Policy Directive

Coordination of responses to urgent system-level medicine or medical device issues

Summary This Policy Directive outlines a framework that supports timely, effective, systematic and coordinated responses to medicine or medical device issues that present a potentially high or extreme risk to patient safety or system performance.

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Applies to Ministry of Health, Local Health Districts, Board Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Health Pathology, Public Health System Support Division, Cancer Institute, NSW Ambulance Service

Distributed to Ministry of Health, Public Health System, NSW Ambulance Service

Audience Clinical Governance;biomedical engineers;Pharmacy;All clinical staff, pharmacy staff, Directors of Clinical Governance

Secretary, NSW Health

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.

NSW GOVERNMENT Health

POLICY STATEMENT

COORDINATION OF RESPONSES TO URGENT SYSTEM-LEVEL MEDICINE OR MEDICAL DEVICE ISSUES

PURPOSE

System-level notifications and incidents involving medicines or medical devices can present a potentially high or extreme risk to patient safety and system performance. These require a rapid centralised response, beyond the more routine, 'business as usual' local response.

This Policy Directive outlines a framework that supports timely, effective, systematic and coordinated responses to these issues.

MANDATORY REQUIREMENTS

The Clinical Excellence Commission (CEC) is responsible for automatically distributing all formal recall actions issued by the Therapeutic Goods Administration to local health districts (LHD), specialty networks (SN) and statewide health services (SHS, such as NSW Ambulance, HealthShare NSW and NSW Health Pathology). Section 4 identifies LHD/SN/SHS responsibilities for managing incoming notifications.

The CEC reviews all TGA recall actions, along with notifications received from other sources.

It is important to note that most medicine and medical device issues will not require urgent system-level coordination, and will be managed directly through existing 'business as usual' local processes.

For the minority of issues (usually high or extreme risk) where urgent system-level coordination is needed, the CEC will convene the Inter-Agency Management Team (CEC, HealthShare NSW and the Ministry of Health) to undertake further risk assessment and determine appropriate risk mitigation actions. Section 5 outlines this process.

IMPLEMENTATION

The requirements of this Policy Directive must be in place within three months of its publication.

REVISION HISTORY

Version	Approved by	Amendment notes
May-2019 (PD2019_019)	Deputy Secretary, Population and Public Health	First publication

ATTACHMENTS

1. Coordination of responses to urgent system-level medicine or medical device issues: Procedures

Coordination of responses to urgent system-level medicine or medical device issues

NSW GOVERNMENT Health

PROCEDURES

Issue date: May-2019

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1 SUMMARY OF COORDINATION OF RESPONSES TO URGENT SYSTEM-LEVEL MEDICINE OR MEDICAL DEVICE ISSUES

STEP	SUMMARY
1. Notification (Page 7)	Notification of a concern regarding a medicine/medical device that may adversely impact patient safety or system performance and requires state-level coordination can come from a number of sources. The Clinical Excellence Commission, as lead agency, reviews all notifications.
2. Initial review: (Page 7)	The Clinical Excellence Commission's initial review includes: • **ROUTINE ACTIONS** - The Clinical Excellence Commission, as host of the NSW Therapeutic Goods Administration (TGA) Recall Coordinator, automatically distributes all TGA recall actions to NSW Health system. • **SYSTEM RISK** – The Clinical Excellence Commission makes an initial assessment regarding potential system risk and whether further assessment is required. • The Clinical Excellence Commission records the outcome of the initial review. *The Clinical Excellence Commission notifies the Ministry's System Purchasing and Performance Division as soon as potential operational impact on system performance is identified (e.g. possible cancellation/delay in service delivery at LHD/SN/SHS level).*
3. Information gathering (Page 8)	The Clinical Excellence Commission and HealthShare gather specific details on the issue (with support from relevant agencies and key experts) to inform a risk assessment. If, after gathering further information, the risk is considered manageable within existing systems, then no further action is required. The Clinical Excellence Commission reassesses if new information becomes available.
4. Inter-agency Management Team convened (Page 9)	The Clinical Excellence Commission coordinates the Inter-agency Management Team.
5. Risk assessment process (Page 10)	The Inter-agency Management Team: • Considers what additional information is required • Considers the potential impact of the issue • Categorises the risk – extreme, high, medium or low
6. Risk mitigation and management strategy (Page 13)	The Inter-agency Management Team then considers what risk mitigation strategies are appropriate for managing the issue, for example: • Determining who will implement specific risk mitigation strategies (i.e. mobilising appropriate supply/logistics) • Communicating with LHD/SN/SHSs or private health facilities about actions to reduce identified risks • Sourcing and assessing alternative products • Prioritising and rationing available products • Preparing information on replacement products
7. Risk communication (Page 14)	The Clinical Excellence Commission prepares consolidated information for the relevant stakeholders. The Inter-agency Management Team reviews and endorses communications.
8. Surveillance (Page16)	The Inter-agency Management Team considers surveillance data when assessing risk. New data must be reviewed when re-assessing risk.
9. Debrief (Page 16)	Debrief sessions present an opportunity to consider: • Lessons learned, including actions that worked well • Plans and procedures that require updating • Gaps that may require further planning

See Section 5 for more detail.

