

WG No. 22-04

**THE NATIONAL HEALTH SERVICE (WALES) ACT
2006**

**The Primary Care (Contracted Services: Immunisations)
(Amendment) Directions 2022**

Made

4 February 2022

Coming into force

5 February 2022

The Welsh Ministers, in exercise of the powers conferred on them by sections 10, 12(3) and 203(9) and (10) of the National Health Service (Wales) Act 2006⁽¹⁾, make the following Directions.

Title, application and commencement

1.—(1) The title of these Directions is the Primary Care (Contracted Services: Immunisations) (Amendment) Directions 2022.

(2) These Directions are given to Local Health Boards.

(3) These Directions come into force on 5 February 2022.

Amendment of the Primary Care (Contracted Services: Immunisations) Directions 2021

2.—(1) The Primary Care (Contracted Services: Immunisations) Directions 2021⁽²⁾ are amended as follows.

(2) In Direction 2—

(a) in the definition of “Covid-19 vaccine”—

(i) after “Moderna vaccine,” insert “Novavax vaccine,”

(ii) for “or” substitute “,” and

(iii) after “Pfizer-BioNTech vaccine” insert “or Vaccine Janssen”;

(b) in the definition of—

(i) “Moderna vaccine”, for “COVID-19 mRNA Vaccine Moderna” substitute “Spikevax® COVID-19 mRNA vaccine (Moderna)”,

(ii) “Oxford Astra/Zeneca vaccine”, for “(ChAdOx1 nCoV-19) (Oxford) Vaccine” substitute “Vaxzevria® COVID-19 vaccine (AstraZeneca)”, and

(iii) “Pfizer-BioNTech vaccine”, for “COVID-19 mRNA Vaccine BNT162b2 or Comirnaty proprietary brand” substitute “Comirnaty® COVID-19 mRNA vaccine (Pfizer BioNTech)”; and

(1) 2006 c. 42.

(2) WG No. 21-70.

(c) in the appropriate place insert—

““Novavax vaccine” means the Nuvaxovid® COVID-19 vaccine (NVX-CoV2373) developed by Novavax;

“Vaccine Janssen” means the COVID-19 Vaccine Janssen (Ad26.COV2-S [recombinant]);”.

(3) For Schedule 1 (Primary Care Contracted Services: Immunisations (Covid-19 vaccines) Specification) substitute the Schedule to these Directions.

Amendment of the Primary Care (Contracted Service: Immunisations) (Amendment) Directions 2021

3.—(1) The Primary Care (Contracted Services: Immunisations) (Amendment) Directions 2021⁽¹⁾ are amended as follows.

(2) In Direction 2 paragraph (3), omit sub-paragraphs (b) to (d).

Signed by Alex Slade, Deputy Director, Primary Care and Health Science under the authority of the Minister for Health and Social Services, one of the Welsh Ministers



Date: 4 February 2022

(1) WG No. 21-97.

“SCHEDULE 1

Primary Care Contracted Services: Immunisations (Covid-19 Vaccines) Specification

1. Introduction

The long term response to the Covid-19 pandemic requires the deployment of a safe and effective vaccine with enough uptake in the ‘at risk’ and overall population to protect individual patients and reduce the burden on, and risk to, NHS services.

Rapid progress has been made with high levels of uptake across all age ranges. The vaccination programme continues to evolve and, as part of their planning, Local Health Boards have to consider a range of factors, including workforce, logistics and infrastructure. They also must take account of developments in the advice issued by the Joint Committee for Vaccination and Immunisation (“JCVI”) along with other guidance, as well as how best to meet the needs of their population.

Planning and the delivery of an evolving programme is therefore ongoing and has to respond to changes in the course of the pandemic, particularly with regard to those individuals eligible for a vaccine. This continues to be a whole NHS Wales approach with the strategic intent of immunising as many eligible individuals, as swiftly as possible, safely and with minimum waste.

Primary Care providers in Wales have an excellent track-record of delivering immunisation programmes, including the Covid-19 vaccine. They have the skilled and experienced workforce necessary to support the delivery of a mass vaccination programme.

As we move through the current and future phases of the vaccination programme, it is crucial that Local Health Boards remain flexible and enable primary care providers to continue to engage in vaccine delivery where that is needed, whilst also balancing this with ongoing delivery of essential services.

This Primary Care Contracted Services: Immunisations scheme (“PCCS:I”) Specification specifically relates to the delivery of the Moderna vaccine, the Novavax vaccine, the Oxford-Astra/Zeneca vaccine, the Pfizer-BioNTech vaccine and the Vaccine Janssen Covid-19 vaccines (which are together referred to in the Directions and this Specification as “the Covid-19 Vaccines”) by primary care providers, defined for the purpose of this specification as “engaged providers”.

2. Background

SARS-CoV-2 virus is the official name of the strain of coronavirus that causes the disease known as Covid-19. When a human is exposed to the SARS-CoV-2 virus, spike glycoprotein (S) found on the surface of the virus binds to ACE2 receptors on human cells to gain entry to the cells and cause an infection. Early vaccines act by boosting the ability of the body to recognise and develop an immune response to the spike protein, and this will help stop the SARS-CoV-2 virus from entering human cells and therefore prevent infection.

Vaccinating people against the SARS-CoV-2 virus is key to reducing the severe morbidity and mortality it causes, and providing a long term solution to controlling Covid-19. When safe and effective vaccines against Covid-19 are available it is essential that they are delivered quickly to those who need it.

The Moderna and Pfizer-BioNTech vaccines are nucleoside-modified messenger RNA (mRNA) vaccines. mRNA vaccines use the pathogen’s genetic code as the vaccine; this

then exploits the host cells to translate the code then make the target spike protein. The protein then acts as an intracellular antigen to stimulate the immune response. mRNA is then normally degraded within a few days. The Pfizer-BioNTech vaccine has been generated entirely in vitro and is formulated in lipid nanoparticles which are taken up by the host cells.

The Oxford/AstraZeneca vaccine is a non-replicating viral vector vaccine made from a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees. The virus has been genetically changed so that it is impossible for it to replicate in humans.

Vaccine Janssen is a monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 vector that encodes a SARS-CoV-2 full-length spike (S) glycoprotein in a stabilised conformation. Following administration, the S glycoprotein of SARS-CoV-2 is transiently expressed, stimulating both neutralising and other functional S-specific antibodies, as well as cellular immune responses directed against the S antigen, which may contribute to protection against COVID-19.

The Novavax vaccine (NVX-CoV2373) is a recombinant spike protein nanoparticle-based vaccine. It contains the full-length SARS-CoV-2 spike protein and a saponin-based Matrix-M adjuvant. Protein-based vaccines cannot replicate and therefore cannot infect individuals. Matrix-M is an adjuvant added to enhance the immune response to the vaccine.

Covid-19 vaccine supply to Wales is being managed centrally by the Welsh Government in conjunction with Local Health Boards. Engaged providers who participate in the PCCS:I will not be required to purchase any stock of a Covid-19 vaccine. All vaccines will be free and private supplies of vaccine will not be available.

A Patient Group Direction for administering Covid-19 vaccines has been authorised by each Local Health Board.

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (https://www.legislation.gov.uk/ukxi/2020/1125/pdfs/ukxi_20201125_en.pdf) also allow Covid-19 vaccines to be administered according to a two-step national protocol using registered, trained and competent health care professionals to carry out the clinical assessment, consent and preparation steps of delivery, whilst suitably trained, non-registered and competent members of staff will be able to administer a vaccine itself under clinical supervision by a registered health care professional. The Human Medicines Regulations do not specify who these non-registered vaccinators might be.

Clinical guidance for the Covid-19 vaccines, including the relevant national protocol for each vaccine, can be accessed via the following link;

- <https://gov.wales/clinical-guidance-coronavirus>

Those persons engaged in delivery of Covid-19 vaccines under this PCCS:I will be covered by existing indemnity arrangements pursuant to regulation 8 of the NHS (Clinical Negligence Scheme) (Wales) Regulations 2019.

3. Primary Care Contracted Services: Immunisations Scheme Aims

This PCCS:I provides a mechanism for primary care providers to enter into an arrangement with their Local Health Board (“the relevant Local Health Board”) to enable the provision of services to administer the Covid-19 vaccines as part of the health service in Wales and the wider Covid-19 vaccination programme led by Local Health Boards.

