The PGD Screening Tool, for screening PGDs prior to approval by the authorising organisation.

Screening Tool for the development of PGDs

This screening tool is designed to facilitate the development of PGDs prior to approval by the authorised organisation. The tool may be used as guidance by the practitioner developing PGD or ideally as a tool to help those who are responsible for ensuring that PGDs meet the criteria as dictated by the legal framework, prior to approval by the organisation.

It is intended that the tool is used on up to five occasions to help review five separate PGDs.
The first section in **blue** details the basic requirements for a PGD that is being developed to meet the criteria laid out in the legal framework HDL 2001(7).

The second section in **green** enables practitioners to develop PGDs that encompass more than the basic information requirements. This section includes some best practice that was highlighted as part of The PGD Project.

Please note that this screening tool was developed in conjunction with The PGD Reference Group for the PGD Project.

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BLUE SECTION CONFIRMATION THAT DEVELOPMENT OF A PGD IS APPROPRIATE

This section details the minimum legal requirements for the development of a PGD.

By using the checklist provided any omissions within a PGD should be easily identified.

(Please indicate if the PGD meets the standard by ticking ✓ the box.)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
A: The PGD is for the 'supply' or 'administration' of a prescription only medicine (POM) or a Pharmacy medicine (P). • In the majority of cases patients should be reviewed by an independent or supplementary prescriber and medication prescribed on an individual basis. • PGDs should only be developed for conditions or situations where patients are unable to be identified prior to presentation for treatment eg. for use in the emergency situation, for administration of vaccinations.	❑	❑	❑	❑	❑
B: Development of the PGD will improve patient care. • It is clear provision of care via a PGD will be advantageous for the patient and this is stated within the PGD. • Patient care will not be compromised by development of the PGD.	❑	❑	❑	❑	❑
C: The medicine has UK Marketing Authorisation (UK Product Licence) and the medicine is legally allowed to be 'supplied' or 'administered' under a PGD. • Medicines without UK Marketing Authorisation (a UK Product Licence) should NOT be supplied or administered under a PGD. • Where a medicine has Marketing Authorisation (a UK Product Licence) but the clinical indication of the PGD is NOT for an indication included in the licence, then this 'unlicensed use' should be stated within the PGD. • Where the PGD is for a newly marketed medicine (a black triangle medicine (▼)) the PGD should be developed with caution and the status of the medicine is clearly highlighted within the PGD (eg. PGD for Unlicensed use of Medicine). • All suspected adverse drug reactions from medicines included in a PGD should be reported to the Committee for The Safety of Medicines.	❑	❑	❑	❑	❑
STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
D: The medicine with the strength, form and legal classification (eg. POM) are clearly defined within the PGD.					

• The duration of treatment, maximum total dosage, individual dosage, quantity to be supplied on one occasion, route, frequency of administration and the minimum or maximum period over which the medicine should be administered are all required to be stated as appropriate. • The specific product characteristics (SPC) for the product have been consulted. • Where there is a range of doses for the medicine, there is justification of the dose stated within the PGD.	❑	❑	❑	❑	❑
E: The patient group who will receive treatment under the PGD is clearly defined. • Where children are involved, doses are clearly defined by age, weight (kg) and where appropriate the maturity of the child. (Note: this may not be applicable for vaccines) • PGDs for specialist groups of patients, should be developed with the involvement of a local clinical specialist in the particular clinical area.	❑	❑	❑	❑	❑
F: The names of the clinical areas and the locations where the PGD will operate are clearly defined. • The speciality(ies)/locations where the PGD will operate need to be clearly defined Eg. Ward 8 XXXX, all acute medical receiving units within xxx. • The organisation authorising the PGD needs to be defined (eg. the Hospital Division).	❑	❑	❑	❑	❑
G: The PGD has a start date and an expiry date (review date). • The start date and expiry/review dates are within 2 years or before, should new information become available.	❑	❑	❑	❑	❑

