APPENDIX 4B
GUIDANCE NOTES FOR COMPLETION OF THE PGD TEMPLATE

Development of a PGD must not start until a PGD Proposal has been approved by DTC. See Section 1 Trust PGD Protocol. Contact Pharmacy Clinical Governance PGDs for further advice if needed.

You must refer to the PGD Protocol and the NHS PGD website to ensure that PGD content and subsequent practice remains appropriate and legal. “To PGD or not to PGD” on the NHS PGD Website may be a useful reference source.

You should also refer to the Trust Medicines Policy and associated Codes of Practice.

See Trust PGD webpage for links to resources and for further information.

Do not work in isolation and ensure that all relevant stakeholders are consulted and agree with PGD content.

Failure to follow Trust PGD Protocol and associated policies and guidance may result in a document or practice that does not fulfil legal or Trust requirements.

1. Using the template

This guidance is a reference source to help you write a PGD using the latest blank PGD template.

Remember that a PGD is a formally agreed written instruction and should be written in a style which would allow a practitioner to follow that instruction in a step wise manner.

The most recent approved version of the blank template must be used for writing new PGDs. It should also be used for PGDs which require major changes following review and should be considered when PGDs are updated in order to reflect any changes to format or template content.

The blank template is available in Word format on the Trust intranet. Complete the blank template, adding the relevant information, marked in red in these guidance notes. You must not delete any information in blue or black unless instructed to do so within the text.

If other templates are used e.g. London Sexual Health PGD Group or national templates, you must add any locally relevant information to them to ensure that they meet Trust and legal requirements. Contact Pharmacy Clinical Governance PGDs for further advice before using such templates.
FURTHER GUIDANCE AND INFORMATION:

PGDs must not include unlicensed medicines. See PGD Protocol for information when including:
- Black Triangle Drugs
- Medicines used outside the terms of the Summary of Product Characteristics (off-label medicines)
- Controlled Drugs
- Antimicrobials

Use the PGD Development Checklist to ensure that you meet all legal and Trust requirements when developing the PGD

Ensure that all areas are completed in full and as recommended.

If you are in any doubt about completion of any section, discuss with the nominated deputy for Head of Nursing/Professional Lead or pharmacist or doctor(s) involved in the PGD development or contact Pharmacy Clinical Governance for further advice.

You can see examples of Trust approved PGDs on the Clinical Guidance pages on the intranet or quality assured examples from other Trusts on the NHS PGD Website. Take care if referring to PGDs obtained from other Trusts or accessed via search engines such as Google as quality cannot be assured by GSTFT.

COMMENTS AND SUGGESTIONS

The PGD template has been developed to help people write PGDs that comply fully with all legal and Trust requirements and at the same time be a useful clinical application. We would welcome any comments and suggestions you may have to improve this template guide or the template itself.
PATIENT GROUP DIRECTION (PGD)
FOR THE SUPPLY* AND/OR ADMINISTRATION* OF
NAME OF MEDICINE/FORM
BY REGISTERED HEALTH PROFESSIONAL
GROUP(S)
FOR CONDITION/SITUATION/PATIENT GROUP IN
LOCATION/SERVICE

*If PGD is for supply only and for self administration by patient, state “for supply of” and delete “and/or administration”.

Ensure title is clear and easy to follow e.g MEDICINE NAME/FORM by PROFESSIONALS TITLE / for treatment of x in LOCATION

If the PGD is for a penicillin: add the following to the title page and header throughout PGD:
PENICILLIN ALLERGIC PATIENTS ARE EXCLUDED FROM THIS PGD

TRUST AUTHORISATION

Note: PGDs will be approved using electronic authorisation system (WaFR). An authorisation statement and dates of approval will be added by Pharmacy Clinical Governance.

<table>
<thead>
<tr>
<th>NAME</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Albert Ferro</td>
<td>Leave blank</td>
</tr>
<tr>
<td>Chair Trust Drug and Therapeutics Committee (DTC)</td>
<td>Leave blank</td>
</tr>
</tbody>
</table>

Change History

<table>
<thead>
<tr>
<th>Version and Date</th>
<th>Change details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add a brief summary e.g SPC/guidelines updates</td>
<td></td>
</tr>
</tbody>
</table>
Add title of PGD in headers from page 2 onwards.

