

From the Chief Medical Officer

Dr Michael McBride

From the Chief Pharmaceutical Officer

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Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

HSS(MD)72/2020

For Action:

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- Public Health Agency
- Health and Social Care Board
- HSC Trusts
- NIAS

GP Medical Advisers, HSCB

All General Practitioners and GP Locums

(for onward distribution to practice staff)

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Our Ref: HSS(MD)72/2020

Date: 27 October 2020

Dear Colleagues

THE HUMAN MEDICINES (CORONAVIRUS AND INFLUENZA) (AMENDMENT) REGULATIONS 2020: AMENDMENTS TO THE HUMAN MEDICINES REGULATIONS 2012

The purpose of this letter is to inform you that amendments have been made to the Human Medicines Regulations 2012 to support the rapid and effective rollout of a COVID-19 vaccine and the influenza (flu) vaccine in the UK.

The Statutory Instrument (SI) is titled **The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020** and was co-signed by the Minister of Health for Northern Ireland and the Secretary of State for the Department of Health and Social Care in England. It was laid in Parliament on the 16th October 2020. A link to the SI is available at: <https://www.legislation.gov.uk/ukxi/2020/1125/contents/made>

The purpose of the amendments is:

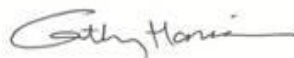
- To strengthen existing regulations to allow for the temporary licensing of medicines and vaccines, on an exceptional basis, pending the granting of a full licence.
- To extend the current immunity from civil liability to companies placing the vaccine on the market, rather than just manufacturers and healthcare workers. This will protect them from legal liability in civil cases but does not give them blanket immunity from civil liability.

- To allow a wider range of trained personnel to administer COVID-19 or flu vaccines. There are three key changes to ensure that the UK has the available workforce to administer the COVID-19 vaccines and influenza vaccines:
 - Expanding the scope of patient group directions to allow for them to be issued for the administration of any medicine, including COVID-19 vaccines and flu vaccines, the supply of which has been temporarily authorised under regulation 174. This change will enable the workforce that already operates under PGDs to deliver vaccinations to continue to do so.
 - Introducing a new type of national immunisation protocol, to be authorised by UK ministers in England, Scotland, Wales and Northern Ireland, which will allow those who are registered healthcare professionals who do not normally vaccinate, and people who are not registered health care professionals, to safely administer a licensed or temporarily authorised COVID-19 or influenza vaccine.
 - Expand the workforce legally allowed to administer vaccines under health service occupational health schemes, so that additional health care professionals in the occupational health workforce will be able to administer these particular vaccines.
- To ensure that the vaccines and treatments used in response to certain specific types of public health threat, such as a COVID-19 vaccine, can be promoted as part of national vaccination or treatment campaigns.
- To make short-term provisions to facilitate the swift and safe transfer of COVID-19 and flu vaccines under NHS/HSC or armed services' authorised arrangements by providing an exemption from the need for a wholesale dealer's licence.

Yours sincerely



Dr Michael McBride
Chief Medical Officer



Cathy Harrison
Chief Pharmaceutical Officer

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Director of Nursing, Public Health Agency
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Trade Union Side

This letter is available on the Department of Health website at
<https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications>