

National Protocol for Spikevax® Bivalent Original/Omicron COVID-19 vaccine (Moderna)

(Spikevax® Bivalent Original/Omicron 50 micrograms per 0.5mL dose dispersion for injection)

Reference no: Spikevax® Bivalent Original/Omicron COVID-19 vaccine protocol
Version no: v1.0
Valid from: 1 September 2022
Review date: 31 March 2023
Expiry date: 31 August 2023

This protocol is for the administration of Spikevax® Bivalent Original/Omicron COVID-19 vaccine to individuals in accordance with the national COVID-19 vaccination programme.

This protocol is for the administration of Spikevax® Bivalent Original/Omicron COVID-19 vaccine by appropriately trained persons in accordance with [regulation 247A](#) of [Human Medicines Regulations 2012 \(HMR 2012\)](#), added by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020¹](#)

Welsh Government, Public Health Wales and Welsh Medicines Information Centre have developed this protocol for authorisation by Welsh Ministers to facilitate the delivery of the national COVID-19 vaccination programme.

This protocol may be adhered to wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see 'stages of activity' table in [Characteristics of staff](#)). Alternatively, multiple persons may undertake activity stages in the vaccination pathway in accordance with this protocol and the general requirements of the Human Medicines Regulations 2012 and Medicines Act 1968 as appropriate. Where multiple person models are used, the service provider/engaged provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider/engaged provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol and that there is adequate supervision in place. As a minimum, competence requirements stipulated in the protocol under [Characteristics of staff](#) must be adhered to.

Persons must be authorised by name to work under this protocol. They must ensure they meet the staff characteristics for the activity they are undertaking, and make a declaration of competence and be authorised in writing. This can be done by completing [Section 4](#) of this protocol or maintaining an equivalent electronic record.

A clinical supervisor must take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users. Whenever the protocol is used, the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the protocol must be recorded for the session. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Staff working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility. Staff working to the protocol must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all members of staff or individual members of staff at any time and has authority to stop and start service provision under the protocol as necessary. Every member of staff has a responsibility to, and should, report immediately to the clinical supervisor any concerns

¹ To include any relevant updates, changes or amendments to legislation

they have about working under the protocol in general or about a specific individual, process, issue or event.

Operation under this protocol is the responsibility of health boards/NHS trusts/engaged providers. Health boards/NHS Trusts/engaged providers using this protocol should retain copies, along with the details of those authorised to work under it, for 10 years after the protocol expires.

Persons must check that they are using the current version of this protocol and current versions of any documents this protocol refers to. Amendments may become necessary prior to the published expiry date. Current versions of national protocols for COVID-19 vaccines, authorised by the Welsh Ministers in accordance with regulation 247A of the Human Medicines Regulations 2012, can be found via: [Clinical guidance: coronavirus | Sub-topic | GOV.WALES](#)

Change history

Version number	Change details	Date
V1.0	New protocol for Spikevax [®] Bivalent Original/Omicron COVID-19 vaccine	1 September 2022


1. Ministerial authorisation

In accordance with [regulation 247A](#) of [Human Medicines Regulation 2012](#), added by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, this protocol is not legally valid until approved by the Welsh Ministers.

On 1 September 2022 the Welsh Ministers approved this protocol in accordance with [regulation 247A](#) of Human Medicines Regulation 2012.

Unless explicitly revoked, the Welsh Minister's approval of this protocol remains valid in the event of any subsequent variation to the Spikevax® Bivalent Original/Omicron COVID-19 vaccination specifications or key reference material set out in this protocol.

This protocol provides clinical authorisation by the Chief Medical Officer (CMO) or Deputy Chief Medical Officer (DCMO) for the delivery of the national COVID-19 vaccination programme.

Clinical authorisation			
Role	Name	Sign	Date
CMO	Frank Atherton		1/09/2022

Any Health Board/NHS Trust/engaged provider administering Spikevax® Bivalent Original/Omicron COVID-19 vaccine under this protocol must work strictly within the terms of this protocol and, where required to, in accordance with any Directions made by the Welsh Ministers in respect of the delivery of the national COVID-19 vaccination programme.

