

EAST MIDLANDS DRUG ALERTS/RECALLS

Information & Procedures

1. **MHRA 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. 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 and 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

2. **In-hours Drug Recalls**

In-hours will be defined as 09:00 to 17:00 Monday to Friday, excluding Bank Holidays.

- 2.1 Drug Alerts will be received by the Trent Medicines Information Centre (TMIC), Leicester Royal Infirmary, by fax from the Medicines & Healthcare Products Regulatory Agency (MHRA), London.
- 2.2 All Drug Alerts, whatever their class, will be faxed by TMIC immediately to the 'In hours' distribution list (Appendix A).
- 2.3 An email confirmation copy 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.
- 2.4 A Control Sheet (CS1) will be completed, to which will be attached a copy of the Alert, fax cover, fax report and confirmation email.
- 2.5 On completion of the process, the Control Sheet will be signed by the person undertaking the process and then the Director of Medicines Information.
- 2.6 This documentation will be scanned for permanent archiving. The hardcopy originals will be retained for 12 months.
- 2.7 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.
- 2.8 If the time of the receipt of the FAX and/or the urgency of the message demands it, TMIC will also institute a telephone notification to hospital contacts.

3. Outside working hours Drug Recalls

Outside working 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 Alerts. Other Alerts will be deferred for action on the next working day.

A. Lead Trust (Derby)

- 3.1 Drug Alerts will be received by the On-Call Pharmacist, Royal Derby Hospital (RDH), by fax from the MHRA. There will be an initial warning of a pending Alert by phone, normally followed by a fax of the Alert.
- 3.2 The RDH On-Call Pharmacist must confirm that the MHRA will fax the alert to the RDH Pharmacy fax (**01332 365016**).
- 3.3 The RDH On-Call Pharmacist will determine the appropriate course of action dependant on the urgency of the Alert and the time received from the MHRA:

| DRUG ALERT RECEIVED | ACTION |
|--|---|
| After 5.00 pm on Monday – Thursday or Sunday | Assess the importance of the Alert. If it cannot wait till the following morning, proceed as in 3.4. If it can wait, hold until the next morning and pass the Drug Alert proforma to Admin / MI Staff who will action as if received as an 'In-hours' alert (see section 2 above) |
| After 5.00 pm on Friday | Proceed as in 3.4. |
| Any time Saturday or any time up to 5.00 pm on Sunday. | Proceed as in 3.4. |

- 3.4 As soon as the need for urgent action has been determined, the RDH On-Call Pharmacist will fax (see Appendix B) the Alert to:
 - Pharmacy – Queens Medical Centre (QMC), Nottingham
 - Pharmacy – Leicester Royal Infirmary (LRI)
 - Pharmacy – Lincoln County Hospital (LCC)
 - Pharmacy – Sherwood Forest Hospitals (SFH)
 - Trent Medicines Information Centre (TMIC)
- 3.5 The RDH On-Call Pharmacist will make a follow-up telephone call to the switchboard at QMC, LRI, LCC and SFH
 - For Saturday mornings ask for the most senior pharmacist on duty.
 - Otherwise ask to be connected to the on-call pharmacist.
 - Say that **“an urgent Drug Alert has been faxed, which requires immediate attention”**.
- 3.6 Control Sheet (CS2) will be completed, including the names of the contact pharmacists, which will be attached a copy of the Alert and fax cover.
- 3.7 On completion of the process, the Control Sheet will be signed by the person undertaking the process and then a copy sent (faxed or emailed) to the Trent Medicines Information Centre within 24 hours.

