Royal Pharmaceutical Society
Of Great Britain

Fitness to Practise and Legal Affairs Directorate Fact Sheet: Seven

Patient Group Directions: A Resource Pack for Pharmacists

This is an information sheet designed to be of assistance to pharmacists and registered pharmacy technicians. The contents have not been issued as Council policy, but it is intended as a resource which pharmacists and registered pharmacy technicians may use to review their practices and policies. It is not intended to interpret the law, the Code of Ethics or Council policies, but offers common sense guidance on issues of topical interest.

If any questions arise from this document, please do not hesitate to contact the Fitness to Practise and Legal Affairs Directorate on 020-7572-2308 for further clarification. Email queries may be sent to ftp@rpsgb.org

The Society wishes to give grateful thanks to those who have assisted with the compilation of this pack. In particular, thanks go to Mr. Peter Jones, Prescribing Advisor to Salford West PCG, for his help in providing model PGDs. In addition thanks go to Mrs Beth Taylor, Southwark PCT, for contributing the flow chart, “To PGD or not to PGD?” Finally, the Society wishes to thank the National Pharmacy Association for contributing the tips for community pharmacists involved with PGDs.

1 Lambeth High Street, London SE1 7JN
Head Office Telephone 020 7735 9141 Facsimile 020 7735 7629 e-mail: enquiries@rpsgb.org
Jeremy Holmes MA Chief Executive and Registrar
Patron: Her Majesty The Queen

Introduction

A Patient Group Direction (PGD) is a written direction relating to sale/supply and/or administration of a prescription only medicine, (POM), to persons generally, (subject to specified exclusions) and is signed by a doctor or dentist, and by a pharmacist.

A PGD must not be confused with a Written Direction. Under Article 12 of the Prescription Only Medicines (Human Use) Order 1997, as amended, (hereafter referred to as the POM Order), the supply of a POM can be made within the course of the business of a hospital, in accordance with the written direction of an appropriate practitioner. Amendments made to Article 12 of the POM Order mean that a written direction must be patient specific. In addition, supply on the authority of a patient specific written direction is extended to apply to primary care and hospital trusts and other NHS bodies. (For information relating to supplies outside the scope of the NHS, see Section 4).

In most cases, the most appropriate clinical care will be provided on an individual basis by a specific prescriber to a specific individual patient. PGDs for the sale/supply and/or administration of medicines should only be considered where it would offer a benefit to patient care without compromising safety in any way. This is best achieved by involving representatives of all the health care professions involved, including a representative from the professional group expected to supply or administer medicines under the direction. A senior representative of each profession should be responsible for ensuring the suitability and competence of the professionals operating within the scheme. Pharmacists signing off PGDs need to be satisfied that this matter has been addressed appropriately.

To help determine whether or not you need a PGD, the flow diagram in Appendix 1 “To PGD or Not to PGD” may be of use.

Pharmacists involved with PGDs in any way must operate within all the legal requirements as well as the professional requirements of the Code of Ethics.

1. Details Required for a Valid PGD

To be valid, a PGD must contain the following information:

- The period during which the PGD shall have effect; (guidance has indicated that the PGD should be reviewed at least every two years)
- The description or class of POM to which the PGD relates;
- Whether there are any restrictions on the quantity of medicine which may be sold or supplied on any one occasion, and, if so, what those restrictions are. (This information is not required if the PGD relates to administration only);
- The clinical situations which the POM of that description or class may be used to treat;
- The clinical criteria under which a person shall be eligible for treatment;
- Whether any class of person is excluded from treatment under the PGD and, if so, what class of person;
- Whether there are circumstances when further advice should be sought from a doctor or dentist, and, if so, what circumstances;
- The pharmaceutical form or forms in which the POM of that description or class are to be administered;
- The strength, or maximum strength, at which the POM of that description or class are to be administered;

- The applicable dosage or maximum dosage;
- The route of administration;
- The frequency of administration;
- Any minimum or maximum period of administration applicable to the POM of that description or class;
- Whether there are any relevant warnings to note, and, if so, what warnings;
- Whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
- Arrangements for referral for medical advice;
- Details of the records to be kept of the sale/supply and/or the administration of medicines under the PGD.

In addition to the above criteria, it is a requirement of the legislation that the PGD is signed by a doctor or dentist as appropriate, and by a senior pharmacist.

Appendix 3 shows a blank template for a PGD. Appendix 4 shows a sample template for a PGD for Relenza.

2. Classes of Persons Permitted to Supply or Administer Medicines Under PGDs

The following is a list of persons who are permitted under the Regulations to supply or administer medicines under a PGD:

- Registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State;
- Pharmacists;
- Registered dietitians;
- Registered midwives;
- Registered nurses;
- Registered occupational therapists;
- Registered orthotists and prosthetists;
- Registered speech and language therapists;
- Registered optometrists;
- Registered chiropodists;
- Registered orthoptists;
- Registered physiotherapists;
- Registered radiographers.

It is important to note that the above professionals may only sell/supply and/or administer medicines under a PGD as named individuals.

3. Circumstances under which PGDs are permissible within the NHS

PGDs within the NHS fall into three main categories.

- The first category allows the supply and/or administration of medicines by NHS bodies.
- The second circumstance where PGDs are permissible is where it is to assist a doctor or dentist providing primary care national health services.

- The third type allows an NHS body to authorise a PGD for the sale/supply and/or administration of medicines by a person lawfully conducting a registered retail pharmacy business.

There are different requirements for each type of PGD.

A) PGDs for the Supply or Administration of Medicines By, Or On Behalf Of, NHS Bodies

This category allows individuals listed in Section 2 to supply and/or administer a POM on behalf of an NHS body as listed below.

For the purposes of the POM Order, an NHS body means:
- the Common Services Agency;
- a Strategic Health Authority, a Health Authority or a Special Health Authority;
- an NHS Trust or an NHS Foundation Trust;
- a Primary Care Trust.

The PGD must:
- be signed on behalf of the NHS body;
- contain all the particulars listed in Section 1;
- designate in writing on behalf of the authorising person the individual or individuals who may supply and/or administer medicines under the PGD; who must belong to one of the classes of person specified in Section 2;
- relate to medicines that have a product licence, a marketing authorisation or a homoeopathic certificate of registration at the time of supply and/or administration;
- be in effect at the time of supply and/or administration.

B) PGDs to Assist Doctors and Dentists in Providing Primary Care National Health Services

This category of PGD allows individuals listed in Section 2 to supply and/or administer a POM in order to assist a doctor or a dentist in the provision of NHS primary medical services, or NHS primary dental services, respectively.

The PGD must:
- relate to the supply and/or administration of a POM in order to assist a doctor or a dentist in providing NHS primary medical or dental services, whether or not it also relates to such supply and/or administration in order to assist any other doctor or dentist.
- be signed by the doctor or dentist for whom the supply is to assist, or, where it relates to supply to assist one or more doctors or dentists, be signed by one of them;
- contain all the particulars listed above in Section 1;
- be signed also on behalf of the Primary Care Trust, Local Health Board, Health Board or Health and Social Services Board that is responsible for the arrangements under which the services are provided;
- designate in writing by the doctor or dentist in question (or where it relates to supply to assist one or more doctors or dentists, by one of them), the individual or individuals who may supply and/or administer medicines under the PGD; who must belong to one of the classes of person specified in Section 2;
- relate to medicines that have a product licence, a marketing authorisation or homoeopathic certificate of registration at the time of supply/administration;
- be in effect at the time of supply and/or administration.

In this fact sheet the provision of NHS primary dental services, in relation to England and Wales, means the provision of primary dental services under Part 1 of the National Health Service Act 1977. In relation to Scotland this means the provision of general dental services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997.

The provision of NHS primary medical services, in relation to England and Wales, means the provision of primary medical services under Part I of the National Health Service Act 1977. In relation to Scotland, the provision of primary medical services under Part I of the National Health Service (Scotland) Act 1978.

C) PGDs for the Sale/Supply and/or Administration of Medicines by Persons Lawfully Conducting a Registered Retail Pharmacy

This category of PGD allows an NHS body (Common Services Agency, a Strategic Health Authority, a Health Authority or a Special Health Authority, an NHS Trust or an NHS Foundation Trust, a Primary Care Trust) to authorise a PGD for the sale/supply and/or administration of medicines by a person lawfully conducting a registered retail pharmacy business.

The PGD must:

- be signed on behalf of the relevant NHS body (Common Services Agency, a Strategic Health Authority, a Health Authority or a Special Health Authority, an NHS Trust or an NHS Foundation Trust, a Primary Care Trust);
- relate to medicines that have a product licence or a marketing authorisation or homoeopathic certificate of registration at the time of sale/supply and/or administration;
- contain all the particulars listed above in Section 1;
- be in effect at the time of sale/supply and/or administration;
- where the POM is supplied for the purpose of being administered or administered by the person lawfully conducting a retail pharmacy business, the person administering must belong to one of the classes of person specified in Section 2 and must be designated in writing.

With all of the above types of PGD it is worth noting that the medicine need not be handed to the patient in person. The medicine could, for instance, be handed to the patient's representative or carer.

However, the PGD must be for a particular person. For instance, a supply of Vermox could not be made under a PGD for the treatment of threadworm for use when required by any unspecified members of a family. Each individual member of the family must be assessed against the inclusion criteria and a supply made only to those members of the family who comply with the requirements of the PGD.

In addition, the PGD need not relate to specific premises. All the requirements that have been set out above must be complied with, but the supply or administration could take place at locations including a patient's home, a surgery or health centre, a pharmacy or an NHS walk-in centre.

4. Circumstances in Which PGDs are Permissible Within the Private Sector

A patient specific written direction can lawfully allow the supply of a POM within the course of the business of a private hospital. However, since April 4th 2003, the Regulations have also allowed for PGDs within the private sector under certain circumstances, where the medicine is supplied for the purpose of being administered to a particular person in accordance with a Patient Group Direction.

PGDs for the Sale/Supply and/or Administration of POMs by Independent Hospitals, Clinics or Medical Agencies

The PGD must:

- be in effect at the time of sale/supply and/or administration;
- relate to medicines that have a marketing authorisation or a homoeopathic certificate of registration;
- contain all the particulars listed in Section 1;
- be signed by or on behalf of the registered provider and by the relevant manager for the independent clinic, hospital or medical agency if there is one;
- designate in writing by or on behalf of the registered provider or the relevant manager if there is one, the individuals selling/supplying and/or administering under the PGD, who must belong to one of the classes of person specified in Section 2.

For the purposes of the Regulations, the registered provider means, in England and Wales, the person who is registered under Part II of the Care Standards Act 2000 as the person carrying on the establishment or agency. In Scotland, the registered provider is the person who is registered under Part I of the Regulation of Care (Scotland) Act 2001 as the person providing the establishment or agency.

The term relevant manager means, in England and Wales, the person who is registered under Part II of the Care Standards Act 2000 as the manager of the establishment or agency, but who is not the registered provider. Alternatively, if there isn't such a person, the relevant manager is the person appointed by the registered provider to manage the establishment or agency.

In Scotland, the term relevant manager means, the person, (but not the registered provider) who was identified as the individual who is to manage the establishment or agency under Part I of the Regulation of Care (Scotland) Act 2001.

PGDs to Assist in the Provision of Health Care by or on Behalf of the Police, the Prison Services or the Armed Forces

This category of PGD allows individuals listed in Section 2 to supply and/or administer a POM in order to assist the provision of healthcare by, or on behalf of, or under arrangements made by the police, the prison service or, as Her Majesty's Forces.

The PGD must:

- be to assist in the provision of health care by, or on behalf of, or under arrangements made by a police force, a prison service or Her Majesty's Forces;

- be in effect at the time of supply and/or administration;
- contain all the particulars listed above see Section 1;
- designate in writing, by or on behalf of the authorising person, the individual(s) who may supply and/or administer medicines under the PGD. The individual(s) must belong to one of those classes of persons specified in Section 2;
- be for medicines with a product licence or a marketing authorisation or homoeopathic certificate of registration at the time of supply and/or administration;
- in the case of the prison service, in England or Wales, be signed by or on behalf of the governor of the prison where the health care is being provided. In Scotland, the Scottish Prison Service Management Board;
- in the case of a police force, in England or Wales, be signed by or on behalf of the Chief Officer of Police for that police force and by a doctor who is not employed or engaged by, and does not provide services under arrangements made with any police force. In Scotland, the Chief Constable of that police force and by a doctor who is not employed or engaged by, and does not provide services under arrangements made with any police force;
- in the case of Her Majesty's Forces, be signed by, or on behalf of, the Surgeon General, a Medical Director General or a Chief Executive of an Executive Agency of the Ministry of Defence;
- or on whose behalf the health care is provided, or with whom arrangements are made for the provision of such care.

PGDs Authorising Sale/Supply and/or Administration by a Person Lawfully Conducting a Retail Pharmacy

The Regulations also allow any of the bodies listed above, (i.e. an independent hospital, clinic or medical agency, a police force, a prison service or Her Majesty's Forces) to authorise the sale/supply and/or administration of a POM under a PGD by the person lawfully conducting a registered retail pharmacy.