Assembly, final preparation and administration of vaccines supplied and administered under this protocol must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines must also be in accordance with general requirements of the Human Medicines Regulations 2012 and Medicines Act 1968, and with the instructions for usage that are conditions of the authorisation to supply the product. These conditions for usage are in the Information for UK Healthcare Professionals, published alongside the regulatory approval conditions of authorisation and available at: <https://www.gov.uk/government/publications/regulatory-approval-of-spikevax-bivalent-originalomicron-booster-vaccine> and includes administration according to official recommendations, contained in Immunisation against infectious Disease chapter 14a (the 'Green Book') available at: <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>.

Note: The national COVID-19 vaccination programme may also be provided under patient group direction or on a patient specific basis (that is by or on the directions of an appropriate independent prescriber). Supply and administration in these instances should be in accordance with arrangements for the delivery of the national COVID-19 vaccination programme and are not related to this protocol.

2. Characteristics of staff

Classes of persons permitted to administer medicinal products under this protocol

This protocol may be adhered to wholly from assessment through to post-vaccination by a single appropriately registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this protocol.

Activity stages of the vaccination pathway under this protocol

Stage 1	a. Assess the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual
Stage 2	• Vaccine Preparation
Stage 3	• Vaccine Administration
Stage 4	• Record Keeping
Stage 5	• Post-immunisation observation

Those working under this protocol must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking.

Where multiple person models are used, the health board/NHS trust/engaged provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The health board/NHS trust/engaged provider is responsible for ensuring that persons are trained, competent and appropriately supervised to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

All persons must be authorised by name as an approved person under the current terms of this protocol before working to it, see [Section 4](#)

All staff listed on the practitioner/staff authorisation sheet (section 4) will be covered by NHS indemnity extended by the Health Board who is responsible for the COVID 19 vaccination programme in that locality.

Protocols do not remove inherent obligations or accountability. All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.

There are three underpinning principles to which every person undertaking activities under the remit of this protocol must adhere –

Training

- They must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and health board standard operating procedures and in line with the [training recommendations for COVID-19 vaccinators](#).
- They must have completed the [national COVID-19 vaccination e-learning programme](#), including the relevant vaccine specific session (or the Spikevax® Bivalent Original/Omicron COVID-19 vaccine ([recorded](#)) [slide set](#)), and/or locally provided COVID-19 vaccine training. Public Health Wales have an e-Learning landing page: [Immunity eLearning - Public Health Wales \(nhs.wales\)](#). This page offers support on how to access these resources via ESR, or for staff outside of NHS Wales via the [learning@Wales](#) platform. Training resources and guidance documents are also available to view on the Public Health Wales micro-site: <https://phw.nhs.wales/topics/immunity-and-vaccines/covid-19-vaccination-information/>

Competency

- Clinical supervisors must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
- All persons must
 - be an appropriate prescriber; or
 - be one of the following registered professionals:
 - nurses, nursing associates and midwives currently registered with the Nursing and Midwifery Council (NMC)
 - pharmacists currently registered with the General Pharmaceutical Council (GPhC)
 - chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
 - dental hygienists and dental therapists registered with the General Dental Council; or
 - optometrists registered with the General Optical Council; or
 - if not in one of the professionally registered groups mentioned above, or is a new vaccinator, and those returning to immunisation after a prolonged interval (more than 12 months), complete the COVID-19 vaccinator competency assessment tool for formal evaluation and sign-off of their clinical competency. They should be supervised administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently.
- Experienced vaccinators should use the competency tool to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer COVID-19 vaccine.