DETAILS OF THE PROFESSIONALS DEVELOPING THE PGD (Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
H: The practitioner group is defined within the legal framework as being: • An ambulance paramedic, chiropodist/podiatrist, dietician, health visitor, nurse, midwife, pharmacist, physiotherapist, optometrist, orthoptist, radiographer, or other profession as defined by the legal framework. • The practitioner needs to be currently registered with the appropriate professional body. • The PGD needs to include a statement to ensure that the practitioner is informed that they need to follow the appropriate code of conduct as defined by their professional body.	❑	❑	❑	❑	❑
I: The practitioners are required to be educated. • The basic education required by each practitioner, prior to operating under the PGD, is defined eg. Level 1 registered nurse. • The need for practitioners to undertake CPD within the therapeutic area of the PGD is defined within the PGD. • The need for continuing competency and updating of knowledge is recognised within the PGD eg. 'Refresher' Training after initial training, should be provided on a regular basis by a local specialist in the therapeutic field. • An individual/department is named within the PGD for the provision of this specific training (eg. generally a clinical specialist to ensure continued knowledge of therapeutic area).	❑	❑	❑	❑	❑
J: A senior doctor/dentist has signed the PGD. • When developing a PGD there must be medical staff/a dentist's involvement. The practitioner involved needs to have suitable experience and seniority within the organisation. • Such individuals need to be registered within the UK and employed by the authorising organisation.	❑	❑	❑	❑	❑
K: A pharmacist has signed the PGD, indicating involvement in the development process. • When developing a PGD there must be the involvement of a pharmacist.	❑	❑	❑	❑	❑

• Such individuals need to be registered within the UK and employed by the authorising body. • The PGD is signed by a pharmacist who has been involved in its development. • A 'senior pharmacist' should ensure that issues regarding medicine storage are regulated by The Medicines Act (1968) and that the facilities available to practitioners when operating under the PGD have been considered,eg. availability of medicines required in case of anaphylaxis/the security of medicines whilst stored at a clinic.					
STANDARD	**PGD ref.**	**PGD ref.**	**PGD ref.**	**PGD ref.**	**PGD ref.**
L: The senior professional practitioner employed by the organisation, has signed the PGD. • The senior professional head of the specific practitioner groups need to have signed the PGD eg. a nurse developing a PGD, their senior professional colleague needs to approve the PGD. However, where PGDs are developed by multiprofessionals (eg. for operation by >one professional group) a senior professional may delegate this duty to one single senior professional from the various professional groups. In such instances the signatory needs to clearly understand their responsibilities for operation of the PGD.	❑	❑	❑	❑	❑
M: The name of the organisation within which the PGD will operate is clearly defined. • The organisation authorising the PGD needs to be defined (eg. The Hospital Division).	❑	❑	❑	❑	❑
N: If the PGD is for an anti-microbial. • A microbiologist has been involved in the development of the PGD • The PGD is signed by the microbiologist, who has been involved in the development of the PGD. • Anti-microbial resistance is a serious public health issue and PGDs involving anti-microbials need to refer to local microbiological policies/guidelines.	❑	❑	❑	❑	❑

DETAILS OF THE CLINICAL INDICATION COVERED BY THE PGD (Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
O: The clinical condition(s) covered by the PGD are clearly defined.	❑	❑	❑	❑	❑
P: When further advice should be sought from a medical practitioner/dentist arrangements for this referral are defined within the PGD. • Some patients may be excluded from the PGD and need to be referred to an independent/supplementary prescriber.	❑	❑	❑	❑	❑
Q: If the PGD is for a child then any age restrictions and/or weight restrictions are clearly detailed within the PGD. • A clinical specialist should be involved in the review of PGDs for children. • Doses of medicines should be clearly defined by age, weight and where appropriate the maturity of the child assessed. (Note: this may not be applicable to vaccines) • The formulation of the medicine is suitable for administration to children.	❑	❑	❑	❑	❑
R: The inclusion criteria for patients to receive treatment under the PGD are clearly defined. • If several separate PGDs have been submitted for similar indications but for treatment with different medication practitioners need to be able to decide which PGD to follow (eg. PGDs for psoriasis where a step wise treatment plan is appropriate depending on the severity of the condition). • If there is more than one strength or form of the medicine being administered or supplied (to provide continuity of treatment), then when to administer or supply the different strengths/forms is clearly defined within the PGD.	❑	❑	❑	❑	❑

