Specific areas of interest for reporting suspected adverse drug reactions

Although MHRA monitor suspected ADRs associated with all medicines on the market, the following areas are particularly of interest in receiving reports on suspected ADRs involving:

Children – because:

- children react differently to medicines –the pharmacodynamics and pharmacokinetics of a medicine may be very different in children compared with adults – for example the liver and kidneys in a child may have not be fully developed and may affect how the child metabolises and excretes the medicine compared to an adult
- many drugs which are routinely used to treat children are not extensively tested in children for their use; many are not specifically licensed for use in children and could be used 'off-label use', so it is particularly important to focus on their safety in children
- medicines may affect the way a child grows and develops or may cause delayed adverse reactions which do not occur in adults
- available formulations may not allow precise dosing in children or they may contain excipients that should not be used in children such as alcohol
- the nature and course of illnesses and suspected ADRs may differ between adults and children, for example otitis media, treatment of chronic cough in children

Reactions associated with misuse, overdose, medication errors or from use of unlicensed and off-label medicines should also be reported by completing a Yellow Card. If in doubt whether to report a suspected adverse drug reaction please complete a Yellow Card. Even if reported through the British Paediatric Surveillance Unit's Orange Card Scheme, any identified suspected adverse drug reactions should also be submitted to the Yellow Card Scheme.

Over 65s - because:

- older individuals may be more susceptible to developing reactions as they may metabolise medicines less effectively, and be more sensitive to their effects
- for both pharmacokinetic and pharmacodynamic reasons, they may be more susceptible to developing reactions

Biological medicines (such as blood products, antibodies and advanced therapies such as gene and tissue therapy) and vaccines – because a variety of biological medicines and vaccines are fundamentally different from standard chemical medicines in terms of their complexity and the characteristics of such products won't be identical. For this reason it's very important that surveillance is carried out on a brand/product-specific basis which may vary from batch-to-batch. For example, there are more than 10 different brands of flu vaccines available in the UK each year and often these are only reported as 'influenza vaccine'. So it's important to include the brand name and batch number in your Yellow Card report

Rare or delayed drug effects – because

Sometimes ADRs may appear months or even years after drug exposure, eg cancers, retroperitoneal fibrosis, Reye's syndrome was associated with aspirin eight decades after it was first marketed. All established drugs and vaccines are continually monitored under the Yellow Card Scheme and although it may be difficult to relate such effects to previous use of a medicine, it is important to report any such suspicions or associations.

Drug interactions – because:

- some precipitant drugs (the drug causing the interaction) can alter the pharmacokinteics of object drugs (the drug affected by the interaction) where the precipitant drug can alter the absorption, distribution metabolism or excretion of the object drug
- some drugs have pharmacodynamic interactions and can change the response of on or multiple drugs having an additive or antagonistic (reducing the response) effects
- either types of drug interactions can result in ADRs in some individuals
- the frequency of drug-drug interactions can increase with the number of medications

Congenital anomalies – because:

If a baby is born with a congenital abnormality, or if a pregnancy results in a malformed aborted foetus, please consider whether this might represent an ADR to a medicine, and report it to us if appropriate. In the report, please give information about any medicine taken during the pregnancy, including self-medication and the date of the last menstrual period.

Herbal remedies – because:

There are many herbal remedies available over-the-counter from outlets other than pharmacies, or supplied by herbal practitioners, and only some of these are actually licensed for use. It is important that we monitor both licensed and unlicensed herbal products to ensure their safety; therefore we ask you to report suspected ADRs to any herbal remedy.

It is important that you provide us with as much information as possible about the remedy, including its ingredients, the source or supplier, if known, and the condition that the product was being used for. If the remedy was supplied by a herbal practitioner, it would be useful to receive their name and address. You should also retain a sample of the product if the reaction is severe, in case further investigations are required.

Please note that you can also report suspected ADRs that arise as a result of error, misuse, abuse or off-label use.

Reporting reminder: