South East Coast Ambulance Service NHS
NHS Foundation Trust

Handling of Drug Alerts and Recalls

Standard Operating Procedure (SOP)

Contents

Introduction

1.1. Medicines at SECAmb are stored on Ambulance Stations, on Emergency Response Vehicles, in the distribution Centre and at Logistics hubs, also on Trust vehicles of various types

1.2. These medicines may be subject to a product recall, either by the manufacturer via the Medicine Alerts received from the MHRA (Medicines and Healthcare Products Regulatory Authority) or by the Medicines team

1.3. The reason for the recall can be varied but may include a faulty batch, a reported untoward incident relating to one of the medicines used within the Trust, adverse storage or a change in product or practise by the Trust

Scope

1.4. This SOP provides information on where the recall information comes from and how it is cascaded down through the organisation. It will also;

1.5. Provide guidance on how to deal both with MHRA recalls and recalls from within the Trust.

1.6. Describe the means to identify where the stock is held in the event the product needs to be removed from stock

1.7. The appropriate action to be taken depending on significance and urgency of the recall

1.8. Actions to be taken / considered when recalling a product

1.9. Guidance for alerts received out of the normal working hours of the medicines team

Procedure for Recall of Medicines

1.10. **Where does the recall information come from**

1.10.1. For a national alert the MHRA will send alerts notices to the Medical Director, Medication Safety Officer (MSO) and the CAS liaison officer. In normal working hours of Monday to Friday 8.30am to 4pm this information will be forwarded to the medicines governance team for the appropriate action to be taken.

1.10.2. Outside of working hours the alert notice will go to the Gold or Silver tactical command officer.

1.10.3. For internal recalls for product changes the Medicines team will implement a staged recall which will include notification via the communications team

1.11. **How to deal with the recall**

1.11.1. The timeframe in which the recall is actioned is determined by the type and nature of recall.

1.11.2. The MHRA recalls are classified as; class 1, immediate action, class 2, action within 48 hours, class 3, action within 5 days and class 4 is used for minor defects and is for general communication see appendix 1 for full details of the alerts classifications

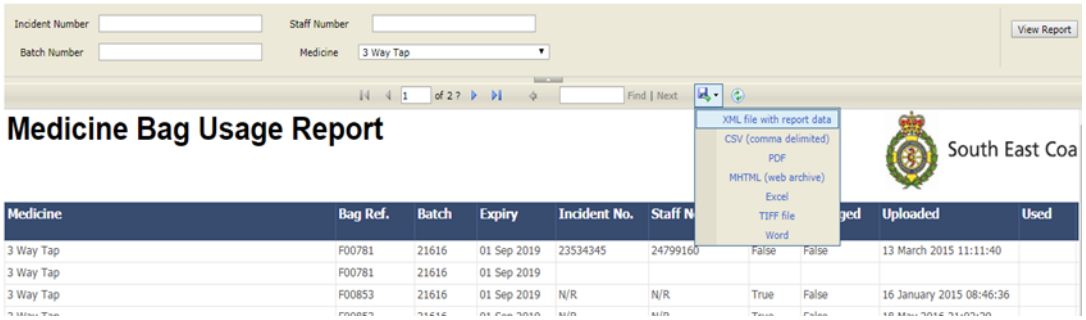
1.11.3. **If the recall is a class 1 and is out of hours for the medicines team proceed to section 3.5 Alerts Received Out of Hours**

1.11.4. The internal recalls for change of product will be as part of a managed change.

1.11.5. Check the if the Trust stocks or has received the product, the brand presentation and batch number that is subject to the recall

1.11.6. Log onto the ACESO computer system which is the stock management system for all medicines for South East Coast Ambulance Service

1.11.7.



1.11.8. Select the “Medicines Stock List” tab and type the drug name in the search box, then press the magnifying glass to run your search.

1.11.9. .

1.11.10. Next select the “Actions” tab and choose the Excel option. This will download a spreadsheet with all of the history for use of that product.

1.11.11. Select all data so that it is highlighted then select the “sort and filter” option. Within this selection, press the filter option.