PGD CLINICAL AUTHORISATION

Note: PGDs will be approved using electronic authorisation system (WaFR). An authorisation statement and dates of approval will be added by Pharmacy Clinical Governance.

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>JOB TITLE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Author Name</td>
<td>INSERT DESIGNATED POSITION</td>
<td>Leave blank</td>
</tr>
<tr>
<td>Lead Clinical Pharmacist Name</td>
<td>INSERT DESIGNATED POSITION</td>
<td>Leave blank</td>
</tr>
<tr>
<td>Lead senior doctor/dentist (Consultant) Name</td>
<td>INSERT DESIGNATED POSITION</td>
<td>Leave blank</td>
</tr>
<tr>
<td>Service manager (if not same as Lead author)</td>
<td>INSERT DESIGNATED POSITION</td>
<td>Leave blank</td>
</tr>
<tr>
<td>Other Name</td>
<td>INSERT DESIGNATED POSITION</td>
<td>Leave blank</td>
</tr>
</tbody>
</table>

CLINICAL DIRECTORATE AUTHORISED SIGNATORIES

Note: PGDs will be approved using electronic authorisation system (WaFR). An authorisation statement and dates of approval will be added by Pharmacy Clinical Governance.

<table>
<thead>
<tr>
<th>NAME</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name Head of Nursing/Professional Lead</td>
<td>Leave blank</td>
</tr>
<tr>
<td>Name Clinical Director</td>
<td>Leave blank</td>
</tr>
</tbody>
</table>
MEDICINE TO BE SUPPLIED AND/OR ADMINISTERED UNDER THE PGD

Note –only one medicine per PGD. If more than one medicine, this must have been agreed with DTC at the proposal stage and prior to PGD development.

This PGD includes the following medicine:

- State name of medicine, strength and form. (use BNF format e.g. Azithromycin 250mg capsules or Azithromycin 200mg/5mL oral suspension)
- Only add brand name if you want the PGD to be brand specific or avoid confusion. Remember that if a brand is specified, only that brand may be supplied under the PGD.

The lead author (Name) has ensured that the following policies and procedures have been adhered to in the development of this PGD:

- Guy’s and St Thomas’ NHS Foundation Trust Medicines Policy and associated Codes of Practice
- Guy’s and St Thomas’ NHS Foundation Trust PGD Protocol.
- Guy’s and St Thomas’ NHS Foundation Trust PGD template guidance notes.

The decision to supply and/or administer any medication rests with the individual registered practitioner who must abide by the PGD and Trust policies.

Practice under this PGD must be audited at least once during the approved period of the PGD and no later than one year prior to PGD expiry, before PGD review takes place.
<table>
<thead>
<tr>
<th>CONTENTS</th>
<th>PAGE NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine to be supplied and/or administered under the PGD</td>
<td></td>
</tr>
<tr>
<td>Staff Characteristics</td>
<td></td>
</tr>
<tr>
<td>Drug Monograph(s)</td>
<td></td>
</tr>
<tr>
<td>Name of medicine, strength and form. (use BNF format e.g. Atenolol 50 mg tablets)</td>
<td></td>
</tr>
<tr>
<td>Note – only one medicine per PGD unless agreed otherwise at proposal stage. If more than one medicine, you must discuss with Pharmacy Clinical Governance prior to development.</td>
<td></td>
</tr>
<tr>
<td>References (must include manufacturer’s information (SPC)/BNF</td>
<td></td>
</tr>
<tr>
<td>Appendix 1</td>
<td></td>
</tr>
<tr>
<td>Agreement by Registered Practitioner</td>
<td></td>
</tr>
</tbody>
</table>
STAFF CHARACTERISTICS

| The named health professional authorised to supply and/or administer medications under the PGD must meet all of the following criteria: |
| Qualifications |
| • Include professional title/grade/band |
| • Specify current employment |
| Specialist qualifications |
| • Successful completion of specified courses, (insert) |
| • Any other relevant training or qualifications. (including working at Band X in xxxx area for xxx [specify period]) |
| Specialist competencies |
| • Provides evidence of successful completion of Trust Medicines Management test |
| • Provides evidence of successful completion of – add detail of specific training and competencies (add need for evidence of annual updates as required). |
| • Provides evidence of competencies for using PGDs such as successful completion of CPPE PGD e learning or equivalent. |
| • Specify mandatory training such as CPR/life support/anaphylaxis competencies with evidence of updates as required. |
| • Actively partaking in CPD and annual Individual Performance Review |

A training programme and a competency assessment checklist should be completed by each authorised practitioner to provide evidence of competency to practice under the PGD.

