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Procedure number: *Insert local SOP number*

Procedure title: Yellow Card submissions via MiDatabank version 3

## Background

Yellow Card (YC) reports of suspected adverse drug reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) are an important aspect of pharmacovigilance in the UK. MI pharmacists and technicians frequently come across adverse drug reactions (ADRs) when answering enquiries. YC reports can now be generated by MiDatabank. This SOP covers the reporting of ADRs by staff using the new ADR reporting function in MiDatabank version 3.

Further information and support material relating to MiDatabank can be found at: [www.midatabank.com](http://www.midatabank.com)

The 'Good Practice Guide for Yellow Card submissions via MiDatabank V3' is an appendix to this SOP it summarises the reporting criteria and provides links to a range of MHRA resources on ADR reporting.

Information on ADR reporting can also be found in the 'Guidance on prescribing' section in the [BNF](#).

## Objective/ aim of procedure

To ensure:

- Good documentation is achieved for all Yellow Card reports submitted via MiDatabank.
- Standardisation of the quality of YC reports submitted to the MHRA.
- MI staff are reminded of their professional responsibility to report all ADRs that fit the MHRA reporting criteria.
- MI staff report appropriately any suspected ADRs identified through their work.

## Risk Management Notes

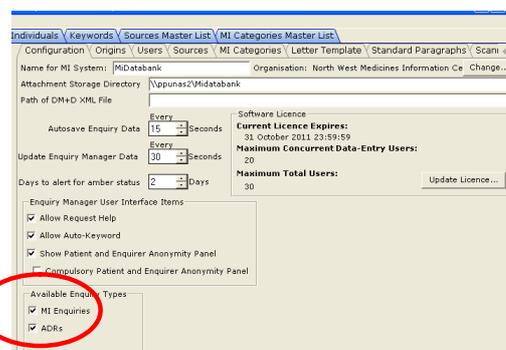
It is essential that no patient-identifiable data is included in the YC. This is to comply with patient confidentiality and information governance regulations. Patient-identifiable data include the full name, date of birth, the NHS number in England or the CHI number in Scotland. Local patient ID numbers e.g. hospital number, GP practice record number, cannot be used to identify the patient outside the organisation and can be included in the YC.

Appropriate documentation in MiDatabank ensures that YC information can be easily located at a later date, to provide any necessary follow-up data to the MHRA if they request it.

## Procedure

### 1. Initial set-up - enabling ADR reporting in the MiDatabank Administration mode

- 1.1. Ensure ADR function is launched in the administration mode of MiDatabank by ticking 'ADRs' as an available enquiry type in the configuration screen.



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1.2. The ADR function will now appear on the enquiry input screen of the Enquiry manager (top right hand side of screen with 'eye' icon).

## 2. Good Practice Points

2.1. See Appendix 1 for the Good Practice Guide

## 3. Input

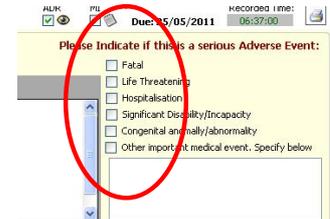
3.1. Enter the enquiry as normal on MiDatabank (see local SOP). If the enquiry relates to a suspected ADR ensure the ADR button (top right of screen) is ticked to display the ADR tab (this will only appear if ADR reporting has been enabled in the Administrator mode), this can be done or undone at any point while the enquiry is open. Complete research and answer fields as for a normal enquiry.



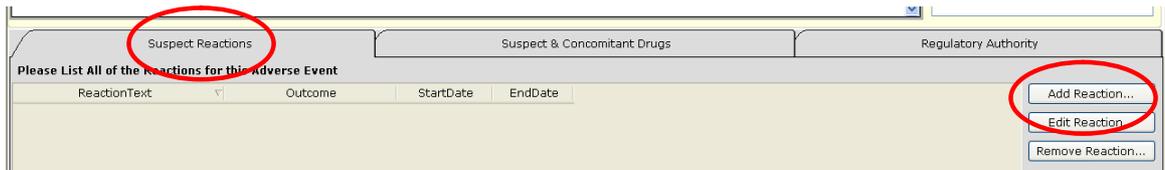
3.2. Click on ADR Input tab. Enter a description of the ADR in the top section. Type into the box or copy and paste from the input screen (use toolbar Edit and Paste as you cannot use right click and paste in this field). Ensure no patient-identifiable data is included in this section.



