From the Chief Medical Officer
Dr Michael McBride

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

HSS(MD) 2/2021

FOR ACTION

Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/ NIAS
GP Medical Advisers, Health & 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

Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Tel: 028 9052 0563
Email: Michael.McBride@health-ni.gov.uk

Our Ref: HSS(MD) 2/2021
Date: 5 January 2021

Dear Colleague

DEPLOYMENT OF COVID-19 VACCINE OXFORD / ASTRAZENECA GOVERNANCE, HANDLING AND PREPARATION IN GENERAL PRACTICE

ACTION REQUIRED
Chief Executives must ensure this information is drawn to the attention of all staff involved in the COVID-19 vaccination programme.

The PHA must ensure this information is cascaded to their staff working on COVID-19 vaccine deployment and the health protection team.

The HSCB must ensure this information is cascaded to all General Practitioners and practice managers for onward distribution to all staff involved in the COVID-19 vaccination programme including general practice pharmacists.

Firstly, we would like to thank you and your teams for the exceptional work being undertaken to prepare for the primary care based COVID-19 vaccination programme beginning today in a small number of practices, ahead of the wider rollout of the programme from the week commencing 11 January 2021. This letter provides further detail around the expectations for governance, handling and preparation of the Oxford / AstraZeneca vaccine in general practice, to supplement the overview of the primary care programme as set out in **HSS(MD) 93/2020.**

Legal basis and expectations of HMR regulation 174 (temporary) authorisation for supply of the vaccine products

It is important that all registered healthcare professionals dealing with the vaccines are familiar with the law underpinning their regulatory authorisation and the consequential expectations of professional accountability and practice. The UK medicines regulatory framework empowers the Medicines and Healthcare products Regulatory Agency (MHRA) acting on behalf of the licensing authority (the UK and NI Health Ministers) to temporarily authorise the supply or distribution of unlicensed medicinal products in response to certain public health events, for example a pandemic.

The specific legislation is set out in regulation 174 and 174A of the Human Medicines Regulations (HMR) 2012, as amended. Regulation 174A provides for conditions to be attached to the temporary authorisation, which will generally be done in order to assure the safety, quality and efficacy of the specific medicine. Ministers would consider doing so after taking advice of the independent expert advisory committee for medicines, the Commission on Human Medicines. Supply and administration of the medicine (COVID-19 vaccine in this case) must comply with the conditions. These conditions will be in addition to the normal regulatory requirements for control of manufacture, distribution, compliance with appropriate good practices, monitoring and reporting of adverse reactions etc.

Healthcare organisations and healthcare professionals are also subject to legislation and good governance requirements. The relevant exemptions that exist for healthcare professionals at the final stages of supply are in Regulation 3 of the HMRs (for doctors, dentists, nurses and midwives) and section 10 of the Medicines Act 1968 (for pharmacists in certain health care settings such as registered pharmacies). Regulation 3 of HMR provides that:

- A medicinal product can be manufactured or assembled by a doctor without the need for a manufacturer's licence or marketing authorisation provided that the medicinal product is supplied to a patient of that doctor in the course of the treatment of that patient or to a patient of another doctor who is a member of the same medical practice and is not manufactured or, as the case may be, assembled on a large scale by an industrial process; and

- A medicinal product can be assembled by a registered nurse or a registered midwife without a manufacturer's licence if the nurse or midwife is acting in the course of his or her profession and is not assembled on a large scale by an industrial process.

For the purposes of the national vaccination programme against COVID-19, there may be a number of different settings in which doctors and nurses will be undertaking the final dilution and drawing up of the vaccine, or will be responsible for another health care professional undertaking the final dilution and drawing up of the vaccine in their name, for administration to patients who are only temporarily their patients and under their care. Where what is being done is professionally appropriate, both for the person doing the final preparation and, if different, the person in whose name the final preparation is being done, this will be treated as compliant with regulation 3.

In practice, the professional expectations for the primary care vaccination programme are as follows:

Regulatory compliance by the doctor/GP under reg.3 of the Human Medicines Regulations 2012 means they have to understand the process being done in their name and be accountable for it. However, it is not essential that the preparation of the vaccine prior to administration is undertaken by a GP or by pharmacy professionals. What is essential is that it is being done by doctors acting within their professional competence or by someone acting on the doctor's behalf who is acting within their professional competence. Ordinarily the skills in question would be the skills one would expect to find amongst pharmacy professionals, but there will for example be nurses who have the right qualifications, skills and experience.

Supporting deployment of the COVID-19 Oxford / AstraZeneca vaccine

General practice will be used to handling vaccines with storage conditions of 2-8 degrees Centigrade, as well as the use of multidose vials of other medicines. However, a multidose vaccine with no preservative, as is the case with this vaccine, is unusual, and so good aseptic technique will be important in order to maintain the safety, quality and effectiveness of the vaccine.

Good systems of medicines management remain critical to ensure safe deployment and use of vaccines, particularly as more specially trained vaccinators come on stream, and so it is important that practices work with the Health and Social Care Board and their GP Federation pharmacy team to ensure that pharmaceutical expertise and oversight is in place to support the safe handling and use of the vaccine in general practice. General practice pharmacists are well placed to play a leading role in providing pharmaceutical advice on vaccine management as well as ensuring that robust systems are in place for pharmacovigilance including reporting of adverse events to the MHRA through the Yellow Card scheme. To underpin the use of the COVID-19 Vaccine Oxford/AstraZeneca, the NHS Specialist Pharmacy Service has produced a suite of resources which general practice pharmacy teams may find helpful to utilise for this purpose, and which are available here.

Information for healthcare professionals and the conditions for the temporary authorisation of COVID-19 Vaccine Oxford/AstraZeneca can be found here. Please familiarise yourselves and your teams with these as soon as possible. The Regional Patient Group Direction for COVID-19 Vaccine Oxford / AstraZeneca has been developed by the Public Health Agency, and is available on the HSC Primary Care Intranet.

Arrangements are being put in place for practices to order supplies of the COVID-19 Vaccine Oxford/AstraZeneca via the Movianto web based ordering system. The Health and Social Care Board will work with practices to agree quantities that will be available to practices to order and will provide further details in the coming days. Practices should note that they will also need to ensure that they order adequate quantities of consumables such as needles and syringes when placing their order for vaccine supply via the web based ordering system, as these need to be ordered separately. While every effort is being made to ensure timely delivery of orders that are placed with Movianto, practices should not schedule vaccination clinics before deliveries of vaccine have been confirmed.

Once again, thank you for your enormous efforts to ensure the safe and timely rollout of the COVID-19 vaccination programme and to maintain existing services at this challenging time.

Yours sincerely

DR MICHAEL McBRIDE
Chief Medical Officer

MRS 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