SECTION 11: Medicine Recall and Alerts Procedure

This policy describes the procedure for responding to communications relating to medicines including Medicine Recalls, Drug Alerts, National Patient Safety Alerts, Immediate Public Health Messages and Medical Device Alerts:

(1) Internally across NHSGGC hospital and primary care practice as appropriate.
(2) Externally to health boards supplied by NHSGGC Pharmacy Distribution Centre (PDC).

This document should be read in conjunction with *Appendix 1 Pharmacy Services Management of External Communications Relating to Medicines Alerts* which provides details on types of communication and usual routes for receipt and dissemination.

1. BACKGROUND

Pharmacy Services (PS) have a responsibility to ensure that the above information, once received from The Scottish Government, Medicines and Healthcare products Regulatory Agency (MHRA) or other sources, are communicated effectively across the Board area and to ensure appropriate action is undertaken.

Pharmacy Public Health undertake communication of alerts on behalf of Pharmacy Services and for Medical Director. These communications are received by e-mail.

This policy has been prepared to ensure that such communications are handled promptly and efficiently and that information is disseminated to the relevant personnel within the appropriate timescale.

2. DEFINITIONS

National Patient Safety Alerts (NatPSA)

The National Patient Safety Alerting Committee (NatPSAC) was formed within NHS England to improve the effectiveness of communications relating to safety alerts. Whilst this committee has no remit in Scotland, there are occasions where the alerts from NatPSAC are applicable across the whole of the UK.

One of the processes developed was the introduction of national patient safety alerts, these alerts can only be issued from an accredited body. There is also a requirement for healthcare providers to review and update their processes for responding to these alerts. NatPSA must also conform to a particular format and meet given criteria before they are issued. Clear actions and timescales are included in these type of alerts.

NPSA alerts may be patient safety alerts or those that were previously classed as drug alerts.

Following this update, MHRA reviewed the classification for drug alerts (see Classification section). Those alerts previously called as Class 1 drug alerts, are now classified as National Patient Safety Alerts (NatPSA). Class 2, 3 and 4 have also been reviewed and renamed.

Medicine Recalls / Drug Alerts

Medicine manufacturers and importers are obliged to report to the MHRA any quality defect in a medicinal product which could result in a recall or restriction on supply. Where a defect is considered to be a risk to public health, the marketing authorisation holder withdraws the affected product from use and the MHRA issues a 'Drug Alert' letter.

The decision on whether a licence holder's recall action is supported by an MHRA Drug Alert depends on the amount of product distributed, the likely number of customers and the nature of the risk. For example if the licence holder has distributed relatively small volumes to a few customers and is able to contact these customers directly, a Drug Alert is unlikely to contribute significantly to the effectiveness of the recall, and may only be disruptive. Even when an MHRA Drug Alert is issued, the recall is still the primary responsibility of the licence holder. Action taken by the MHRA is secondary to and supportive of the action taken by the licence holder.

Company Led Recalls

In some circumstances, the MHRA allows company-led recalls which do not result in the distribution of a drug alert. Usually these are cases with a known and limited distribution. The response to these recalls will usually be led by the Pharmacy Distribution Centre for NHSGGC without Pharmacy PH involvement.

Communication may come from various routes, including MHRA alerts.

Medicine Supply Information (Shortages)

These types of alerts can be shared from various sources but usually relate to a significant disruption within the medicine supply chain, impacting on access to a particular medicine or product.

Management of these communications is primarily managed for Pharmacy Services by the Pharmacy Distribution Centre and Central Prescribing Team.

Appendix 1 provides further information on the different type of communications relating to drug alerts, recalls and other medicine related information.

Immediate Public Health (PH) Messages

Immediate PH Messages may arise from the Chief Medical Officer (CMO), Scottish Government Health Department (SGHD), Public Health Scotland (PHS), Department of Health (DoH) or Medicines and Health Regulatory Authority (MHRA) and may refer to:

- Suspension of a product license

- Warning of an adverse effect
- Introduction of precautions in use
- Cascade of a public health outbreak.