2 INTRODUCTION

Deficiencies in quality, efficacy, safety or access to therapeutic goods (e.g. medicines, and medical devices) can pose a risk to patient safety and/or have an impact on health system service delivery if not carefully managed. Examples of this can include medication contamination or shortages, and medical device failures.

The majority of these issues can be managed locally by each impacted local health district (LHD), specialty network (SN) or statewide health service (SHS, ie NSW Ambulance or NSW Health Pathology) through existing 'business-as-usual processes.

Sometimes we need to centrally coordinate a response to address critical patient safety concerns and mitigate a broader risk to the health system.

A centralised response can contribute:

- Broader cross-Health, national and international visibility to inform risk management
- Coordination of key pillar and agency resources and expertise to support rapid and effective responses (e.g. system-wide negotiation with suppliers)
- The provision of state-wide supplementary guidance to mitigate risks (e.g. advice on alternative products, clinical considerations in the choice of a substitute, clinical prioritisation for access and additional safeguards required to use the substitute product)
- Economies of scale during a widespread response, so substantial effort is not duplicated

This policy directive sets forth a framework to support timely, effective, systematic and coordinated system-level management of urgent medicine and medical device notifications and issues.

These issues may result from, but are not limited to:

- Product defect/contamination
- Manufacturing disruptions (e.g. raw ingredient shortage or plant shutdown)
- Supply chain disruptions
- Increased product demand
- Regulatory issues and recalls
- Business decision to no longer manufacture or stock an item
- Increasing global reliance on single manufacturers

Vaccine shortages are managed through a separate process by Health Protection NSW.

3 INTER-AGENCY MANAGEMENT TEAM

Multiple agencies respond to the notification of issues with medicines, devices and other products that may pose a risk to patient safety.

Key external stakeholders include:

- Therapeutic Goods Administration (TGA)
- Commonwealth Department of Health
- Health agencies in other states and territories

Attachment 1 describes the TGA's recall action framework, and how that system connects with this policy directive.

In NSW, the Clinical Excellence Commission (CEC) leads our response to urgent system-level medicine and medical device issues.

This includes reviewing potential risks to patient safety, coordinating routine actions (e.g. automatic distribution of TGA recall actions) and escalating more complex situations for broader assessment and risk mitigation.

For more complex responses, the CEC is supported by the Inter-agency Management Team (IMT). IMT members will leverage their relevant expertise to inform a risk assessment, make decisions regarding incident management, and coordinate the response.

In addition to the CEC, core members of the IMT include the Ministry of Health's Office of the Chief Health Officer and HealthShare NSW. If the issue relates to a medicine or poison, the Ministry of Health's Legal and Regulatory Services Branch is also involved. The roles of the core agencies are outlined in Table 1.

The IMT may seek input from key experts and advisory agencies (e.g. Agency for Clinical Innovation and its clinical networks, LHD/SN/SHS clinical and pharmacy representatives, Health Protection NSW, Cancer Institute NSW) to inform risk assessment and mitigation activities and to facilitate communication with key stakeholders. These groups are invited to participate in the IMT as needed.

All agencies must prioritise comprehensive and rapid responses to requests from the CEC or other IMT members for clinical input or other information in connection to urgent emerging issues relating to medicines and medical devices.

IMT agencies must ensure that adequate staffing resources are available to coordinate the response, including after hours, holiday periods and during period of leave.

In extreme instances of immediate, life-threatening risk or major system impact, coordination of the response may transition to the Chief Health Officer or Deputy Secretary, System Purchasing and Performance (depending on the nature of the incident).

Table 1: Core agencies' responsibilities

CORE AGENCY	RESPONSIBILITIES FOR URGENT SYSTEM-LEVEL MEDICINE OR MEDICAL DEVICE NOTIFICATIONS AND ISSUES
Clinical Excellence Commission	● Leads responses to urgent system-level medicine and medical device issues in the NSW Health system, including Inter-agency Management Team coordination ● Hosts the TGA Recall Coordinator function for NSW (as per TGA's Uniform Recall Procedures for Therapeutic Goods) ● Provides a central liaison and coordination point for LHD/SN/SHS recall coordinators ● Routinely monitors all TGA safety communications ● Undertakes the initial risk assessment of notifications and escalates as required for a broader response (e.g. System Purchasing and Performance Division) ● Coordinates clinical input from Agency for Clinical Innovation, Cancer Institute NSW and other health bodies as needed ● Manages the Safety Alert Broadcast System (SABS) system and communication with LHD/SN/SHS Directors of Clinical Governance ● Maintains email lists for recall alert distributions ● Maintains this policy directive and related contact lists for core agencies ● Coordinates advice to identify and assess suitability of alternate products ● Coordinates the development and issuing of situation reports for key stakeholders during rapidly evolving extreme/high risk incidents as required
Office of the Chief Health Officer, NSW Ministry of Health (MoH)	● Supports the Chief Health Officer's functions relating to clinical leadership and coordination of responses to public health emergencies ● Supports Clinical Excellence Commission to access parts of the Health system which do not have an existing relationship with other core agencies and which may not have routine involvement with these types of incidents ● Escalates issues to the Chief Health Officer, Secretary and Minister for Health
HealthShare NSW	● Contributes to situational intelligence by consolidating affected product and potential alternative product information with current state-wide usage and supplier market position, including products that are not on state contract (may include liaising with suppliers and LHD/SN/SHSs for customer lists and stock holdings) ● Gathers intelligence on rate of consumption of implicated products to the greatest extent possible ● Identifies product alternatives, market ability to support these alternatives and procurement strategy ● Manages communication with suppliers/distributors, LHD/SN/SHS clinical product managers, biomedical engineers and pharmacies ● Manages all aspects of centralised procurement ● Provides advice on terms and conditions of existing contracts and procurement matters
Legal and Regulatory Services Branch (MoH)	● Provides strategic advice on pharmaceutical and related issues ● Contributes to advice on alternative pharmaceuticals ● Maintains the Directors of Pharmacy contact list and manages communication with LHD/SN/SHS Directors of Pharmacy and pharmacy-related peak bodies/professional associations ● Access to field officers for investigations if required ● Leads communication with licensed private health facilities

4 LOCAL HEALTH DISTRICTS, SPECIALITY NETWORKS & STATEWIDE HEALTH SERVICES

Local health districts (LHDs), specialty networks (SNs) and statewide health services (SHSs) are responsible for mitigating risks within their health services. Table 2 outlines responsibilities of key positions.

Formal communication about urgent medicine and medical device issues will be via existing line management channels (e.g. Chief Executives, Directors of Clinical Governance and nominated medicine and medical device recall coordinators).

The Chief Executive or executive on-call will be the default contact point for out of hours notifications/responses. In certain circumstances the Inter-agency Management Team (IMT) may liaise with groups with particular expertise, such as clinical product managers, biomedical engineers, or clinicians identified through Agency for Clinical Innovation networks to better understand clinical impacts and system vulnerability.

Table 2: Key LHD/SN/SHS responsibilities

POSITION	RESPONSIBILITIES FOR URGENT MEDICINE OR MEDICAL DEVICE NOTIFICATIONS AND ISSUES
Chief Executive (CE)	• Ensures an efficient and effective local process for receipt, distribution, implementation of and response to SABS notifications, recall actions and other urgent notifications is in place, including outside of business hours • Ensures a system is in place to escalate emerging issues to the Clinical Excellence Commission and notify the Therapeutic Goods Administration as appropriate • Nominates at least one LHD/SN/SHS recall coordinator to receive and respond to medicine and medical devices recall alerts (can be a generic/rotating position; notify CEC of changes: CEC-recalls@health.nsw.gov.au) • Ensures records are maintained in accordance with good governance
Director of Clinical Governance (DCG)	• Manages requests from Clinical Excellence Commission for information on product use/holdings • Ensures implementation of nominated action/s from safety communiqués (e.g. Safety Alert Broadcast System notices or memos to Chief Executives) • Coordinates advice on alternative products and their potential use within the health service as requested
Recall coordinator/s	• Coordinates the prompt removal of recalled items (or implements other recall letter instructions) • Keeps LHD/SN/SHS executive and affected staff informed about recall actions according to internal procedures • Ensures arrangements are in place during business hours to regularly monitor recall coordinator points of contact *The role of medicine recall coordinators is outlined in the policy directive Medication Handling in NSW Public Health Facilities (PD2013_043).*

5 RISK MANAGEMENT FRAMEWORK FOR THE ASSESSMENT OF MEDICINE OR MEDICAL DEVICE NOTIFICATIONS

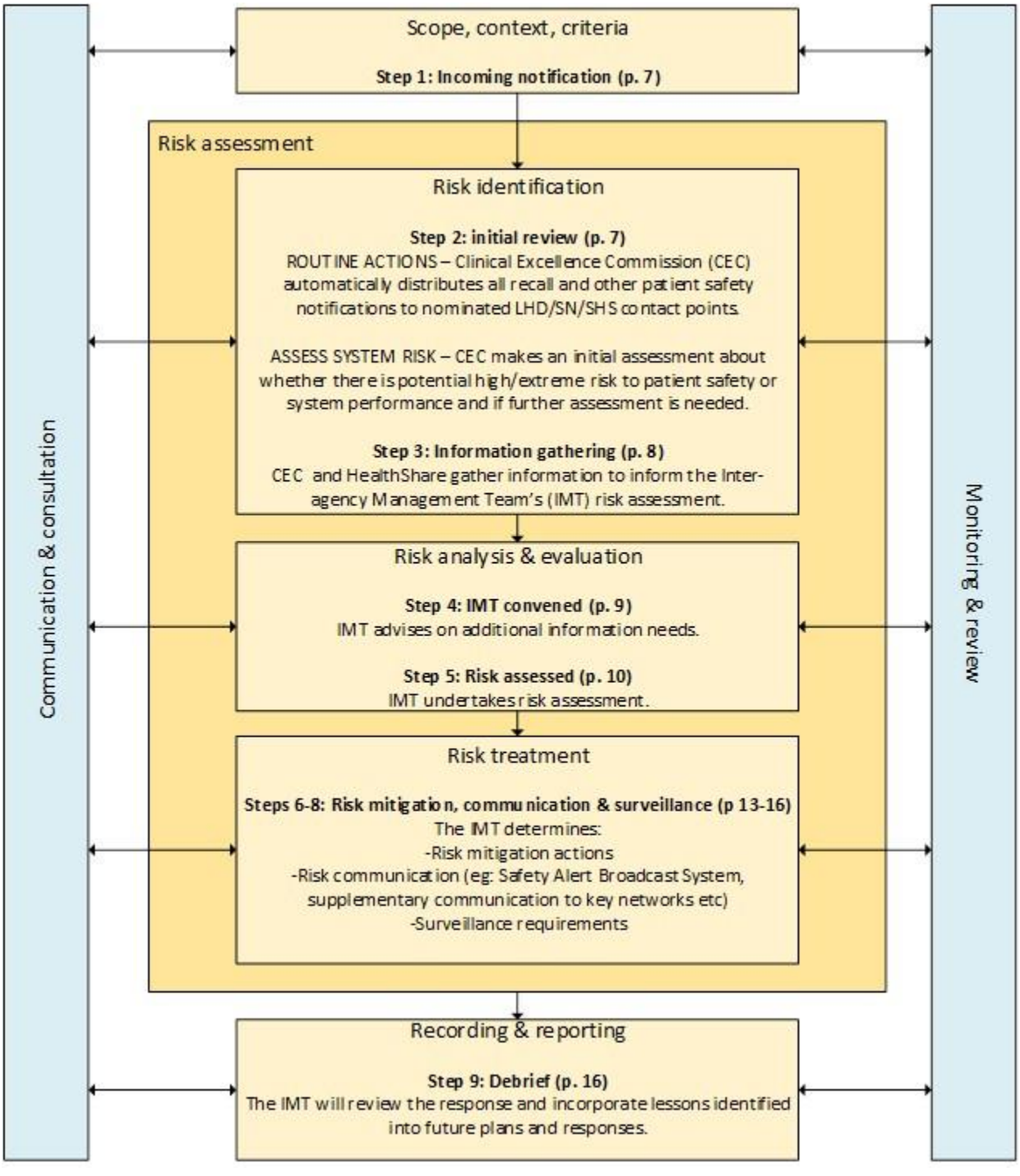


Figure 1: Summary of risk management framework for the assessment of medicine and medical device notifications as aligned with *AS ISO 31000:2018 Risk management – Guidelines*.

STEP 1: INCOMING NOTIFICATION

The Clinical Excellence Commission (CEC) is the default point of contact for all notifications of incidents or potential issues concerning medicines or medical devices.

As the CEC is the TGA's NSW Recall Coordinator, this includes all recall actions and other safety advisories issued by the TGA (see step 2 and Attachment 1 for more information about how NSW Health connects with the TGA's recall actions system).

Notifications can also come from a range of additional sources. This could include product sponsors, wholesalers, clinicians, Chief Executives (CEs), Directors of Clinical Governance (DCGs), reportable incident briefs, Incident Information Management System (IIMS) notifications, LHD/SN pharmacists, HealthShare NSW, Australian Commission on Safety and Quality in Health Care (ACSQHC) Medicine and Medical Device Alerts and Advisories Portal, health agencies in other jurisdictions, the TGA or the Commonwealth Chief Medical Officer.

Notifications to the CEC should be emailed to CEC-recalls@health.nsw.gov.au. Urgent notifications must be immediately followed up by a phone call to the CEC via CEC main telephone number (02) 9269 5500.

Suspected adverse events from medical devices and medicines must be reported to the TGA (http://www.tga.gov.au/reporting-problems) and entered in the Incident Information Management System (IIMS) by the relevant LHD/SN/SHS. LHD/SN/SHSs must have systems in place to ensure notification to TGA occurs.

STEP 2: INITIAL REVIEW

Routine dissemination

The Clinical Excellence Commission (CEC) automatically forwards all TGA recall actions to nominated LHD/SN/SHS recipients to ensure there is no delay in delivery to a potentially impacted service.

In addition to the automatic notification to nominated LHD/SN/SHS recipients, the CEC also directly notifies Directors of Clinical Governance of all TGA class I recall actions. On occasion, TGA class II recall actions may also be shared directly with Directors of Clinical Governance.

For further details on TGA recall alerts refer to Attachment 1.

Initial assessment of potential system risk

The CEC reviews all notifications as soon as practicable.

This involves an initial assessment of potential system risk, determining whether further investigation is needed and considering whether a response to this risk would be most appropriately coordinated centrally.

The CEC escalates as quickly as possible to the Office of the Chief Health Officer and HealthShare NSW (and Legal and Regulatory Services Branch if medicine-related) if there is a potential high or extreme risk to the broader health system. Any potential immediate life-threatening risks are escalated directly to the Chief Health Officer.

Examples of medicine/medical devices notifications that would be appropriate for broader assessment by the Inter-agency Management Team include:

- Critical safety issue beyond local response coordination capacity
- The recall of widely used or critical products with no readily available alternatives
- An emerging patient safety issue affecting a highly vulnerable patient group

The CEC notifies the Ministry's System Purchasing and Performance Division if there is a potential operational impact on system performance (e.g. possible cancellation/delay in service delivery at LHD/SN/SHS level).

The CEC also notifies the Ministry's Regulation and Compliance Unit if there are specific implications for licensed private health facilities.

For auditing purposes the CEC keeps a record of each notification and note the initial review outcome.

STEP 3: INFORMATION GATHERING

The Inter-agency Management Team (IMT) undertakes a more detailed risk assessment of any medicine/medical device notification that represents a potential risk to the system or a critical patient safety issue.

In order to adequately inform this risk assessment, the Clinical Excellence Commission (CEC), with support from HealthShare, collects as many specific details as possible prior to convening the IMT, for example:

- Specific product details
- Notification source
- Details about the notification (e.g. product failure, shortage or adverse event)
- Details regarding product use and clinical impact, including settings where the product is commonly used
- Details about anticipated duration of incident
- Details about availability, efficacy and suitability of alternative products
- Clarification of whether rural and remote areas may be disproportionately impacted
- Any actions already taken/communication disseminated

To support information gathering and a diversity of perspective, the CEC can:

- Review relevant evidence and IIMS reports
- Assess comparative risk
- Consult with relevant clinical experts to identify clinical impact and potential solutions (for example, via Agency for Clinical Innovation's networks or the Cancer Institute NSW)
    - Note: There is an expectation that supporting agencies respond to requests for clinical input rapidly and comprehensively. Agencies may need to provide ongoing input as the situation continues to evolve.
- Consult with HealthShare NSW regarding usage and availability of potential alternatives. HealthShare NSW may need to seek rapid advice from the sponsor and/or clinical product managers or biomedical engineers
- Consult with, or consider clinical and safety advice from relevant bodies such as:
    - TGA (which may have information on alternative suppliers and characteristics of patients likely to be affected that can serve as a solid basis for further risk assessment by NSW Health)
    - Australian Commission on Safety and Quality in Health Care
    - Department of Health
    - other states and territories
    - other international research and government bodies such as US Food and Drug Administration

If, after reviewing this additional information, the risk is considered to be manageable without further state-level coordination, no additional action is required. If new information becomes available, CEC reassesses the risk.

STEP 4: INTER-AGENCY MANAGEMENT TEAM CONVENED

The role of the Inter-agency Management Team (IMT) is to undertake a more comprehensive risk assessment, make decisions regarding risk mitigation strategies, coordinate the response and contribute to safety communiqués.

If an issue requires a rapid response, Clinical Excellence Commission (CEC) should convene the IMT as soon as possible. While the CEC is most likely to receive the initial notification, any of the core agencies can convene an IMT.

The CEC's Senior Manager - Medication Safety, Director - Patient Safety, or Deputy Director - Governance and Assurance chairs the IMT. Senior managers from the core agencies provide support.

Clear documentation of IMT meeting discussions and decisions, including regular re-assessment of the risk rating, is required throughout the management of the response. Each IMT agency is responsible for escalating internally to its senior executive team.

STEP 5: RISK ASSESSMENT PROCESS

A risk assessment process provides the structure to gather and organise information, inform decision making and support proportional response to incidents.

The Inter-agency Management Team (IMT) should comprehensively assess the risk as early as possible. Risk assessment is a dynamic process that incorporates changes in circumstances and new information.

The risk characterisation process should consider:

- The predicted duration of the incident
- The number of people or patients (or key groups), and the vulnerability of the population likely to be affected
- The potential impact on affected groups
- The potential impact on service delivery more broadly
- The function/usage of the implicated product or medicine
- The availability, efficacy and suitability of alternatives
- The ease of mitigation

The Inter-agency Management Team conducts the risk assessment using a four-tier risk rating system (Table 3).

Table 3: Risk assessment rating system (guide only)

Risk rating	Description
LOW	Incidents involving medicines**,** products or devices with directly interchangeable alternatives Short-term incidents affecting a small number of patients where treatment/use of product can be delayed. According to the NSW Health Enterprise Risk Management Framework (2015_043) this may include: • Patient care level has increased unrelated to the natural course of the illness • First aid provided to patient unrelated to the natural course of the illness • Some disruption within a location but manageable by altering operational routine • No interruption to services • Periodic loss of public support • Minimal impact on local operations, local management review and occasional adverse local publicity
MEDIUM	Incidents involving non-essential medicines**,** products or devices where alternatives are available, but not directly interchangeable Short-term incidents affecting a large number of patients where treatment/use of product can be delayed. According to the NSW Health Enterprise Risk Management Framework (2015_043) this may include: • Potential/unexpected temporary reduction of patient's bodily function unrelated to the natural course of the illness which differs from the expected outcome • Disruption of a number of services within a location with possible flow on to other locations in the area • Increasing and broadening adverse publicity at a local level, loss of consumer confidence, escalating patient/consumer complaints. • Extended loss of public support/opinion for a facility/service

