11.6: GGC Suspected Medicines Defects Policy

This policy describes the Procedure for responding to and reporting suspected defects in medicines and other healthcare products, both
(1) Internally across hospital and primary care practice as appropriate and
(2) Externally from NHS Greater Glasgow & Clyde (GGC) to Scottish Government (Chief Pharmaceutical Officer), National Procurement and the product manufacturer.

1. BACKGROUND

The circular covering this arrangement stems from 1991 and in recent years the Pharmaceutical Public Health (PPH) section has taken the lead role for NHS Greater Glasgow and Clyde. A consistent approach is required across Pharmacy & Prescribing Support Unit (PPSU). There are practical advantages for the PPSU in this arrangement – the Sector Chief Technician or Community Pharmacist can focus on the immediate local needs and can remain at 'arms length' from the communication process in consultation with the Leads for Quality Assurance (QA) / Quality Control (QC) and Medicines Information (MI).

2. DEFINITION OF A DEFECT

It is sometimes difficult to distinguish suspected defects from medication incidents, medication errors and adverse drug reactions. Defects should focus on the actual or potential consequences of a medicine which does not conform to specifications.
The Medicines & Healthcare products Regulatory Agency (MHRA) defines a defect has occurred when

- Proves to be harmful under normal conditions of use.
- Lacking in therapeutic efficacy.
- The qualitative and quantitative composition of the product is not as declared.
- The controls on the medicinal product and/or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out.

3. CLASSIFICATION OF A DEFECT

Hazardous: A defect, which has the capability to adversely affect the health of the patient.
Major: A defect, which impairs the therapeutic activity of the product but may not be hazardous.
Minor: A defect, which has no important effect upon the therapeutic activity of the product, and does not otherwise produce a hazard.

4. FOCUS

PPSU involvement will be restricted to medicines / pharmaceuticals which are supplied via Pharmacy (Pharmacy Distribution Centre, PDC) or direct to hospitals via national contract (e.g. infusion fluids).

Separate consideration is required for reporting suspected defects / incidents associated with (a) vaccines and (b) products (e.g. devices) which are utilised to administer medicines. Procedures for vaccines are currently subject to review via Health Protection Scotland.

Procedures for devices have been highlighted in (January 2007) communication from MHRA and updated January 2008. This has been superseded in NHS Scotland by advice that "all adverse incidents involving medical equipment should be reported to Scottish Healthcare Supplies" (SAN(SC)07/01).

5. SCOPE

This procedure applies to both the managed service and community pharmacy; in the former case, PPSU Clinical Governance / Risk Management can support both the content and the process for communication; in the latter case, the Community Pharmacy Development Team will function as the conduit for communication.

6. CONTEXT

The PPSU has a duty to ensure that all potential or suspected medicine / product defects are given due attention and are communicated to the relevant personnel for appropriate action:

(a) The defect may detected by a healthcare professional prior to issue to patients
or
(b) A consensus may be reached that a clinical incident has occurred which may be attributable to a defective medicinal product

In either case, a medicine defect form should be completed by the pharmacist/technician to whom the defect was reported and forwarded in the first instance to Lead Specialist in Pharmaceutical Public Health (SiPPH) for action and the Sector Chief Technician for information. The reporting individual should also advise their lead clinical pharmacist.

In community pharmacy all cases should be referred to the Responsible Pharmacist if identified by another member of staff. The community pharmacy contractor must ensure that there are robust systems in place to comply with notifications of defective products. As defective medicines and appliances have implications for the wider health service, there is a clear responsibility to inform the supplier of the product and the MHRA. The Community Pharmacy Development Team should also be advised of any action taken.

The SiPPH will in turn liaise with the Leads for QA / QC and Medicines Information to determine the action to be taken. Consultation when required will be undertaken with the PPSU Leads for Acute Services, Clinical governance, Primary Care and Prescribing Advice.

Each case will be unique and the circumstances may be exceptional. It is vital to establish the right 'threshold' for reporting to a wider audience across the Board, via regional or national Directors of Pharmacy and if required to Scottish Government / Chief Pharmaceutical Officer. An internal 'case by case' review should be undertaken, based on the classification definitions on p1, with potential actions to include:

- *Caution in use*
- *Interim quarantine of suspect batch or batches*
- *Withdrawal of a product line*

7. PROCEDURE

See Appendix B. The suspected defective product must be retained and preserved. If samples are required for analysis or other purposes, they should ideally be obtained from another part of the same batch. If these samples would not provide the information needed the material implicated should be used.

- Useful questions to consider
  Was the product stored correctly? (To exclude incorrect storage as the cause of the suspected defect)
- If the defect is visible, was the defect identified in a new previously unopened container or had the container previously been used? (To exclude user errors such as product mix-ups)
- Are there other unopened containers of the same batch available, which could be checked?
- If the product requires preparation, such as addition of a diluent, was the correct procedure followed and/or correct diluent used?
- If the product is used with a medical device, could the device be the cause of the incident?