4. Cluster Working

Engaged providers are strongly encouraged to work collectively within cluster groupings, whether or not these have previously been in place and irrespective of which primary care

services a provider usually provides, in order to maximise the level of vaccine delivery. For example, for a general medical practitioner this may mean administering vaccinations to people who are not registered with the provider administering the vaccine, whilst for other providers, it could also mean administering vaccines at venues away from their normal working location.

5. Eligible Cohorts and Individuals for Vaccination under the Primary Care Contracted Services: Immunisations Scheme

The JCVI advises UK health departments on immunisation and determines eligibility for each Covid-19 vaccine. Prioritisation amongst the eligible groups depends on vaccine characteristics and advice from the JCVI. This means that the use of each Covid-19 vaccine needs to be considered as part of the wider Covid-19 vaccination programme, where multiple vaccines and multiple models of delivery are in use.

All engaged providers should familiarise themselves with the current advice on eligible groups and individuals issued by the JCVI and/or the Chief Medical Officer to the Welsh Government, along with any guidance or Directions issued by the Welsh Ministers, prior to administering a Covid-19 vaccine to an eligible individual, specifically taking account of the vaccine type and dose required for the individual allocated to them by the relevant Local Health Board.

This PCCS:I Specification only relates to those specific groups and individuals eligible for a Covid-19 vaccine as determined by the relevant Local Health Board based on the JCVI and Welsh Government advice. Engaged providers who participate in this PCCS:I should ensure all of their staff are aware of who is eligible for vaccination under this Specification and the prioritised sequence for delivery.

All JCVI advice and guidance applicable to the Covid-19 vaccines programme, including the priority groups and the vaccination of eligible cohorts of individuals, can be accessed via;

- <https://www.gov.uk/government/collections/covid-19-vaccination-programme>.

Welsh Government advice, guidance and directions applicable to the Covid-19 vaccines programme can be accessed via;

- <https://gov.wales/vaccine-coronavirus>, and
- <https://gov.wales/working-for-the-nhs-and-social-care-coronavirus>.

For full details of vaccination against Covid-19, health care practitioners should refer to the relevant chapters of the Green Book “Immunisation against infectious disease” at;

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

and MHRA authorisation documents at;

COVID-19 - GOV.UK (www.gov.uk)

6. Conditions for Service Delivery

In order for a primary care provider to be considered for participation in this PCCS:I, specifically to provide services administering Covid-19 vaccines in accordance with this Specification, all of the following conditions must be met—

- (a) There must be an up-to-date and appropriate level of equipment for **resuscitation and anaphylaxis**, specifically adrenaline, at any site where vaccination occurs.
- (b) All persons who are involved in administration of vaccinations must be—

- (i) adequately **trained** in administration of multi-dose vaccinations, vaccine storage, handling, security and assessment and management of **resuscitation, anaphylaxis and aseptic no-touch techniques**, and
 - (ii) trained in the use of PPE, be supplied with and wear the appropriate PPE for the setting in which they are working.
- (c) All venues where vaccination occurs must have **been risk-assessed for transmission of coronavirus based on local guidance** and action taken to reduce risk where possible.
 - (d) Patients, who for the purposes of this Specification are defined to mean a person who will be or has been administered a vaccine under this PCCS:I, should be advised in advance not to attend if feeling unwell. Nonetheless, some patients may present to the vaccination location unwell, or may become unwell whilst attending the vaccination location. Facilities must be in place for the assessment and management of patients who are unwell and this must include resources to manage fainting and anaphylaxis/cardiac arrest to a primary care level of skill. Reliance on 999 Paramedics is not appropriate. Engaged providers should consult the relevant protocol, advice and guidance to ensure that any observation and monitoring requirements for recipients of a Covid-19 vaccine are complied with.
 - (e) The engaged provider and any person involved in the administration of a Covid-19 vaccine must have undertaken an appropriate training programme specific to the vaccine being used. Public Health Wales has provided an e-learning module: <https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>
 - (f) Engaged providers are encouraged to collaborate with other engaged providers within existing clusters but also, where necessary, to form new clusters specifically to deliver this PCCS:I, which can be with providers outside of their own profession, if they have not already done so.
 - (f) A clinical record of immunisation with a Covid-19 vaccine must be entered onto the Welsh Immunisation System (“WIS”). Arrangements are being made at UK level with GP system providers for the WIS (and NHSE NIMS) to populate patient records automatically in order to avoid double entry.