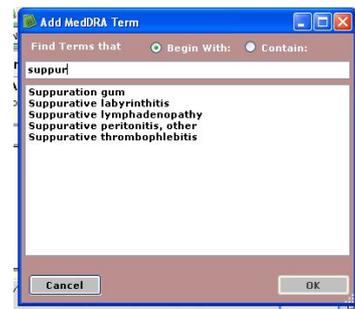
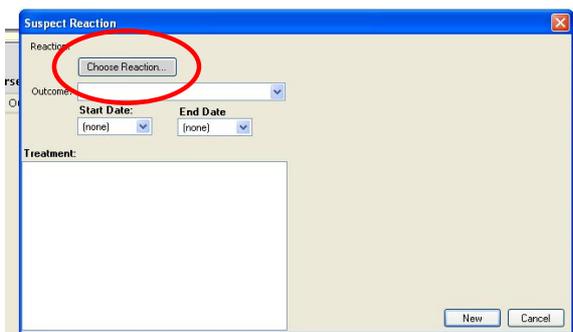
3.3. If the reaction is serious click on one of the tick-boxes related to the seriousness of the ADR in the right hand panel.



3.4. Click on the first tab labelled "Suspect Reactions" (left hand side on lower part of screen), and then click "Add Reaction" which is displayed on the right hand side of the window.



3.5. Click on "Choose Reaction" and a new dialogue box labelled "Add MedDRA Term" appears. (MedDRA is the Medical Dictionary for Regulatory Activities, used



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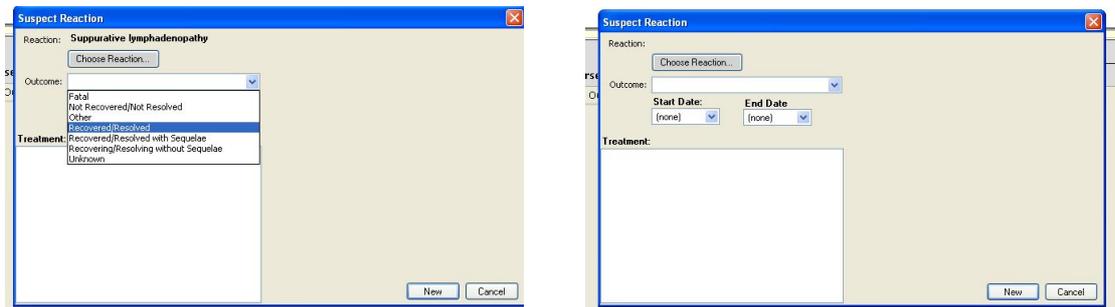
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internationally to describe diseases, indications and adverse reactions.) Enter the first letters of the suspected reaction and using either 'Contain' or 'Begin with', select a term from the list that appears. If no exact match appears, it may be worth switching the words around to find an exact MedDRA term e.g. suppurative lymphadenitis vs. lymphadenitis suppurative or choose the nearest term and add a free text note explaining the exact term provided by the enquirer in the 'Adverse Event Description' box. Press OK and the reaction selected appears in the 'Suspect Reaction' dialogue box.