Completed competency assessment checklists and an up to date list with signatures of registered practitioners who are authorised to practice under this PGD are kept in…….(clinical area or electronic location)…………………..by (role of Manager not name)…..

This should include an outline of the PGD training programme and a competency assessment checklist.

Practitioners not listed are not authorised to practice under this PGD.
This drug title box must be included in all PGDs and at the start of each drug monograph where the PGD is for more than one medicine.

**DRUG NAME /STRENGTH/FORM**
Use generic whenever possible. If brand specific state generic then brand in brackets – note this will restrict supply of medicine to specific brands listed. State name strength (as BNF layout) and form. PGDs must not include unlicensed medicines.

Quantity to supply STATE PACK SIZE as the number of doses e.g. 28 tablets or capsules/200 unit doses/15g/100 mL.

You do not need to add quantity in this header if the PGD is only for administration.

If there is more than one strength or pack size, make sure that this is clear.

<table>
<thead>
<tr>
<th><strong>CLINICAL CONDITION TO WHICH THIS DIRECTION APPLIES</strong></th>
<th>Define situation /condition/ and indication e.g. treatment of mild to moderate pain or fever (temp &gt;37.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INCLUSION CRITERIA</strong></td>
<td>Use bullet points to list inclusions</td>
</tr>
<tr>
<td>Use BNF/BNFC/SPC.</td>
<td>• Define age range/sex e.g. Patients aged 12 years and over</td>
</tr>
<tr>
<td>Take into account any clinical guidelines or policies that are available locally or nationally e.g. Trust antimicrobial guidelines/NICE/Green Book/BASHH/FSRH.</td>
<td>• Do you include pregnant women?</td>
</tr>
<tr>
<td></td>
<td>• Do you include breast feeding women?</td>
</tr>
<tr>
<td></td>
<td>• Clinical criteria</td>
</tr>
<tr>
<td></td>
<td>• Must reflect local and/or national clinical guidelines or policies where available.</td>
</tr>
</tbody>
</table>
### EXCLUSION CRITERIA
(I.E. SITUATIONS NOT COVERED BY THE PGD)

Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally e.g. Trust guidelines/NICE.

Wherever possible, always explain reasons of exclusion and action to be taken so practitioners can explain reasons to patients if they are excluded and have to be referred.

<table>
<thead>
<tr>
<th>Use bullet points to list exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Who is not eligible to receive the medicine e.g. upper and lower age limit.</td>
</tr>
<tr>
<td>- Must reflect local and/or national clinical guidelines or policies where available.</td>
</tr>
</tbody>
</table>

Reasons for exclusion may include:

- Age
- Concurrent conditions
- Concurrent treatment - such as patients taking medicines which may give rise to toxicity or need for increased dose e.g. salbutamol PGD – exclusion - patients taking beta blockers (beta blockers can induce asthma and will also prevent action of salbutamol)
- Previous adverse events or adverse reactions to the medicine
- Hypersensitivity to the medicine/related medicines or any of its ingredients
- Pregnancy and breast feeding - explain reason for exclusion if not related to SPC recommendations
- Anything else stated in the SPC that may give reason for exclusion of specific patients e.g patients with porphyria
- Degrees of renal/hepatic insufficiency – be specific if possible

State cut off points for exclusion / limitations for service i.e. to age or patient groups e.g. “children under 2 years old” not just “children”

If possible, reasons for exclusion to be provided e.g. patients taking x (increases toxicity of y)

### ACTION IF EXCLUDED

Enter details of action to be taken if excluded i.e. referral to a prescriber/records to be kept

### CAUTIONS/NEED FOR FURTHER ADVICE/ACTION TO BE TAKEN

Always explain reasons and action to be taken

Note – if the decision for action is “consult with a doctor/dentist or other prescriber”, you should exclude this group of patients.