HIGH	Incidents involving essential medicines, products or devices where alternatives are available but are either: • Not directly interchangeable or • Not registered for use in Australia or • Registered, but not currently available in Australia. The outcome of the incident has/could have a significant impact on patient safety. Incidents may have an impact on delivery of health services which is difficult to mitigate and may affect multiple locations. According to the NSW Health Enterprise Risk Management Framework (2015_043) this may include: • Potential/unexpected patient death or permanent loss/reduction of bodily function unrelated to the natural course of the illness • Services compromised as service providers are unable to provide effective support and other areas of NSW Health are known to be affected • Sustained adverse publicity at a state-wide level leading to the requirement for external intervention • Systemic and sustained loss of public support/opinion across a service
EXTREME	Incidents involving essential medicines**,** products or devices where: • No suitable alternatives are available or • Alternatives pose significant risks which are difficult to mitigate. The outcome of the incident has/could have a major impact on patient safety. Incidents may have a substantial impact on delivery of health services which is difficult to mitigate and may affect multiple locations. According to the NSW Health Enterprise Risk Management Framework (2015_043) this may include: • Potential/unexpected multiple patient deaths unrelated to the natural course of the illness • State-wide system dysfunction resulting in total shutdown of service delivery or operations • Sustained adverse national publicity. • Significant loss of public confidence, loss of reputation and/or media interest across NSW in services.

Table 3 is a guide only, and the risk assessment must consider exceptional and unique factors of each issue. Clinical judgement should be used when evaluating the risk of each incident.

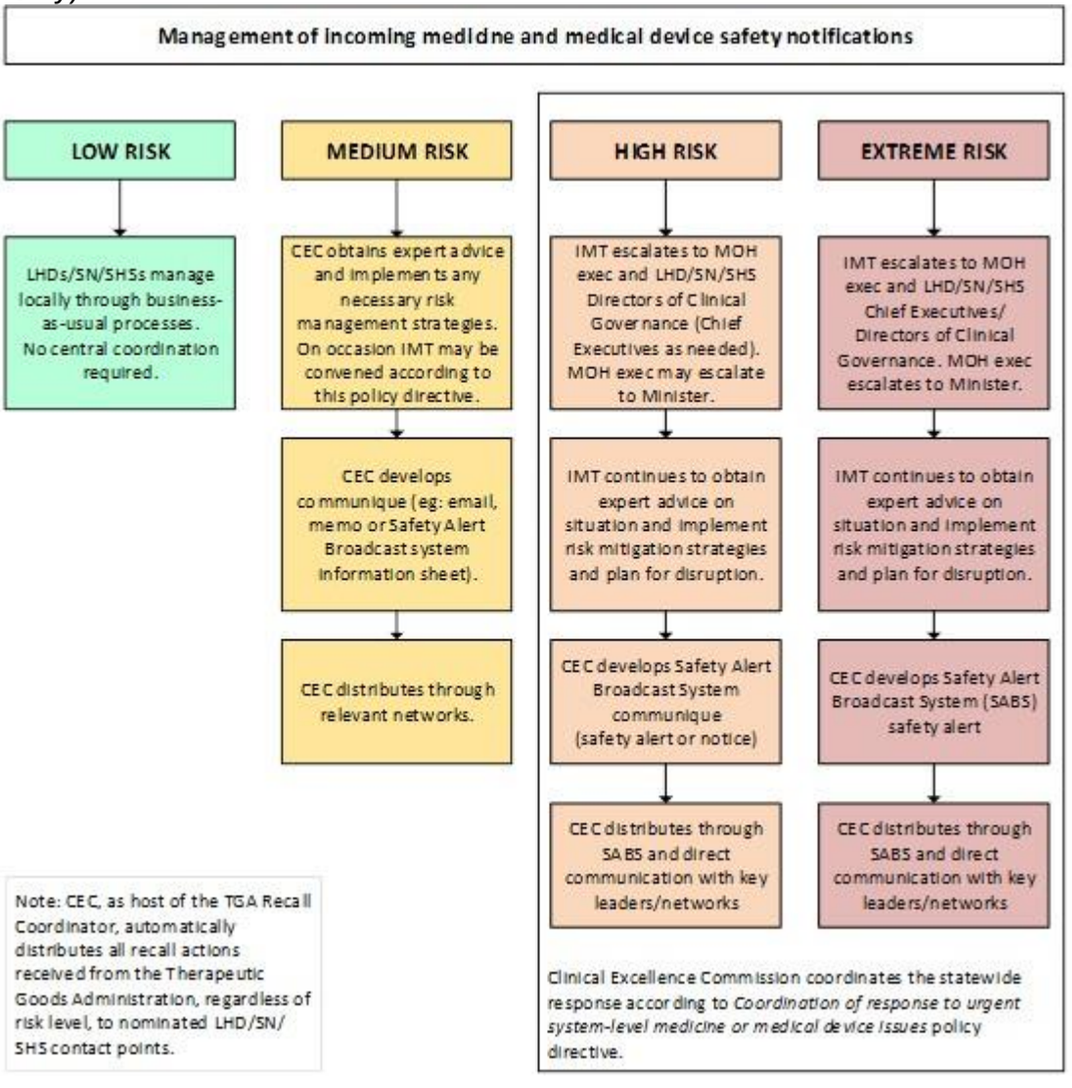
STEP 6: RISK MITIGATION/MANAGEMENT

Risk mitigation plans should address risks directly associated with the incident as well as those which may arise from use of potential alternative products or other aspects of the proposed response.