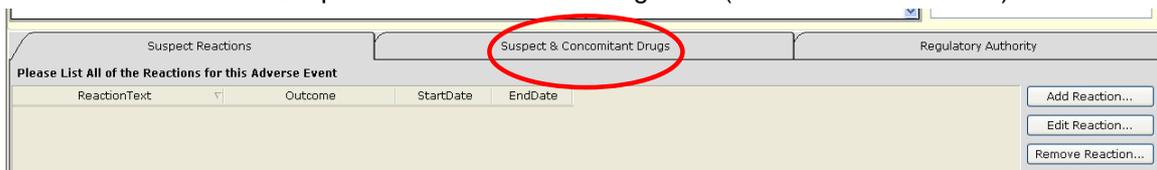
- 3.6. Click on the arrow next to 'Outcome' and select one option from the drop down menu e.g. fatal, recovered/resolved. Enter the Start Date and End Date (leave as 'none' if reaction continuing) for Suspect Reactions using the drop-down calendars. If there is more than one suspected reaction start again at 'Add reaction' – see 3.4 above. There is no limit to the number of reactions that can be added.



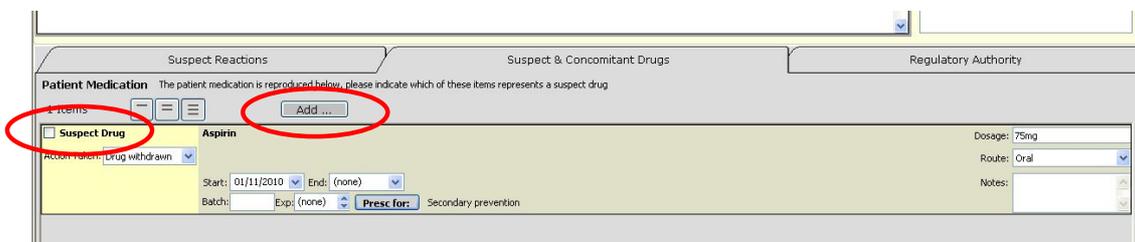
- 3.7. Free type in the 'Treatment' box any treatment that was given for the reaction e.g. to treat an anaphylactic reaction the patient may be given IV hydrocortisone, IV chlorphenamine and fluids. When you have completed all fields in the dialogue box click 'New' to accept the information.

- 3.8. If more than one reaction has occurred, repeat steps 3.4 to 3.7 for each reaction.

- 3.9. Click on the "Suspect and Concomitant Drugs" tab (in middle of the screen).



If drugs have been added via the medication tab on the input screen they will appear on the "Suspect and Concomitant Drugs" screen. Remember to indicate which is/are the suspect drug/s.



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Review Date:

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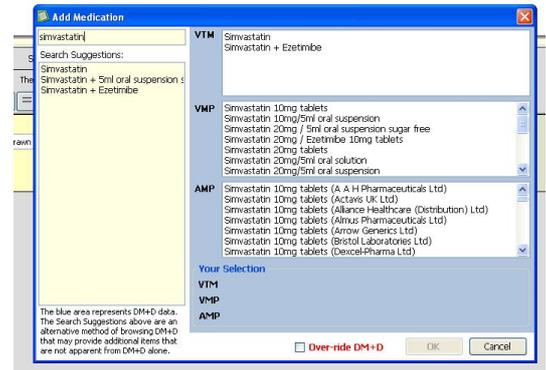
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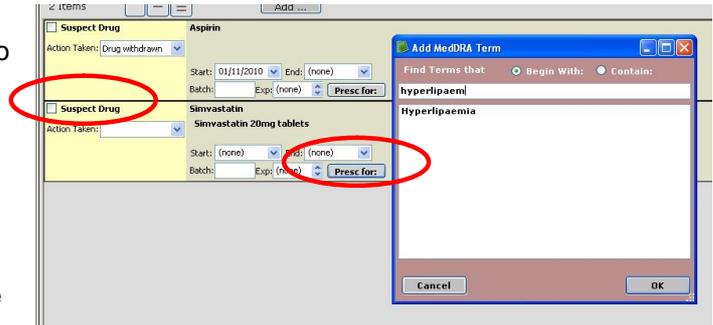
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If the drugs are not already entered they can be added by clicking on the “Add” button on the ‘Suspect and Concomitant Drugs’ screen. Select a drug from the Dictionary of Medicines and Devices, “DM+D” dialogue box that appears, using as much detail as you have e.g. strength, form, brand of preparation. If you do not have any details choose the VTM (virtual therapeutic moiety) term. If the medicine is not listed in DM&D (new, OTC, foreign) tick the ‘over-ride DM&D’ at the bottom of the dialogue box and free text into the input box.

