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Immunisation by nurses and other healthcare professionals

Introduction

The preferred way for patients to receive medicines is for trained healthcare professionals to prescribe for individual patients on a one-to-one basis. However, in some circumstances, it may be more appropriate for a patient to receive a medicine, including a vaccine (i.e. have it supplied and/or administered) directly from another healthcare professional. Unless covered by exemptions to the Medicines Act 1968, there are two ways of achieving this: either by Patient Specific Direction (PSD) or Patient Group Direction (PGD).

This chapter describes what PSDs and PGDs are and their use in immunisation.

Patient Specific Directions

A PSD is a written instruction from an independent prescriber (doctor, dentist or independent nurse prescriber) to another healthcare professional, to supply and/or administer a medicine directly to a named patient, or to several named patients.

Patient Group Directions

PGDs are defined as written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment (SI 2000/1917).

PGDs are not a form of prescribing but provide a legal framework for the supply and/or administration of medicines by a range of qualified healthcare professionals (nurses, midwives, pharmacists, optometrists, podiatrists/chiropractors, radiographers, orthoptists, physiotherapists, ambulance paramedics, dietitians, occupational therapists, prosthetists/orthotists and speech and language therapists). Employing organisations must ensure that all users of PGDs are fully competent and trained in their use.

When is a PSD appropriate?

PSDs are used once a patient has been assessed by a prescriber and that prescriber (doctor, dentist or independent nurse prescriber) instructs another healthcare professional in writing to supply or administer a medicine directly to that named patient or to several named patients. As a PSD is individually tailored to the needs of a single patient, it should be used in preference to a PGD wherever appropriate.

The usual method for the supply and administration of vaccines in the routine childhood immunisation programme is via a PSD. The authorisation for this is usually the responsibility of the GP or an independent nurse prescriber at the six to eight-week check and is recorded as an instruction in the Personal Child Health Record (PCHR or Red Book). This agreement allows immunisations to be given in GP surgeries or clinics. Where a PSD exists, there is no need for a PGD.

When is a PGD appropriate?

PGDs should be reserved for those limited situations where this offers advantage for patient care without compromising patient safety. With regard to immunisation, these situations may include nurse-led travel clinics, nurse-led immunisation sessions in schools and prisons, and nurses working with disadvantaged groups such as refugees, asylum seekers, looked-after children and drug users. In future, and with the development of new roles and new ways of working, such services will also involve a wider range of healthcare professionals working to deliver an immunisation programme.

Use of black triangle (▼) vaccines

Black triangle (▼) vaccines used in immunisation programmes may be included in PGDs, providing they are used in accordance with the recommendations of the Joint Committee on Vaccination and Immunisation (JCVI) (Health Service Circular, 2000/026). The PGD should state that a black triangle medicine is being included.

Use of unlicensed vaccines

In some circumstances, it may be necessary for the Department of Health to recommend vaccines that do not have a marketing authorisation (previously called a product licence) in the UK. For example, imported vaccines that are otherwise identical to the normal UK product but with overseas labelling may be required to maintain supplies. Such products cannot be administered using a PGD but require a PSD (see above). For

convenience, where several individuals require vaccination, a list of these named individuals can be printed and authorisation signed by the prescriber.

Writing a PGD

The legislation governing PGDs specifies those professionals who should be involved in their development. These are:

- a senior doctor (see below)
- a senior pharmacist (see below)
- a senior person in each profession required to operate within the direction (see below)
- the clinical governance lead or their equivalent (see below) as organisational authority.

Good practice recommends that local drugs and therapeutics committees, area prescribing committees and similar advisory bodies should also be involved in drawing up the directions.

The legislation further specifies that each PGD must contain the following information:

- the name of the business to which the direction applies (i.e. primary care organisations (PCOs) in England, administrative regions in Wales and health boards in Scotland)
- the date the direction comes into force and the date it expires*
- a description of the medicine(s) to which the direction applies
- the class of healthcare professional who may supply or administer the medicine
- signatures of a doctor and a pharmacist
- a signature of a representative from an appropriate health organisation
- the clinical condition or situation to which the direction applies
- a description of those patients excluded from treatment under the direction
- a description of the circumstances in which further advice should be sought from a doctor and arrangements for referral
- details of the appropriate dose and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration and minimum or maximum period over which the medicine should be administered

* The legislation requires that the direction should be reviewed every two years, but in the case of immunisations this may need to be more frequently.

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- relevant warnings, including potential adverse reactions
- details of any necessary follow-up action and the circumstances
- a statement of the records to be kept for audit purposes.

All PGDs must be signed by a senior doctor and a senior pharmacist, both of whom should have been involved in developing the PGD. For each profession required to operate within the direction, a senior person must sign as being responsible for the competencies, qualifications and training of the relevant authorised professionals. In addition, the clinical governance lead or their equivalent (who must not be the author of the PGD) must sign on behalf of the authorising NHS organisation, such as a primary care trust (PCT) or health board.

All professionals must be individually named and have signed the PGD. They must act within their appropriate code of professional conduct. PGDs should conform with the advice given in the latest relevant chapters of the Green Book.

Healthcare professionals are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book chapters may differ from those in the Summary of Product Characteristics (SPC) for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and should be followed. These Green Book recommendations and/or further advice from the Department of Health should be reflected in PGDs.

The PGD should also be in line with information in the Chief Medical Officer (CMO) letters and updates (www.dh.gov.uk/AboutUs/MinistersAndDepartmentLeaders/ChiefMedicalOfficer/fs/en) and/or in the NHS Purchasing and Supply Agency's *Vaccine Update* (www.pasa.nhs.uk/pharma/vaccines.stm).

Further information

The National Prescribing Centre has produced a practical guide and framework of competencies for the use of PGDs (www.npc.co.uk/publications/pgd/pgd.pdf).

The National electronic Library for Medicines (NeLM) has also developed a website providing support to all healthcare professionals who provide care under PGDs (www.nelm.nhs.uk/PGD/default.aspx). It also provides local examples of PGDs, including some relating to the administration of vaccines.

In Scotland, NHS Quality Improvement Scotland has published a Best Practice Statement concerning PGDs (www.nes.scot.nhs.uk/pgds/documents/22111_NHSQIS_Patient_Group.pdf). In addition, NHS Education for Scotland has developed a website to facilitate the development of PGDs by healthcare professionals (www.nes.scot.nhs.uk/pgds/).

References

NHS Executive (2000) *Patient Group Directions*, HSC 2000/026. Leeds: NHSE.

NHS National Prescribing Centre (2004) *Patient Group Directions: A practical guide and framework of competencies for all professionals using patient group directions* www.npc.co.uk/publications/pgd/pgd.pdf.

The Prescription Only Medicines (Human Use) Amendment Order 2000, SI. 2000/1917. London: The Stationery Office.