Plans should be guided by the *Enterprise-Wide Risk Management Policy and Framework* (PD2015_043). Key actions for each risk category are outlined in Figure 2.

The actions outlined in Figure 2 are a guide only. Actions need to be proportionate and factor in the specific characteristics of each issue.

Figure 2: Management of incoming medicine and medical device safety notifications (guide only)



Mitigation strategies include:

- Sourcing and assessing alternative products and preparing information on replacement products
- Prioritising, relocating, quarantining or rationing products
- Undertaking actions recommended by the manufacturer/supplier
- Implementing active surveillance for associated adverse effects (e.g. infections)
- Establishing and seeking guidance from an expert panel
- Communicating with LHD/SN/SHSs, clinical specialty groups and licensed private health facilities about actions to reduce risks
- Managing cost implications for alternative products where possible (e.g. through negotiation for S19a classification with the TGA, or supplier negotiation)

STEP 7: RISK COMMUNICATION

Structured and consistent communication is a key part of any risk mitigation strategy. The Inter-agency Management Team (IMT) provides consolidated information to the relevant stakeholders as soon as practicable, unless the risk is assessed as low and the IMT considers that the risk can be managed locally.

The level of risk dictates the nature of communication to the system. This could be a communication sheet, if the risk is medium, or, if more severe, communication through the Safety Alert Broadcast System (SABS).

In particularly complex situations, urgent teleconferences can be convened with LHD/SN/SHS senior executives. During business hours Directors of Clinical Governance are the first point of contact. For urgent after-hours communication, notifications will be directed to Chief Executives or executive on-call.

In rapidly evolving high-risk or extreme incidents, the IMT can also consider issuing regular situation reports to facilitate consistent, efficient and timely updates to all key stakeholders.

The Safety Alert Broadcast System (SABS)

The Safety Alert Broadcast System (SABS) provides a systematic approach to the distribution of patient safety information to the NSW health system. It includes a mechanism to ensure any required actions for the management of patient safety issues are undertaken by health services. The SABS includes three tiers: Safety Alert, Safety Notice and Safety Information. The different tiers correspond to the level of risk identified. Guidance around using the SABS, including on roles and responsibilities, is outlined in the *Safety Alert Broadcast System Policy Directive* (PD2013_009).

The SABS notices are available on the NSW Health website and are also circulated to licensed private health care facilities.

Communication though specialty networks

Depending on the nature of the incident, the IMT can supplement communication with the system through relevant networks (e.g. pharmacy, clinical specialities, public health).

Communication with community-based health professionals

Communication with community-based health professionals (e.g. general practitioners) will be facilitated through Office of the Chief Health Officer, primarily through the relevant peak and professional bodies. Where possible, Office of the Chief Health Officer will arrange this through existing channels within the Ministry of Health.

Communication with licensed private health facilities

The Ministry's Legal and Regulatory Services Branch leads communication with licensed private health facilities. The Office of the Chief Health Officer can provide support for bulk SMS communication, as per the arrangements in the 'Rapid communication with NSW private health facilities' internal standard operating procedure.

Licensed private health facilities are required to ensure that processes are in place to respond to recall letters received from product sponsors. In addition, private health facilities are encouraged to routinely check the TGA's online searchable database for relevant notices and subscribe to TGA email updates.

Communication with the public

The IMT discusses direct communications with the public with the Ministry of Health Public Affairs Unit.

Table 4 maps out the broad responsibilities of key agencies for the distribution of communications.

Table 4: Channels of communication

Clinical Excellence Commission	• LHD/SN/LHNs (e.g. Chief Executives, Directors of Clinical Governance)* • NSW Therapeutic Advisory Group • Agency for Clinical Innovation networks via network managers/clinical directors • Cancer Institute NSW • Therapeutic Goods Administration
HealthShare NSW	• Suppliers and wholesalers • LHD/SN pharmaceutical contacts • Clinical product managers • Biomedical engineers
Office of the Chief Health Officer (Ministry of Health)	• Professional peak bodies (e.g. primary health networks) via existing channels • LHD/SN/SHSs (e.g. Chief Executives, Directors of Clinical Governance)*
Legal and Regulatory Services	• Licensed private health facilities

(Ministry of Health)	• Pharmacy networks and peak bodies
Public Affairs (Ministry of Health)	• Public via media

**Clinical Excellence Commission will be the primary point of contact with LHD/SN/SHSs. In instances of immediate, life-threatening risk, this responsibility may be shared by or transition to the Office of the Chief Health Officer.*

STEP 8: SURVEILLANCE

The Inter-agency Management Team (IMT) can review information from a range of sources, including the Incident Information Management System (IIMS), the Health Quality Reporting System (HQRS), the Public Health Rapid Emergency, Disease, and Syndromic Surveillance (PHREDSS) system and the Poisons Information Centre to identify any possible patient harm arising from a notification and to inform the ongoing risk assessment.