The PGD must:

- be in effect at the time of supply/administration;
- contain all the particulars listed above see Section 1;
- relate to medicines that have a product licence or a marketing authorisation or homoeopathic certificate of registration at the time of supply/administration ;
- be signed by or on behalf of the authorising body, by or on behalf of the relevant person listed above;
- where the POM is to be administered by the person lawfully conducting a retail pharmacy business, the person administering it must belong to one of the groups of persons listed in Section 2 and be designated in writing by the authorising person as detailed above.

5. Drugs Requiring Special Consideration

Certain drugs will require special consideration before inclusion in a PGD and some are restricted by legislation.

Controlled Drugs

Amendments were made to the Misuse of Drugs Regulations 2001, as amended, in October 2003 to allow PGDs for controlled drugs in certain circumstances.

Schedule 8 of the Misuse of Drugs Regulations 2001 lists the persons who may supply and/or administer a specified controlled drug under a PGD. This list includes:

(a) a person who holds a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State, or a person who is a registered paramedic;
(b) a registered midwife;
(c) a registered optometrist;
(d) a registered chiropodist;
(e) a registered orthoptist;
(f) a registered physiotherapist;
(g) a registered radiographer;
(h) a registered occupational therapist;
(i) a registered orthotist and prosthetist.

In accordance with the Misuse of Drugs Regulations 2001:

- A registered nurse, when acting in her capacity as such, may supply and/or administer diamorphine under a PGD for the treatment of cardiac pain to a person admitted as a patient to a coronary care unit or accident and emergency department of a hospital.
- A registered nurse, pharmacist or any of the other named healthcare professionals listed above (a-i), when acting in their capacity as such, may supply and/or administer any Schedule 5 controlled drug in accordance with a PGD.
- A registered nurse, pharmacist or any of the other named healthcare professionals listed above (a-i), when acting in their capacity as such, may supply and/or administer any Schedule 4 Part 1 controlled drug in accordance with a PGD provided that it is not a drug in parenteral form for the treatment of addiction. In this instance a person is considered addicted to a drug if, and only if, s/he has as a result of repeated administration become so dependent on the drug that s/he has an overpowering desire for the administration of it to be continued.

N.B. Midazolam is currently a Schedule 4 Part 1 controlled drug. However, from 1st January 2008 it will be re-scheduled as a Schedule 3 controlled drug. Despite this it will still be permissible for midazolam to be included in a PGD subject to the same restrictions as a Schedule 4 Part 1 controlled drug.

Under no other circumstances can a controlled drug be considered for inclusion in a PGD.

There is currently a consultation being undertaken to extend the list of items and circumstances under which controlled drugs can be included in PGDs.

Medicines without a Marketing Authorisation and those used outside the terms of the Summary of Product Characteristics (SPC)

Medicines without a UK marketing authorisation are not considered appropriate for inclusion in a PGD. The Regulations specifically state that a medicine can only be included in a PGD if it has a current UK Marketing Authorisation or a homoeopathic certificate of registration. Only medicines with a marketing authorisation can have guarantees of safety, quality and efficacy.

In certain, exceptional circumstances, medicines with a marketing authorisation could be used outside the SPC. Areas for consideration might include paediatrics where no licensed version exists. NICE guidance should be followed to ensure that a medicine used in this way is justified. The PGD must clearly state that the product is being used outside the terms of the SPC and state the reasons why its use is necessary.

Newly licensed drugs subject to special reporting arrangements, (Black Triangle drugs), should also only be considered in exceptional circumstances. Again, good clinical practice guidelines must be followed and the PGD must clearly state the status of the product.

Antimicrobials

Antimicrobial resistance is a major public health concern. The use of antibiotics in PGDs must therefore be given careful consideration. Inclusion in a PGD should only be considered where absolutely necessary and justifiable and where measures to combat resistance will not be compromised. A local microbiologist should be involved in the drawing up of a PGD involving any antimicrobials and the PGD should be regularly audited.

6. Ps and GSLs

The legislation for PGDs provides for exemptions from Section 52 and 53 of the Medicines Act 1968. This therefore allows the supply and/or administration of a P or GSL medicines under a PGD. It is important to remember that all the requirements for a valid PGD, as detailed above, must be adhered to. Only named individuals who belong to one of the classes of persons specified in Section 2 can supply or administer a P or GSL under a PGD.

Further information on the use of a PGD for P and GSL medicines can be found in Appendix 1 and Appendix 2

7. Security, Storage and Appropriate Audit

It is essential that due consideration is given to the arrangements for supply, security and storage of all medicines. NHS guidance has indicated that all medicines should be supplied in pre-packs made up by a pharmacist. However, pharmacists asked to supply pre-packs in this manner must be sure to check with the Medicines and Healthcare products Regulatory Agency (see Appendix 7 for contact details) that they have the appropriate licences to allow them to do so. It may be necessary for supplies to be made from Regional Licensed Repackaging Centres.

The NHS Executive have produced a document, *Controls Assurance Standard – Medicines Management (Safe and Secure Handling),* that provides guidance on the legislation and best practice that should be followed with regard to the handling of medicines.

Proper audit trails should be in place. This would include a secure system for the recording of medicines use under the PGD. NHS Executive guidance has stated that this would ideally include the reconciliation of receipts and supplies of medicines on an individual patient by patient basis. From this it should be possible to identify what patient has had what medicine. The names of the health professionals providing treatment should also be recorded.

Appendix 5 provides more information on audit.

8. Labelling and Patient Information Leaflets

The EU Labelling and Leaflet Directive 2001/83 was incorporated in to UK law in 1994 and, amongst other provisions, it is a legal requirement that the manufacturer's patient information leaflet is provided each time a medicine is supplied. However, it is not a legal requirement to

put a product's batch number and expiry date on a dispensed medicinal product. The particulars required are in Paragraph 3 of Schedule 5 of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, as amended. These requirements will apply equally to medicines supplied under PGDs. These requirements are also reproduced in the latest edition of the Medicines, Ethics and Practice, A Guide for Pharmacists and Pharmacy Technicians.

9. Professional Guidance for Pharmacists and Registered Pharmacy Technicians Involved with PGDs

Section 10 of the Professional Standards Document "Sale and Supply of Medicines", which supports of the Code of Ethics details the professional requirements for pharmacists and registered pharmacy technicians involved with PGDs. It states:

"10. PATIENT GROUP DIRECTIONS
STANDARDS
If you are involved in the supply and/or administration of a medicine under a patient group direction (PGD) you must:
10.1 be satisfied that the PGD is legally valid and that it has been approved by the relevant authorising body.
10.2 ensure that when supplies are made the agreed protocol is followed and the information specified in the PGD is recorded. These records must include the identity of the pharmacist assuming responsibility for each supply.
10.3 ensure you have up-to-date knowledge relating to the clinical situation covered by the PGD, the medicine and its use for the indications specified.
10.4 ensure that you have undertaken any training required for operation of the PGD. If you are involved in writing and/or approving patient group directions (PGD) you are accountable for their content and must ensure that:
10.5 you are familiar with your role and responsibilities and the government advice set out in relevant guidance.
10.6 only PGDs which comply with legal requirements are approved.
10.7 the staff training specified will enable safe operation of the PGD.
10.8 the appropriate people have been involved in the drafting, approval and signing of the PGD.
10.9 you have up-to-date knowledge relating to the clinical situation being covered by the PGD, the medicine and its use for indications specified in the PGD."

10. Indemnity Insurance

Principle 7.7 of the Code of Ethics states:

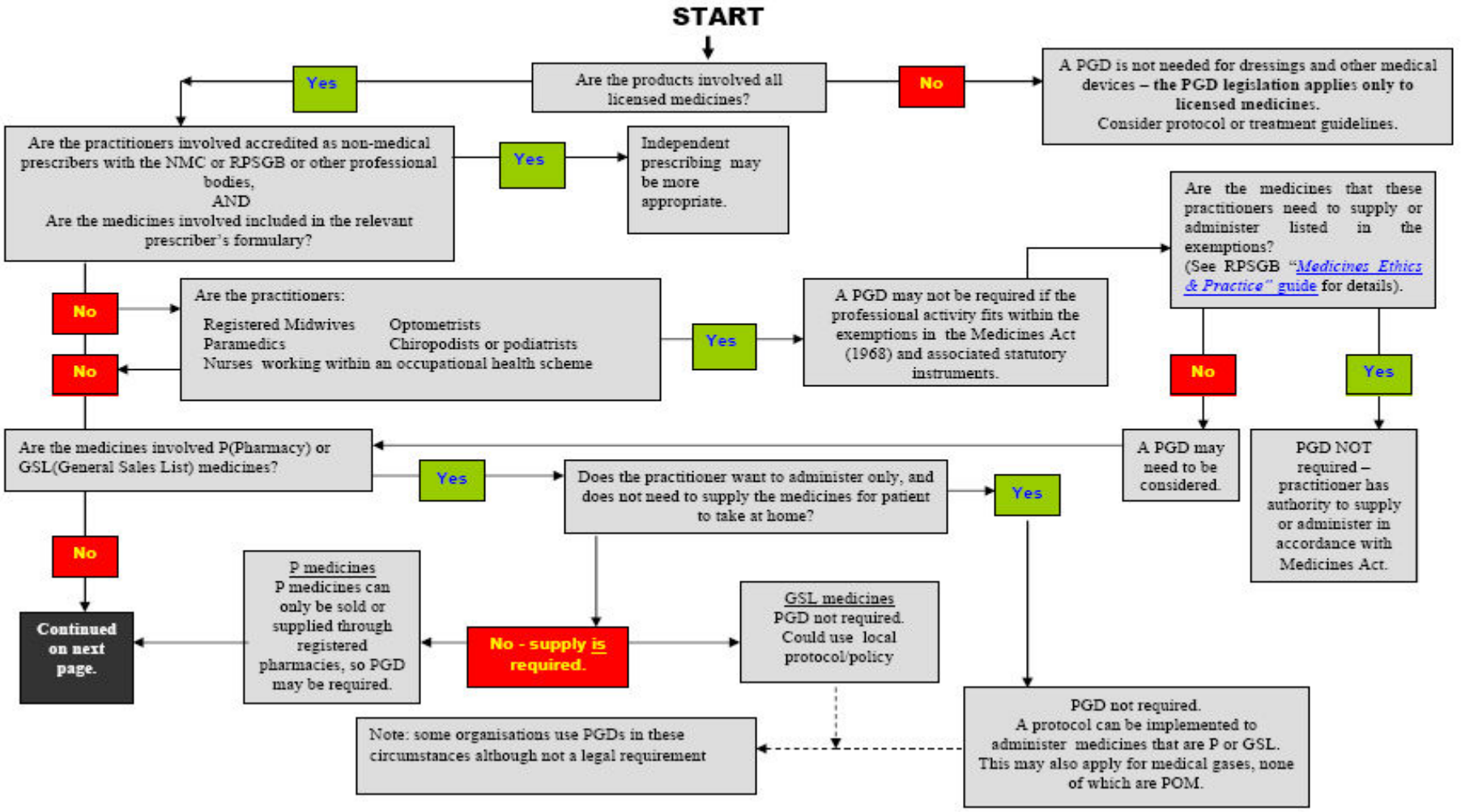
"7.7 Ensure that all professional activities undertaken by you, or under your control, are covered by appropriate professional indemnity arrangements."

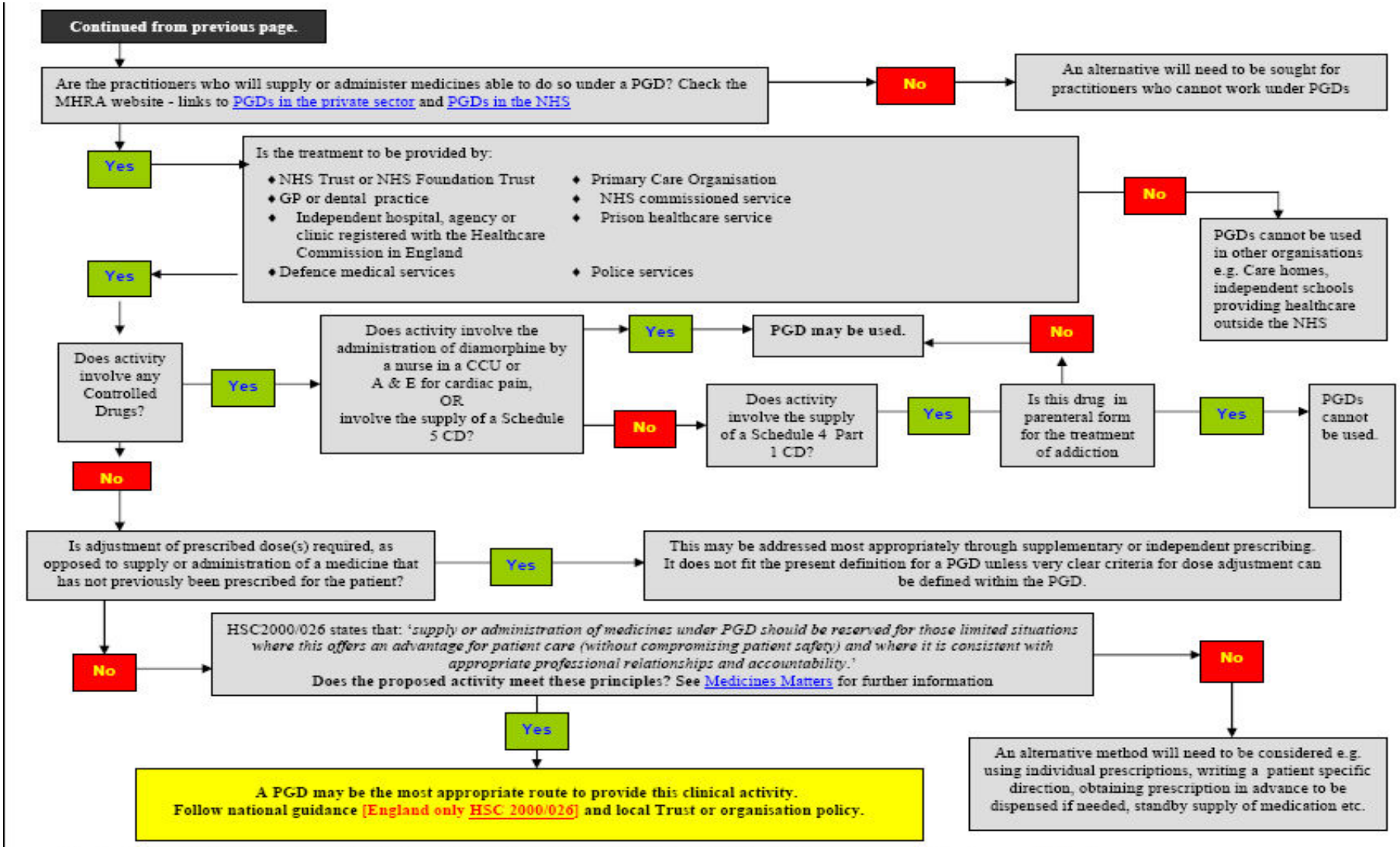
It is essential that pharmacists involved in PGDs in any way have adequate indemnity insurance to cover the tasks they are undertaking. This applies equally to pharmacists involved in the drawing up of PGDs, those responsible for signing them and those responsible for administering and/or supplying medicines under a PGD.

TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

You need to consider whether a Patient Group Direction (PGD) would be appropriate for an area of practice that involves the supply or administration of medicines. Medicines Matters published by Department of Health is a useful reference source which describes the mechanisms available for the prescribing, supply and administration of medicines. This diagram takes the practitioner through a logical process that aims to assist decision-making. **THIS VERSION IS FOR ENGLAND ONLY.**

NOTE: The majority of clinical care should still be provided on an individual, patient-specific basis.





Version 6 : June 2007 Original authors: Beth Taylor and Leigh Machell. Revised by Nelm@gstt.nhs.uk Further copies available at www.pgd.nhs.uk

Appendix 2: Frequently Asked Questions

1. Is it allowable to have a patient group direction for more than one drug?

It is possible to have a Patient Group Direction (PGD) for more than one drug. However, all the information required by legislation must be included and this may therefore make a PGD for more than one drug confusing. The final choice as to whether to have one PGD or several will depend on the drugs in question. In some cases it may make very good sense to have one PGD covering two or more drugs. However, it should not be seen as a short cut to providing all the information required.

2. Do all individuals supplying/administering under PGD have to be named?

Schedule 7 to the POM Order details the requirements for a PGD to be valid. It is not a requirement that the individuals supplying/administering are named as part of the PGD document itself. However, all individuals supplying/administering under the PGD must be designated in writing on behalf of the authorising person and must be named.

3. Is it acceptable to have a dose range specified in the PGD rather than a specific dose?

This is acceptable. The legislation requires that the applicable dose or maximum dose is specified. The PGD may therefore specify a single dose or a range up to a specified maximum. The pharmacist/practitioner signing the PGD must be satisfied that the dose range is clinically appropriate and within the terms of the medicine's marketing authorisation. The clinical criteria for selecting a dose within the range must be specified. The person supplying/administering under the PGD must be assessed as competent to make the dosage decision.

4. Do occupational health schemes need PGDs to supply POMs to their patients?

Occupational health (OH) schemes do not need to produce PGDs for the supply of POMs to their patients as there is a specific allowance within the POM Order that allows persons operating an OH scheme to supply POMs in their own right.

An OH scheme is a scheme in which a person, in the course of the business carried on by him, provides facilities for his employees for the treatment or prevention of disease. All medicinal products can be supplied. The supply must be made in the course of the business of the scheme. The person supplying or administering POMs in the course of the scheme must be a doctor or a registered nurse acting in accordance with the written instructions of a doctor.

Given this specific exemption, there is no requirement for PGDs for an OH scheme.

5. Which NHS body can authorise a PGD to assist doctors or dentists in the provision of primary care services?

The POM Order requires a PGD that is to assist doctors or dentists in the provision of primary care services, to be signed by the NHS body to which the doctor or dentist is contracted to provide NHS services. In practice this means the PGD must be signed on behalf of the PCO.

6. What labelling is required for medicines supplied under a PGD?

All medicines supplied under a PGD must be labelled in accordance with EC Directive 2001/83. In effect, this means that all medicines supplied under PGD must be labelled as dispensed medicinal products. A patient information leaflet must also be supplied to the patient.

7. Does a medicine supplied under PGD have to be given to the patient in person?

No. A medicine could be supplied to a carer or representative if the patient is unable to present in the pharmacy in person. However, the pharmacist has a professional responsibility to ensure that the medicine is suitable and that the patient has all the information necessary for safe and effective use of the medicine. If the pharmacist cannot be satisfied that the supply is appropriate or that all the necessary information will be accurately conveyed, the patient should be referred in line with the referral guidance detailed in the PGD.

8. Does an entry need to be made in the Prescription Register when supplies are made from registered retail pharmacies?

It is a requirement under the Medicines (Sale or Supply)(Miscellaneous Provisions) Regulations 1980, as amended, that the supply of all POMs from registered retail pharmacy premises must be recorded. This does not apply to the supply in accordance with a health prescription or a prescription for an oral contraceptive. There are other exemptions e.g. CDs but they are not relevant to the PGD legislation at this time.

Therefore, in addition to the usual audit trail for PGDs, it is also a requirement to keep a written or computerised record of the supply of a POM from a registered retail pharmacy in accordance with a PGD. There is nothing in the Regulations at present, to suggest what form this record should take. Therefore a pharmacist could keep a record in the prescription register or another bound book kept specifically for that purpose. A record could also be made electronically. Alternatively, a pharmacist could keep a copy of the records required by the authorising NHS body as this should include information on what was supplied to whom.

