

# Press release: Help make medicines safer: report suspected side effects in children and during pregnancy

Taking place from 19-23 November, the campaign forms part of an awareness week involving 32 medicines regulators in the EU, Latin America, Australasia and the Middle East. Regulators will jointly focus on raising reporting numbers for suspected side effects in infants and children, and during pregnancy, including when breastfeeding.

Last year paediatric reports represented only 10 per cent of all Yellow Card reports of suspected side effects, also known as adverse drug reaction (ADR) reports.

While in most cases medicines are safe and effective, side effects can happen. It is important the risks associated with medicines are understood and communicated.

Potential side effects may range from a headache or stomach ache, to flu-like symptoms or just 'feeling a bit off'. Some side effects can be more serious, and reporting these can help medicines regulators monitor the safe use of medicines on the market and take action as appropriate to prevent future harm.

Regulators such as MHRA rely on the reporting of suspected side effects to help make medicines on the market acceptably safe. Unfortunately, all reporting systems suffer from under reporting – this is why the campaign is important to both raise awareness and help strengthen the system.

To support monitoring of medicines used during pregnancy, the Yellow Card app now has additional questions on medicine exposure during pregnancy. Detail is requested on trimester of exposure, scans, previous pregnancies, use of supplements and whether any suspected adverse effect occurred during the pregnancy.

The campaign is supported by the Uppsala Monitoring Centre, a World Health Organisation Collaborating Centre for International Drug Monitoring, who have developed the campaign animations to encourage reporting.

A number of organisations, including the European Medicines Agency, the European Commission and patient organisations such as EURODIS, a non-governmental patient-driven alliance of patient organisations representing rare disease patient organisations in 70 countries, have also pledged their support.

Mick Foy, Head of Pharmacovigilance Strategy for MHRA's Vigilance and Risk Management of Medicines Division, said:

The most important part of our work is making sure the medicines you and your family take are effective and acceptably safe. Our campaign will help raise awareness with parents and carers, including expectant mothers and those planning to have a baby. It's important for them and healthcare professionals to report potential side effects and have confidence their reports are making a difference.

Children and infants can react differently to medicines than adults. It's important for parents and carers to read the medicine's patient information leaflet and ensure they are giving it in the right dose.

Medicines you take while pregnant or breastfeeding can sometimes affect your baby. If you need to take medicine during pregnancy breastfeeding, or even before when you plan to have a baby, it's essential you discuss your treatment, including any potential side effects, with your doctor or healthcare professional.

Everyone can help make medicines safer by reporting any suspected side effects easily and quickly online through our [Yellow Card Scheme](#).

Dr Max Davie, Officer for Health Promotion for the Royal College of Paediatrics and Child Health (RCPCH), said:

Despite some children sharing a health condition, a one size fits all approach to medicine does not work when prescribing their medication. It's important that healthcare professionals work with children and their families to report all side effects, no matter how big or small, to ensure children have access to high quality treatment options that are best suited to their needs.