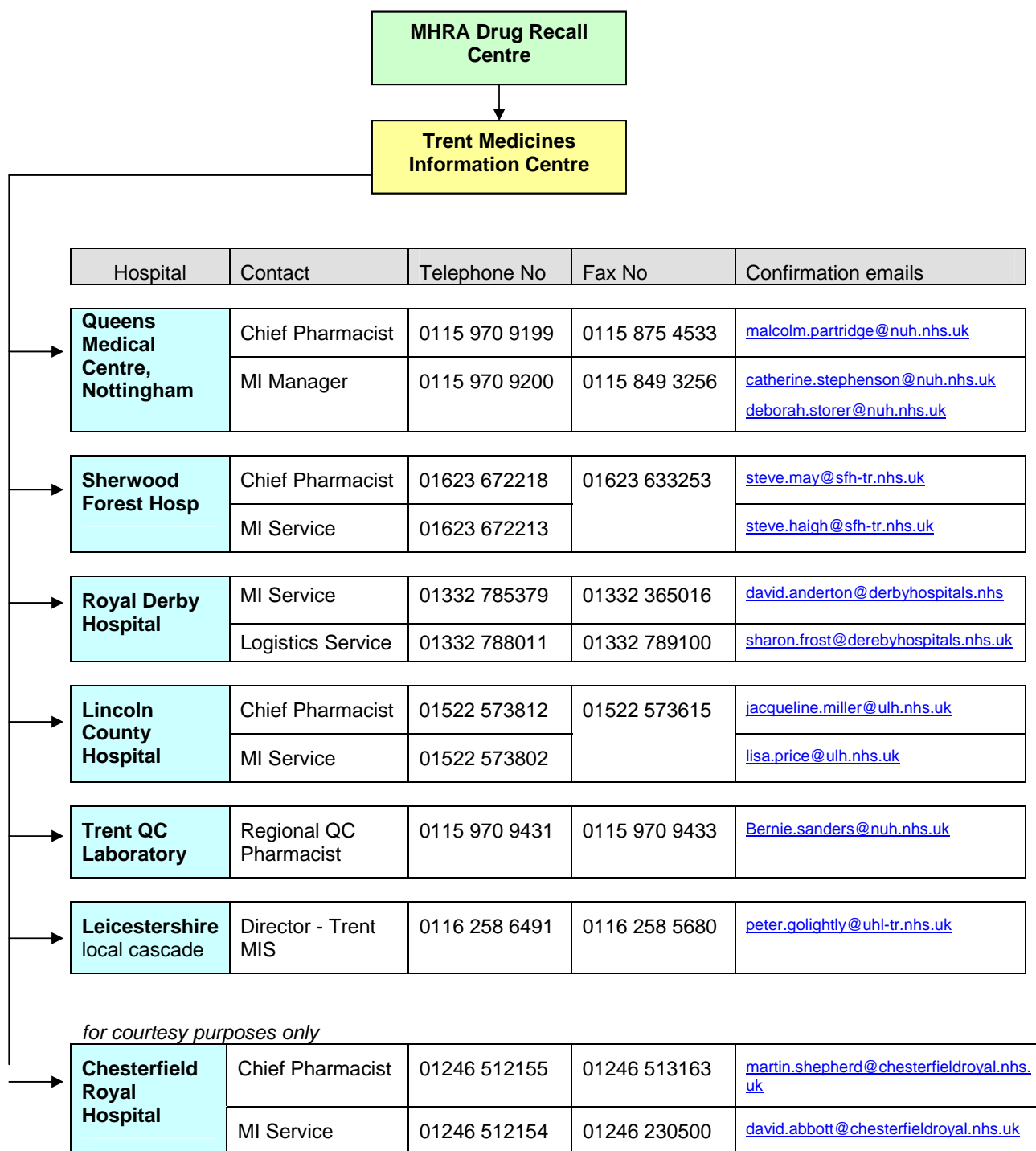
- 3.8 When holding for subsequent action by administrative or MI staff, ensure that clear instructions are left for them if unable to instruct them personally. Seek confirmation subsequently that action has been taken.
- 3.9 If any of the four recipient hospitals has not received the faxed Alert within 30 minutes of telephone notification, the local On-call pharmacist will check their fax machine is working, and contact the On-call pharmacist at RDH to request a further copy.
- 3.10 The On-call pharmacists at RDH, QMC, LRI, LCC and SFH will initiate local cascade processes, including Mental Health Trusts where appropriate, as defined by local policy.

4 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 an annual 'test' of the out-of-hours process.

| DOCUMENT CONTROL | | | | | | | |
|------------------|---|----------------|------------|----------------|------------|-------------|-----|
| Produced by: | Peter Golightly | Checked by: | Tom Gray | Version: | 3.1 | Draft: | 1 |
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| Ref/location | Trent MIS/DrugAlert/EM Drug Recalls(v3.1-final-Nov2009) | | | | | | |

Appendix A: Working hours drug recall cascade



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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: | | |