7. Payment for administration of a Covid-19 vaccine under this PCCS:I

- (a) The Local Health Board must pay to an engaged provider who qualifies for the payment in accordance with Directions 5 to 7, a payment of—
 - (i) £12.58 in respect of each dose of a Covid-19 vaccine administered to a person under this PCCS:I, and
 - (ii) £400 for every 1,000 vaccines administered under this PCCS:I.

8. PCCS:I Specification

Agreement of Eligible Cohorts

- (a) The relevant Local Health Board must develop a proactive and preventative approach to offering the Covid-19 vaccines by adopting robust call and reminder systems to contact individuals within eligible cohorts, with the aims of—
 - (i) maximising uptake in the interests of those persons, and
 - (ii) meeting any public health targets in respect of the administration of each Covid-19 vaccine.
- (b) The relevant Local Health Board must agree with the engaged provider that the engaged provider is to—
 - (i) participate in this PCCS:I to maximise the vaccination with the Covid-19 vaccines of specific cohorts of the population allocated to them by the relevant Local Health Board and in accordance with JCVI and/or the Chief

Medical Officer to the Welsh Government, along with any guidance or Directions issued by the Welsh Ministers (see paragraph 5),

- (ii) accept the order of the cohorts and timescale over which the vaccines will be administered, and
- (iii) in the case of general medical practitioners, vaccinate eligible individuals who are not registered patients of their practice.

Publicity & Promotion

- (c) The engaged provider must **prominently display provided materials** advertising the availability of Covid-19 vaccinations for eligible groups. This should include displaying advertisements on the premises website, using social media as well as inside the premises.
- (d) **Booking** of appointments for vaccination must be booked via the WIS Core. Patients will be able to change their pre-booked appointment, should they need to, via the online booking system.

Model for Delivery

- (e) The engaged provider and relevant Local Health Board must agree the timing and location of vaccination clinic sessions in the plan agreed in accordance with Direction 4(4)(a)(iv).
- (f) The engaged provider is actively encouraged to **work collaboratively with other engaged providers** in a cluster to share resources and maximise efficiencies to deliver this PCCS:I.
- (g) The engaged provider is to notify the relevant Local Health Board of the number of vaccination slots they have available and of all vaccination clinic sessions start and finish times, and their locations, at least 14 days in advance.
- (h) Vaccination appointments and number of people per session must be agreed between the relevant Local Health Board and engaged provider.
- (i) The engaged provider may only administer the appropriate Covid-19 vaccine to those persons allocated to them by the relevant Local Health Board in accordance with the Directions and this PCCS:I Specification, after obtaining consent, and following advice of the JCVI and/or the Chief Medical Officer to the Welsh Government, along with any guidance or directions issued by the Welsh Ministers and guidance in the Green Book.
- (j) The engaged provider must ensure that—
 - (i) all persons who receive vaccinations are eligible under a cohort and suitable clinically in accordance with law and guidance;
 - (ii) informed consent is obtained by a registered health care professional; and
 - (iii) the patient's consent to the vaccination (or the name of the person who gave consent to the vaccination and that person's relationship to the patient) must be recorded in accordance with law and guidance;
- (k) Consent obtained in accordance with sub-paragraph 8(j)(ii) must be recorded (as appropriate) for any necessary information sharing with the relevant Local Health Board, in accordance with data protection law and guidance;
- (l) Engaged providers must ensure a person receives the recommended vaccine as part of a course of vaccination, in order to comply with relevant JCVI and/or Chief Medical Officer to the Welsh Government's advice for each cohort;
- (m) Engaged providers must ensure that—

- (i) the correct dosage of a Covid-19 vaccine is administered to each person as clinically appropriate and in accordance with the JCVI and/or Chief Medical Officer to the Welsh Government's advice;
- (ii) they comply with relevant advice issued by the JCVI and/or the Chief Medical Officer to the Welsh Government, along with any guidance and Directions issued by the Welsh Ministers on, including but not limited to—
 - (aa) which Covid-19 vaccine is the most suitable for each cohort of people;
 - (bb) the relevant minimum interval post administration of a dose and/or infection with coronavirus (as applicable) is observed for administration of each vaccination;
 - (cc) the relevant vaccination time limitations and expiry date following reconstitution;
 - (dd) the number of doses and required dosage of each vaccine required to achieve the desired immune response for each patient; and
 - (ee) any other relevant guidance relating to the administration of the different types of vaccine and the different cohorts from time to time.