The pharmacist or technician initially contacted should complete a proforma after eliciting the details from the relevant healthcare professional (see attached) to record all the relevant information about the product and any related clinical incident; patient confidentiality should be maintained at all times. In community pharmacy the community pharmacy development team will determine if a defect form is required to be completed.

1. This should be referred in the first instance to one of the Specialists in Pharmaceutical PH (SiPPH). A copy should be forwarded to pharmacypublichealth@ggc.scot.nhs.uk
2. The clinician involved should be recommended to record the medicine defect in DATIX. This should be recorded as incident type (patient clinical), category (medication incident) and sub category (expired/defective medicine)

3. If internal PPSU review is desirable, this should include consultation with the Principal Pharmacist (Medicines Information) and the Regional QA Pharmacist.
4. Assuming the defect is clear, and the potential impact hazardous the SiPPH should immediately communicate the information to Scottish Government via the Chief Pharmacist's Office Irene.Fazakerley@scotland.gsi.gov.uk
5. If required QA should report to MHRA via https://yellowcard.mhra.gov.uk/
6. While a product is 'under suspicion', it should be retained on site for further examination and sent to Regional QA Pharmacist.
7. Direct communication between clinical personnel and the license holder / manufacturer is discouraged, in relation to suspected defects and individual patients. It may be more appropriate for the Site Pharmacy Manager /Sector chief technician/ Community Pharmacy Development Team member to establish this line of communication. This is undertaken in liaison with Regional QA pharmacist on a case by case basis.
8. If possible repercussions are identified beyond the original 'locality, the SiPPH should communicate the completed proforma (Step 1) across the PPSU, with advice that the suspected defect has been identified locally. The batch should be quarantined until investigations are complete.
9. An outcome will be sought, whether reassurance that this was an isolated incident or notification that it merits a 'Medicine Recall' or 'Safety Action / Hazard Notice'. This will be communicated via the SiPPH to the relevant PPSU personnel.
10. If the item is on national contract and the medicine defect has been identified as hazardous or major or minor >1 occasion then national procurement should be informed. In PPSU this duty is undertaken by the Pharmacy Distribution Centre pharmacologistics manager
11. Appendix C includes a list of Dos and Don'ts for Medicines Defect reporting

8. ROLES AND RESPONSIBILITIES

- The "Reporter" should complete the form promptly or work with clinical staff to assist completion and then send to Public Health.
- A sample should be sent to QA who will discuss and liaise with the local technical staff regarding counting and quarantine of the affected stock if applicable and also liaise with the local Lead Clinical Pharmacist if local quarantine is required.
- The Lead Clinical Pharmacist's role is awareness of need for quarantine and clinical advice to support risk assessment.
- Lead Clinical Pharmacists to encourage progress of individual report and communicate as appropriate to clinical staff and encourage them to complete the DATIX.
- PPH, QA and MI are responsible for overall risk assessment.
- QA are responsible for liaison with the manufacturer.

9. DOCUMENTATION

Documentation relating to defects is available on GGC Prescribing website to include policy and blank medicine defect proformas http://www.ggcprescribing.org.uk/medicines-policies/ or blank medicine defect proformas on DATIX at http://datix.acute.xglasgow.scot.nhs.uk/datix/docs/ppsu.html and additionally with completed individual medicine defect forms and register of previous suspected defects. Sgd-fs-vs.south.xglasgow.scot.nhs.uk\s-pharmacy$\GOVERNANCE\PHARM PUBLIC HEALTH\Medical Defects

Individual defect reports are accessed on the GGC pharmacy shared drive. Public Health update the initial submitted defect form in real time as they receive updates from those involved in investigating them (including replies from manufacturers, QA etc). If this is not on your computer you need to map to the network drive and the pathway is \\sgd-fs-vs\S-Pharmacy$ Access is via the Governance / Public Health / Medicine Defects folders.

10. TIMESCALE

The interval from identification of the suspected defect to completion of the enquiry (via Scottish Government Health Department (SG) / Department of Health (DoH) / Manufacturer) may extend however PPH will routinely monitor outstanding issues to ensure completion within 12 weeks. Any unresolved reports after 6 months, despite repeated prompts to the company, will be closed and in discussion with MI and regional QA a decision made to escalate to SG.

A regular 'Open Defects' report will be circulated by PPH across PPSU identifying all current medicine defects.

11. CONCLUSION

This guidance will be incorporated within PPSU policies and procedures. The Regional QA Pharmacist and the Lead SiPPH will have joint responsibility for policy review and procedure monitoring. A summary report of all medicines reported will be completed annually by SiPPH for review by PPSU Executive.

