Appendix 1

Good Practice Guide for Yellow Card (YC) Submissions via MiDatabank V3

Please see the 'MiDatabank v3 Quick Start Guide' and the UKMi SOP titled 'Yellow Card submissions via MiDatabank' for more detail.

Data Protection and confidentiality

Please adhere to data protection principles and avoid typing/copying and pasting any patient-identifiable data into the Adverse Event Description box (freetext box at top of ADR Input screen).

N.B. The Yellow Card generated in MiDatabank contains no patient identifiable data as long as patient identifiable details appear only in the 'Patient' field of the Input screen.

The **MHRA** state the following:

Yellow Cards that health professionals use to report suspected adverse reactions to medicines do not include personal information about the patient which could be used to identify an individual (such as name or address). The MHRA does, however, need to know the age and gender of the person who experienced the suspected reaction as this information is important in investigating the factors which may make certain patients more likely to experience a particular side effect. The local identification number on the Yellow Card will enable you but not the MHRA, to identify the patient. This identifier is quoted in correspondence about the case (for instance, when asking for more information about the reaction) so that you can readily identify the patient to whom the correspondence is referring.

What should be reported on a Yellow Card?

1. If in doubt – complete a Yellow Card. There may be some 'grey' areas where you need to use your professional judgement or ask yourself if the patient's quality of life is affected by the ADR.
2. The Yellow Card Scheme is run by the MHRA (Medicines and Healthcare products Regulatory Agency) and the CHM (Commission on Human Medicines). Extensive information to support reporting is available via the MHRA website. Information on specific areas can be found via the following hyperlinks:
   - Adverse drug reactions – brief introduction.
   - Healthcare professional reporting of adverse drug reactions – links to key information.
   - What to report
   - How to report
   - Black triangle drugs including a link to the up-to-date list - issued monthly.
   - Serious versus severe reactions
   - Points to consider when assessing causality
   - Areas of special interest – children, the elderly, congenital abnormalities, delayed drug effects, herbal medicines.
   - Frequently asked questions
   - Drug analysis prints – a list of all suspected reactions reported for individual drugs.
   - Patient reporting – information directed to patients about the Yellow Card Scheme and how patients themselves can report.
   - Pharmacovigilance learning module – a training resource produced by the MHRA including how pharmacovigilance relates to day-to-day clinical situations. 'Test yourself' cases and exercises are available.
   - The Electronic Yellow Card – reporting electronically for individuals not using MiDatabank

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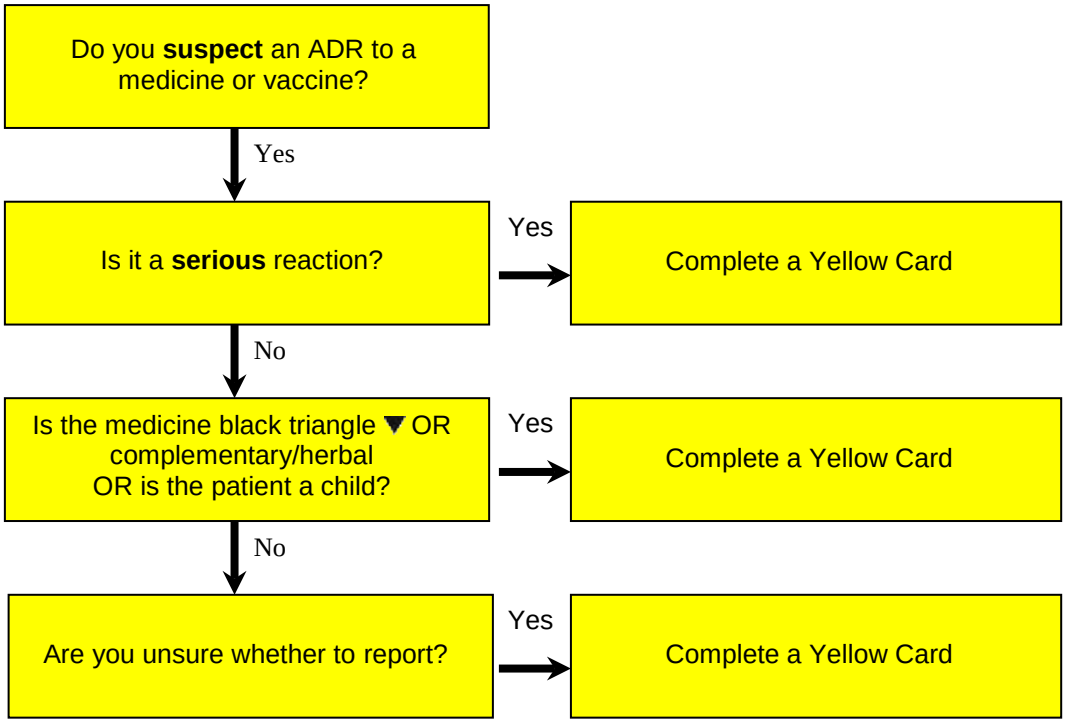
What should be reported on a Yellow Card? – continued:

3. Reporting reminder:



4. There are four critical pieces of information required for a Yellow Card to be valid, these are:
   a. **Suspect drug(s)**
      The name of the drug(s) suspected to have caused the reaction. The following are helpful if known:
      - route of administration
      - daily dose, dose frequency and schedule
      - dates of administration
      - if it is a vaccine, please quote brand and batch numbers
   b. **Suspect reaction(s)**
      Describe the suspected reaction(s) including a diagnosis if relevant. Include:
      - when the reaction occurred
      - seriousness of the reaction
      - any treatment given
      - outcome of reaction
   c. **Patient details**
      Basic information about the patient is vital in assessing reports and obtaining further information. Please provide at least one of the following:
      - patient sex
      - patient age at the time of the reaction
      - if known, please provide the patient's weight
      - patient initials and a local identification number (hospital or practice reference number) to help you identify the patient in any future correspondence
   d. **Reporter details**
      This field must be completed in all cases. Your name and full address is used to acknowledge receipt of the report and follow up for further information if necessary.
5. CPPE have an open learning resource on Adverse Drug Reactions. Pharmacists and technicians registered with the GPhC can register with CPPE . The pack, updated in 2006, is available to download but is being re-developed into an e-learning resource due for launch at the end of 2011.

Who can report via MiDatabank?

All health professionals have a professional responsibility to report adverse reactions that they suspect. For those who can log into MiDatabank it will facilitate this for:

1. All pharmacists (e.g. MI pharmacists, clinical pharmacists).
2. MI technicians.
3. Pre-registration trainee pharmacists. The training MI pharmacist should supervise all steps of ADR input, completion and submission of a Yellow Card report via MiDatabank.

MiDatabank – good practice

1. Obtain and enter as much detail as possible at the time of taking an ADR enquiry to reduce the need for follow-up e.g. start and stop dates for suspect drugs and reactions, full medication history
2. It is courteous and good practice to inform the enquirer that you will consider sending a Yellow Card. However, if this is not possible do not be deterred from reporting. Wording when speaking to the enquirer might be: 'If I find an adverse drug reaction that fits the MHRA reporting criteria after researching this enquiry, I'll submit a Yellow Card.' You may wish to document any reasons why the enquirer doesn't feel a Yellow Card is appropriate e.g. the enquirer now has information that confirms another cause for the symptoms. Tick the button in MiDatabank to confirm if the enquirer was informed for procedural and future QA purposes. Note – You do not need the enquirer's permission to report. If you suspect an ADR and have sufficient information to make a valid report you have a professional responsibility to submit a Yellow Card.
3. The enquirer may 'suspect' a particular medicine but on investigation you feel another medicine may be implicated, an interaction may be suspected or it is not clear which of two or more drugs may be implicated. Please use your discretion which one or combination of medicines you flag as 'suspect'. You can flag more than one medicine as 'suspect' if you are unsure. It does not matter if not all the medicines are directly implicated. The scheme is not about being 100% sure, just suspicious.
4. Yellow Cards should be submitted to the MHRA as soon as possible. Ideally the MHRA like to be notified within 7 days. However, if this is not possible please report whenever the information is available. There is no time limit.
5. The MHRA database sends an automated response to acknowledge receipt of your report. See the SOP for advice on how to deal with an error report.
6. Use the Global ID number generated by MiDatabank in all correspondence with the MHRA about the report