

COVID-19 Vaccination Adverse Drug Reaction Monitoring

It is important to report any side effect experienced to the COVID-19 vaccine to the Medicines & Healthcare products Regulatory Agency (MHRA) via a Yellow Card. Adverse reactions and incidents must also be reported on the Trust incident reporting system (Datix), to the Public Health duty room and to the Head of Pharmacy. This will enable surveillance of the novel vaccine to be undertaken and will enhance the safe use of the vaccine on an ongoing basis. Please consider recording any adverse event as a **priority** and encourage colleagues to do the same.

**Encourage all Healthcare staff and recipients of the vaccine to complete a Yellow Card report
Healthcare staff may register for Yellow Card Vaccine Monitor**

The MHRA runs the Yellow Card Scheme which collects and monitors information on suspected safety concerns on medicines and vaccines. This scheme relies on voluntary reporting of suspected safety concerns by **Healthcare Professionals** or **Members of Public**.

There is a dedicated coronavirus Yellow Card site for healthcare professionals and Members of the public/Vaccine recipients to report suspected side effects of any medicines or vaccines they administer/receive.

Use the Coronavirus Yellow Card reporting site

<https://coronavirus-yellowcard.mhra.gov.uk/>

Yellow Card reports can also be made:

- via the mobile app from the Google Play Store or AppleApp Store
- MHRA freephone (0800 731 6789) 9am to 5pm Monday to Friday
- in clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank and Ulysses)
- Regional Medicines and Poisons Information Service can report on your behalf (via MiDatabank) (028 950 40558) 9am to 5pm Monday to Friday

By **YOU** reporting an adverse reaction scientists and organisations can build on their clinical trial data and ensure ongoing safety of their novel vaccine.

Information required as a minimum to complete a report

Information on the person who experienced the side effect (patient identifiable data removed)

The name of the vaccine that caused the side effect

A description of the side effect

Any other medicines taken at the same time

Any other health conditions

A request to workers in the health and care sector from the MHRA

Staff working in health and care settings can support the MHRA to monitor the safety of COVID-19 vaccines by taking part in a national programme called Yellow Card Vaccine Monitor.

Please sign up to the programme – **the Yellow Card Vaccine Monitor**.

Register with this website before receiving a vaccine at <https://vaccinemonitor-yellowcard.mhra.gov.uk>

Note the vaccine name and batch number, if available.

Read the patient information leaflet carefully as it includes the known possible side-effects, available on the MHRA website.

Learn more about vaccines from Public Health NI leaflets.

Regional Medicines and Poisons Information Service (RMPIS) | Belfast Health & Social Care Trust
Medicines & Poisons advice and adverse drug reaction yellow card (eYC) services: Mon to Fri 9:00 am to 5:00 pm
Telephone **(028) 9504 0558** or email medicineinfo@belfasttrust.hscni.net