Depending on the alert, the Consultant in Public Health will advise on the cascade of information and actions required.

Medical Device Alerts
Medical Device Alerts have largely replaced Safety Action and Hazard Notices and are issued/published by MHRA for implementation across NHS Scotland.

Devices cover a wide range of equipment and testing materials, the majority of which are not directly relevant to pharmacy e.g.

- Devices used in life support / medical emergencies
- Equipment used by people with disabilities

Devices which are more relevant for PS attention include:

- Those used in the diagnosis or treatment of disease or patient monitoring e.g.
  - Blood glucose monitors
  - IV administration sets or pumps
  - Syringes and needles
- In vitro diagnostic medical devices or accessories e.g.
  - Cholesterol testing kits
  - Pregnancy testing kits
  - Other equipment or devices e.g.
  - Condoms
  - Stoma equipment.

Management of these alerts is led by the Pharmacy Services Business Performance and Review Manager team within Clarkston Court.

Other
Distribution of messages other than those received via the official networks (above) will occur in exceptional circumstances when deemed appropriate by the Lead PH Pharmacist (or nominee), relevant service lead, Lead Pharmacist Medicines Information or Regional Quality Assurance Pharmacist, in discussion with appropriate PS colleagues.

CLASSIFICATION

MHRA Drug Alerts are being renamed to Medicines Recalls (to replace what were previously Drug Alerts class 1-3) and Medicines Notifications (to replace what were previously Drug Alert: Caution in Use, Class 4). All Class 1 Medicines Recalls will meet the National Patient Safety Alert criteria and will be issued as National Patient Safety Alerts (NatPSA).

Further information on the classification system can be found here.

NatPSA Class 1 Alerts: Action within 24 hours (including out of hours)

The defect presents a life threatening or serious risk to health.

Class 2 Medicines Recall: Action within 48 hours

The defect may cause mistreatment or harm to the patient, but it is not life threatening or serious.

Class 3 Medicines Recall: Action within 5 days

The defect is unlikely to cause harm to the patient and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification.

Class 4 Medicines Notification: Caution in use

There is no threat to patients or no serious defect likely to impair product use or efficacy. This generally refers to minor defects in packaging or other printed materials.

3. FOCUS

The prime function of the pharmacy service following the raising of an MHRA drug alert is to prevent further issue or dispensing of the defective product. Medical, Nursing and other Health Care Professional Groups have their own systems of communication and it is the heads of these services who have responsibility for the effective communication within their professional groups and reporting to Medical Director to confirm actions undertaken

Additional pharmacy communication may be required to supplement this action by following up with clinical staff responsible for clinical areas who may have received the defective product via internal memo or direct communications at ward level.

Pharmacy will also be responsible for leading and coordinating the initial response, planning and implementation for a NatPSA where appropriate. (See section 5).

4. SCOPE

Alerts and Recalls will be sent to Distributors, Pharmacy teams, GP Surgeries, for patient level depending on the nature of the risk, class of alert, the amount of time that has elapsed since the batch was first distributed and the type of product. In most cases, a NPSA patient safety recall will require communication to patient level; however, this is product specific and assessment of the overall risk to patients must be conducted following initial interventions or steps to identify patients.

The timescales specified on Drug Alerts are advisory to indicate the priority with which action should be taken. Additional consideration should also be given to the mechanism of the communication cascade and the likely time for it to be received and acted on by the relevant healthcare professionals. A local assessment of the most appropriate mechanism and timing for the cascade should be taken initially by the Lead Pharmacist, PPH (or nominee), based on classification of alert. It is desirable to include patients own medicine systems in the

implementation of any action taken subsequent to an alert, irrespective of the classification of the alert or whether it explicitly directs 'patient level recall'.

Copies of Drug Alerts can be accessed at www.sehd.scot.nhs.uk/ and medicines safety information at http://www.mhra.gov.uk/Safetyinformation/index.htm

5. CONTEXT

On occasion, professional discretion is required in the management of medicine alert communications, in relation to speed of response and extent of communication. Pharmaceutical Public Health (PPH) is the principal recipient on behalf of PS.

