

EAST MIDLANDS DRUG ALERTS/RECALLS

Information & Procedures

Drug Alerts

Manufacturers and importers are obliged to report to the Medicines & Healthcare Products Regulatory Agency (MHRA) any quality defect in a medicinal product which could result in a recall or restriction on supply/ use. Other users and distributors of medicinal products are encouraged to do this. Where a defect is considered to be a risk to public health, the marketing authorisation holder withdraws the affected product from use.

MHRA Drug Alerts

In the majority of cases the MHRA issues a 'Drug Alert' letter. This alert is classified from 1 to 4 depending upon the risk presented to the public health by the defective product. Class 1 is the most critical, for example serious mislabelling, microbial contamination or incorrect ingredients, and requires immediate recall; Class 4 is the least critical and advises 'caution in use'.

MHRA Drug Alert Classifications:

- Class 1 – Immediate action (includes out of hours)
- Class 2 – Action within 48 hours
- Class 3 – Action within 5 days
- Class 4 – Caution in use

Trent Medicines Information Centre (TMIC) are the MHRA point of contact within the East Midlands for the cascade of MHRA Drug Alerts to hospital Trusts within the East Midlands

Company-led alerts

On occasion a company may issue a company-led alert. These have been deemed not to meet the criteria for a full MHRA Drug Alert, either because the defect is less serious or because the drug is used in a relatively small cohort of patients.

Company-led alerts do not have the same classification system as a MHRA Drug Alert. Severity of risk should be included in the body of the text of the document, but this is not always the case.

Some, but not all, company-led alerts are distributed via the MHRA email alerting system and are available at the MHRA company-led recall website (<https://www.gov.uk/government/publications/medicines-company-led-recalls>).

In some cases, the manufacturer may issue a company-led alert via an alternative route, e.g. through the wholesaler or direct to dispensaries.

Unlike the MHRA Drug Alert cascade, there is no formal NHS cascade system for company-led alerts.

East Midlands Drug Alert Cascade

This document describes the cascade process within the East Midlands for all MHRA Drug Alerts and for company-led recalls distributed either via the MHRA, or which Trent Medicines Information Centre are made aware of by an alternative route. Hereafter, both MHRA alerts and company-led drug alerts will be jointly referred to as 'drug alerts'.

1. In-hours Drug Recalls

In-hours will be defined as 09:00 to 16.59: Monday to Friday, excluding Bank Holidays.

- 1.1 The MHRA will email MHRA Drug Alerts to TMIC, Leicester Royal Infirmary to initiate the cascade to designated hospitals in the East Midlands Area. TMIC will additionally identify and process company-led recalls which are distributed through the MHRA email alerting system. TMIC will also cascade any other company-led recalls which they become aware of by any other alternative route if they deem this to be appropriate.
- 1.2 All Drug Alerts, whatever their class or origin, will be faxed by TMIC immediately with a fax cover attached to hospitals on the 'In hours' distribution list. (Appendix A).
- 1.3 A confirmation email of the Alert will be sent to up to two defined recipients in each location (*e.g. Chief Pharmacist, MI pharmacist, procurement lead etc.*) which will also request email confirmation of receipt of fax.
- 1.4 Control Sheet (CS1) must be used by the TMIC staff to record the process.
- 1.5 On completion of the process attach a copy of the Alert, fax cover, fax report and confirmation email to the Control Sheet. This should then be signed by the person undertaking the process and the Director of TMIC.
- 1.6 This documentation will be scanned for permanent archiving and the record held on the Trent MI shared computer drive. The hardcopy originals will be retained for 12 months.
- 1.7 Recipients listed in Appendix A will be responsible for local cascade (wards, MI, QC, other hospitals etc.) according to local policy and with appropriate documentation.
- 1.8 If the time of the receipt of the MHRA email and/or the urgency of the message demands it, TMIC will also institute a telephone notification to hospital contacts.