S: The exclusion criteria for patients NOT to receive treatment under the PGD are clearly defined. • The exclusion criteria should not just include 'all those patients who do not meet the inclusion criteria'. • Pregnancy should be noted as an exclusion criterion, as appropriate. • The process for referral when patients are excluded from treatment needs to be clearly defined within the PGD. • A record of the reason for exclusion needs to be documented in the patient's case notes/record as a requirement of the PGD.	❑	❑	❑	❑	❑
STANDARD	**PGD ref.**	**PGD ref.**	**PGD ref.**	**PGD ref.**	**PGD ref.**
T: If a patient declines treatment, the actions to manage the situation are defined. • Where a patient declines to receive treatment under a PGD, this decline of treatment should be documented with the patient's case notes/record as a requirement of the PGD. • The reasons for a patient declining treatment should be stated as a requirement within the PGD. • Referral of the patient to a medical practitioner/dentist should be stated as a requirement within the PGD.	❑	❑	❑	❑	❑
U: Relevant information that should be communicated to the patient, including any potential suspected adverse reactions need to be specified as a requirement within the PGD. • All risks to the patient should be minimised. The practitioner needs to ensure that specific questions are posed to the patient to ensure that the medicine can be administered/supplied safely without the risk of the medication interacting with medication currently taken by the patient. This needs to be stated as a requirement of the PGD. • Where feasible, a patient questionnaire (as a form of risk assessment) should be completed prior to the administration or supply of medication. • Information given to patients should be available in a variety of different formats. Patient information leaflets developed as part of a PGD need to be approved as part of the authorisation process. Ideally commercially available	❑	❑	❑	❑	❑

PILs should be supplied with an original patient pack wherever possible. • The fact that a patient has received information needs to be documented in the patient's case notes/record. Such a requirement needs to be stated within the PGD. • Patients should be informed whom to contact, should they experience a suspected adverse drug reaction (ADR). Such a requirement needs to be stated within the PGD.					
V: Details of any follow up action and monitoring required should be noted.	❑	❑	❑	❑	❑

DETAILS OF THE PROFESSIONALS RESPONSIBLE FOR DEVELOPMENT AND APPROVAL OF THE PGD

(Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
W: The professionals who will operate under the PGD are named individually. • Within the PGD the individual practitioners have signed the PGD or a standard form, as agreed by the organisation, is used to record the practitioner's signature. • The individual practitioners have signed a form (eg. a memorandum of understanding) that details their responsibilities and their understanding of the content of the PGD and their role and responsibility for the administration or supply of medication under the PGD.	❑	❑	❑	❑	❑
X:The PGD will be finally approved by a recognised multidisciplinary group. • PGDs need to be developed by a multidisciplinary group, the membership of which must include a doctor/dentist, pharmacist and a representative from the professional group developing the PGD. PGDs must then be authorised by a multidisciplinary group for use within the organisation eg. the drug and therapeutics committee.	❑	❑	❑	❑	❑

Y: An individual with responsibility for clinical governance should finally sign and approve the PGD for use within the organisation. • The Medical Director usually has overall responsibility for clinical governance and therefore the final approval for PGDs within the organisation. • The Lead for Clinical Governance within the organisation may have delegated responsibility for approval to another member of the organisation.	❑	❑	❑	❑	❑

DETAILS OF THE DOCUMENTATION HELD FOR AUDIT PURPOSES (Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
Z: There is a clear audit trail for all paperwork/documentation for the medicines administered or supplied under the PGD. • A record of administration of the medicine under a PGD should be documented in the patient's case notes/record. • A record of the name of the practitioner involved, the name of the medicine, the strength of medication, the dosage form, the dose and the date and time of administration should be documented and this should be a requirement of the PGD. • The batch number and expiry date of any medication supplied under a PGD should be documented and this should be detailed as a requirement in the PGD.	❑	❑	❑	❑	❑
ZA: PGDs should be audited on a regular basis to ensure that local practice concurs with the defined practice detailed within the PGD. • PGDs should be audited at least 6 months after introduction to ensure that current practice concurs with the detail as defined in the PGD. This should be stated as a requirement within the PGD. • Random samples of PGDs should be 'audited' on an annual basis to ensure the adequate documentation and recording of information. This should be stated as a requirement within the PGD.	❑	❑	❑	❑	❑

ZB: Monitoring arrangements for the patient during and after treatment are clearly defined within the PGD. • Any communication with the GP/healthcare worker should be detailed in the patient's case notes/record, as appropriate. • Patients should be informed of contact details should they require further information following the administration/supply of medication. This should be stated as a requirement within the PGD.	❑	❑	❑	❑	❑

Green section <u>Examples of Good Practice For The Development of Patient Group Directions</u>

This section should only be consulted when the PGD has met all of the standards detailed in the blue section above.
The detail within this section was identified as part of the scoping exercise for the PGD Project.

