

Patient Group Directions, Written Instructions and Occupational Health Services

This Q&A has been written in response to enquiries we have received concerning the use of Patient Group Directions (PGDs) and written instructions in Occupational Health Services (OHS) in England and follows discussions with the SPS PGD Advisory Board, the Care Quality Commission (CQC), UK Health Security Agency (UKHSA), the Royal College of Nursing (RCN), BMA Occupational Medicines Committee, an independent healthcare provider and the Medicines and Healthcare Regulatory Agency (MHRA).

An Occupational Health Service (OHS) is a multidisciplinary service that aims to protect and promote workers' physical, mental and social health and well-being through actions related both to the work environment and to the workers themselves¹. For the purposes of this Q&A the terms Occupational Health Scheme and Occupational Health Service are deemed interchangeable.

Schedule 17 of The [Human Medicines Regulations 2012 provides specific exemptions](#) for OHS from some of the restrictions that apply to prescription only medicines. Under Schedule 17 medicinal products can be supplied or administered in the course of the OHS by a registered nurse acting in accordance with the written and signed instruction of a doctor; this instruction is commonly documented as a written instruction².

In 2022 permanent legislation changes were made to Schedule 17 to allow registered nurses, registered midwives, registered nursing associates; operating department practitioners, paramedics or physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register; and pharmacists employed or engaged by a person operating an occupational health scheme to administer influenza and coronavirus vaccines as part of an NHS Body or Local Authority (LA) occupational health scheme.

A written instruction is different to a PGD and is an arrangement between the named healthcare professionals as detailed above and the authorising doctor. A written instruction isn't subject to the same legislated framework of a PGD. PGDs and written instructions are not interchangeable. A written instruction template is available from the BMA¹.

Under the [Human Medicines Regulations 2012](#), NHS bodies and local authorities are exempt from the restrictions that apply to the supply of prescription only medicines, where they are supplied or administered in accordance with a PGD⁵; however they can only use PGDs to provide OHS to their own staff where they have an in-house OHS.

Independent providers can only use PGDs when they are registered with CQC to provide one or more regulated activity, in compliance with section 10 of the [Health and Social Care Act 2008](#). OHS are not a regulated activity and as such are not registered with the CQC; as a result, PGDs cannot be used by independent providers of OHS^{3,4,6}. This is also the case when an NHS or other publicly funded body provides OHS to another organisation, be it private or publicly funded, as the OHS is being provided as a private service.

Given the complexities of this area of practice the PGD Advisory Board have concluded that the best way to advise on the use of PGDs and written instructions in OHS is to outline common scenarios that occur in practice and advise on each one below.

Question	Answer
What is the preferred mechanism within the legislation to use for administering staff vaccinations?	Where vaccinations cannot be provided on a patient specific basis, the Written Instruction is the preferred way for OHS services to be delivered.
Can an <u>NHS Body or local authority</u> adopt the national written instruction to provide influenza and coronavirus vaccinations under an Occupational Health Service to its staff (including peer to peer* vaccination)?	<p>Yes.</p> <p>A national written instruction template is available for adoption by NHS and Local Authority (LA) organisations to facilitate the administration of the 'flu vaccine as part of their OHS and peer to peer vaccination by appropriate vaccinators**.</p> <p>For more information please refer to the written instruction templates and supporting factsheet at https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/</p> <p>NB The national inactivated influenza vaccine PGD from UKHSA does not include vaccination as part of an occupational health service, or peer to peer vaccination. This is also the case for published National Protocols for 'flu vaccination.</p>
Can an <u>independent healthcare provider</u> adopt the national written instruction to provide influenza and coronavirus vaccinations under an Occupational Health Service to its staff (including peer to peer* vaccination)?	<p>Yes.</p> <p>A national written instruction template is available for adoption by organisations other than NHS and Local Authority to facilitate the administration of the 'flu vaccine as part of their OHS and peer to peer vaccination by registered nurses only.</p> <p>For more information please refer to the written instruction templates and supporting factsheet at https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/</p> <p>NB The national inactivated influenza vaccine PGD from UKHSA does not include vaccination as part of an occupational health service, or peer to peer vaccination. This is also the case for published National Protocols for 'flu vaccination.</p>
Can an NHS organisation providing an in-house Occupational Health Service use PGDs to supply or administer medicines to their <u>own</u> staff or staff who are contracted to work for their organisation?	<p>Yes.</p> <p>It is understood that NHS organisations with in-house OHS have used PGDs to create a robust framework for administration of medicines to their employees for many years. This is not a legal requirement, if the service is being provided by a doctor or registered nurse acting in accordance with the written instructions of a doctor, as exemptions under the Human Medicines Regulations 2012 can be used².</p> <p>NICE guidance (MPG 2 2017) recommends that PGDs should not be used where they are not required and HMR 2012 provides alternative exemptions in Schedule 17 for the delivery of occupational health services. As such the use of the written instruction rather than a PGD should be considered first as PGD use may not be appropriate unless it offers a benefit to service delivery i.e. provision by healthcare practitioners other than nurses (or occupational health vaccinators for 'flu/coronavirus vaccinations) who may legally operate under a PGD. As the registered vaccinators able to operate under a written instruction for NHS OHS has been extended the need for a PGD for the influenza and</p>