9. Who is responsible for ensuring the competence of the professionals supplying or administering under PGDs?

A senior member of each of the healthcare professions involved in supplying or administering medicines under a particular PGD should be responsible for ensuring that personnel are adequately trained and competent to undertake such a role.

10. Can a medicine be supplied under a PGD from a community pharmacy if the designated pharmacist is not available?

No. Only named individuals, designated in writing by the authorising NHS body can supply or administer under PGDs. It is therefore essential that when a named pharmacist is not available, the locum pharmacist and pharmacy staff have instructions on how to deal with customer requests and where to refer patients for treatment if required.

11. I am a locum pharmacist authorised to supply a medicine under a PGD in one PCO. I work in several PCO areas. Does the fact that I can supply in one area mean I can supply in others?

No. Each PGD is PCO specific. An individual supplying or administering under a PGD must be designated in writing on behalf of the authorising NHS body. If a pharmacist is not designated

in writing for a particular PGD they could not supply or administer under it regardless of whether they are authorised elsewhere for other PGDs.

12. What is the position if a medicine is being used outside the terms of its SPC?

A medicine with a valid marketing authorisation gives guarantees of safety, quality and efficacy for its licensed indications. Once a product is used outside the terms of its SPC, no such guarantees exist. NHS Executive guidance states that a medicine being used outside of the terms of its SPC, can be included in a PGD in exceptional circumstances and where its use is justified by current best clinical practice. The status of the product must be clearly indicated in the PGD.

Those pharmacists involved in drawing up PGDs, and those supplying or administering under PGDs as authorised individuals, must use their professional expertise to ensure that the use of a product outside the terms of its SPC is appropriate given that there are no guarantees of safety, quality or efficacy. Pharmacists must ensure that the benefits to the patient will outweigh the risks.

13. If there is a PGD for a P medicine, when should the pharmacist sell over the counter and when should the PGD route be used?

This issue should be raised when the PGD is being developed, so as to minimise misunderstandings and conflict. For example, it could be agreed that a person who is normally exempt from prescription charges could be supplied within the PGD context if they fall within its scope. A person who is not exempt from prescription charges could be supplied under PGD if they fall within its scope, or alternatively they could be supplied over the counter. This decision may be based on the price of the product.

If this information is not specified in the PGD itself, the pharmacist supplying must use their professional discretion to make their decision.

14. What are my responsibilities as a pharmacist signing a PGD if other healthcare professionals are to be supplying or administering under it?

A pharmacist signing a PGD is professionally accountable within the team devising the PGD. Part of this will be to confirm that satisfactory arrangements are in place to ensure that those supplying/administering under the PGD are suitably trained and competent to do so. NHS guidance indicates that a senior member of that profession should be involved with this process.

Appendix 3: Template Patient Group Direction

Patient group Direction For (*Name of drug.)*

Name of Body Authorising the PGD

PGD comes into effect	Appropriate date
PGD to be reviewed	Appropriate date
Supply/Administration of	Name of drug including form and strength
Legal Classification	POM, P, GSL
Black Triangle?	If yes state reasons for inclusion
Outside terms of SPC?	If yes state reasons for inclusion
Clinical situations for which medicine is to be used	Clinical conditions for which the POM can be supplied/administered
Clinical criteria for inclusion	Clinical criteria under which a person shall be eligible for treatment
Criteria for exclusion	Clinical criteria under which a person shall not be eligible for treatment
Reasons for seeking further advice from doctor/dentist	What circumstances should further advice be sought, if any
Dosage	Applicable dosage/maximum dosage
Route of administration	As appropriate
Frequency of administration	As appropriate
Period of administration	Maximum/minimum period of administration as appropriate
Warnings	Applicable warnings to note
Follow-up	What follow-up is appropriate, if any
Arrangements for referral	As appropriate
Details of records to be kept	As appropriate

Names of individuals permitted to supply/administer under the PGD	*Names of all individuals who are permitted to supply/administer under the PGD. All must belong to one of the designated classes of healthcare professional.*

Signed by	Relevant □uthorizing body, (see fact sheet for appropriate signatories required by legislation)
Signed by	Doctor/Dentist as appropriate
Signed by	Pharmacist
Signed by	*Doctor/Dentist whom the supply is to assist, where the PGD is to assist doctors/dentists in providing primary care NHS services.*

Appendix 4: Sample Patient Group Direction

Note: This is not designed to be a model PGD. The purpose of this sample is to demonstrate use of the template provided in this pack. Each authorising body is responsible for the information contained within their own PGDs and this sample should not be treated as a model PGD for these purposes.

Patient Group Direction For Relenza through Community Pharmacies In XXX PCT.

PGD comes into effect	*1st January 2003*
PGD to be reviewed	*1st January 2005*
Supply	*Relenza (Zanamivir) 5mg powder in blister for inhalation*
Legal Classification	*POM*
Black Triangle.	*NICE guidance recommends supply under PGD by community pharmacies*
Outside terms of SPC?	*No*
Clinical situations for which medicine is to be used	*Zanamivir is to be supplied for the treatment of influenza characterised by sudden onset of pyrexia, aches, pains and loss of appetite. Sore throat and dry cough are often associated with influenza as are nausea and vomiting.*
Clinical criteria for inclusion	*When influenza is circulating in the local community, (>50/100,000 consultations per week,) Zanamivir may be supplied to patients fitting one or more of the following at risk groups.* 1. Patients aged 12-65 with: • Chronic respiratory disease requiring regular medication • Significant cardiovascular disease excluding uncomplicated hypertension • Immunosuppression, whether due to

	treatment or illness • Diabetes mellitus 2. All patients aged >65. Patients must be presenting within 36 hours of symptom onset with most of the following symptoms: • Rapid onset from feeling well to feeling very unwell • Prostrating malaise • Profound myalgia • Marked fever >37.8C oral temperature • Headache, early and maybe severe • Minimal appetite • Minimal nasal secretions Patients may also present with a cough and sore throat although these are common symptoms of other upper respiratory tract infections. Patient may also have nausea and vomiting.

Criteria for exclusion	*Patients should be excluded if:* • Not in at risk groups defined above • Child under the age of 12 • Breast feeding
Reasons for seeking further advice from doctor/dentist	*Patients should be referred to GP if:* • Rash • Difficulty breathing • Disturbance of consciousness • Pregnancy • Other significant symptoms not mentioned under criteria for inclusion
Dosage	*Contents of two blisters (2x5mg)*
Route of administration	*To be inhaled via the diskhaler device*
Frequency of administration	*Twice a day*
Period of administration	*Five days*
Warnings	*Adverse reactions are rare but may include:* • Oropharyngeal oedema • Bronchospasm • Dyspnoea • Throat tightening or constriction • Rash
Follow-up	*None*
Arrangements for referral	*Advice for contacting GP when necessary*
Details of records to be kept	As required by the authorising NHS body. See also audit tools provided in the resource pack. Where POMs are supplied under PGD from registered retail pharmacy premises, a separate entry is required to comply with the Miscellaneous Provisions.

Name of owner of pharmacy business	*Name of owner of pharmacy business, (pharmacist or body corporate) who is authorised to supply under PGD.*

Signed by	Relevant NHS body, (clinical governance lead)
Signed by	Doctor
Signed by	Pharmacist

Note: The above information shows use of the template in ensuring that all information required by legislation is included in a PGD. Pharmacists involved in the development of similar PGDs may well wish to consider other matters for inclusion such as advice for patients at increased risk of bronchospasm, use of bronchodilators in asthma patients and verbal or written advice for patients or carers etc. The authorising NHS body is responsible for ensuring that all the legal provisions are in place and that clinically the PGD is appropriate.

Appendix 5: Audit

It is good practice to audit any new service soon after starting it. This is in order to see whether the service is being delivered to a suitable standard and whether it could be improved. We have given some advice on methods that you could employ to check the quality of the supply of medicines under Patient Group Directions.

1. Record Keeping

The records kept in the pharmacy should be able to demonstrate whether the Patient Group Direction has been followed. They should also allow an audit trail to be followed to show that the pharmacist has made an appropriate supply to the client.

We would expect that this would include whether the client met the inclusion criteria and whether the exclusion criteria were assessed. We would also expect that the record would include the client's name, age (if relevant) and address or postcode. Many Patient Group Directions are likely to require the signature of the client being supplied and the pharmacist making the supply.

It is good practice to record the counselling given to the client and the action taken.

The example record form shows how this might be done.* The records act as both a record of the transaction and a prompt for the pharmacist making the supply.

* (Adapted from the Manchester Community Pharmacy Patient Group Direction - Protocol for the supply and administration of progestogen-only contraception, POEC (levonelle 2))

2. Audit

The records kept by the pharmacist allow the process to be audited by the pharmacist involved. The following are suggestions of possible areas for audit:-

Record keeping

A simple audit would be to look at the records and ascertain whether they have been completed properly. Incomplete record keeping could lead to the Health Authority or Primary Care Organisation removing recognition of the pharmacist from the scheme.

Inclusion/exclusion criteria

The pharmacist may wish to check whether s/he is following the inclusion and exclusion criteria in all cases. A simple review of the records will demonstrate whether this is being followed.

Counselling

If the Patient Group Direction does not lay down criteria for the counselling that should be given each time, each pharmacist will be able to decide how much counselling they will give. It is good practice to make a formal decision about how much counselling and what areas the pharmacist would wish to cover with each supply.

In order to audit the counselling the pharmacist could review the actual counselling noted in the records against his/her decision about how much counselling was required.

The pharmacist may then want to reflect on whether they are actually delivering all the counselling that they thought necessary and decide whether to change his/her practice.

Significant events

An important form of auditing practice is to note any significant events that have happened during a supply on a medicine under Patient Group Direction. A significant event could be a supply was particularly difficult or went particularly well.

After a supply that you did not handle particularly well, try to reflect on why you had a problem. What could you differently next time? How could you dealt with the client better? Could your staff give you some insight into how to improve your techniques?

Similarly, after a supply that you were particularly happy about – what did you do particularly well? Is there something that you could incorporate into future supplies?

Significant events can be a particularly important form of learning experience. If possible, share your experience, either good or bad, with colleagues and staff so that they can also learn from it.

Patient Group Direction for Relenza through Community Pharmacies

Pharmacy stamp

Patient's name:

Date of consultation:

Age / DoB:

Post Code:

1. Is Influenza circulating in the local community? ☐ Yes ☐ No

2. Risk Group.

When influenza is circulating in the local community, Zanamivir may be supplied to patients fitting one or more of the following at risk groups.

Risk Group	
1. Patients aged 12-65 with: ▪ Chronic respiratory disease requiring regular medication	☐ Yes ☐ No
▪ Significant cardiovascular disease excluding uncomplicated hypertension	☐ Yes ☐ No ☐ Don't know
▪ Immunosuppression, whether due to treatment or illness	☐ Yes ☐ No ☐ Don't know
▪ Diabetes mellitus	☐ Yes ☐ No ☐ Don't know
2. All patients aged > 65	☐ Yes ☐ No

3. Inclusion criteria

Patients should be in the risk groups above and meet the following inclusion criteria

Inclusion Criteria	
Patients must be presenting within 36 hours of symptom onset with most of the following symptoms:	
▪ Rapid onset from feeling well to feeling very unwell	☐ Yes ☐ No ☐ Don't know
▪ Profound myalgia	☐ Yes ☐ No ☐ Don't know
▪ Immunosuppression, whether due to treatment or illness	☐ Yes ☐ No ☐ Don't know
▪ Market fever >37.8C oral temperature	☐ Yes ☐ No ☐ Don't know
▪ Headache, early and maybe severe	☐ Yes ☐ No ☐ Don't know
▪ Minimal appetite	☐ Yes ☐ No ☐ Don't know
▪ Minimal nasal secretions	☐ Yes ☐ No ☐ Don't know
Patients may also be present with a cough and sore throat although these are common symptoms of other upper respiratory tract infections. Patient may also have nausea and vomiting.	

4. Exclusion Criteria

Patients should be excluded if:

Exclusion Criteria	
▪ Not in a risk group defined above	☐ Yes ☐ No ☐ Don't know
▪ Child under the age of 12	☐ Yes ☐ No ☐ Don't know
▪ Breast feeding	☐ Yes ☐ No ☐ Don't know

5. Referral Criteria

Referral Criteria	
	If 'yes' refer
▪ Rash	☐ Yes ☐ No ☐ Don't know
▪ Difficulty breathing	☐ Yes ☐ No ☐ Don't know
▪ Disturbance of consciousness	☐ Yes ☐ No ☐ Don't know
▪ Pregnancy	☐ Yes ☐ No ☐ Don't know
▪ Other significant symptoms not mentioned under criteria for inclusion	☐ Yes ☐ No ☐ Don't know

6 Counselling

Please note the counselling given to the patient.

Dose	☐ Yes	☐ No
Administration	☐ Yes	☐ No
Adverse reactions	☐ Yes	☐ No
Advice about seeing GP when necessary	☐ Yes	☐ No

7. Action taken:

Supply:

Batch number / expiry date of Relenza supplied:

Referral:

Advice given:

The above information is correct to the best of my knowledge. I have been counselled on the use of Relenza and understand the advice given to me by thepharmacist.

Client's Signature: Date:

The action specified was based on the information given to me by the patient, which, to the best of my knowledge, is correct.

Pharmacist's Signature: Date:

Appendix 6: Tips For Community Pharmacists Working With PGDs

Community pharmacists will be amongst those healthcare professionals who may become involved in the supply and administration of specified medicines under a PGD. The issues surrounding the development and implementation of PGDs are complex and require careful interpretation. In this section, we set out to suggest ways in which community pharmacists can try to get support for a pharmacy based PGD and look at the types of medication which may be suitable for inclusion.

How can I set up a PGD for use in my pharmacy?

The introduction of PGDs takes pharmacists a step nearer to prescribing. However, at this early stage, it is essential that we consider the needs of patients and other health care professionals in the early stages of the process.

It is important that any pharmacy-based PGD is going to fulfil a local need and successfully demonstrate to local and national decision makers that community pharmacists are indeed a vital link the primary care chain.

Consider your locality. What are the demographics of the population? Is a significant part of your population elderly or are there high numbers of mothers with young children? Are teenage pregnancies a problem in your area? Do patients on anticoagulant therapy have to travel a distance for their regular INR tests? Does your local practice have an asthmatic or diabetic clinic?

There is little point in concentrating on the development of a PGD for the supply of emergency hormonal contraception in an area with low rates of teenage pregnancies or terminations for example.

Try to think of a pharmacy-based PGD as a mechanism by which community pharmacists can help to free up GP time for those patients who really need to be seen in the surgery by dealing with less serious or acute problems in the pharmacy.

Once you have assessed the health needs of your locality, it would be prudent to consult with other stakeholders in the area. Firstly, consider other community pharmacists operating in the area. It is likely that a PCT or other equivalent NHS body would view a joint approach from all contractors in a locality for the development of a PGD with greater credibility than an application from a single pharmacist operating in isolation.

Once you have the support of your colleagues, approach a friendly GP or officer of the NHS body in whose area the PGD would be operated and try to estimate their support for the PGD. The PCT or equivalent chief pharmacist would also be a useful contact to approach since he or she will have to sign off the PGD. If you have done your homework properly in assessing the need for the PGD, then hopefully you will find plenty of support. If not, you may need to reassess the need for the PGD or approach a different GP who may be more supportive. You may need to provide evidence of the success of a similar PGD in a different locality. The NPA and RPSGB will be able to give you advice on how to find this information.

At this stage, assuming that your PGD has been accepted in principle, you will need to ensure that the PGD is drawn up within the legal framework described earlier in this pack. This includes having the PGD signed off by a senior doctor, senior pharmacist and by a representative of the authorising body concerned.

Depending on the exact nature of the PGD, it is likely that additional training will be required for those pharmacists operating under the PGD. You will need to discuss this with those personnel responsible for the drawing-up and signing off of the PGD.

Adequate professional indemnity insurance is essential for any pharmacist involved in PGDs in any way. This includes pharmacists who are involved in the drawing-up of the PGD, those signing off the PGD and those operating under the PGD. You should inform your insurers of each individual PGD that you are involved with. This is because it would be difficult to give 'blanket' cover as the individual content of each PGD can vary widely. Make sure that you get written confirmation that you are covered for any extended role that you are involved with, including the writing, authorising and implementation of PGDs. If you have professional indemnity insurance with the CDA, you should make sure that you send them copies of any PGD with which you are involved before they become operational to ensure that cover is in place at the right time.

What medicines may be the subject of a PGD in community pharmacy?

So far, we have seen PGDs for the supply of emergency hormonal contraception and Relenza ® in community pharmacy.

When you start to think of examples of PGDs that would meet a need in your locality, consider also the types of conditions that regularly present in your pharmacy that you would be confident to treat, but for the fact that the first-line therapy is a prescription only medicine.

Bearing in mind the needs of your locality as described above, the following drugs may be suitable for inclusion in a pharmacy-based PGD:

• Trimethoprim for uncomplicated UTIs
• Chloramphenicol or fusidic acid for the treatment of bacterial conjunctivitis
• Mebendazole for thread worm infestation
• Higher strength topical steroids for eczema and dermatitis
• Zyban for smoking cessation
• Prescription only versions of medication for conditions such as thrush and nappy rash for NHS patients
• Warfarin for patients attending a pharmacy-based anti-coagulation clinic
• Treatment for impetigo

The inclusion of antimicrobials in PGDs requires careful consideration because of public health concerns over resistance. However, they may be included where considered absolutely necessary and where measures are taken to ensure resistance is not compromised. Similarly, new products with black triangle warnings would not normally be suitable for inclusion in a PGD.

This list is by no means exhaustive and you may be able to think of many more drugs, which if included on a PGD, could improve patient care and access to services. In the future we may see other examples PGDs for use by community pharmacists running an asthma management or cardio-vascular clinic. In both of these examples, the prescriber may have made a diagnosis and identified a patient as suitable for treatment but it will be the pharmacist who decides which particular drug is supplied for that condition, or the dose may be adjusted to obtain greater therapeutic benefit.

Community pharmacists in the United States of America have developed a role in administering vaccines including those for the prevention of influenza and pneumococcal

infection, to patients. It may be possible that in the future, suitably accredited community pharmacists may also become involved in this type of activity through PGDs in this country. This would ensure that many more patients, both those at risk and the 'walking well', would be able to receive appropriate immunisation, particularly in areas with little or no access to other health care professionals.

Summary

This is both an exciting and challenging time for community pharmacy. The right PGD, in the right place, at the right time, for the right patients, will help to improve the quality of patient care and facilitate access to a health care professional and suitable treatment for patients in the NHS and private sector.

The National Pharmaceutical Association has considerable resources to assist members in developing professional services, including information on developing and costing a service, writing a proposal, selling services and meeting with GPs. The NHS Service Development Department is also able to provide one to one advice and support for members. For further information contact: 01727 858687.

Appendix 7

Contacts

Medicines and Healthcare products Regulatory Agency
Telephone: 020-7084-2000
Email: info@mhra.gsi.gov.uk
Website: www.mhra.gov.uk

Home Office
Telephone: 020-7035-0464
Email: chris.edwards@homeoffice.gsi.gov.uk

Department of Health
Telephone: 020-7210-4850
Email: dhmail@dh.gsi.gov.uk
Website: www.dh.gov.uk

The Scottish Executive
Telephone: 0131-244-2440
Email: ceu@scotland.gov.uk
Website: www.show.scot.nhs.uk/sehd

Department of Health and Social Services (Wales)
Telephone: 02920-370-011
Website: www.wales.nhs.uk

NHS Patient Group Direction website: www.portal.nelm.nhs.uk/pgd/default.aspx