Proposal to include a form to capture all the information required to a complete valid Yellow Card within the UK Medicines Information network's paperless enquiry management system - MiDatabank.

MiDatabank is the paperless enquiry management and administration system used by the majority of UK medicines information (UKMI) pharmacists to record, manage and store their medicines information enquiries. MiDatabank has been developed by CoAcS (www.coacs.com) with the support of MI pharmacists. All information relating to enquiries including patient specific information is recorded.

MI pharmacists within the UK answer approximately 400,000 enquiries a year of which about 10 -15% are related to adverse drug reactions. At a recent MiDatabank development meeting a proposal was made to develop a form to be integrated within MiDatabank that would capture, from adverse drug reaction related enquiries, all the information needed to produce a valid Yellow Card report. The form would be submitted either by post or email to the MHRA. A copy of the form would be archived within the enquiry record on MiDatabank.

The development group discussed the proposal, including the advantages and disadvantages listed below, and the consensus of the group was that this was a good idea and worth investigating. We would value an MHRA opinion on the appropriateness of such an initiative especially in view of the Data Protection and Freedom of Information Act issues raised below.

Advantages
1. An improved awareness of the Yellow Card Scheme and the information required to complete a valid Yellow Card report among MiDatabank users.
2. Utilising MiDatabank, a system familiar to all MI pharmacists, should facilitate and increase ADR reporting to the Yellow Card Scheme by MI pharmacists.
3. The MiDatabank development group are committed to helping MI pharmacists fulfil clinical governance and professional responsibilities.

Disadvantages
1. A Data Protection Act (DPA) request from patients who have been the subject of a Yellow Card recorded in MiDatabank will reveal that a Yellow Card has been completed and enable the patient to see the entire contents of the Yellow Card including data from clinicians that may have been submitted in confidence. The Yellow Card Scheme does not contain patient names but MiDatabank would link reports to specific named patients. However, if a DPA request was made the medical notes would also be made available and the above concerns would be equally relevant. Therefore, advice on whether this concern is valid would be appreciated.
2. Freedom of Information or Data Protection Act requests may reveal that Yellow Cards have been completed by an MI pharmacist without the express consent of the patient or their consultant. However, this scenario may also arise in relation to medical notes where paper copies of reports made by all healthcare professionals are recommended to be filed.
3. Although the data submitted via MiDatabank would be the same as on a Yellow Card the format of the form submitted would not be identical to either the electronic Yellow Card or the paper Yellow Cards.
4. UKMI pharmacists are not responsible for the direct care of patients that they are asked about.

The MiDatabank system is a dynamic system and building the ADR reporting facility into the system is predicted to be relatively straight forward. The MiDatabank system has a secure login and complies with data protection legislation.

Proposal development
Before further development of this initiative the advice of the MHRA is sought regarding its appropriateness, and in respect of the disadvantages outlined above.

Should the proposal move beyond this stage, the MHRA will be kept fully informed and involved throughout the development process and it is hoped that they will actively support it.

Further information
For further information about MiDatabank go to www.midatabank.com
For further information about the UKMi network go to www.ukmi.nhs.uk

MiDatabank development group - November 2008