	<p>coronavirus vaccines has been reduced and is unlikely to be required. Where NHS organisations want to utilise a PGD for an occupational health service it would be the responsibility of the NHS organisation to develop and authorise the PGD in accordance with HMR 2012.</p> <p>This advice includes all NHS organisations including, but not exclusively, NHS Foundations Trusts, NHS Trusts, NHS England and CCGs.</p>
<p>Can a publicly funded non-NHS organisation providing an in-house Occupational Health Service use PGDs to supply or administer medicines to their own staff or staff who are contracted to work for the organisation?</p>	<p>Yes.</p> <p>A PGD may be used but this is not a legal requirement, if the service is being provided by a doctor or registered nurse acting in accordance with the written instructions of a doctor, as exemptions under the Human Medicines Regulations 2012 can be used and should be considered in preference to PGDs².</p> <p>NICE guidance (MPG 2 2017) recommends that PGDs should not be used where they are not required and HMR 2012 provides alternative exemptions in Schedule 17 for the delivery of occupational health services. As such the use of the written instruction rather than a PGD should be considered first as PGD use may not be appropriate unless it offers a benefit to service delivery i.e. provision by healthcare practitioners other than nurses (or occupational health vaccinators for 'flu/coronavirus vaccinations) who may legally operate under a PGD. As the registered vaccinators able to operate under a written instruction for a LA OHS has been extended the need for a PGD for the influenza and coronavirus vaccines has been reduced and is unlikely to be required. Where LA organisations want to utilise a PGD for an occupational health service it would be the responsibility of the LA organisation to develop and authorise the PGD in accordance with HMR 2012.</p> <p>For the purposes of this advice publicly funded non-NHS organisations are: Public Health England; Local Authorities</p>
<p>Can an NHS organisation who does not operate an in-house OHS use PGDs to administer the seasonal 'flu vaccine to their staff (including peer to peer vaccination)?</p> <p><i>Note: This includes staff offering commissioned services, sub-contracted staff, agency staff, individuals undertaking work placements with the organisation and volunteers</i></p>	<p>Yes.</p> <p>For seasonal 'flu vaccination only it is acceptable for an NHS organisation which does not operate an in-house OHS to offer staff the seasonal 'flu vaccination under a PGD where it has been locally determined that a written instruction cannot adequately meet the needs of the service. NICE guidance (MPG 2 2017) recommends that PGDs should not be used where they are not required and HMR 2012 provides alternative exemptions in Schedule 17 for the delivery of occupational health services. As such the use of the written instruction rather than a PGD should be considered first as PGD use may not be appropriate unless it offers a benefit to service delivery i.e. provision by healthcare practitioners other than nurses (or occupational health vaccinators for 'flu/coronavirus vaccinations) who may legally operate under a PGD. As the registered vaccinators able to operate under a written instruction for NHS OHS has been extended, the need for a PGD for the influenza and coronavirus vaccines has been reduced and is unlikely to be required. Where NHS organisations want to utilise a PGD for an occupational health service it would be the responsibility of the NHS organisation to develop and authorise the PGD in accordance with HMR 2012.</p> <p>All other OHS provided medicines/vaccines must be provided via the organisation's OHS provider.</p>

	<p>Note - this advice includes all NHS organisations including, but not exclusively, NHS Foundations Trusts, NHS Trusts, NHS England and CCGs (ICBs from July 2022) and publicly funded non-NHS organisations are Public Health England and Local Authorities.</p>
<p>Can an NHS or publicly funded non-NHS organisation providing an Occupational Health Service to employees of another organisation (NHS, publicly funded non-NHS, private or independent sector healthcare provider or any other private person(s) or business) use PGDs?</p>	<p>No.</p> <p>NHS organisations and publicly funded non-NHS organisations should note that provision of an OHS to employees of another organisation is provision of a private OHS.</p> <p>In this case, PGDs do not provide a legal framework for the supply and/or administration of medicines in the course of an OHS and cannot be used.</p> <p>Private services can only use PGDs for activities for which they are registered with the CQC. The legislation does not require OHS services to register with the CQC so these services cannot use a PGD³.</p> <p>Therefore, such OHS can only be provided by a doctor, independent prescriber or registered nurse working in line with the legal exemptions afforded to OHS in the Human Medicines Regulations 2012².</p> <p>Please note that the OHS exemptions cannot be used by professions other than registered nurses and the written instruction must be signed by an OHS doctor.</p> <p>For the purposes of this advice publicly funded non-NHS organisations are: Public Health England; Local Authorities</p>
<p>Can an NHS Body or local authority providing an Occupational Health Service to employees of another organisation (NHS, publicly funded non-NHS, private or independent sector healthcare provider or any other private person(s) or business) use a written instruction?</p>	<p>Yes.</p>
<p>Can an independent or other healthcare provider providing an Occupational Health Service use PGDs?</p>	<p>No.</p> <p>PGDs do not provide a legal framework for the supply and/or administration of medicines in the course of an occupational health service provided by independent healthcare providers and cannot be used.</p> <p>Private services can only use PGDs for activities for which they are registered with the CQC. The legislation does not require OHS services to register with the CQC so these services cannot use a PGD³.</p> <p>Therefore, such OHS can only be provided by a doctor, an independent prescriber or registered nurse working in line with the legal exemptions afforded to OHS in the Human Medicines Regulations 2012².</p>