1.11.12. Select the batch number column and search for the batch number required in the list. Untick the “select all” option and tick the batch number that is required. If the batch number has **not been** found then the product has not been received or used in the Trust.

1.11.13. If the batch number **is found** then you can establish where it was sent by reviewing the last column titled “Ambulance Station”.

1.11.14. If the product has not been found to be received by the Trust then complete the action log see appendix 2 and inform the Chief Pharmacist detailing actions taken and the recall can be closed.

1.11.15. If the product and batch number is found to have been received into the Trust then further actions will be required as detailed below

1.12. **Identify where the stock is held**

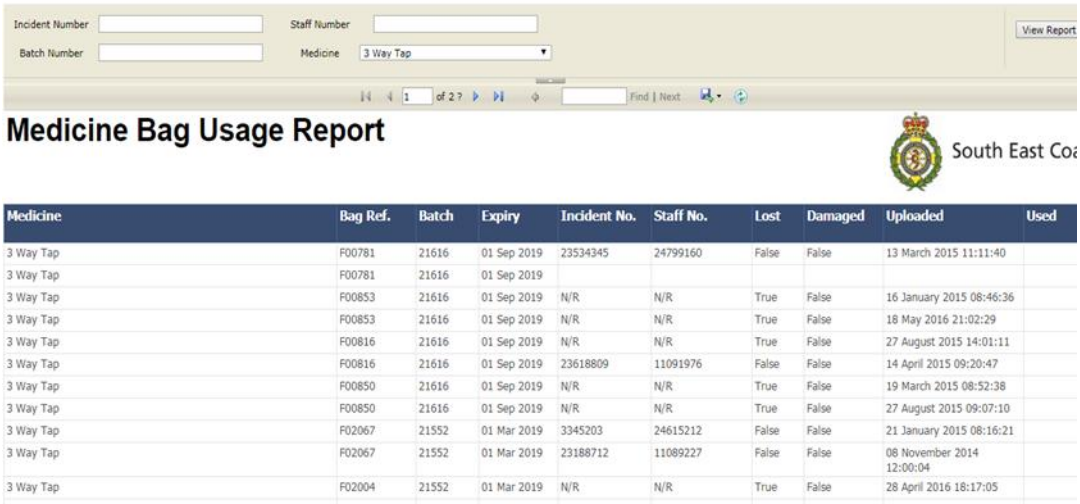
1.12.1. The stations and locations the product has been sent to can be found from the above information see 3.2.12

1.12.2. To obtain data for the products used in the pouches proceed as follows;

1.12.3. Log onto the ACESO computer stock management system

1.12.4. Select the reports module within the ACESO system and click on “medicine bag stock used”.

1.12.5. Type the affected batch number into the “Batch number” box and select the drug name from the drop down menu. Then press “view report”.



Medicine	Bag Ref.	Batch	Expiry	Incident No.	Staff No.	Lost	Damaged	Uploaded	Used
3 Way Tap	F00781	21616	01 Sep 2019	23534345	24799160	False	False	13 March 2015 11:11:40	
3 Way Tap	F00781	21616	01 Sep 2019						
3 Way Tap	F00853	21616	01 Sep 2019	N/R	N/R	True	False	16 January 2015 08:46:36	
3 Way Tap	F00853	21616	01 Sep 2019	N/R	N/R	True	False	18 May 2016 21:02:29	
3 Way Tap	F00816	21616	01 Sep 2019	N/R	N/R	True	False	27 August 2015 14:01:11	
3 Way Tap	F00816	21616	01 Sep 2019	23618809	11091976	False	False	14 April 2015 09:20:47	
3 Way Tap	F00850	21616	01 Sep 2019	N/R	N/R	True	False	19 March 2015 08:52:38	
3 Way Tap	F00850	21616	01 Sep 2019	N/R	N/R	True	False	27 August 2015 09:07:10	
3 Way Tap	F02067	21552	01 Mar 2019	3345203	24615212	False	False	21 January 2015 08:16:21	
3 Way Tap	F02067	21552	01 Mar 2019	23188712	11089227	False	False	08 November 2014 12:00:04	
3 Way Tap	F02004	21552	01 Mar 2019	N/R	N/R	True	False	28 April 2016 18:17:05	

1.12.6. If no information is displayed under the Medicines Bag Usage Report Title and the column titles, then the batch entered has not been used during the packing process

1.12.7. If data is displayed in the table then select the disk icon and download the information to an excel file. This will allow you to work with the data.