(Please indicate if the PGD meets the standard by ticking ✓the box.)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
A: The template used to develop the PGD is an agreed standard template for the organisation. • The name, form and strength of the medication to be clearly stated on the front cover of the document. • The practitioner group that will operate under the PGD to be easily identified on the front cover of the document. • The start date and expiry date of the PGD to be easily identified on the front cover of the PGD.	❑	❑	❑	❑	❑
B: The names of the clinical areas and the locations where the PGD will operate are clearly defined. • The PGD (or standard paperwork as agreed within the organisation) details each hospital/clinical location where the PGD is authorised to operate.	❑	❑	❑	❑	❑
C: If the patient group treated under the PGD includes children. • A clinical specialist has been involved in the review of the PGD.	❑	❑	❑	❑	❑
D: The evidence base used to develop the PGD is detailed within the PGD. • Details of any literature review undertaken with references. • The information indicating that the PGD reflects best clinical practice • Reference made to any national guidelines is reviewed (eg. SIGN, NICE).	❑	❑	❑	❑	❑

E: If the medicine that will be administered or supplied under the PGD is a newly marketed medicine and requires close surveillance/ monitoring (eg. a black triangle medicine) the status of the medicine is clearly defined within the PGD. • There is evidence to support the use of the medicine within the PGD. • The PGD clearly identifies the status of the medicine.	❑	❑	❑	❑	❑
F: Where the PGD includes a medicine which has UK Marketing Authorisation (a UK Product Licence), but the clinical indication for inclusion under the PGD is NOT included within the UK Marketing Authorisation, this status is clearly highlighted within the PGD. • Evidence to support the clinical indication is justified within the PGD.	❑	❑	❑	❑	❑
G: If the PGD is for an anti-microbial • Reference is made within the PGD to local antibiotic policies.	❑	❑	❑	❑	❑
H: If a patient is to be excluded from treatment under the PGD: • The process for referral to a medical/dental practitioner is defined within the PGD.	❑	❑	❑	❑	❑
I: The PGD details any form of risk assessment that has been undertaken prior to administration/supply of medication. • The risk assessment may take the form of a screening form/questionnaire eg. prior to administration of vaccines, prior to supply of Emergency Hormonal Contraception (EHC). • The risk assessment tool may be appended to the PGD to enable regular review and updating of the information.	❑	❑	❑	❑	❑
J: The PGD details the process for receiving patient consent for treatment. • Details of the process are defined within the PGD. • The detail is recorded on a separate form that is filed with the patient's case notes/records.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
K: Within the PGD there is a named individual/position within the organisation who will ensure that PGDs are kept up to date and that practitioners are educated prior to operating under the PGD. • The names and signatures of practitioners operating under the PGD need to be kept up-to-date. • Those operating under the PGD are suitably qualified/trained to do so.	❑	❑	❑	❑	❑
L: Where a medicine is supplied to a patient for self-administration the PGD details the process that will enable all medication to be accounted for at all times. • The process may detail that a register is held for all medication received by the practitioner and all medication supplied to the patient. • The process should inform that a unique patient identifier should be documented. • The process should inform that the batch number and expiry date of the medicine should be documented with the date when the medicine was supplied.	❑	❑	❑	❑	❑
M: Where a medicine is 'administered' under a PGD the practitioner will ensure that adequate information is recorded. • The name of the medicine, the strength of the medicine, the form of the medicine, the name of the practitioner administering the medicine, the date and time of administration of the medicine. • The PGD should detail that the practitioner needs to document that a medicine has been administered 'under a PGD' and they should sign and date the entry.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
N: Part of the PGD includes a section that defines the role and responsibility of the practitioner. • The PGD may include an agreement of understanding that will be signed by each of the practitioners who will operate under the PGD. • This agreement of understanding may be part of the PGD or may be separate documentation that is held centrally within the organisation.	❑	❑	❑	❑	❑
O: The monitoring of the medicines at the site where the PGD is operational has been considered. • Cold chain issues (keeping any temperature labile medicines at the correct temperature during transport/within the clinical area), records of receipt, records of supply of the medication have been considered.	❑	❑	❑	❑	❑
P: There is a clear documented audit trail for all medication administered or supplied. • There is a named individual/role within the organisation with this responsibility and this is defined within the PGD.	❑	❑	❑	❑	❑
Q: The PGD details all of the clinical locations where the PGD will be held. • All operational sites. • At a central point within the organisation. • The originator of the PGD should keep the original signed copy of the PGD with other areas including pharmacy retaining a photocopy of the PGD.	❑	❑	❑	❑	❑