In addition and where indicated as relevant to the role-

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SPC), and be familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the [Green Book](#).
- They must be familiar with, and alert to changes in the relevant health board/NHS trust/ standard operating procedures (SOPs) and health board/NHS trust/engaged provider arrangements for the national COVID-19 vaccination programme
- They must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- They must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions.
- For Stage 1 activity persons must have the necessary knowledge, experience and skill to be competent to assess the individual presenting for vaccination, provide information, obtain informed consent and provide advice to the individual
- They must have access to the health board/NHS trust/contacter protocols and relevant [COVID-19 vaccination programme](#) online resources such as the [Green Book](#), particularly [Chapter 14a](#), and the UKHSA [COVID-19 vaccination programme: Information for healthcare](#)

[practitioners](#) document, all of these are available at <https://phw.nhs.wales/topics/immunisation-and-vaccines/covid-19-vaccination-information/resources-for-health-and-social-care-professionals/>. These documents are updated from time to time, and vaccinators must check for updates and maintain their competence.

- They must be competent in intramuscular injection technique if they are administering the vaccine, this should include a practical element.
- For those preparing the vaccine, they must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose.
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the Welsh Immunisation System (WIS), have received training and be competent in the use of that system, meeting competencies 3k and 3l of the [COVID-19 vaccinator competency assessment tool](#)
- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

Supervision

- A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential. Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the COVID-19 immunisation programme.
- Non-registered persons must be supervised and supported by a registered healthcare professional at all times.
- The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision, see [page 1](#), for the overall provision of clinical care provided under the legal authority of the protocol.

3. Key references

Key references	<p>Spikevax® Bivalent Original/Omicron COVID-19 vaccine</p> <ul style="list-style-type: none">• Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Available at: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book <p>Joint Committee on Vaccination and Immunisation (JCVI) statements on COVID-19 vaccination programme: published and available via: https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation</p> <ul style="list-style-type: none">• Definition of clinically extremely vulnerable groups https://gov.wales/guidance-protecting-people-defined-medical-grounds-clinically-extremely-vulnerable-coronavirus <p>Regulatory approval of Spikevax® Bivalent Original/Omicron COVID-19 vaccine, Available at: https://www.gov.uk/government/publications/regulatory-approval-of-spikevax-bivalent-originalomicron-booster-vaccine</p> <ul style="list-style-type: none">• Patient Group Direction for Spikevax® Bivalent Original/Omicron COVID-19 vaccine. Available at: Patient Group Directions (PGDs) and Protocols Landing Page - Public Health Wales (nhs.wales) <p>Other Official Guidance</p> <p>General</p> <ul style="list-style-type: none">• Welsh Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. 20 March 2013 http://www.wales.nhs.uk/sites3/documents/254/whtm%2007-01.pdf• UKHSA Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors• Resuscitation Council UK, Anaphylaxis Guidelines https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings• Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/ukxi/2012/1916/regulation/247A• UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/ukxi/2020/1125/contents/made
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	<ul style="list-style-type: none">• The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents/made• The Medicines Act 1968 https://www.legislation.gov.uk/ukpga/1968/67/contents
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4. Practitioner/staff authorisation sheet

Spikevax® Bivalent Original/Omicron COVID-19 vaccine protocol v1.0 Valid from: 01/09/2022 Expiry: 31/08/2023

This authorisation sheet should be retained to serve as a record of those persons authorised to work under this protocol.

By signing this protocol you are indicating that you agree to its contents and that you will work within it.

Protocols do not remove inherent professional obligations or accountability. All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should abide by their professional code of conduct.

It is the responsibility of each person operating under this protocol to do so within the bounds of their own competence.

I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it.								
Name	Designation	Activity Stage:					Signature	Date
		1	2	3	4	5		

Authorising registered healthcare professional

I confirm that I, as a registered healthcare professional who is familiar with the competence required in all aspects of this protocol, provide authority on behalf of the below named provider organisation, that the persons named above are competent to work under this protocol and may provide vaccination activities indicated above in accordance with this protocol in the course of working for (insert health board/NHS trust/engaged provider)			
Name	Designation	Signature	Date

Note to authorising registered healthcare professional

Score through unused rows in the list of persons to prevent additions post authorisation.

If the clinical supervisor is also the authorising registered healthcare professional, they may make a self-declaration of competency above.