

Dear Colleagues

## WINTER VACCINATION PROGRAMME 2022 UPDATE – SEASONAL FLU IMMUNISATION AND COVID-19 BOOSTERS

We are writing to provide you with further information about the winter seasonal flu immunisation and COVID-19 booster vaccination programme 2022.

### Key Updates

1. Programme deployment of Pfizer-BioNTech mRNA bivalent Original/Omicron vaccine, hereinafter referred to as Comirnaty® bivalent.
  - Programme pace and completion date.
  - Off label use of Pfizer BioNTech COVID-19 BNT162b2 vaccine (Comirnaty®) 10 micrograms as a booster dose for 5-11 year-olds.
  - Off label use of Novavax COVID-19 vaccine (Nuvaxovid®) as a booster dose for persons aged over 18.

### Pfizer-BioNTech mRNA (Comirnaty) bivalent Original/Omicron BA. 1 vaccine

#### 2. MHRA authorisation

The MHRA granted [authorisation for Pfizer - BioNTech mRNA \(Comirnaty\) bivalent Original/Omicron BA.1](#) for use as a booster dose for individuals aged 12 years and above, on 3 September 2022.

#### 3. JCVI Advice

The JCVI [issued advice](#) on 3 September 2022, approving the use of the Comirnaty® bivalent as a booster dose for individuals over the age of 12, as part of the winter booster campaign.

**From Chief Medical Officer  
Chief Nursing Officer  
Chief Pharmaceutical Officer**  
Professor Sir Gregor Smith  
Professor Alex McMahon  
Professor Alison Strath

---

15 September 2022

---

SGHD/CMO(2022)32

#### **For action**

Chief Executives, NHS Boards  
Medical Directors, NHS Boards  
Nurse Directors, NHS Boards  
Primary Care Leads, NHS Boards  
Directors of Nursing & Midwifery,  
NHS Boards  
Chief Officers of Integration  
Authorities  
Chief Executives, Local  
Authorities  
Directors of Pharmacy  
Directors of Public Health  
General Practitioners  
Practice Nurses  
School Nurses  
Immunisation Co-ordinators  
CPHMs  
Scottish Ambulance Service

#### **For information**

Chairs, NHS Boards  
Infectious Disease Consultants  
Consultant Physicians  
Public Health Scotland  
Chief Executive, Public Health  
Scotland  
NHS 24

---

#### **Further Enquiries**

Policy Issues  
Vaccination Policy Team  
[seasonalfluprogramme@gov.scot](mailto:seasonalfluprogramme@gov.scot)

Medical Issues  
Dr Lorna Willocks  
Senior Medical Officer  
St Andrew's House  
[Lorna.Willocks@gov.scot](mailto:Lorna.Willocks@gov.scot)

PGD/Pharmaceutical  
William Malcolm  
Public Health Scotland  
[William.Malcolm@nhs.scot](mailto:William.Malcolm@nhs.scot)

Vaccine Supply Issues  
[nss.vaccineenquiries@nhs.scot](mailto:nss.vaccineenquiries@nhs.scot)

#### 4. Dose Interval

The Comirnaty® bivalent vaccine requires a minimal 12 week interval between the previous vaccine dose and the booster dose.

#### 5. Observation period

It is recommended in the [Green Book Chapter](#) that all recipients of the Pfizer-BioNTech vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers [recommended suspension](#) of this requirement for the two mRNA vaccines (Pfizer BioNTech and Moderna) in both children and adults. The suspension of the observation period in individuals without a history of allergy has since been agreed by the Commission on Human Medicines and also applies to the Comirnaty® bivalent vaccine.

However, the Scottish Government has made further recommendations that all doses of COVID-19 mRNA vaccines be followed by a 5 minute observation period and Health Boards are expected to implement this recommendation.

#### 6. Workforce Education

In order to support practitioners NHS Education Scotland (NES) and Public Health Scotland (PHS) have developed a number of resources for vaccinators in relation to COVID-19 and seasonal flu vaccines. These are available on the NES [TURAS platform](#). These resource continue to be updated and a resource relating to the Comirnaty® Bivalent vaccine will be available shortly.