The initial stage in the distribution of medicine alert communications involves Lead Pharmacist, PPH, or nominated depute. Consideration should be given to the required scope of the communication on a need to know basis, both for action and for information. Guidance on distribution will typically be provided by the originator of the message, although local adaptation may be required. The seriousness and urgency of the problem will also be considered e.g. whether a warning should be given by telephone initially and whether communication can be limited to a few recipients or a general notice is necessary.

In event of a NatPSA Class 1 alert that requires patient level action, Lead Pharmacist, PPH will work in collaboration with colleagues from Medicines Governance and Information, acute, primary care, community pharmacy and pharmacologists teams to identify and form appropriate short life working groups to respond to these alerts when necessary.

The routine implementation of these procedures is described below. The Lead Pharmacist, PPH may wish to liaise with colleagues in Community Pharmacy Development, Medicines Management and Acute and Mental Health Services to confirm the communication plan and to ensure awareness of the Alert and the requirement for distribution. In each of the primary recipient locations, a local procedure is required for the management of Alerts which includes detailed step-by-step instructions to describe the method for communication and the recording of the actions taken.

A summary of the types of medicine alerts and the required actions can be found in Appendix 1. Local teams will also have their own processes for action and implementation.

6. PROCEDURE

Pharmacy Public Health

1. On receipt of the message into the generic mailbox, PPH administration staff should immediately alert the Lead Pharmacist, PPH or depute, for instructions and authorisation to disseminate the alert.

2. The PH Pharmacist will review the alert and advise on communication as per Appendix 1.

3. Pharmacist and administration staff agree the circulation list and authorise the required communication procedure.

4. In event of the Lead Pharmacist PPH or depute being unavailable and a class 1 alert requires assessment, PPH administration should seek advice from Deputy Director of Pharmacy (Governance), Regional Quality Assurance Pharmacist or senior pharmacist from Medicine Governance and Information team.
   - For Class 2, 3 or 4 medicine recall or notifications, a delay within the specified time frame may be acceptable, to allow professional review by a PH Pharmacist.

5. Email the Drug Alert as follows:
   - Acute site generic inboxes …. for action/ information
   - Pharmacy Distribution Centre…for action /information.
   - CP Development Team …for cascade/ information to community pharmacies.
   - Prescribing Team …for cascade/ information to primary care HSCP pharmacy teams.
   - Pharmacy Services …for information
   - Chief Pharmacy Technician (Pharmacologists)…for action / information
   - Sector Chief Pharmacy Technicians …for action/ information
   - Team Lead Pharmacy Technician …for action/ information
   - Lead Clinical Pharmacists … for action/ information
   - Pharmacy Services Executive team ……. For information
   - Lead Pharmacist, Clinical Services (Primary care) …for information
   - Lead Pharmacist, Patient Services … for information
   - Professional Technical Manager …for information
   - PH Specialist Pharmacists…for information
   - Regional QA Lead Pharmacist ….. for action as required.
   - Medicines Information …..for action as required
   - Clinical Trials Pharmacy team ….. for action as required
   - Argyll and Bute HSCP ….. for cascade/information.
   - Primary Care Support …for cascade/ information to General Practice, dental and optometry.
   - GPs: Forward to Family Health Services Manager
     - This will cover GPs in both GG & Clyde, including locums
     - This will also cover Optical Practices, if required

   Please note that SGHD communications routinely advise that DPH or Medical Directors should communicate to GPs. In GGC, this is a PPH responsibility)
   - Out of Hours Service for communication to GP OOH Services
   - Practice Nurses: Forward to Practice Nurse Adviser
   - Dental profession-: Forward to Oral Health Project Manager for GP Dentists
   - For Dental Specialists in the Managed Service forward to Community Dental Service
   - Board Medical Director's PA / Nurse Director's PA….. for information/cascade.
   - Deputy Medical Directors (acute and primary care) …for cascade/ information
   - Sexual & Reproductive Health