	Please note that the OHS exemptions cannot be used by professions other than registered nurses and the written instruction must be signed by an OHS doctor.
Can an independent or other healthcare provider providing an Occupational Health Service to employees of another organisation (NHS, publicly funded non-NHS, private or independent sector healthcare provider or any other private person(s) or business) use a written instruction?	Yes.
Can the national protocol (NP) for 'flu vaccination be used to provide OHS or peer to peer 'flu vaccinations?	No. The national protocol for 'flu vaccination does not include the vaccination of healthcare staff and cannot be used to provide peer to peer or OHS 'flu vaccinations.
Can community pharmacies offer vaccinations funded by employers?	This is not considered an Occupational Health Service. If an organisation wishes to pay for employees to receive vaccination (for example seasonal influenza or travel vaccines required for work related travel) to staff who are not included in the national specification to receive a NHS funded vaccine they can do so via community pharmacies who offer such services under private PGDs. This is commonly carried out under a private voucher scheme.

Recommendations for action

Where this guidance suggests that PGDs should not be used, they should be replaced with separate written instructions alongside locally approved procedures or guidelines to support safe administration of the medicine

Notes

The written instructions must be signed by a doctor and set out the circumstances in which a medicine is to be used in the course of the OHS – for an example of a written instruction see Appendix 6 in the BMA Guide for the Occupational Physician¹ and the [written instruction template for seasonal influenza vaccination](#). **Please note there will now be two written instruction templates for seasonal influenza vaccination, one for use by an NHS body or Local authority and another for independent or other providers).**

Where the term doctor is used within this document with relation to an OHS written instruction the doctor signing the written instruction should be a doctor with an OHS specialism. The only exception to this relates to a written instruction for the administration of seasonal 'flu vaccination to staff (for further information see factsheet at <https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/>)

Where the term staff is used this includes staff offering commissioned services, sub-contracted staff, agency staff, individuals undertaking work placements with the organisation and volunteers.

* for the purpose of the written instruction, **peer to peer vaccination** refers to the administration of the seasonal influenza vaccine or coronavirus vaccine by an appropriately trained and registered nurse (or for an NHS body or local authority an approved OHS vaccinator as listed within this document) to another employee of the same organisation.

** **Occupational health vaccinators** are defined in Regulations 8 of the HMR 2012. In accordance with Regulation 8 and Schedule 17 of HMR 2012, occupational health vaccinators employed or engaged by a person operating an occupational health scheme who may operate under a written instruction are: Registered nurses, midwives and nursing associates currently registered with the Nursing and Midwifery Council (NMC); operating department practitioners, paramedics and physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register; Pharmacists registered with the General Pharmaceutical Council.

References

- 1 - BMA the occupational Physician Accessed online May 2021 https://www.bma.org.uk/media/1072/bma_the_occupational_physician_oct_2019.pdf
- 2 - Human Medicines Regulations 2012. Schedule 17. Part 1 Regulations 223(5)(b) and (c) 235,250(5) and 253(5)(d). Accessed online January 2020 <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>
3. The Human Medicines Regulations 2012 Part 12 Chapter 3 Exemptions relating to supply in specific circumstances Regulation 231 Accessed online January 2020 <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>
4. NICE Patient Group Directions Medicines practice guideline 2 Published: 2 August 2013 (updated March 2017) www.nice.org.uk/guidance/mpg2 Accessed online January 2020
5. Human Medicines Regulations 2012 Schedule 16 Regulation 229 and SI No 178 (2015) <http://www.legislation.gov.uk/uksi/2012/1916/contents/made> Accessed online January 2020
6. Health and Social Care Act 2008 Section 10 Requirement to register as a service provider <https://www.legislation.gov.uk/ukpga/2008/14/section/10> Accessed online January 2020