- This section is not intended to be a duplication of Section 4.1 of the SPC.
- Use bullet points to list cautions and the action to be taken
- You should only add cautions where specific action which does not involve consultation with a doctor/dentist (see note opposite)
- This may include interactions where clinically significant and relevant to this PGD but are not contraindications. (but see note opposite)
- Make sure that there are no “grey areas” – instructions must be specific i.e enter specific details of the caution and action to be taken

**Examples**

- Patients taking warfarin may be at increased risk of
<table>
<thead>
<tr>
<th>ACTION IF PATIENT DECLINES</th>
<th>Enter details of action to be taken i.e. discussion of potential consequences/ referral to a prescriber/records to be kept</th>
</tr>
</thead>
</table>

bleeding. Provide relevant advice to patient

- Interaction with cholestyramine. Provide relevant advice to patient.

Split the monograph here onto more than one page if necessary but make sure pages are numbered. Do not continue Drug details sub sections across pages. Have the drug title box at the top of each page.
### DRUG DETAILS

| **NAME, FORM & STRENGTH OF MEDICINE** | Use clear format to express strength and form in BNF style e.g.  
| o Amoxicillin Capsules 250 mg  
| o Amoxicillin Suspension 125mg/5 mL  
| o Amoxicillin Injection 500 mg |
| **USE OUTSIDE THE TERMS OF THE SUMMARY OF PRODUCT CHARACTERISTICS (SPC)** | add reference / note to support use in unlicensed / off-label circumstances e.g. Best practice advice given by British Association for Sexual Health and HIV (BASHH) is used for this guidance in this PGD and may vary from the Manufacturer’s Summary of Product Characteristics. |
| **ROUTE/METHOD** | To avoid errors, state in full and do not use Latin or abbreviations e.g. oral not p.o. / eyedrops not guttae |
| **DOSAGE/FREQUENCY** | State dose in full. Do not use Latin or abbreviations e.g. stat or tds  
| Liaise with clinical pharmacist on practical issues relating to dosage and quantity to supply.  
| Decide on format to express dosage especially in children – for example, if on a mg/kg basis – will doses be rounded up or down to the nearest spoonful? Liaise with clinical pharmacist to agree.  
| If using dose ranges – use a table format so that information is clear and easy to follow.  
| Note: see Trust PGD protocol about availability of appropriately labelled packs.  
| For POMs to be taken away, express dosage format to exactly match that of the pharmacy label e.g. one tablet to be taken three times a day. State practical information such as “after food” or “dissolved in water” which must also appear on the label.  
| For GSL and P medicines to be taken away, you do not need to state specific dosage in the PGD but at minimum should state:  
| See pack for details of appropriate dosage |
| **MAXIMUM OR MINIMUM TREATMENT PERIOD** | This may be specific e.g. 5 days for an antibiotic or e.g. no more than x number of days for an analgesic. If supply to be taken away, liaise with clinical pharmacist to ensure that appropriately labelled packs are available for the relevant duration of treatment. |
### SIDE EFFECTS

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Patients should be actively encouraged to report any suspected adverse reaction, particularly to black triangle medicines adverse reactions or to medicines used in the treatment of children.

- Use bullet points to clearly list the most common side effects and any potential serious symptoms the practitioner or the patient needs to look out for. You do not need to list every side effect listed in the SPC.
- Refer to SPC/BNF and any CSM advice
- It may be helpful to add the information in order of frequency e.g. Common (more than 1 in 100 people)

This list may not represent all reported side effects of this medicine. Refer to the most current SPC for more information.

Practitioners must refer to and be familiar with reporting processes for adverse reactions as laid out in the Medicines Policy Code of Practice for Administration.

For yellow card reporting, see MHRA website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
| **ADVICE TO PATIENT/CARER** | • Provide Manufacturer’s Patient Information Leaflet  
  • Provide approved Trust Information Leaflet (name, add link if on intranet)  
  • Advice to be given if medicine is being used off-labell (if appropriate - see PGD Protocol)  
  • If more than one medicine is to be supplied/administered to the patient during the session, explain how they will be used e.g. x will be administered 30 minutes before Y or e.g. x will be supplied only if the patient is excluded from having Y or patient will be supplied all medicines unless they are excluded from having them.  
  • Counselling points e.g. do not drive for two hours after having these eyedrops  
  • Practical advice on self-care if appropriate  
  • Advice on recognising side effects and what to do. (see Side effects)  
  • Advice on where to seek help if treatment fails or condition worsens  
  • Add any other information that would be helpful to the patient at this point of their care e.g signposting to local self help groups/ issue of an information prescription.  
  • Add referral details for any other support the patient may require  
  • Add advice to patient to access further help or information if required at a later stage, depending on circumstances. These may include contacting NHS 111, seeing a community pharmacist or contacting the Pharmacy Medicines Helpline or Evelina Let's Talk Medicines Helpline.  
  • Add any other additional advice for medicines which are supplied for self administration by the patient or by their carer (NB – legislation requires this to be non-injectables only):  
    • Any further instructions for administration and to aid compliance (state)  
    • Storage or expiry information e.g. store in a fridge |