- Private Hospitals
- Police Custody Suites
- Prison Health Managers
  - HMP Barlinnie Health Centre
  - HMP Greenock
  - HMP Low Moss
  - HMP Lilias
- Others e.g. Director of Public Health, Head of Public Health Protection Unit

6. **Individual sites have responsibility to check stock holding within their own area and to take appropriate action as per communication or alert.**

7. In the event that the Alert/Immediate Message applies to a GSL product, send to

- NHS GGC Communications Team:
- Media Relations Manager
- Senior Press Officer

This will allow communication via the local newspaper network in an effort to highlight the information in the public domain.

PS Recipients

Each of the primary recipients of the medicine alert communication should initiate local procedures to ensure timely and effective onwards communication and action to all relevant personnel, including responsibility they may have for any additional supply.

The Principal Pharmacist (QA/QC) will review all communications and may identify the need for supplementary information in selected cases in support of the local response by hospital and/or community pharmacists.

Special case for medicines pre-packaged by Pharmaceutical Services Scotland (PSS)

Note: PSS is the replacement name for Tayside Pharmaceuticals, Ninewells Hospital

Such medicines carry the PSS batch number only, not the original batch number assigned by the manufacturer. In the scenario where a batch of pre-packs may be affected by a Medicine Recall, PSS will be aware of the pre-pack distribution pattern:

- PSS will inform PDC of the affected products within NHS GGC
- PDC, via PPH, will notify the all GGC sites who in turn will:
  - Initiate recall arrangements and return stock as advised by PDC.

Special case for patient level recall

This occurs typically with a NatPSA Class 1 alert. The principle is to recall the relevant batch of the affected medicine from all locations, including where the batch is known to have been dispensed to individual patient e.g.

a. Hospital Pharmacy
    i. Medicines Management self administration systems
    ii. Discharge prescriptions
    iii. A&E pre-packs
b. Community pharmacy
    i. Individual prescriptions
    ii. Care home monitored dosage systems
    iii. Compliance aids

Clearly this adds a level of complexity to the procedures, with a need for patient counselling and assurance of continuity of supply via an unaffected batch.

As with NatPSA responses, Lead Pharmacist, PPH will be responsible for coordinating initial response and formation of an action group with representation from:

- Medicines Governance Team
- Primary Care
- Acute Pharmacy
- Community Pharmacy
- Any specialist group as required, e.g. mental health, addiction services

This group will be responsible for advising, coordinating and overseeing any appropriate actions provided within the alert or necessary in order to maintain the safety of the patients.

Out of Hours

In event of an alert requiring attention over the weekend or public holiday, a member of the Pharmacy Services Exec team will be contacted, usually be telephone, and are responsible for initiating the information cascade. This will involve emailing all community pharmacies using the email distribution list and alerting any on call pharmacy teams. This is the primary contact approach for community pharmacy contractors.

Communication to OOH GP services and prison services will also be required.

All other communication will be managed by PPH on the next working day.

Early Warning System

The Community Pharmacy Development Team has established a communication cascade for rapid dissemination of information which requires the urgent attention of the GGC Pharmacy Contractors e.g. to forewarn pharmacies of any incidents relative to drugs, i.e. forged prescriptions, drug problems, security matters, Class 1 drug alerts, Immediate PH messages etc

This is structured by HSCP. A 'master station' pharmacy has been identified for each HSCP. The contact details of each pharmacy in the cascade, together with their opening hours, are also

shown. The procedure involves the master station initiating the chain of calls by telephoning the next pharmacy on the list who in turn, will telephone the next pharmacy and so forth until the last pharmacy call to 'close the loop' with the Master Station thus completing the cycle.

A copy of the early warning system is available here.