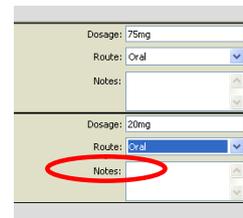
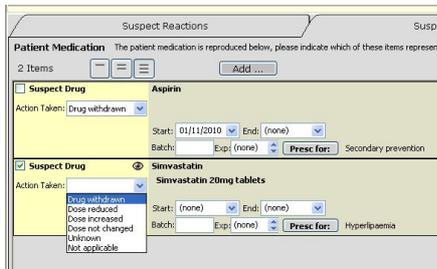


Tick the ‘Suspect Drug’ box on left hand side in yellow window, next to each drug that is suspected to have caused the ADR. Also complete the ‘Presc for’ box to provide details of the indication for the Suspect Drug, the ‘MedDRA term’ box appears.



To remove drugs, right click on the drug and choose ‘Delete drug’.

3.10. For suspect drugs, use the drop-down menu to complete the “Action Taken” box. Add Start and End dates where known. Add dose and route on the right hand side of the panel, if known.



Each concomitant drug can be added in the same way, but don’t tick the ‘Suspect Drug’ box next to those which are not thought to be implicated in the Suspect Reaction. For concomitant drugs that have been prescribed long-term the exact start dates are less important. If the start date is not known use a date corresponding to 1<sup>st</sup> January for the year in which the drug was/was thought to be started. If you have no idea when that was but know the patient has been on the medicine for many years e.g. five or ten years please choose 1<sup>st</sup> January five or ten years ago and/or add a note in the ‘notes’ box.

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3.11. The final step is to click on the 'Regulatory Authority' tab. The Yellow Card is generated from this screen. Ensure the reporter details on the bottom left hand side of the window are correct; these will reflect the details of the person who is logged into MiDatabank and the address at which MiDatabank is registered.

3.12. If for any reason an alternative individual is to be designated as the reporter select "Other (Please specify)" and a new screen is displayed. Enter the details of the alternative reporter. This may be desirable if the reporter logged into MiDatabank is a temporary or short term member of staff, in these circumstances the MI manager would be an appropriate alternative reporter. This ensures that if further information is requested by the MHRA at a later date the reporter's email address is still valid.

3.13. The Yellow Card report is not valid unless all the compulsory fields are completed (patient details (age), reaction details, suspect drug details and reporter details). If any of these fields are not complete advice will appear in the 'Missing compulsory data' box on the right hand side of the screen. Complete the missing fields.

3.14. Before the report can be submitted to the MHRA, the MiDatabank user must view the report. This is done by pressing the "View ADR Report for Regulatory Authority" button in the Regulatory Authority tab. This results in a new window displaying the YC report. Check the YC for completeness and accuracy.

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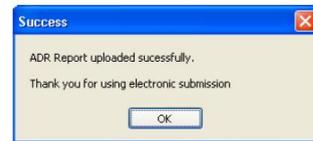
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3.15. To submit the report click on button labelled 'Electronically Submit ADR Report to Regulatory Agency'.



3.16. You should receive an automated notification from the MHRA to indicate that your YC has been successfully received. This may take several seconds. Your submission is now complete.

If your submission has not been successful you will get an error report – see below. The wording in line three will vary depending on the type of error. If you receive an error message the report should be saved as a pdf file and emailed to the MHRA using the following address [miyellowcard@mhra.gsi.gov.uk](mailto:miyellowcard@mhra.gsi.gov.uk).