#### 7. Supply

Currently we are expecting delivery of the new Pfizer Bivalent vaccine which we believe, in addition to Moderna Spikevax bivalent, will give us adequate supply of bivalent vaccines to vaccinate all groups identified in the JCVI guidance of 15 July 2022.

#### **Off label use: Pfizer BioNTech COVID-19 BNT162b2 vaccine (Comirnaty®) 10 micrograms as a booster dose for 5-11 year olds**

8. The JCVI has recommended that children aged 5-11 years of age who are in a recognised risk group as described in table 4 of the Green Book and those who are household contacts of individuals who are immunosuppressed as defined in tables 3 or 4 of the Green Book should be offered a booster dose of the Pfizer BioNTech COVID-19 BNT162b2 vaccine (Comirnaty®) 10 micrograms. This will be off-label as it is only authorised for use by the MHRA as a primary dose and not as a booster dose. The national specimen PGD and the National Protocol have been issued to Health Boards and reflect the off-label use as outlined by the JCVI and Green Book.

#### **Off label use: of Novavax COVID-19 vaccine (Nuvaxovid®) as a booster dose for persons aged 18 years and over**

9. Novavax COVID-19 vaccine (Nuvaxovid®) is only to be used in cases where mRNA vaccines are not considered clinically suitable. Novavax COVID-19

vaccine (Nuvaxovid®) is authorised by the MHRA for primary vaccination of adults and children aged 12 years and over, but not for booster doses. The JCVI has advised it can be used “off label” as a booster dose for those aged 18 and over. There is no National Protocol for Novavax COVID-19 vaccine (Nuvaxovid®) and when required, for those for whom mRNA vaccines are not considered clinically suitable, it can be administered by Health Boards using their Patient Group Direction (PGD). This ensures that the assessment and administration are undertaken by a registered healthcare professional providing a satisfactory and acceptable level of clinical input to the decision making process to use the Novavax COVID-19 vaccine (Nuvaxovid®) vaccine. Health Care Support Workers cannot operate under a PGD and delegation from a registered healthcare professional is not permitted.

### **Programme Pace and Completion Date**

10. The Scottish Government has asked Health Boards to make best endeavours to complete vaccinations by the start of December in alignment with the JCVI advice. The FVCV Programme continues to work with Health Boards to explore how to best support this activity.

### **Workforce Skill Mix - Registered Healthcare Professional (RHCP) : Health Care Support Worker (HCSW) Ratio**

11. [Review of the National Framework for Vaccine Administration](#) by HCSWs in Scotland is under discussion. In the interim the Scottish Executive Nurse Directors (SEND) have agreed that updated guidance be released through the Chief Nursing Officer Directorate (CNOD) to allow for operational flexibility and to bring us in line with the other UK Nations.
12. **Guidance:** HCSWs in Scotland must not take informed consent from patients for vaccination or make any clinical decision. HCSWs must always work as part of a team with registered practitioners so that any informed consent or clinical issues can be discussed quickly with a registered health professional on site. As a minimum standard it is expected that:
- Appropriate supervision arrangements and skill mix must be identified in local delivery plans and agreed with board Executive Nurse Directors
  - Supervision arrangements for experienced and established teams is set no lower than 1:6
  - Supervision levels of 1:3 is the ideal or preferred standard and should be considered if possible, particularly in relation to less experienced staff

### **Co-administration of flu and Covid vaccines by Midwifery Teams**

13. In order to maximise uptake and protection for this group, the preferred approach to the vaccination of pregnant women is for co-administration of both flu and Covid-19 vaccines, by midwifery teams, at existing appointments. The Chief Midwife is in support of this approach. Where possible Boards are asked to offer co administration with seasonal flu within their local arrangements.
14. Women who become pregnant before 1 April 2023 will be eligible for the vaccines.

## **At risk cohort refresh**

15. As a patient group that undergoes significant transience, the programme will recalculate the cohort files for this group in November. This ensures that we continue to identify those most at-risk and invite them for vaccination, thus reducing the number of local clinical referrals required.