1.12.8. Open the exported file and delete the top 3 rows. This will leave a simple spreadsheet which can be filtered by column.

1.12.9. Select all data so that it is highlighted and select the “sort and filter” option. Within this selection press the filter option.

1.12.10. Select the incident data column. Any rows which contain data are products which have already been used.

1.12.11. Select the column filter which is on “incident data”. Click the option to “select all” which is at the top of the list. Scroll down the list and tick “blank”. This will leave you with all pouches that are still in circulation and contain the recalled drug.

1.13. **Further action to be taken**

1.13.1. Now it is established the stock has been received by the Trust further action is required depending in the severity of the recall

1.13.2. **Class 1 recall**

1.13.2.1. Inform the Chief Pharmacist or in their absence the Medical Director that a recall is required and the approximate quantities of stock held within SECAamb

1.13.2.2. Contact the medicines supplier to establish if stock of a different batch number / brand is available checking the concentration and presentation is identical to the recalled product

1.13.2.3. Following confirmation from the chief pharmacist place an order sufficient to replace the stock recalled

1.13.2.4. If the product is contained within the pouch system establish from the data previously obtained from ACESO how many pouches are affected

1.13.2.5. If **all** the pouches are affected the chief pharmacist should consider instructions to be sent to the operational staff to withdraw the affected product from the pouch and quarantine them. An alternative presentation or product should be issued as appropriate until the pouches can be recalled and re-packed

1.13.2.6. If there are sufficient pouches containing the unaffected product available to replace the affected pouches a recall should be started

1.13.2.7. Consideration should be given to locate any patients that may have received the affected product by using Trusts Computer Aided Dispatch (CAD) system

1.13.3. **Class 2 Recall**

1.13.3.1. Action is required within 48 hours if the Trust has received stock point 3.4.2 onwards should be followed as soon as possible

1.13.4. **Class 3 Recall**

1.13.4.1. Action is required within 5 days if the Trust has received stock point 3.4.2 onwards should be followed as soon as possible

1.13.5. **Class 4 Recall**

1.13.5.1. If the Trust has received stock no recall is required but notification bulletin should be sent out via the communication department for information

1.13.6. **Actions to be taken / considered when recalling a product**

1.13.6.1. Prepare a Trust recall notice with the details of the recall and detail actions required by the staff on ambulance stations. The alert template can be found on the T Drive – Medical – Sussex – Medicines Governance – Drug Medicine Alerts – Drug and Medicine Alerts – Drug Alert Template appendix 3

1.13.6.2. Add the alert to the register on the “T” drive and save a copy of the alert as a PDF document. The folder containing the register is T Drive – Medical – Sussex – Medicines Governance – Drug Medicine Alerts – Drug and Medicine Alerts – Alert Log.

1.13.6.3. The notification should be emailed to “Operational Managers, Operational Unit Managers, Operational Team Leaders, Make Ready Centre Managers, Logistics support and Clinical Supervisors”. Copy in the Chief Pharmacist, Medical Director and Senior Technician and Medicines Distribution Team

1.13.6.4. Record the returns from each location to ensure all of the effected product is returned and where applicable removed from the stock holding on ACESO

1.13.6.5. For pouches collate the numbers as found when confirmed by Trust departments and stations so that it is clear to see how many pouches remain outstanding then contact the locations for the remaining pouches for an immediate return

1.13.6.6. Arrange for all stock to be returned to Paddock Wood for storage in a quarantine area which is away from stock and the packing process.

