

The following questions and answers were developed to support the Q&A webinar: Preparing for the update to Human Medicines Regulations 4 March 2026

Question	Answer
What is a VGD?	<p>A VGD is a Vaccine Group Direction. It is a written direction that relates to the supply and administration of a vaccine. VGDs will replace the National Protocols.</p> <p>National Protocols will cease on 31st March 2026. VGDs are similar to National Protocols in principle as well as document layout to the COVID-19 and influenza protocols.</p> <p>VGDs contain the same clinical content as a PGD.</p>
In a COVID -19 vaccination session, where HCSWs are supporting administration of the vaccine, is there a need for a PGD and a VGD?	<p>No, in this scenario a VGD would be appropriate for a registrant and non - registrant to use. However as with PGDs and National Protocols, anyone operating under the VGD must meet any requirements set out in the VGD document and be designated as someone who can work under the VGD.</p> <p>For registrants we expect the requirements will be the same for VGDs and PGDs.</p> <p>A VGD contains the same content as a PGD, only allows delegation of administration to a non-registrant.</p> <p>Non-registrants need to be supervised by a registered healthcare professional who is themselves authorised to independently operate under the VGD and who is present in the same location.</p>
When will the VGD be available?	<p>The VGD is expected to be with the health boards on or after the 1st April when the use of VGDs will become lawful. This will allow health boards time to approve it following local governance processes before 13th April 2026</p>
Does the VGD need to be approved by the health board?	<p>Yes, just like PGDs, VGDs require organisational approval to be lawful. VGDs would follow the same local process as PGDs do when they are locally adopted.</p>
Will VGDs be used for other vaccination programmes?	<p>VGDs must be developed by the relevant public health agency in each part of the UK (i.e. UKHSA in England, PHW in Wales, and equivalents in Scotland and NI).</p> <p>Practically, we expect Welsh Medicines Advice Service (WMAS) will develop the VGDs for use in Wales, but they will be approved by PHW. Initially the VGDs will be created for COVID-19 and Influenza as the National Protocols previously served.</p> <p>Further use of VGD's will be considered in response to public health need in consultation with NHS and wider health colleagues and only following careful assessment. The age or type of cohort, whether a catch up is required and the care</p>

	setting will all need to be considered in the decision to develop a new VGD.
What about assessment and informed consent?	For a VGD assessment and informed consent can only be undertaken by a registered healthcare professional who is able to work under a PGD. Healthcare professionals who cannot work under PGDs or VGDs cannot authorise a non-registrant to vaccinate someone under the VGD. This includes doctors. Doctors (and dentists) can prescribe a vaccine or make a patient specific direction allowing non-registrants to administer the vaccine to a specified patient.
Can tasks be delegated in the VGD?	Yes. Unlike the PGD where only one registered healthcare professional can operate all stages, the VGD allows the process of giving a vaccine to be carried out by different people (non-registrants or registrants) BUT assessment and informed consent (step 1) must be obtained by the registered healthcare professional.
Will there be any resources to refer to?	Yes. The Specialist Pharmacy Service will publish a set of resources w/c 23 rd March (TBC). The resources will be available on their website https://www.sps.nhs.uk/ A PGD module developed by the NHS Specialist Pharmacy Service (SPS) and Health Education England will be updated to outline Vaccine Group Directions and the legislation changes. The updated version is anticipated on 1st April 2026. Public Health Wales will host the module here: Immunisation eLearning - Public Health Wales
What is the process for documenting stages in WIS? I.e. assessment and consent, consent for administration.	There will be a temporary workaround using the notes section on the patient record to record the Registrant details who carried out the assessment and consent process. From September 2026 the consultation form will be amended to allow for registrant and non-registrant to access and record details.
Would Primary Care use a VGD or continue with PSD's?	There has been no change to the regulations governing use of PGD's or PSD's, which can continue to be used in appropriate circumstances. If a primary care contractor chooses to deliver vaccinations as part of the national programme under a VGD then they are able to do so, provided they meet the supervision, competency and wider requirements set out in the VGD document for the health board.
Does the updated legislation affect Patient Specific Directions (PSDs)?	No, the legislation around PSDs is not affected by the update to the Human Medicines Regulations. Further information can be found here: Patient Specific Directions (PSD) – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

<p>Does the registrant who undertakes the assessment and consent process need to be the same person who provides supervision?</p>	<p>Yes. A condition of the VGD is that the individual who administers the vaccine is at the same location and under the supervision of an individual who has assessed and determined that the person who is to receive the medicinal product is eligible for the treatment, and obtained and recorded the informed consent of, or in respect of, the person who is to receive the vaccine.</p> <p>In this context supervision could mean directly observing the non-registrant or being clinically responsible for the actions of the non-registrant even if not directly observing them on each occasion they administer a vaccine.</p>
<p>The immunisation process under a VGD has 4 steps, the national protocol had 5 steps. Why has step 5 been removed?</p>	<p>Step 5 of the national protocol was post immunisation observation. This was included as a step when COVID vaccines were first used as a precaution due to lack of data on ADR profile.</p> <p>The green book (chapter 4) states: Recipients of any vaccine should be observed for immediate ADRs. There is no evidence to support the practice of keeping patients under longer observation.</p> <p>Post immunisation observation is therefore now not required as a separate step in the immunisation process.</p>
<p>Can a VGD be used to vaccinate any age group?</p>	<p>The new legislation will allow VGDs to be used for non-registrants to vaccinate any age group. Age constraints can be written into the VGD if felt necessary depending on the vaccine programme. The Human medicines regulations do not set out a specific age restriction; any limits will be decided upon locally. In Wales it is not envisaged that VGD's will be used for infant cohorts in the forthcoming COVID-19 programme. Wider programmes will be considered in due course.</p>

If you have any additional questions, please contact your local vaccine health board contact. They should be able to help you. [Vaccine contacts - Public Health Wales](#)