From the Chief Medical Officer
Dr Michael McBride

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

HSS(MD) 88/2020

FOR ACTION
Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/ NIAS
GP Medical Advisers, Health and Social Care Board
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

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Our Ref: HSS(MD) 88/2020
Date: 21 December 2020

Dear Colleagues

THE HUMAN MEDICINES (CORONAVIRUS) (FURTHER AMENDMENTS) REGULATIONS 2020

The purpose of this letter is to inform you that further amendments have been made to the Human Medicines Regulations 2012.

The Statutory Instrument (SI) is titled **The Human Medicines (Coronavirus) (Further Amendments) 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 before Parliament on the 18 December 2020. A link to the SI is available at: http://www.legislation.gov.uk/id/uksi/2020/1594

The SI makes the following amendments:

i. Firstly, it enables certain providers of NHS/HSC and public health services, for example NHS/HSC trusts, to issue Patient Group Directions (PGDs) in relation to parenterally administered medicinal products under powers that previously could only be used to issue PGDs in relation to medicinal products that are not parenterally administered.

ii. Secondly, the SI provides that PGDs that allow retail pharmacy businesses to administer COVID-19 or influenza vaccines may be used at a location other than a registered pharmacy.

iii. Thirdly, the SI allows doctors, nurses and pharmacists to prepare or assemble COVID-19 vaccinations, or supervise their preparation or assembly, in

circumstances in which they were not previously permitted to do so without the appropriate licences.

iv. Fourthly, it provides for authorised medicinal products which are to be used for the reformulation of COVID-19 vaccines, most commonly diluents, to be "assembled" into new products (for example by packing them down into different quantities and relabelling them), without those new products needing to be covered by new marketing authorisations.

v. Fifthly, it allows holders of a wholesale dealer's licence – without a manufacturer's licence – to relabel COVID-19 vaccines with a new shelf life to take account of the thawing of the product.

vi. Finally the SI corrects errors made by the Human Medicines (Amendments etc.) (EU Exit) Regulations (S.I. 2020/1488) that arise out of a failure to take account of the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125) to restore the effect of some of the changes made by these Regulations.

These amendments will support the rapid and effective rollout of a COVID-19 vaccine in the UK.

Yours sincerely

Dr Michael McBride
Chief Medical Officer

Cathy Harrison
Chief Pharmaceutical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)
Assistant Director Public Health (Health Protection), Public Health Agency
Director of Nursing, Public Health Agency
Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board *(for onward distribution to Community Pharmacies)*
Directors of Pharmacy HSC Trusts
Director of Social Care and Children, HSCB
Family Practitioner Service Leads, Health and Social Care Board *(for cascade to GP Out of Hours services)*
Medical Directors, HSC Trusts *(for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads)*
Nursing Directors, HSC Trusts *(for onward distribution to all Community Nurses, and Midwives)*
Directors of Children's Services, HSC Trusts
RQIA (*for onward transmission to all independent providers including independent hospitals*)

Medicines Management Pharmacists, HSC Board *(for cascade to prescribing advisers)*
Regional Medicines Information Service, Belfast HSC Trust
Regional Pharmaceutical Procurement Service, Northern HSC Trust
Professor Donna Fitzsimons, Head of School of Nursing and Midwifery QUB
Professor Sonja McIlfatrick, Head of School of Nursing, University of Ulster
Caroline Lee, CEC
Donna Gallagher, Open University
Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU
Professor Colin McCoy, Head of School, School of Pharmacy, QUB
Professor Colin Adair, Director of the NI Centre for Pharmacy Learning and Development, QUB
Joe Brogan, Assistant Director of Integrated Care, HSCB
Donncha O'Carolan, HSCB *(for distribution to all General Dental Practitioners)*
Raymond Curran, Head of Ophthalmic Services, HSCB *(for distribution to Community Optometrists)*
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