1.13.6.7. Once the recall is complete ensure the Medicines recall action log, appendix two has been populated with all the action that has been taken. An electronic copy should be filed on the “t” drive and a paper copy filed in the quarantine file kept at Paddock Wood

1.13.6.8. Any affected products should be packaged and return to the supplier for credit or destroy the affected product as directed in the recall notice

1.13.6.9. Inform the Chief Pharmacist the recall is completed and forward a copy of the action log

1.14. **Alerts Received Out of Hours**

1.14.1. Alerts received out of the working hours of the medicines team must be passed immediately to the Gold or Silver Tactical Command on Call Officer for the Trust.

1.14.2. A medicines recall action log form (appendix two) must be commenced by the Gold or Silver on Call Officer which should be forwarded to the medicines governance team

1.14.3. For a **MHRA class one or two recall** the Trust stock list should be checked immediately to ascertain whether the product is kept within the organisation. If product is not found on the stock list then the action log should be completed and sent to medicines@secamb.nhs.uk no further action is required

1.14.4. If the product found is on the stock list all stock should be checked.

1.14.5. The details of the recall must be communicated to all operational staff using the CAD data screen.

1.14.6. All duty OTL’s must be contacted by email and asked to ensure that all stocks within their Operating Units are checked, this includes vehicles, cupboards and emergency stocks where applicable. The email must also be copied to the Medicines team and the stores managers for action on their next shift.

1.14.7. Any stock found must be quarantined immediately and recorded on the action log form in the comments box.

1.14.8. All staff must ensure that the recall is reported to oncoming staff via their end of shift reports until the Trust confirms that the alert has been closed.

1.14.9. If the alert is class 3 or 4, or actions have been taken on class 1 or 2 alerts but the Chief Pharmacist becomes available then the alert should be handed over in full to them and the Medicines Governance Team where actions can continue.

1.14.10. Any medicines alerts received outside of the medicines team normal hours must be followed up by the medicines team at the start of the next shift.

Responsibilities

1.15. The Chief Executive Officer (CEO) has overall responsibility for medicines use and governance in SECAmb.

1.16. The Executive Medical Director through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance.

1.17. The Executive Director of Operations, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this procedure. The Executive Director of Operations also has overall responsibility for holding his/her staff to account for any deviation from this procedure.

1.18. The Executive Director of Operations delegates local responsibility and accountability for this procedure to the Regional Operation Managers, Operational Unit Managers, Operational Managers, Specialist Managers and where relevant the Head of Fleet and Logistics.

1.19. The Regional Operation Managers, Operational Unit Managers, Operational Managers, Specialist Managers and where relevant the Head of Fleet and Logistics delegate local responsibility and accountability for this procedure to their staff including the Operational Team Leaders, Logistics Manager, and others.

1.20. The Chief Pharmacist supports the Executive Medical Director and Executive Director of Operations providing professional advice with regards all medicines related procedures and practices. The Chief Pharmacist is also the Medicines Safety Officer for the Trust.

1.21. The Chief Pharmacist delegate's local responsibility for Medicines Management practice to her/his staff.

1.22. The Executive Director of Nursing and Quality has overall responsibility for CAS alerts in the organisation.

1.23. The CAS liaison officer is responsible for cascading medicines alerts to the Executive Medical Director, Exective Director of Operations and Chief Pharmacist.

1.24. All staff who handle medicines are personally accountable for complying with this SOP, for reporting any concerns and for the safe and secure handling of all medicines.

1.25. The Chief Pharmacists should ensure all medicines alerts are actioned by the Trust and the medicines recall action log is completed and filed

1.26. The medicines team should action the alerts as stated in this SOP ensuring the Chief Pharmacist and / or the Medical Director kept informed of the progress and outcomes. The medicines recall action log is completed and filed

1.27. The logistics manager should check their own stock holding, provide support in collecting and ensuring isolation of any affected stocks from stations and assist by providing delivery of replacement stocks to stations

1.28. All duty Operational Managers and/or Team Leaders should follow the actions required to facilitate the recall ensuring good communication to all staff and the medicines team.

1.29. Emergency Operations Centre managers should cascade the recall information via CAD screens of operational vehicles and airwave terminals.

Audit

1.30. The recall action log record must be filed and kept with the MHRA recall notification for two years.

1.31. Deviations from this SOP must be investigated immediately.

1.32. Any deviations that cannot immediately be resolved must be immediately escalated to the Chief Pharmacist via an IWR-1 report.

References

1.33. A Guide to Defective Medicinal Products, Medicines and Healthcare Products Regulatory Agency (MHRA) 22 July 2005
https://www.gov.uk/government/publications/a-guide-to-defective-medicinal-products

Appendix One: MHRA Medicines Alerts Classification

The MHRA use an internationally agreed classification which will detail how urgently action is to be taken:

Class 1: The defect presents a life threatening or serious risk to health. rRquires immediate recall actions to be taken.

Class 2: The defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious. Requires action to be taken within 48 hours of the recall being issued.

Class 3: 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. Action is required within 5 days of the recall being issued.

Class 4: There is no threat to patients or no serious defect likely to impair product use or efficacy. These are generally used for minor defects in packaging or other printed materials. Requires caution to be exercised when issuing or using the product.

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Appendix Two: Medicines Recall Action Log

<table>
<tr><td>Medicine Name</td><td colspan="5"></td></tr>
<tr><td>Recall Received</td><td>Date:</td><td>Time:</td><td colspan="3">By Whom:</td></tr>
<tr><td>Class of Recall
(Please circle as indicated by MHRA alert)</td><td>Class One – Immediate Action</td><td>Class Two – Within 48 hours</td><td>Class Three – Within 5 days</td><td colspan="2">Class Four – Caution to be exercised</td></tr>
<tr><td>Medicine Stocked by Trust?</td><td colspan="2">Yes</td><td colspan="3">No
If No – Alert can be closed and no further action is required</td></tr>
<tr><td rowspan="4">Pouch or Team Effected

Highlight ALL pouches or staff groups which may be effected

(Pouch and Station Stock List can be found in the Medicine Recall Folder)</td><td rowspan="2">Operational Pouches</td><td>Arrest</td><td colspan="3">Hypoglycaemia</td></tr>
<tr><td>Cardiac</td><td colspan="3">Respiratory</td></tr>
<tr><td>Airport Team</td><td>Fluids</td><td colspan="3">Specialist</td></tr>
<tr><td>CFR</td><td colspan="4">Responder Pouch</td></tr>
<tr><td>Restricted Access</td><td colspan="4">Volunteer Pouch</td></tr>
<tr><td colspan="2"></td><td colspan="2">PP Drug</td><td>CCP Drug</td></tr>
<tr><td colspan="2"></td><td colspan="3">CD/Station Stock</td></tr>
<tr><td>Duty Gold Officer Informed
(Out of Hours)</td><td>Date:</td><td>Time:</td><td colspan="3">By Whom:</td></tr>
<tr><td>CAD Alert Message Cascaded:</td><td>Date:</td><td>Time:</td><td colspan="3">By Whom:</td></tr>
<tr><td>Comments/Feedback from stations:</td><td colspan="5"></td></tr>
<tr><td>Action Log Handed Over to Chief Pharmacist: (Out of hours)</td><td>Date:</td><td colspan="2">Time:</td><td colspan="2">By Whom:</td></tr>
</table>

A copy of this log will be retained by the Medicines Governance Team on the T drive – Medical – Sussex – Medicines Governance – Drug/Medicine Alerts – Recalls.

South East Coast Ambulance Service NHS

Appendix Three: Alert Template

Drug & Medicine

ALERT NUMBER: DM0001

Immediate action required		**Withdrawal /urgent check**	
Change required in practice or supp		Change in protocol / appearance of medici	
For information only		Information for clinicians	

EXTERNAL	
PRIVATE	
FRONTLINE STAFF	X

Date of alert	
Date alert should be reviewed	
Name of medicine / drug	
Presentation of medicine / drug	
Preparation (if appropriate)	
Supplier name (if appropriate)	
Batch number (if appropriate)	

Details of Alert

Action Required