number of direct telephone lines for computer and phone access), TV, radio, recorders (video and audio) and secretarial support. Companies may wish to consider independent power supply and a stand-alone computer facility.

These facilities must be able to be accessed outside normal business hours and consideration should be given to the availability of food, air conditioning, bathing and resting facilities at these times.

The CMT must be supported by an efficient secretariat that will prepare all necessary documentation and be able to operate all electrical equipment, but need not necessarily participate in the actual management of the crisis.

General operating procedures about having daily mail opened and coordinating back-up for absent staff helps to ensure that potential issues are not overlooked.

5.2 TELEPHONE TAMPERING THREAT PROCEDURE

- It is important that staff are adequately trained to take the call.
- The following instruction should be made available to all Switchboard Operators, Senior Executives and their Secretaries.
- Copies of the telephone tampering report information form should be immediately accessible in areas occupied by such personnel.
- The company Crisis Management Plan should set out a procedure for handling threatening phone calls that are received outside of normal business hours.
- The company should identify procedures for tracking threatening phone calls.

5.3 TELEPHONE TAMPERING REPORT INFORMATION

WHAT TO DO UPON RECEIVING A THREAT BY TELEPHONE

Many threats made by telephone begin with the caller saying, “*Listen very carefully. I’m only going to say this once*”. The caller may use different wording, but he (or she) will usually set the ground rules for the conversation. If you receive a telephone call from a person who begins the conversation in such a manner, immediately give the caller your full attention. Remain calm and attempt to obtain as much information as possible. Familiarise yourself with the form below. Complete the form immediately after receiving a threatening call and report the incident immediately, following company procedures.

These forms should be collected and assessed to adjust messages relayed to enquirers and to adjust other communication activities for optimal effect. The information collected may also determine other follow up actions that need to take place.

ACTION

WHEN THE CALL IS RECOGNISED AS BEING THREATENING –

1. Try to keep the caller talking by asking the questions below.
2. Listen carefully for the caller’s voice, attitude/manner and any background noises.
3. **Do not hang up** in case the call is traceable through your switchboard. Record the exact time of the call and the number or line on which the call was received.
4. Don’t put the caller on hold.
5. Don’t transfer the caller.
6. Ask the caller the following questions and if possible, tape record the conversation:
 - Which of our products is involved?
 - What has been done to them? (e.g. poison, nails, glass etc)
 - How did you do it? (e.g. injection, replacing product etc)
 - Where have the tampered products been placed?
 - Which cities?
 - Which towns?
 - Which suburbs?
 - Which stores?
 - How many packs have been tampered with?
 - Why did you interfere with these products?
 - What do you want?
 - Who are you?
 - Where do you live?
 - How/where can we reach you?
7. Report the call **immediately** to senior management.
8. Record the call using FORM 1F – THREATENING CALLS – PHONE SHEET in the [Industry protocol - Product Contamination and Extortion – A Protocol for the Therapeutic Goods Industry Feb 2004](#).

5.4 INITIAL ASSESSMENT CHECK LIST

Information collection for assessment of threat

Level of familiarity with organisation.

- Use of position titles
- Use of Department and Section names
- Knowledge of the physical layout of the organisation
- Knowledge of geographical layout of the organisation
- Level of familiarity with corporate individuals
- Knowledge of communication links
- Stated relationship to organisation

Level of familiarity with individual.

- Use of personal names
- Use of nicknames
- Use of names of family members
- Knowledge of personal movements

Level of familiarity with operation/industry.

- Use of jargon
- Use of technical terms – including context
- Knowledge of distribution/service networks

Information collection for assessment of Demand

The demand:

- What is the demand?
- What is the rationale behind the demand?
- In what form is payment to be made?
- How is the payment to be made?

The threat:

- What is the threat?
- How, when and where will the threat be carried out?
- Has there been a demonstration of capability? If so, was this:
 - (i) a direct or open demonstration;
 - (ii) a covert demonstration;
 - (iii) an inferred capability?
- Is there an ability to carry out the threat?
- What assistance is available to assess the threat:
 - (i) within the organisation;
 - (ii) external to the organisation?
- Method of future contact.

APPENDIX 6 – EVIDENCE HANDLING CHECKLIST

(appendix amended Sep 09, Ed 24)

This checklist should be made available to all Mail Room Staff, Secretaries to senior company executives and any other personnel responsible for the opening of incoming mail. Copies of this sheet should be immediately accessible in all areas by such personnel.

EVIDENCE HANDLING CHECK LIST – TAMPERING

What is of paramount importance in any investigation is what happens from the start of the incident to the first Police involvement.

The following guidelines should be of assistance to your organisation should it be involved in a Criminal Investigation.

EXHIBIT/PACKAGE RECEIVED

Establish beyond doubt how it was received:

- Courier – your own or a contractor
- Private person
- Australia Post
- Left at premises
- Faxed
- Dropped in mail box
- E-mailed
- Other

Were there any internal or external access controls needed to be passed for delivery?

