From the Chief Medical Officer
Professor Sir Michael McBride

Department of
Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Tel: 028 9052 0563
Email: cmooffice@health-ni.gov.uk
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BY EMAIL - [redacted]

Ms Kathy Gray

Dear Ms Gray

Thank you for your recent correspondence of 7 November 2022 in which you enclose a copy of a FOI response you received from the Medicines and Healthcare products Regulatory Agency (MHRA) and in which you suggest there is a legal requirement for recipients of COVID-19 vaccinations to be informed of the adverse reactions associated with COVID-19 vaccines so that true informed consent can be given.

First, it is important to recognise that like all medicines, vaccines can cause side effects. These side effects need to be balanced against the expected benefits in preventing illness. The UK Health Security Agency has previously analysed the direct and indirect impact of the vaccination programme on infections and mortality. It has been estimated that up to 26 September 2021, the UK vaccination programme prevented between 23.9 and 24.3 million infections and between 123,600 and 131,300 deaths.

The MHRA remains content that all COVID-19 vaccines in use meet the required standards of safety, quality and efficacy and that the benefits of COVID-19 vaccination in preventing COVID-19 and serious complications associated with COVID-19 far outweigh any currently known side effects in the vast majority of patients.

As part of the consent process, individuals who avail of the offer of COVID-19 vaccination are made aware of potential side effects, as outlined in the relevant product's Summary of Product Characteristics. Following widespread use of COVID-19 vaccines across the UK since December 2020, the vast majority of suspected adverse reaction reports confirm the safety profile seen in clinical trials. Most reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as a 'flu-like' illness, headache, chills, fatigue, nausea, fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these reactions are

short lived and not associated with more serious illness and likely reflect an expected, normal immune response to the vaccines.

The MHRA continually monitors safety during widespread use of a vaccine and has a proactive strategy in place to do this, working closely with public health partners in reviewing the effectiveness and impact of the vaccines to ensure the benefits continue to outweigh any possible side effects.

Part of this monitoring role includes reviewing reports of suspected side effects. Any member of the public or health professional can submit suspected side effects through the Yellow Card scheme. **It is very important to note that a Yellow Card report does not necessarily mean the vaccine caused that reaction or event.**

* MHRA ask for any suspicions to be reported, even if the reporter isn't sure if it was caused by the vaccine. Some events may have happened anyway, regardless of vaccination. This is particularly the case when millions of people are vaccinated, and especially when vaccines are being given to the most elderly people and people who have underlying illness. Yellow Card reports are continually reviewed to detect possible new side effects that may require regulatory action, and to differentiate these from things that would have happened regardless of the vaccine or medicine being administered, for instance due to underlying or undiagnosed illness.

We trust that you will find this response helpful.

Yours sincerely

PROF.SIR MICHAEL McBRIDE
Chief Medical Officer

CATHY HARRISON
Chief Pharmaceutical Officer

MARIA McILGORM
Chief Nursing Officer