11.9 Medicine Recall and Alerts Procedure

This policy describes the procedure for responding to Medicine Recalls, Drug 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)

1. BACKGROUND

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

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.

Immediate Public Health (PH) Messages

Immediate PH Messages may arise from the Chief Medical Officer (CMO), Scottish Government Health Department (SGHD), 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

They should typically be handled in the same way as a Class 1 Drug Alert to enable rapid cascade throughout PPSU.

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 Pharmacy 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

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 Governance or Regional Quality Assurance Pharmacist, in discussion with appropriate Pharmacy Services colleagues.

CLASSIFICATION

The MHRA uses an internationally agreed classification system for Drug Alerts, depending on the risk presented to the public health by the defective product. Each Alert is classified from 1 to 4:

Class 1: **Action now (including out of hours)**
The defect presents a life threatening or serious risk to health.

Class 2: **Action within 48 hours**
The defect may cause mistreatment or harm to the patient, but it is not life threatening or serious.

Class 3: **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 **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. Pharmacy communication will supplement this by following up with clinical staff responsible for clinical areas who may have received the defective product.

4. SCOPE

Alerts and Recalls will be to Distributors, Pharmacies, GP Surgeries, or patient level depending on the nature of the risk, the amount of time that has elapsed since the batch was first distributed and the type of product. In most cases, a Class 1 recall will require communication to patient level; however, this is product specific and assessment of the overall risk to patients must be conducted.

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 Public Health (PH) Pharmacist (or nominee). 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

Professional discretion is required in the management of drug alert communications, in relation to speed of response and extent of communication. Pharmaceutical Public Health (PPH) is the principal recipient on behalf of Pharmacy Services.

The initial stage in the distribution of drug alert communications involves the Specialist in Pharmacy Public Health (PPH) or their nominee who will be a Public Health Pharmacist (Lead for PPH). 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.

The routine implementation of these procedures is described below. The Lead for 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.

6. PROCEDURE

Pharmaceutical Public Health

1. On receipt of the message from the SGHD, refer PPH administration staff should immediately alert the Lead for PPH for instructions and authorisation.

2. The Lead for PPH will review the circulation list and authorise the required communication procedure (Drug Alert List 1, 2 or 3). Check with Pharmacy Distribution Centre if the medicine in question has been circulated by the PDC and if so, include a message to say "**Please return any affected stock to the PDC following standard PDC returns procedure within 1 week of receiving this alert and mark for the attention of the ULM Room**". In exceptional urgent circumstances, the Pharmacy Telephone Cascade will be activated.

3. If the Specialist in Pharmacy Public Health or Lead for PPH is not accessible, PPH administration should contact Medicines Governance Lead for advice. Otherwise:
   - For a Class 1 Alert, proceed with communication to all users
   - For Class 2, 3 or 4 Alerts, a delay within the specified time frame may be acceptable, to allow professional review by a PH Pharmacy Specialist

4. Email the Drug Alert as follows:

Drug Alert List 1: E-mail Routine*:

- Chief and Sector Chief Pharmacy Technicians/Team Leads
- Lead Clinical Pharmacists...for action / information
- Chief Pharmacy Technician (Pharmacologistics)…for action / information
- Lead Pharmacy and Patient Services and Lead Directorate Pharmacists…for information.
- Pharmacy Distribution Centre (support@ggcpdc.zendesk.com)…for action /information.
- Lead MH Partnership and Community Services Pharmacist…for information.
- CP Development Team Leads…for information.
- Head Prescribing Governance for Central Prescribing Team…for information.
- Clinical Governance Lead Pharmacist…for information
- The Head of Non-Medical Prescribing…for review and onwards communication, as required
- Regional QA Pharmacist
- PH Specialist Pharmacists…for information
- Pharmacy PH Facilitators …… with particular interest in
  - All Immediate PH Messages
  - Any Medicine Recall, Immediate PH Message or Medical Device Alert which has implications for community pharmacy
- Medicines Information …..for action as required
- Head of Pharmacy services / PA & Lead for Acute Care, Mental Health & Innovation … for information.
- Board Medical Director's PA….. for information.
- Chiefs of Medicine.... for action as required.
- NHS GGC Specialist Pharmacists (Addictions Team)
- Sexual & Reproductive Health
- Private Hospitals*
- Police Custody Suites
- Prison Health Managers
- Barlinnie Health Centre

- Greenock Prison
- Low Moss Prison
- NHS Highland.... for action as required

Drug Alert List 2: Email: Community Pharmacy

- The CP Development Team via the customised distribution list (Drug Alert List for Community Pharmacy) …

Drug Alert List 3: E-mail: Selective*

- 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
- Others e.g. Director of Public Health, Head of Public Health Protection Unit

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.

Pharmacy Services Recipients

Each of the primary recipients of the Drug Alert / Immediate PH Message / Medical Device Alert will initiate local procedures to ensure timely and effective onwards communication 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.

*PPH administration maintain contact lists

Special case for medicines pre-packaged by Tayside Pharmaceuticals

Such medicines carry the Tayside 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:
Tayside will be aware of the pre-pack distribution pattern:

- Tayside will inform PDC of the location of the affected batches in NHS GGC
- PDC will notify the relevant 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 Class 1 Drug Alert / Medicine Recall. 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 patients 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

Out of Hours / 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.

This information together with a register of late opening and Sunday opening pharmacies can be found on the Pharmacy Services shared drive (intranet site), via the following path: \\sgd-fs-vs\s-pharmacy$\COMMUNITY CARE\COMMUNITY PHARMACY\Contracts Team\Early Warning System

Field Code Changed

Hospital Pharmacy Key Contacts

Hospital Pharmacy key hospital contact numbers are shown below. For out of hours (OOH) contact a single telephone call from Pharmacy Public Health to each sector should be sufficient 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**

OOH for RAH, Paisley and IRH – on call Pharmacist for RAH on 07919698044

Sector Chief Pharmacy Technician – 01412 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**

Sector Chief Pharmacy Technician – 0141 355 1651

*PPH administration maintain detailed contact lists

7. ROLES AND RESPONSIBILITIES

The initial stage in the distribution of drug alert communications involves the Specialist in Pharmacy Public Health or Lead for PPH. It is their responsibility to assess 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.

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.

8. DOCUMENTATION

There is no specific documentation

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

http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf