PV Office – Handling Drug Alerts

Purpose of document:
To outline the process for handling MHRA drug alerts.

Personnel:
Pharmacovigilance Administrator
Pharmacovigilance and Safety Manager

Background
Manufacturers and Importers are obliged to report to the Medicines and Healthcare products Regulatory agency (MHRA) any quality defect in a medicinal product that could result in a recall or a restriction on supply.

Where a defect is considered to be a risk to the public, the marketing authorisation holder withdraws the affected product from use and the MHRA issues a "drug alert" letter. The alert is classified from 1 – 4 depending on the risk to the public by the defective product. Class 1 is the most critical and requires immediate recall, Class 4 is the least critical and advises "caution in use".

Within NHS GG&C Pharmacy Services, a cascade system operated for dissemination of drug alerts. The PV office is included in that email cascade.

The Lead Pharmacist Clinical Trials or their designees are responsible for tracking, reviewing all drug alerts received, and assessing their impact on CTIMPs that are sponsored either in part of wholly by NHS GG&C.

Guideline notes

1) Two emails are received with regards to drug alerts.

2) The first is a general email sent from NHS GG&C Pharmacy Services. The second is from the R&D Sponsor Pharmacist and details if the drug in question impacts on any trials sponsored either in part or wholly NHS GG&C.

   On receipt the emails are reviewed by the Pharmacovigilance and Safety Manager.

3) If the R&D Sponsor pharmacist indicates that the drug alert impacts on any trial where the PV Office is responsible for Pharmacovigilance the Pharmacovigilance and Safety Manager will ensure that a copy of the email is filed within the Sponsor PV file for the relevant trial.

4) The Pharmacovigilance and Safety Manager will check to see if any SAEs have been received for the period of time in which participants where potentially exposed to the defective IMP and relay this information to the R&D Sponsor Pharmacist and the Chief Investigator to determine if there has been any impact on the trial from a safety perspective.

Document Details:

Prepared by: Marc Jones Signed: …… Date: / /

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Document History

Version	Details	Date
1.0	Version 1.0 creation	02/09/2012
2.0	Change to details collected in Drug Alerts Tracker Guideline No allocated	29/11/2013
3.0	Reviewed and released as part of SOPs reorganisation process. Guideline has moved to SOP category 55 NHS GG&C Sponsor Pharmacovigilance and renumbered (previously 18.016A). 'Prepared by' changed to Caroline Watson, 'Approved by' changed to Julie Brittenden.	15/07/2016
4.0	Updated to reflect a change in process. PV office will no longer track all drug alerts as this is carried out by the R&D Sponsor Pharmacists. For drug alerts that are noted to affect a trial handled by the PV Office, records will be checked to determine if any SAEs occurred during that period. Change in author & approver.	19/12/2018