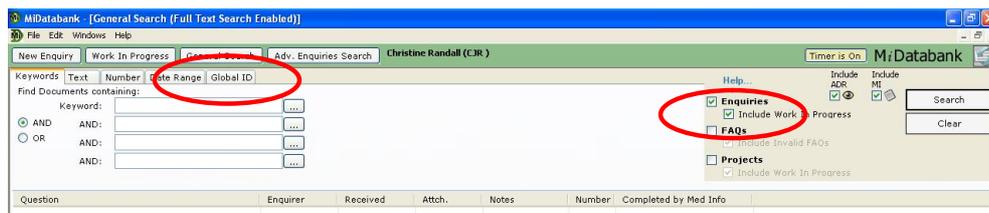


3.17. Each YC report is automatically assigned an individual registration number by MiDatabank, this number will be used by the MHRA in any future correspondence. This number is the 'Global ID' number and it is appear on the YC. It is important that this number is always quoted in any further correspondence with the MHRA about the YC report. The local ID is the MiDatabank enquiry number.

→ Title: Possible ADR - bleeding following low dose aspirin  
Local ID: 67044  
Global ID: 0f4aa773-a14f-4cab-bbd7-49a751ace6a0



3.18. Finally complete and close enquiry as usual. The image of the YC is stored by MiDatabank within the enquiry record and can be viewed by searching for the enquiry. Search for the enquiry either by using Keywords in the normal way or by searching for



the Global ID using the tab on the 'General search' screen.

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- 3.19. To find enquiries that include a YC submission ensure that the 'Include ADR' box is ticked on the search screen. If this is not ticked no enquiries including YCs will be found.



#### 4. Follow-up data

- 4.1. The MHRA may require follow-up data for a YC report, especially if data on the initial report was incomplete e.g. dates not included, or further clarification or outcome is desirable if the reaction is serious. The MHRA will use the Global ID number as a reference for the YC report. The MHRA will contact the YC reporter if follow up data is required. Currently this is by letter, but will be by email at some point the future. To supply the requested data it may be necessary to contact the original enquirer. This should be done as soon as possible. Any follow-up data should be emailed to the MHRA using the address [miyellowcard@mhra.gsi.gov.uk](mailto:miyellowcard@mhra.gsi.gov.uk) - if the MHRA receive the information by email it removes the need for it to be scanned into their database. The YC reference number/Global ID should be included in all follow-up correspondence.

If it proves impossible to obtain the further information within a reasonable timeframe (e.g. two months) let the MHRA know via the email above. It is not necessary to keep MiDatabank ADR enquiries open just in case follow up is requested, as all the YC information is retrievable from the archived report.

#### 5. Responsibility

- 5.1. When pre-registration trainee pharmacists are on MI rotations, the training or 'responsible' MI pharmacist must ensure complete capture of ADR information including:
- 5.1.1. Suspect drug name with start and stop dates.
  - 5.1.2. Suspect reaction with start and stop dates plus outcome.
  - 5.1.3. Full medication history.
  - 5.1.4. Patient details – gender, age and initials.
- 5.2. Pre-registration trainee pharmacists are included on the MHRA list of allowable reporters so may include their details as reporter on the YC submission, but only under the supervision of a qualified pharmacist.
- 5.3. The training or 'responsible' MI Pharmacist must cover during training the need for pre-registration trainee pharmacist to forward any letters or emails from the MHRA to MI, for them to deal with appropriately including any follow-up requests. If the pre-registration trainee pharmacist is not available, it is the MI pharmacist's responsibility to complete the follow up. If the pre-registration trainee pharmacist is close to the end of their pre-registration period at the time of reporting and due to leave the hospital it may be desirable for the report to be submitted by the MI manager.

#### 6. Quality Assurance (QA) Audit

- 6.1. QA Audits in future will assess:
- 6.1.1. How many ADR enquiries were reportable as YCs.

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- 6.1.2. How many YCs were actually submitted via MiDatabank.
- 6.2. Peer review/preparation for QA Audits:
  - 6.2.1. Search ADR enquiries in MiDatabank over the previous month for example. Assess how many of these were reportable compared to the actual number of YCs submitted.
  - 6.2.2. Raise awareness via training sessions on identifying ADRs and assessing whether they fit the YC reporting criteria.

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