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ALERTS, SAFETY NOTICES AND OTHER GUIDANCE PROCEDURE

Introduction and Aim

This procedure underpins the Alerts, Safety Notices and other Guidance Policy.

The aim of this procedure is to provide an effective and auditable management system for the distribution, monitoring and record keeping of all alerts, safety notices and other guidance throughout Public Health Wales.

It should be noted that the term alerts is used throughout this document to refer to alerts, safety notices and other guidance.

Linked Policies, Procedures and Written Control Documents

Alerts, Safety Notices and other Guidance Policy

Scope

This policy refers to all staff working within Public Health Wales. In the interests of brevity, the term staff is used throughout this document to refer to staff, contractors, agency staff, volunteers, and secondees.

Equality and Health Impact Assessment

This Procedure is covered by the EHIA for the Alerts, Safety Notices and other Guidance Policy

Approved by

Quality, Safety and Improvement Committee

Approval Date

15 January 2019

Review Date

15 January 2022

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Accountable Executive Director/Director

Director for Quality, Nursing and Allied Health Professionals

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Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Corporate Governance](#).

Summary of reviews/amendments

Version number	Date of Review	Date of Approval	Date published	Summary of Amendments
1.0		15/01/2019	06/02/2019	New document

1. Introduction

The aim of this procedure is to provide an effective and auditable management system for the distribution, monitoring and record keeping of all alerts throughout Public Health Wales.

Public Health Wales is committed to providing, so far as is reasonably practicable, safe and healthy working conditions, equipment and systems of work that minimise risk to the health and safety of all its employees, service users and others who may be working on Trust premises or undertaking work on behalf of Public Health Wales at locations across Wales.

This policy covers a wide variety of alerts issued from numerous bodies, including:

- The Department of Health Estates and Facilities (DHEFD)
- Shared Services Partnership – Facilities Management
- Public Health Links from the Welsh Government
- The National Patient Safety Agency (NPSA)
- The Medicines and Healthcare Products Regulatory Agency (MHRA) (Medical Devices and Pharmaceutical Alerts)
- Health and Safety Executive (HSE)
- National Institute for Clinical Excellence (NICE)

The list is not exhaustive and from time to time other documents may be received which require an equivalent response by the Trust.

This Procedure should be read in conjunction with the Alerts, Safety Notices and other guidance Policy.

2. Roles and Responsibilities

All staff will:

- Comply with the requirements of any alert issued through the Chief Risk Officer

The Chief Risk Officer will:

- Receive all alerts issued to Public Health Wales
- Maintain a register of all alerts and related actions taken
- Ensure that all alerts are assessed for applicability to Public Health Wales
- Where required, ensure that all alerts are disseminated, without delay to the relevant Directorate Business Manager

- Provide any required response to the issuing authority within the timescales defined
- Provide quarterly reports to the Public Health Wales Quality, Safety and Improvement Committee on the performance of the system
- From time to time audit the system to ensure compliance

Directorate Business Managers will:

- Receive all alerts issued through the Chief Risk Officer
- Ensure that all alerts are assessed without delay for applicability to their Directorate
- Within 7 days establish whether or not the alert is applicable to their Directorate and confirm the same to the Chief Risk Officer
- Ensure that any and all action required to comply with the alert are carried out within the timescales set out
- Respond to the Chief Risk Officer within the timescales set out confirming that all actions are complete or providing an explanation for any delays / non-compliances

3. Procedure

Grades of alert

Alerts / safety notices normally fall into four categories as follows:

Immediate Action

Used in cases of actual death or serious injury, or where death or serious injury would have occurred but for fortuitous circumstances or the timely intervention of healthcare professional (or a carer):

- Where the medical device is or is likely to be implicated:
- Where the recipient is expected to take immediate action on the advice.

Action

Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems, or to support or follow-up manufacturers' field modifications.

Update

Used to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device group bases, and where further follow-up safety information is judged to be beneficial.

Information Request

Used to alert users about specific issues that may become a problem and where feedback is requested.

Receipt of alerts and initial assessment

Alerts will be received through the Chief Risk Officer's team, usually by email and will be recorded on a central database.

The Chief Risk Officer will make an initial assessment in consultation with the business to establish if the alert applies to Public Health Wales. If it is immediately clear that the alert is not applicable, then a response will be sent to the issuing authority with no further action required on behalf of Directorates.

If there is any suggestion that the alert is applicable however, then this procedure will be followed.

Alerts requiring action

The Chief Risk Officer will distribute the alert, together with the Public Health Wales response form (see Appendix A) to all Directorate Business Managers.

Business Managers will be required to establish in consultation with their Directorate colleagues whether or not the alert applies to their Directorate.

If the Business Manager is satisfied that it does not, then they must complete the form (Appendix A) and return it to the Chief Risk Officer within 7 days of receipt.

If the alert does apply to the Directorate then the Business Manager must notify the Chief Risk Officer within 7 days of receipt, and provide an assessment of how much work is required to comply with the alert, along with confirmation that any deadlines given within the alert can be met. The Business Manager will then

complete Appendix A detailing the action taken and return the form as above.

Responding to issuing authorities

The Chief Risk Officer will ensure that any required responses are sent to issuing authorities within the deadlines set out by them when the alert is issued.

4. Training requirements

The Chief Risk Officer will provide training to all Business Managers in the implementation of this procedure.

5. Monitoring compliance

The Chief Risk Officer will from time to time audit the system to ensure compliance. A quarterly report will be provided to the Quality, Safety and Improvement Committee on the performance of the system.

Appendix A

Alert / Safety Notice Circulation Response Form (A)

Circulation of Alerts / Safety Notices	
Title of Alert / Safety Notice:	Date Received:
Directorate Business Manager to complete this section and return to the Chief Risk Officer within seven days	
Applicable to Division: Yes <input type="checkbox"/> No <input type="checkbox"/>	
If applicable please state action taken:	
Directorate Business Manager Signature:	Date

Form to be returned electronically to the Chief Risk Officer within seven days of receipt