12. REFERENCES

- 'A guide to defective medicinal products ... for healthcare professionals, manufacturers and distributors'. MHRA (2004) http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007572.pdf
- 'Medical device alert'. MHRA (2007), MDA/2007/001
- 'Reporting adverse incidents and disseminating safety warnings in Scotland'. Scottish Healthcare Supplies (2007), SAN(SC)07/01
- Device Bulletin reporting adverse incidents and disseminating medical device alerts DB 2008 (1).
- Guidance to NHS Scotland Hospital Pharmacy Services for investigating and reporting suspected defective medicines final draft (June 2011)

APPENDIX A: Defect Reporting Form

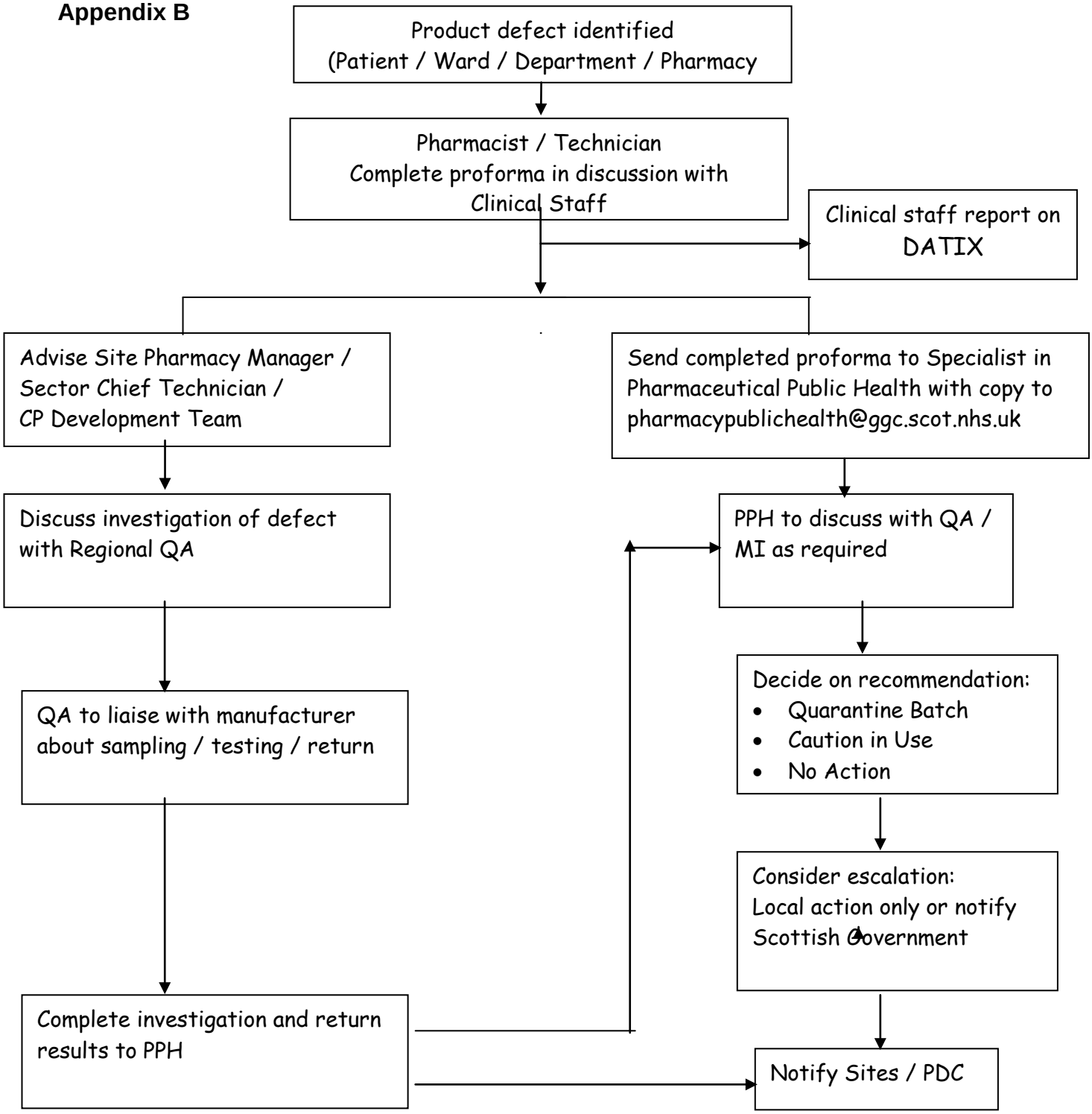
Information required when reporting defects in Medicinal Products send to pharmacypublichealth@ggc.scot.nhs.uk