Recall

- Who delivered – male, female, short/tall, dress, voice, what said, etc.
- Is there a surveillance camera/video image available? If the incident is a continuing one, this equipment should be considered.

What condition was the material in when it was received?

Handling of exhibits/packages

Who received the material in the first instance?

- Name(s)
- Position(s)
- Contact Number(s)
- Date(s)
- Time(s)

Record the details using FORM 1G – RECEIPT OF EXTORTION THREAT – ADVICE BY LETTER OR AUDIO TAPE in the [Industry Protocol - Product](#)

[Contamination and Extortion – A Protocol for the Therapeutic Goods Industry Feb 2004.](#)

Who has handled the material?

- Name(s)
- Position(s)
- Date(s)
- Time(s)
- Reason(s)

DO NOT HANDLE – If found and its arrival/receipt is unknown (it could contain an anti-movement device).

If delivery known –

- Handle as little as possible, move it to a secure location.
- Consider fingerprints/physical evidence on the package.
- Use gloves, cotton/plastic, carry by edges/corners.
- For protection, place on large piece of cardboard/container/envelope.
- Do not pin, staple, glue, open or deface.
- Do not photocopy
- If opened, collect/store in another container, handle as little as possible, collect packing material.
- Secure area/evacuate area as need indicates.

DO NOT:

- Place packages in plastic bags and seal.
- Handle, open, alter, pin, staple, glue or deface.
- Move package if it is found and its delivery/arrival is unknown.

Subsequent handling of evidence

Who has handled the material subsequent to its receipt?

- Name(s)?
- Position(s)?
- Contact Number(s)?
- Date(s)?
- Time(s)?
- Reason(s)?

Continuity of possession of exhibits is a must. The following is a suggested register:

	TIME / DATE RECEIVED	BY WHOM Signature of print name & phone no.	DESCRIPTION OF PACKAGE	WHERE TO How secured	TO WHOM Signature print name & phone no
1					
2					
3					

CHECK LIST

DO	DO NOT
Record time/date received	Touch
Record who received it	Open
Record who delivered it	Pin
Record who found it	Staple
Record features of receipt	Glue
Record continuity of possession	Deface
Record safe security	Place packages in plastic or seal the bag
Record movement to safe location	Photocopy
Record arrival of Police	
Record who item handed to	
If opened, keep wrapping/packing	
Advise senior management immediately	

APPENDIX 7 - ACTION PLAN

CHECK LIST

The following is an outline of the actions that should follow the receipt of a report of suspected tampering. This check list is purposely general in nature and should be considered in the context of an organisation's own Crisis Management Plan.

1. Evidence Handling Check List
2. Convene Initial Assessment Team
3. Initial Assessment Check List

NO CRISIS

4. Follow Up (If Required)
5. Record
6. File

CRISIS

7. Implement Crisis Management Plan
8. Involve Authorities

CRISIS RESOLVED

9. Debriefing
10. Follow Up (If Required)
11. Record
12. File

CRISIS NOT RESOLVED

13. Implement Standby Procedures

APPENDIX 8 - ESTABLISHING A TOLL FREE TELEPHONE NUMBER

In the event of a crisis directly affecting the public, it may be advantageous to set up a toll free telephone number to take customer enquiries.

Large organisations will have a phone service provider account executive who can assist with the set up of such a number.

Small organisations can call 13 2000 for assistance.

The Freecall 1800 provisioning centre can be contacted by phone on 1800 800 513 or fax 1800 257 195.

The normal lead time is about 3 working days but in the case of a crisis an order can be fastracked.

APPENDIX 9 – AMENDMENT HISTORY

Changes to the Crisis Management Guidelines since December 2000, other than quarterly updates to Appendices 1, 2 & 3.

Page No.	Details of Change	Date	Edition No.
2	Insert Hyperlinked Table of Contents	May 13	Ed 31
4,8	Cross reference to Industry Protocol – <i>Product Contamination and Extortion – A Protocol for the Therapeutic Goods Industry February 2004 (PC&E)</i> .	Sep 09	Ed 24
6	Additional process box added “Review & Amend Plan”	Sep 09	Ed 24
11	Revised advice for keeping the threat phone call going and recording the details, consistent with Industry Protocol - PC&E	Sep 09	Ed 24
12	Revised advice for handling of physical evidence, consistent with Industry Protocol – PC&E	Sep 09	Ed 24
15	Additional advice of important items to be addressed.	Sep 09	Ed 24
23	Inserted new Appendix - APPENDIX 3 – BLOOD & BLOOD PRODUCTS CONTACT LIST. Renumbered the following appendices and page numbers accordingly.	May 13	Ed 31
26	Addition of reference to FORM 1F – THREATENING CALLS – PHONE SHEET in the Industry Protocol – PC&E and Deletion of the RECORD OF THREATENING PHONE CALL from the Guideline.	Sep 09	Ed 24
28	Addition of reference to FORM 1G – RECEIPT OF EXTORTION THREAT – ADVICE BY LETTER OR AUDIO TAPE	Sep 09	Ed 24
30	Additional items added to DO NOT column in checklist.	Sep 09	Ed 24