| **FOLLOW UP** | Enter requirements e.g. clinical observations after administration/ letter to GP/ further appointments |
### RECORDS

The following must all be recorded:

- Patient inclusion or exclusion from PGD
- Date and time of supply and/or administration
- Patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD
- Details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration
- Batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant local or national guidance – make clear if this applies or delete if not applicable
- A statement that supply or administration is by using a PGD
- Name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine
- Relevant information that was provided to the patient or their carer
- Whether patient consent to treatment was obtained, in line with the Trust Policy of Consent to Examination or Treatment
- Add any other record that is relevant to practice under the PGD if not specified above (delete this statement if necessary)

### REFERENCES

- **Summary of Product Characteristics (SPC)** – include date of revision of text
- **British National Formulary Number Year**

Where relevant:

- **Local guidelines**
- **National guidelines**
- **Journal/other references (Vancouver reference style)**

- Manufacturer’s Summary of Product Characteristics (SPC)  
  Name. Manufacturer. Accessed via add link on date [date of revision of the text-date]. NB – if using a generic, you do not need to add a reference here for every single generic brand.

  <http://www.medicinescomplete.com> [Accessed on [date]]

- Trust approved Patient Information Leaflet(s) (if any included) – state title and date of approval/approval reference. Add hyperlink
- Guy’s and St Thomas NHS Foundation Trust PGD Protocol
- Patient Group Directions. NICE Medicines Practice Guideline MPG2 (2013)  
  [http://www.nice.org.uk/guidance/MPG2](http://www.nice.org.uk/guidance/MPG2)
APPENDIX 1  AGREEMENT BY REGISTERED PRACTITIONER

I have received, read and fully understand the following:

- The Drug Monograph(s) included in the PGD (list if more than one)
- Operational policy/policies/local guidelines – state full title or delete
- Guy’s and St Thomas’ NHS Foundation Trust Medicines Policy and associated Codes of Practice.
- Guy’s and St Thomas’ NHS Foundation Trust PGD Protocol

I have received the training set out in the PGD which practitioners must undertake before being authorised to supply and/or administer any medicinal product under the PGD.

I have provided evidence to the assessor that I fulfil the specialist competencies required to practice under the PGD.

I agree to act as a practitioner within the terms of the PGD and to supply and/or administer medicinal products in accordance with the PGD.

In return, the Trust accepts vicarious liability for the practitioner acting under the terms of the PGD where the practitioner has been deemed competent to practice under the PGD.

I understand that by agreeing to act as a practitioner under the PGD, I am extending my role and job description. I understand that my acceptance of this extension of my role and job description has not been a compulsory requirement of Guy’s and St Thomas’ NHS Foundation Trust.

I agree to inform the Trust of any changes in my circumstances that would affect my ability to act as a practitioner under the PGD e.g. registration status.

<table>
<thead>
<tr>
<th>PRACTITIONER NAME (BLOCK CAPITALS)</th>
<th>PRACTITIONER SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
</table>

FOR COMPLETION BY DESIGNATED MANAGER:
Authorisation of Registered Practitioner by:

<table>
<thead>
<tr>
<th>DESIGNATED MANAGER NAME (BLOCK CAPITALS)</th>
<th>DESIGNATED MANAGER SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
</table>

(TO CONFIRM THAT TRAINING HAS BEEN ATTAINED TO A SATISFACTORY STANDARD AND THAT A COMPETENCY ASSESSMENT CHECKLIST HAS BEEN COMPLETED.)

Original signed copy with PGD to be kept by practitioner and a copy of this agreement to be kept by designated manager.

<table>
<thead>
<tr>
<th>Added to list of registered practitioners</th>
<th>DATE</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removed from list of registered practitioners (add reason)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>