Origin of report: Name of Reporting Pharmacist / Technician / Ward Staff	
Position and Status	
Name of Ward Pharmacist if appropriate	
Department / Hospital / Community Pharmacy	
Name of Lead Clinical Pharmacist	
Product: Name (Approved and Brand)	
Manufacturer	
Dosage Form / Strength / Route of Administration	
Container Type and Size	
Batch/Lot No(s).	
Expiry Date	
a) Clinical observations: • Incident(s) leading to the suspicion the product is defective	
• Clinical implication(s) and consideration whether the defect is minor, major or hazardous	
• Name of doctor/nurse involved	
• Location of Incident	
• Date of Incident	
• Has incident been recorded on DATIX? (ward staff should be promoted to complete)	
b) Pharmaceutical observations: • Is the product available locally or nationally? (PDC to complete)	
• Is distribution of product batch known to NHS Board? (PDC to complete)	
• Is the item on national contract? If yes, has report to NP been sent? (PDC to complete)	
• Has the pharmacy a stockholding of other batches of the same product?	
• Approximate length of time during which the suspect batch of material has been in use?	
• Information on storage /reconstitution of the product?	

c) Actions: • Summary of action taken. • Please complete all details as fully as possible and to note: sample of affected product should be forwarded to QA for investigation.	
• Has the manufacturer been informed? (QA to complete)	
Recommendation: Caution in Use * / Quarantine / Immediate Withdrawal / Replacement (PPH to complete)	
For PPH use only: Ref Number:	

Note: * Definition of terms in NHSGGC Suspected Medicines Defects Policy at www.ggcprescribing.org.uk/medicines-policies/

Appendix B



For full details see N:\GOVERNANCE\PHARM PUBLIC_HEALTH\Medical Defects\Policy , http://datix.acute.xglasgow.scot.nhs.uk/datix/docs/ppsu.html or http://www.ggcprescribing.org.uk/medicines-policies/

Appendix C Suspected Medicine Defects

A regular report of the current medicine defects reports is circulated throughout PPSU. To review progress, refer to the appropriate defect form available on the shared drive. If this is not on your computer contact IT to request that your login account is added to the "SGH-Pharmacy-Governance (FC)" Group in XGGC/SGHDOM. You will be asked for your logon name and the domain that you normally log on to.
Recommendations include:
Caution in use: No specific action but report any future occurrences as soon as possible
Quarantine: Ensure extent of quarantine is recorded on defect form
Withdrawal from use: Ensure colleagues are aware and appropriate replacement product is available for use
If you have update on the progress of any defect please advise pharmaceutical public health in order that PPH can update the form on the shared drive
Do

- Refer to the guidance document on NHSGGC Prescribing website http://www.ggcprescribing.org.uk/medicines-policies/ (Section 11).
- Advise the clinician e.g. nurse, medic, AHP reporting the incident to complete a DATIX report.
- Ensure a copy of the Defect Report is sent to Pharmacy Public Health (PPH) at pharmacypublichealth@ggc.scot.nhs.uk promptly
- Ensure you note the name of the Lead Clinical Pharmacist with responsibility for the department on the Defect Report form to help PPH escalate action on a defect when necessary.
- Add all relevant detail to the Defect Form as soon as possible as personnel may forget details of the incident very quickly. (Refer to the 'Useful Questions to Consider' section of the guidance document to help you decide what is needed).
- Advise any other local team members e.g. Chief Sector Technician, clinical pharmacists, ward pharmacists that you have filed a Defect Report as appropriate.
- Forward any appropriate samples of the affected medicine to the Regional Quality Control Pharmacist (RQAP) at the Pharmacy distribution Centre clearly marked for their attention. (Make a note on the Defect Report form if a sample is unsuitable to be forwarded to the RQAP).

Don't

- Assume a more senior member of staff will undertake the task, this might cause an unnecessary delay and details of the incident may be lost or a report may not be made.
- Group defect reports for the same product together. There may be completely different clinical outcomes for the patients involved and it might give false assurance of the scale of a defect.
- Forget to monitor medical defect reports of medicines subject to 'Caution in Use' advice if a repeat event occurs, check that the status of the defect does not change to 'Quarantine' status.
- Delay reporting a medicines defect because you're not sure of its classification, the Defect Form can be amended at a later date and PPH will advise what approach is required after discussion with the RQAP e.g. 'Caution in Use'.
- Send samples of an affected medicine or appliance which clearly pose a biohazard to the RQAP e.g. bloodstained items, syringes which have been used to inject medicines, sharps.
- Amend the Defect Report form on the Shared drive. If amendments or updates are required contact PPH at pharmacypublichealth@ggc.scot.nhs.uk
- Forget to tell your local team that you have filed a Defect Report