## **Age cut off for those aged 4, turning 5 during the programme**

16. As those under 5 years of age are not permitted a COVID-19 vaccination, the cut off for this group has been defined as 1 September 2022 to minimise the risk of inappropriate referrals. This group file will be refreshed at different points throughout the programme, allowing for identification of those who have turned 5, up until 31 March 2023. The first refresh will be in November, alongside the at risk group noted above.

## **Communications and Resources**

17. The national marketing campaign commenced across radio and digital on 15 August with an initial focus on health and social care workers and the over 65s. The campaign will be targeted at other cohorts as it progresses. The childhood flu vaccination campaign commenced on 29 August.

18. The Scottish Government has provided a range of communications materials, messaging and assets to Health Boards and partners to help promote the vaccination offer to the general public and specific audiences. Public Health Scotland has developed toolkits to encourage the promotion of the Winter vaccinations that will support NHS and social care colleagues: [Overview - Winter vaccinations - Seasonal immunisations - Immunisations - Our areas of work - Public Health Scotland](#). Further materials will be provided as we progress through the programme and the associated cohorts.

19. The public should be signposted to [NHS Inform](#) for up to date information on the vaccination programme.

Thank you again for all your hard work in these most challenging of circumstances.

Yours sincerely,

*Gregor Smith*

*Alex McMahon*

*Alison Strath*

**Professor Sir Gregor Smith  
Chief Medical Officer**

**Professor Alex McMahon  
Chief Nursing Officer**

**Professor Alison Strath  
Chief Pharmaceutical  
Officer**

## Annex A: Covid Vaccinations – Use and naming conventions

Supply Team Abbreviation	Programme & Green Book	MHRA / JCVI Age	Use	JCVI Name	Other Descriptions
Spikevax Bivalent	Moderna bivalent (Spikevax® bivalent Original/Omicron vaccine)	18+	Booster only	Moderna mRNA (Spikevax) bivalent Original 'wild-type'/Omicron BA.1	dm+d: COVID 19 Vaccine Spikevax 0 (Zero)/O (Omicron) 0.1mg/ml dispersion for injection multidose vial INN: Elasomeran and imelasomeran
Spikevax Original	Moderna COVID-19 vaccine (Spikevax®)	18+	Primary dose + booster	Moderna mRNA (Spikevax) Original 'wild-type'	Spikevax COVID 19 mRNA (nucleoside modified vaccine 0.1mg/0.5mL dose dispersion for injection multidose vial INN: Elasomeran
Comirnaty Bivalent	Pfizer-BioNTech COVID-19 vaccine (Comirnaty® bivalent Original/Omicron)	12+	Booster only	Pfizer-BioNTech mRNA (Comirnaty) bivalent Original 'wild-type'/Omicron BA.1 vaccine 30 micrograms	dm+d: Comirnaty Original/Omicron BA.1 COVID 19 mRNA Vaccine 15micrograms / 15micrograms/ 0.3ml dose dispersion for injection multidose vial INN: Tozinameran and riltozinameran
Comirnaty 30 Concentrate	Pfizer BioNTech COVID-19 BNT162b2 vaccine (Comirnaty®) 30 micrograms	12+	Primary dose + booster	Pfizer-BioNTech mRNA (Comirnaty) 'wild-type' 30 micrograms	dm+d: Comirnaty COVID 19 mRNA Vaccine 30micrograms/0.3ml dose concentrate for dispersion for injection multidose vial INN: Tozinameran
Comirnaty 10 Concentrate	Pfizer BioNTech COVID-19 BNT162b2 vaccine (Comirnaty®) 10 micrograms	5-11	Primary dose (booster off label)	Pfizer-BioNTech mRNA (Comirnaty) 'wild-type' 10 micrograms	dm+d: Comirnaty Children 5 11 years COVID 19 mRNA Vaccine 10micrograms/0.2ml dose concentrate for dispersion for injection multidose vial INN: Tozinameran
Nuvaxovid	Novavax COVID-19 vaccine (Nuvaxovid®)	MHRA 12+ JCVI 18+	Primary dose (booster off label)	Novavax Matrix-M adjuvanted wild-type vaccine (Nuvaxovid)	dm+d : COVID 19 Vaccine Nuvaxovid (recombinant, adjuvanted) 5micrograms/0.5ml dose suspension for injection multidose vial