Hospital Pharmacy Key Contacts

Hospital Pharmacy key hospital contact numbers are shown below. For out of hours (OOH) alerts that require action within 24 hours and before the next expected normal working day, a member of the Pharmacy Services Exec team will contact on-call pharmacist in each sector to initiate the full hospital pharmacy cascade. The same principle applies within normal hours through direct contact with the Sector Chief Pharmacy Technicians.

(a) South Sector - Queen Elizabeth University Hospital, New Victoria and Royal Hospital for Children

OOH for Queen Elizabeth University Hospital, New Victoria and Royal Hospital for Children – on call Pharmacist for QEUH/RHC via hospital switchboard (dial 1000).

Sector Chief Pharmacy Technician – 0141 452 2980

(b) North Sector - Glasgow Royal Infirmary, Stobhill, Gartnavel General Hospital. WoSOC, Vale of Leven

OOH for Glasgow Royal Infirmary and Stobhill – on call Pharmacist for GRI via hospital switchboard (dial 1000).

OOH for Gartnavel General, Vale of Leven – on call Pharmacist for GGH or VoL via hospital switchboard (dial 1000).

OOH for WoSOC - On-Call Pharmacist via WoSOC via switchboard (dial 1000).

Sector Chief Pharmacy Technician – 0141 211 4774

(c) Clyde Sector - RAH, Paisley and Inverclyde Royal Hospital

On call Pharmacist for RAH or IRH via hospital switchboard (dial 1000).

For outside of hospital, call RAH switchboard on 0141 314 7294

IRH switchboard on 0141 314 9504

Sector Chief Pharmacy Technician – 0141 532 7584

(d) Mental Health – all Mental Health sites

OOH for Leverndale, Gartnavel Royal, and Stobhill Mental Health Campus – On-call Pharmacist via hospital switchboard (dial 1000)

Sector Chief Pharmacy Technician – 0141 532 7584

(e) **Prep. Services**

Within hours Lead Pharmacist Preparative Services - mobile 07966942034
OOH - via NHSGGC Rotawatch - Pharmacy ON Call Aseptic City Wide

(f) **Clinical Trials**

OOH contact via generic mail box: r&dimp@ggc.scot.nhs.uk

7. ROLES AND RESPONSIBILITIES

The initial stage in the distribution of drug alert communications involves the Lead Pharmacist, PPH or nominated depute. It is their responsibility to assess classification of alert, timescales and scope of communication.

PPH administration will maintain up to date distribution lists and contacts for cascade of an alert to appropriate lists.

Once PPH have cascaded a drug alert by email to the appropriate list it is the responsibility of each speciality or service to cascade the information further e.g. CPD team to community pharmacy. Acute services should report affected stock to PDC; community pharmacies will utilise their own procedures and return to their wholesalers.

With the use of patients own medicines systems in hospitals, Pharmacists, Pharmacy Technicians, Nurses and Doctors need to remain vigilant to the fact that patients may still have defective medicines in their possession which they may bring with them on admission to hospital. It is recommended that drug alerts remain active for one month from the date of issue and that patients, who own medicines, when brought in to hospital, are actively checked against the alert for that time duration.

Further action – Class 1 alerts or patient level recalls

In event of a NatPSA class 1 alert, there will be a coordinated pharmacy led response, led initially by Lead Pharmacist PPh, supported by pharmacy colleagues. This will involve a response stakeholder group comprising of representation from key senior leads from acute, primary care, community pharmacy, and speciality groups as required e.g. alcohol and drug recovery service (ADRS), palliative care.

8. DOCUMENTATION

Appendix 1 Pharmacy Services Management of External Communications Relating to Medicines Alerts.

PPH SOP for communication and standard text of emails

OOH SOP for Pharmacy Services Exec.

Medical Device Alert SOP.

9. TIMESCALE

Timescales are set in accordance with the nature of the Alert or Recall by PPH

10. CONCLUSION

An effective communication for urgent information contributes to safe and effective use of medicines.

11. REFERENCES

Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)

Changes to MHRA Drug alert titles and classification - GOV.UK (www.gov.uk)

CAS - Search Alert (mhra.gov.uk)