2. Outside working hours Drug Recalls

Out of hours will be defined as 17.00 to 08.59 Monday to Friday, all day Saturday and Sunday and Bank Holidays. **This process will only be used for Class 1 MHRA Drug Alerts. Other Alerts will be deferred for action on the next working day. Note that company-led recalls will not occur out of hours.**

- 3.1 Out of hours, the MHRA will contact the UHL on-call pharmacist directly by telephone (via the UHL switchboard). Details of the Alert should be documented on Control sheet CS2.
- 3.2 The MHRA will also post the alert on the [CAS website](#). Click on the CAS link, find the alert and print off a copy.
- 3.3 The UHL On-Call Pharmacist must then fax the alert to the following hospitals (see Appendix B):
 - Pharmacy – Queens Medical Centre (QMC), Nottingham
 - Pharmacy – Royal Derby Hospital (RDH)
 - Pharmacy – Lincoln County Hospital (LCH)
 - Pharmacy – Sherwood Forest Hospitals (SFH)

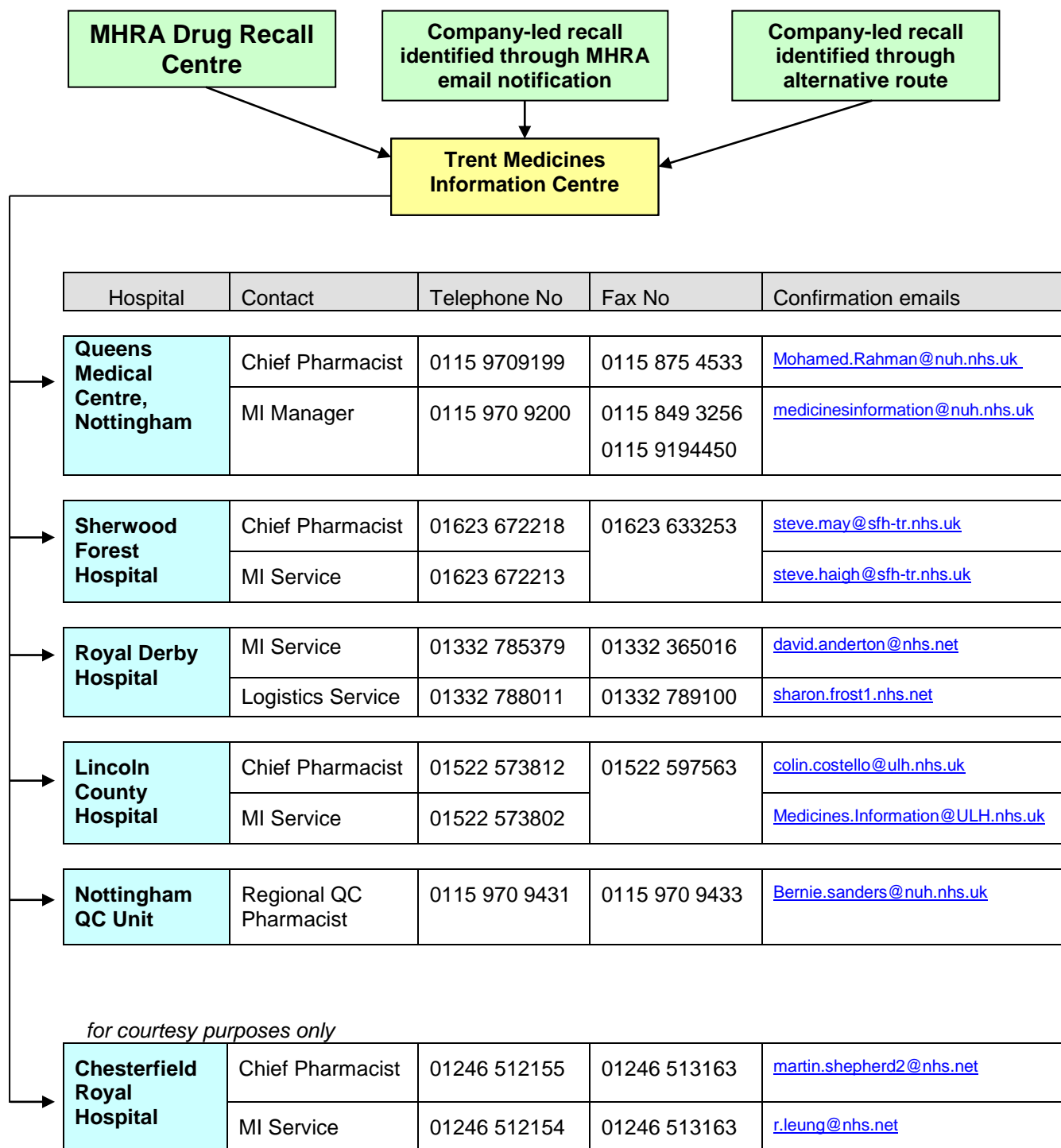
- 3.4 This should be followed up with a telephone call via the hospital switchboards to alert them that a Class1 Alert has been faxed.
- Ask for the most senior pharmacist on duty if the pharmacy department is likely to be open.
 - Otherwise ask to be connected to the on-call pharmacist.
 - Say that **“an urgent Drug Alert has been received, which requires immediate attention”**.
- 3.5 Control Sheet (CS2) must be used by the UHL on-call pharmacist, to record all stages of the process.
- 2.1 On completion of the process, the Control should be signed by the person undertaking the process and sent to the Director of TMIC for signing (leave with MI admin staff).
- 3.6 If further action is required by MI staff, ensure that clear instructions are left for them if unable to instruct them personally. Seek confirmation subsequently that action has been taken.
- 3.7 The On-call pharmacists at RDH, QMC, LRI, LCH and SFH will initiate local cascade processes, including Mental Health Trusts where appropriate, as defined by local policy.