Health Protection NSW can provide recommendations on any enhanced clinical or laboratory surveillance.

STEP 9: DEBRIEF

The Clinical Excellence Commission leads an IMT debrief session following any significant coordinated response. The session aims to identify what worked well, as well as areas for enhancement.

6 LIST OF ATTACHMENTS

1. TGA notifications
2. Links to key documents

ATTACHMENT 1: Therapeutic Goods Administration notifications

The Therapeutic Goods Administration (TGA) regulates supply of prescription, non-prescription and complementary medicines, medical devices (for definition see: https://www.tga.gov.au/what-medical-device), products used to test for various diseases and conditions, vaccines and blood products. The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose.[1]

TGA recall actions under the Uniform Recall Procedure for Therapeutic Goods[2]

A recall action is an action taken to resolve a deficiency in relation to safety, quality, efficacy, performance or presentation with a therapeutic good already supplied in the market.

There are four distinct recall actions:

1. **Recall** – the permanent removal of an affected therapeutic good from supply or use in the market
2. **Product defect correction** – repair, modification, adjustment, update or re-labelling of a therapeutic good (corrects a specific or potential deficiency)
3. **Hazard alert** – information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
4. **Product defect alert** – information to raise awareness of concerns about safety, quality, efficacy or performance and describe actions that clinicians or patients may take to mitigate risks due to product deficiencies

The TGA formally issues recall actions to its identified NSW Recall Coordinator, the Clinical Excellence Commission (CEC). The CEC automatically forwards all recall actions to nominated contact points with local health districts, specialty networks and statewide health services.

This Policy Directive describes the process for managing the small minority of recall actions and other medicine or medical device-related notifications and issues that require urgent, system-level coordination.

Recall actions are also available from the TGA's website.

Note: sponsors have the primary responsibility for communicating to customers about recall actions, in accordance with the TGA's Uniform Recall Procedure for Therapeutic Goods.

[1] https://www.tga.gov.au/what-tga-regulates
[2] https://www.tga.gov.au/recalls-and-non-recall-actions

Recall classification

Recall actions are classified into one of the following classes based on the potential risk the deficiency poses to patients/consumers:

- Class I – reasonable probability that the use of, or exposure to, the deficient therapeutic good will cause serious adverse health consequences or death
  (for example: medicine label and box contents are different, or higher fracture rates for implantable cardiac leads that may result in implantable defibrillators not providing effective therapy)

- Class II – use of, or exposure to, the deficient therapeutic good may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote
  (for example: non-compliance with medicine specifications such as fill or weight, or infusion pumps giving visual or audible alarms due to software or hardware issues resulting in delay in infusion)

- Class III – use of, or exposure to, the deficient therapeutic good is not likely to cause adverse health consequences
  (for example: faulty packaging such as incorrect batch number, or the outer packaging of a medical devices that indicates a different size to the one supplied in the box, but it would be obvious to the clinician that the device was the incorrect size)

Recall level

The level of the recall determines who will be notified. There are four levels:

- Wholesale (for example, medicine and medical device wholesalers)
- Hospital (for example, those included in the wholesale level, plus others such as hospitals and ambulance services)
- Retail (for example, those included in the wholesale and hospital levels, plus others such as community pharmacists, supermarkets and dentists)
- Consumer (for example, those included in the wholesale, hospital and retail levels, plus patients and other consumers

ATTACHMENT 2: Links to key documents

This Policy Directive should be read in conjunction with the following NSW Health policy directives. Always check the NSW Health and TGA websites for the most current version of these documents.

DOCUMENT	SUMMARY
Safety Alert Broadcast System Policy Directive **(PD 2013_009)** http://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=PD2013_009	Outlines the Ministry of Health's approach to the communication and management of state-wide patient safety issues
Medication Handling in NSW Public Health Facilities **(PD2013_043)** http://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2013_043	Consolidates best practice principles on medication procurement, storage, prescribing, supplying, dispensing and administration at NSW public health facilities with the requirements of the NSW Poisons and Therapeutic Goods Act 1966 and the Poisons and Therapeutic Goods Regulation 2008, NSW Health policies and NSW Health directives relevant to medication handling
Incident Management Policy (**PD2014_004)** http://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2014_004	Provides direction for a consistent approach to managing and investigating clinical incidents and ensures processes comply with the requirements of the Health Administration Act 1982
Enterprise-Wide Risk Management Policy and Framework – NSW Health policy directive **(PD2015_043)** http://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2015_043	Describes the requirements for NSW Health organisations to establish, maintain and monitor risk management practices in accordance with the Australian/New Zealand Standard ISO 31000:2009, consistent with whole of government policies
Uniform Recall Procedure for Therapeutic Goods (Commonwealth) https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg-v20	Provides a consistent approach for undertaking recall and non-recall actions of therapeutic goods supplied, imported into or exported from Australia