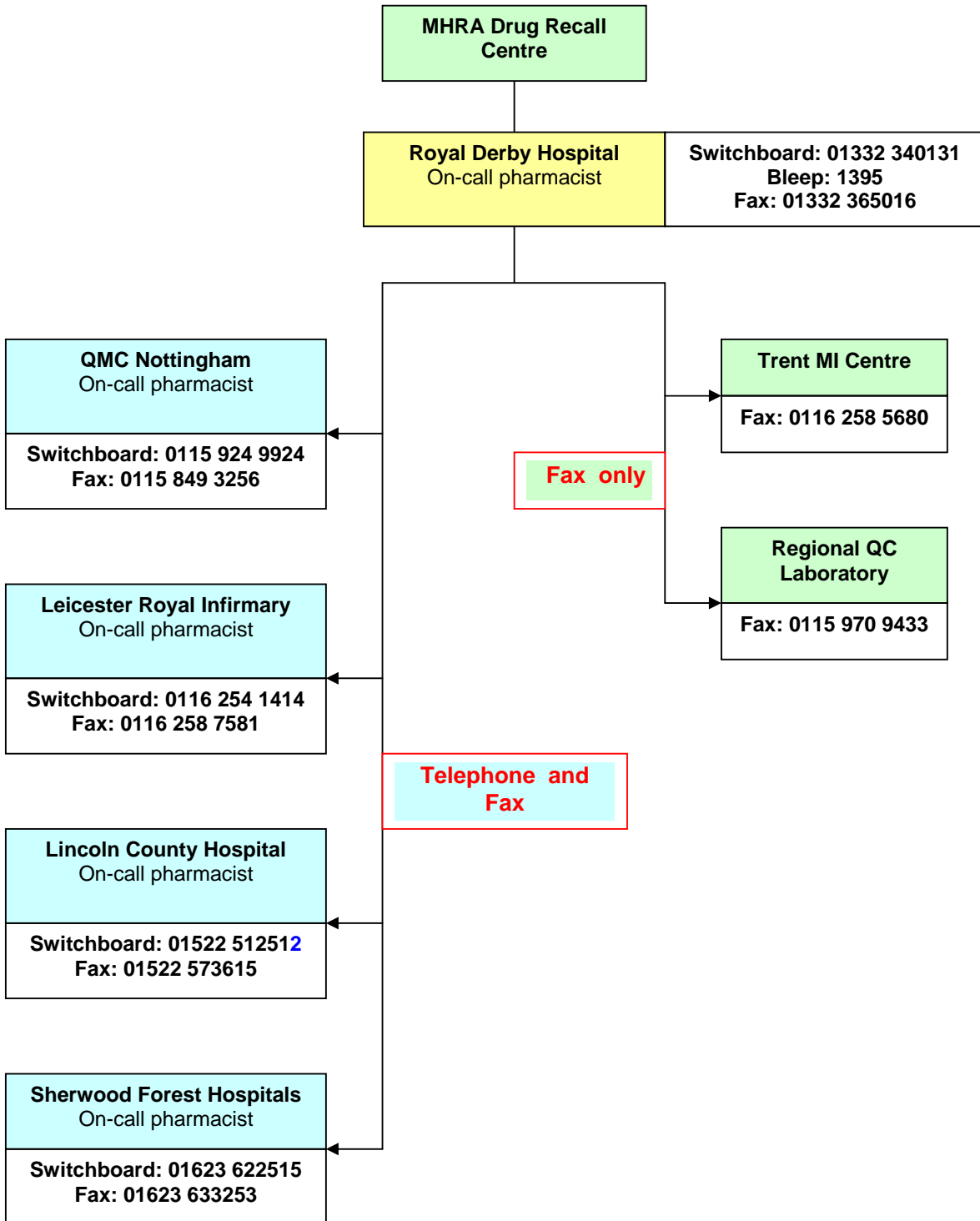
| Action for TMIS | Time faxed | Time phoned (pm) | Time emailed | Time of feedback email |
|-----------------------------|----------------------------------|------------------|--------------|------------------------|
| Derby City Hospital | | | | |
| Lincoln County Hospital | | | | |
| Nottingham QMC | | | | |
| 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 need 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 | | Reference No: EL |
|--------------------|---------------------------------|-------------------------------|
| Date: | Time of notification from MHRA: | Message taken by: |
| Product: | Batch No: | PL No: |
| Action required: | | |
| Reason for recall: | | |

| Hospital | Time faxed | Time telephoned | Name of pharmacist spoken to | Time message given to On-call Pharmacist |
|----------------------|------------|-----------------|------------------------------|--|
| Nottingham QMC | | | | |
| Leicester LRI | | | | |
| Lincoln County Hosp | | | | |
| Sherwood Forest Hosp | | | | |
| Trent MIC | | | | |
| Regional QC Lab | | | | |

Date completed:.....

Signature:

Return to Trent MI Service when complete:
 Fax: 0116 258 5680 Email: druginform@uhl-tr.nhs.uk