3. Governance issues

- 4.1 It is the responsibility of all Trusts (Lead, secondary and tertiary) to additionally initiate the local cascade process as defined by local policy.
- 4.2 It is the responsibility of all Chief Pharmacists to ensure that staff are trained and familiar with the procedures for both in-hours and out-of-hours Alerts
- 4.3 TMIC will put in place an audit process to demonstrate that all components of the scheme are working satisfactorily and in accordance with MHRA and Trust requirements. This will include a regular ‘test’ of the out-of-hours process.
- 4.4 The latest version of this policy will be found on the Midlands Medicine website at http://www.midlandsmedicines.nhs.uk/medman/drug_recalls

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Appendix A: Working hours drug alert cascade



Control Sheet 1 (CS1)

ALL DRUG ALERTS - IN-HOURS DRUG ALERT RECORD FORM

The following processes need to be undertaken for all Drug Alerts.
Hospitals must be faxed immediately with a follow-up email.

Drug Alert Details		Reference No: EL
Date:	Time of notification from MHRA:	Message taken by:
Product:	Batch No:	PL No:
Action required:		
Reason for recall:		

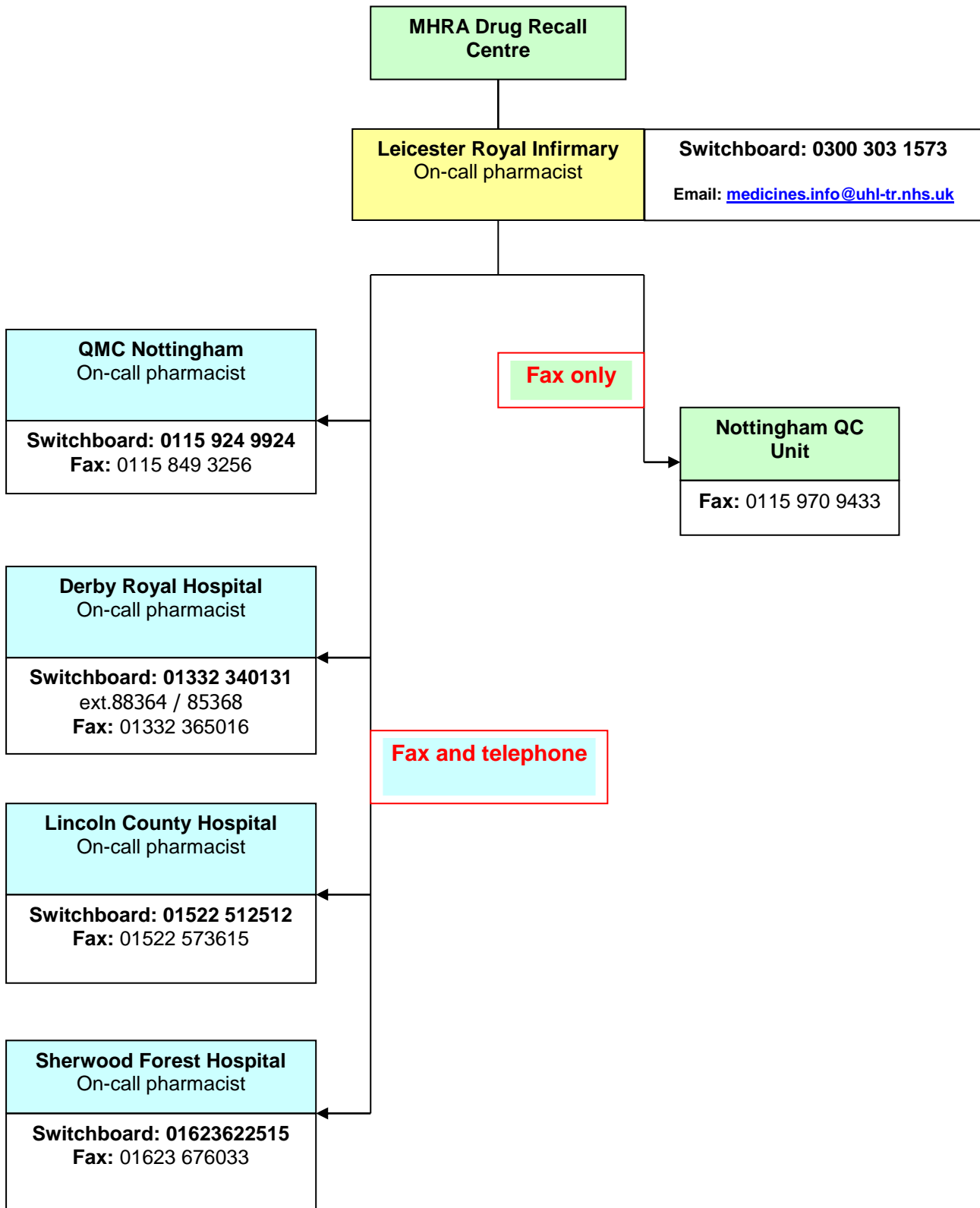
Action for TMIS	Time faxed	Time phoned (pm)	Time emailed	Time of feedback email
Royal Derby Hospital				