Persons involved in administering the vaccine

- (n) The engaged provider must ensure that vaccinations are administered only by a person permitted to do so in accordance with the Human Medicines Regulations 2012, as amended by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, including under a relevant Patient Group Direction or under a National Protocol approved by the Welsh Ministers.
- (o) All health care professionals administering a Covid-19 vaccine, must have—
 - (i) read and understood the clinical guidance available at <http://nww.immunisation.wales.nhs.uk/covid-19-vaccination-programme>;
 - (ii) completed the additional online Covid-19 specific training modules available on the e-learning for health website when available. Engaged providers are to oversee and keep a record to confirm that all persons administering the vaccines have undertaken the training prior to participating in vaccinations;
 - (iii) the necessary experience, skills, training and competency to administer vaccines in general, including completion of the general immunisation training available on e-learning for health, and face-to-face administration training, where relevant;
 - (iv) the necessary experience, skills, training and competency to administer vaccines in general, including training with regard to the recognition and initial treatment of anaphylaxis; and
 - (v) ensured that registered health care professionals were involved in the preparation (in accordance with the manufacturer's instructions) of the vaccine(s) unless unregistered staff have been trained to do this.
- (p) All other persons administering a Covid-19 vaccine must—
 - (i) be authorised, listed, referred to or otherwise identified by reference to the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, including under a relevant Patient Group Direction or National Protocol approved by Welsh Ministers;
 - (ii) while preparing and/or administering vaccinations be supervised by a health care professional fulfilling the requirements of sub-paragraph (o) above;
 - (iii) have completed the additional online Covid-19 specific training modules available on the e-learning for health website when available. Engaged providers must oversee and keep a record to confirm that all staff have undertaken the training prior to participating in administration of the

- vaccination. This includes any additional training associated with new Covid-19 vaccines that become available while this PCCS:I is in operation;
- (iv) have the necessary skills and training to administer vaccines in general, including completion of the general immunisation training available on e-learning for health and face-to-face administration training, where relevant; and
 - (v) the necessary skills and training, including training with regard to the recognition and initial treatment of anaphylaxis.
- (q) Engaged providers must ensure that all Covid-19 vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's, Public Health Wales and Local Health Board instructions and all associated Standard Operating Procedures, including that all refrigerators in which vaccines are stored have a temperature data logger installed inside the refrigerator which continuously monitors the temperature inside the refrigerator and can be downloaded by trained personnel to give a continuous temperature record for that refrigerator. Refrigerator temperature readings must be taken and recorded from the refrigerator temperature thermometer display on all working days and engaged providers must ensure that appropriate action is taken when readings are outside the recommended temperature.
 - (r) Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of multi-dose vials to ensure that wastage is minimised and does not exceed 5% of the total number of vaccines supplied. Wastage levels will be reviewed by the relevant Local Health Board on an ongoing basis. Where wastage exceeds 5% of the vaccines supplied and that wastage is as a result of supply chain or relevant Local Health Board fault, those vaccines shall be removed from any wastage calculations when reviewed by the relevant LHB on an ongoing basis.
 - (s) Engaged providers must ensure that services are accessible, appropriate and sensitive to the needs of all persons. No person allocated by a relevant Local Health Board is to be excluded or experience particular difficulty in accessing and effectively using this PCCS:I due to a protected characteristic under the Equality Act 2010, which includes Age, Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation.

Record-keeping

- (t) The engaged provider must use the **Welsh Immunisation System** to—
 - (i) record consent for vaccination,
 - (ii) note any contraindications,
 - (iii) record when a vaccination has been given, including the batch number and manufacturer expiry date,
 - (iv) record immediate adverse events,
 - (v) record the refrigerator temperature(s) where Covid-19 vaccines are stored, twice daily (start and end of the day) on all working days, as per Local Health Board guidance,
 - (vi) record receipt of delivery of the vaccine on the day of receipt,
 - (vi) record the daily vaccine stock check balance on all working days at the end of the last clinic session,
 - (vii) provide evidence for payments under this PCCS:I, including for Post Payment Verification.

