10. MEDICINES DEFECT REPORTING

The yellow card scheme provided by the MHRA (Medicines Healthcare products Regulatory Authority) collects information on suspected problems or incidents involving :

- Adverse Drug Reactions
- Medical device adverse incidents
- Defective medicines
- Counterfeit or fake medicines or medical devices

A specific monitoring area online may be set up to reflect an additional National focus. Currently (2021) there is a separate site for reporting suspected side effects to medicines and vaccines used in coronavirus treatment. This may vary and it is best to visit the home page for yellow cards to view the available options

10.1 Suspected Medicine Defects

All **suspected** medicine defects should be reported to the ward pharmacist who will take charge of the **investigation and reporting** of the incident by following the appropriate standard operating procedure. If a medicine defect is suspected outside the normal pharmacy opening hours, the on-call pharmacist may be contacted for advice or if a further supply is required, but in most cases reporting can wait until the following day.

If in doubt, report the suspected defect.

- The defective medicines and any equipment involved in administration should be labelled clearly, isolated and **retained** for safe-keeping. The Pharmacy will need to know the name of the product, (including strength and presentation), batch number, expiry date, manufacturer, product license number and full details of the suspected defect;
- If a **patient** is involved, the use of the suspect material must be immediately discontinued;
- The **practitioner** in charge of the patient should be notified at once. If further medication is required, this should be taken from a different batch. If an **intravenous infusion** has been set up, both the administration set and the infusion fluid should be replaced from a different batch;

The following are examples of possible medicine defects:

- particulate matter or growth in IV fluids
- cracks in IV bottles or ampoules
- labelling and packaging defects, i.e. label on container which does not correspond with the outer wrap
- unusual appearance or odour
- unexplained clinical reaction, (e.g. pyrexia)

Suspected medicine defects or counterfeit medicines should be reported to MHRA using the yellow card scheme. These reports are submitted to the defective medicines report centre (DMRC) a division of the MHRA.

For further information about defective medicines please see Guide to defective medicinal products

The relevant Trust incident report should also be completed

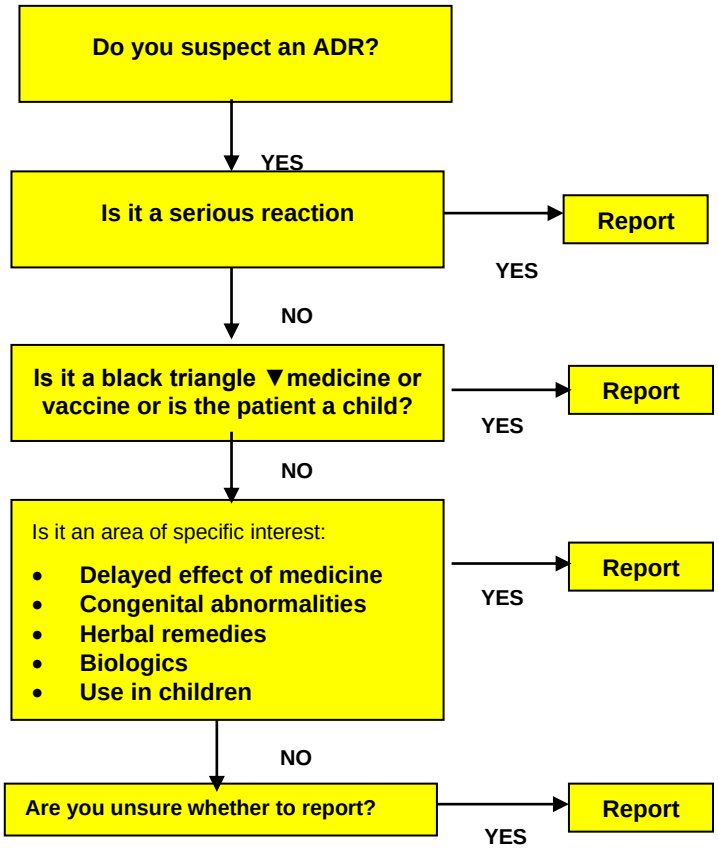
10.2 Adverse Drug Reactions (ADR)

All Healthcare Professionals, patients and carers can report suspected adverse reactions via the Yellow Card Scheme directly to the MHRA. Guidance can be found in the British National Formulary or on the MHRA website

Health professionals are strongly urged either to report or to prompt the submission of a report on any suspected adverse drug reaction. Staff in doubt about the reporting procedures should contact the Medicines Information Service (0116 2586491) for advice. It is recommended that before submitting a report the lead physician should be notified and the event documented in the patient's notes.

A black triangle symbol (▼) identifies newly licensed medicines that are monitored intensively by the MHRA. Such medicines include those that have been licensed for administration by a new route or drug delivery system, or for significant new indications which may alter the established risks and benefits of that medicine

10.2.1 What to report



10.2.2 How to Report

Healthcare professionals are encouraged to use the electronic Yellow Card available online at http://yellowcard.mhra.gov.uk/ or through the yellow card app free to download on iOS or Android devices

Alternatively yellow cards are also available:

- From the 'British National Formulary' (BNF)
- Downloading from the above website
- Through incident reporting systems eg Datix

There are four critical pieces of information which must be included on the report:

- Patient details (does not breach confidentiality agreements).
- Suspect medicine(s)
- Suspect reaction(s)
- Your name and address with contact details.

When completing the form, please give details, if possible, of brand name and batch number. This is particularly important for:

- Over-the-counter medicines
- Slow or delayed release formulations
- Vaccines
- Biotechnology products, e.g. human growth hormone

10.2.3 Where to Report

Electronic forms are the preferable method of reporting and are submitted Online. Completed paper forms should be sent directly to the MHRA using the freepost address indicated on the form or alternatively can be emailed to yellowcard@MHRA.gsi.gov.uk

Where the adverse reaction has had a significant impact on the patient then it is also important to report this via the incident reporting system within the Trust (Datix).

Information from reports is published in a monthly Drug Safety Bulletin available by registering at gov.uk/drug – safety update to receive a copy.