Lincoln County Hospital				
Nottingham QMC				
Sherwood Forest Hospitals				
Regional QC Service				
Chesterfield Royal Hospital				
Leicester Royal Infirmary	for local Leicestershire cascade			

Date completed:.....

Signature:

Signature (Director TMIC)

Appendix B: Out-of-hours drug recall cascade



Control Sheet 2 (CS2)

CLASS 1 DRUG ALERTS – OUT-OF-HOURS DRUG ALERT RECORD FORM

The following telephone processes needs to be undertaken for Out-of-Hours Class 1 Drug Alerts. Hospitals must be faxed and telephoned immediately. Telephone numbers are mostly hospital switchboard telephone numbers - the On-Call pharmacist needs to be contacted. It will normally be necessary to leave the telephone number for the On-Call pharmacist to call back.

Drug Alert Details https://www.cas.dh.gov.uk/Home.aspx			Reference No: EL	
Date:	Time of notification from MHRA:	Message taken by:	Drug Alert Class:	
	Product:			
	Company:			
Batch No:			PL No:	
	Action required:			
	Reason for recall:			
Hospital	Time faxed	Time message given to On-call pharmacist	Name of pharmacist spoken to	
Nottingham QMC				
Derby Royal				
Lincoln County				
Sherwood Forest				
Regional QC		N/A		
Trent MIC		N/A		

Date completed:

Signature:

Return to Trent MI Service when complete:

Fax: 0116 258 5680 Email: medicines.info@uhl-tr.nhs.uk