- (u) By using the Welsh Immunisation System, the record of vaccination of a person by the engaged provider will be sent electronically to the individual's GMS record.
- (v) The engaged provider must—
 - (i) supply Public Health Wales with information on persons who have received a Covid-19 vaccine, via the Welsh Immunisation System, for the purpose of monitoring local and national uptake;
 - (ii) supply NHS Wales Shared Services Partnership with information on persons who have received a Covid-19 vaccine, via the Welsh Immunisation System for the purposes of payment, and/or post payment verification;
 - (iii) provide data, to the cluster lead practice of a cluster (where applicable), Local Health Boards and Welsh Government when required; and
 - (iv) ensure consistent coding for capture of data and compliance with relevant information governance legislation.

Adverse Events

- (w) All adverse events relating to a Covid-19 vaccine must be reported to—
 - (i) the MHRA using the Yellow Card scheme www.yellowcard.gov.uk, and
 - (ii) the Health Board Primary Care Team (by using DATIX or the all Wales Concerns Management System, or existing local arrangements).
- (x) Studies are on-going regarding the co-administration of Covid-19 vaccines with the influenza vaccine. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine.
Engaged providers should refer to the available guidance which can currently be found here.
- (y) The engaged provider must ensure the person receiving a Covid-19 vaccine has understood that failure to receive all recommended doses of a vaccine may render the vaccination ineffective and should ensure that a follow up appointment to receive the subsequent dose has been booked, acknowledging that in exceptional circumstances appointments may need to be moved, before administering the first dose of the vaccine.

Vaccine stock and consumables

- (z) The relevant Local Health Board must—
 - (i) coordinate vaccine supplies; and
 - (ii) provide consumables such as PPE, syringes and needles.

Publicity and Information Materials

- (aa) Publicity materials and information leaflets are to be provided by the relevant Local Health Board.

Security

- (bb) The security assessment related to delivery of a Covid-19 vaccine is continually evolving. In order to ensure the safety of patients, staff and the vaccines themselves, engaged providers must have robust security measures in place.
- (cc) As a minimum this must include—
 - (i) lockable temperature controlled storage (vaccine fridge). This can include adaptation of an existing fridge;

- (ii) lockable internal doors preventing access to vaccine storage by unauthorised persons;
 - (iii) lockable external windows and doors;
 - (iv) an operational intruder alarm, preferably linked to an Alarm Receiving Centre; and
 - (v) a robust and operational security process (including but not limited to premises locking up procedures, incident reporting procedures and ID checking) which all staff are aware of and are compliant with.
- (dd) All packaging relating to Covid-19 vaccines must be destroyed or defaced in such a manner that prevents them being reused for any purpose. This includes the safe and secure disposal of empty vials via the clinical waste stream to ensure they cannot be reused.
- (ee) Additional security measures that should also be considered and are desirable, include—
- (i) operational external CCTV covering all entry points;
 - (ii) external lighting; and
 - (iii) operational internal CCTV covering the location of the vaccine storage.
- (ff) Due to the continually changing nature of the response to Covid-19 and the resources and vaccines that the NHS is able to deploy, these security arrangements must be responsive and may be frequently updated as necessary, dictated by any changes in the threat assessment. Engaged providers are expected to be alive to this issue and committed to providing the best possible delivery of this PCCS:I.

9. Termination of arrangements

- (a) An arrangement between an engaged provider and a relevant Local Health Board for the provision of Covid-19 vaccines services made pursuant to these Directions and this PCCS:I Specification may be terminated—
- (i) automatically, when the Covid-19 vaccination programme comes to an end;
 - (ii) immediately, where the relevant Local Health Board requires that the engaged provider withdraws from the arrangement because the relevant Local Health Board is of the opinion that the engaged provider is not complying with their obligations under this PCCS:I;
 - (iii) by the Local Health Board giving the engaged provider not less than 4 weeks' notice in writing, where the relevant Local Health Board wishes to terminate the arrangement with the engaged provider for any reason other than that specified by paragraph (ii); or
 - (iv) by the engaged provider giving the Local Health Board not less than 4 weeks' notice in writing, where the engaged provider wishes to terminate the arrangement with the relevant Local Health Board for any reason.

10. Application for Participation

Signature of engaged provider

Date”.