NICE National Institute for Health and Care Excellence

# Patient group directions
# Good practice guidance consultation
# 1 April – 29 April 2013

## Good practice guidance consultation comments table

| Ref No | Stakeholder | Section No | Page No | Line No | Comments<br><br>Please insert each new comment in a new row | Project team and Guidance Development Group (GDG) response<br><br>Please respond to each comment |
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| 1 | North West London Hospitals NHS Trust | General | | | The use of the digit 1 instead of writing 'one' is confusing .. e.g. page 21 line 4. I read this as 'option 1' first! (This is not the first time it occurs, but I didn't pick up on all incidences). | Thank you for your comment. Wording was considered by the NICE editorial team. Please see NICE style guide. |
| 2 | North West London Hospitals NHS Trust | General | | | Numbering of recommendations needs checking. | Thank you for your comment. Recommendations will be included in section 2 and therefore the numbering is consistent with NICE style. |
| 3 | North West London Hospitals NHS Trust | 1.2 | 4 | 4/14 | Definition or example of 'devolved administrations' would be helpful. Not everyone working with PGDs will understand this term. | Thank you for your comment. The relevant text in the glossary has now been added to reflect this comment. |
| 4 | North West London Hospitals NHS Trust | 1.3 | 4 | 11/29 | Add….'to these options. Organisations should, of course, consider these options before making a decision to use a PGD'. | Thank you for your comment. The scope cannot be amended following sign off by the NICE Medicines and Prescribing Centre, in line with the Integrated Process Statement. |
| 5 | North West London Hospitals NHS Trust | 1.5 | 6 | 2 | Revised sentence, with added wording…..' In addition, at some key steps in a care pathway, some of these frameworks allow medicines to be | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | | | | | supplied and/or administered directly by a health professional, without the need for prescribing.' | |
| 6 | North West London Hospitals NHS Trust | 1.5 | 6 | 16 | …'to a named patient, or to a list of patients.' | Thank you for your comment. Wording was considered by the NICE editorial team and is consistent with MHRA guidance on this topic. |
| 7 | North West London Hospitals NHS Trust | 1.5 | 6 | 22 | Occupational health schemes.. add a brief explanation.. 'Medicines supplied or administered in the course of an occupational health scheme do not need a PGD or individual prescriptions, but the nurses must conform to specific requirements'. | Thank you for your comment. An FAQ on the PGD website clarifies this comment and can be found here. |
| 8 | North West London Hospitals NHS Trust | 1.5 | 6 | 23 | Addition: 'In pandemic influenza, where supply can be in accordance with a protocol which fulfils specific legal requirements.' | Thank you for your comment. There is a hyperlink for further information about this topic. |
| 9 | North West London Hospitals NHS Trust | 1.5 | 6 | 24 | Add brief explanation of what is allowed and under what circumstances. | Thank you for your comment. There is a hyperlink for further information about this topic. |
| 10 | North West London Hospitals NHS Trust | 1.6 | 8 | 6 | Replace 'effect' by 'effectiveness' | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 11 | North West London Hospitals NHS Trust | 1.6 | 8 | 16 | Addition…'PGDs must also be signed by a clinical governance lead, on behalf of the authorising body…' | Thank you for your comment. The GDG was aware that the clinical governance lead *may* undertake this role; however this is not specified in legislation. |
| 12 | North West London Hospitals NHS Trust | 1.6 | 10 | | Addition: 'Special order unlicensed medicines', or 'specials', that are made to meet the needs of an individual patient.' *(Comment: I realise this definition is given later in the document, but most nurses, etc will not understand the significance of the* | Thank you for your comment. There is a hyperlink provided for further information about this topic. |

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| | | | | | *term, and may not follow the link).* | |
| 13 | North West London Hospitals NHS Trust | 3 | 13 | 6 | Add another bullet point: 'Considering alternatives to the use of a PGD' | Thank you for your comment. Considering alternatives to the use of a PGD is already included in the guidance. See section 3.1. |
| 14 | North West London Hospitals NHS Trust | 3 | 14 | Figure 1 | Add another box to the right of 'Proposal rejected: 'Decide on alternative method of provision of medicine' | Thank you for your comment. This error occurred during uploading to the NICE website. The relevant figure has now been amended to reflect this comment. |
| 15 | North West London Hospitals NHS Trust | 3 | 14 | Figure 1 | Addition to box on authorisation:… 'Training and authorisation of health professionals to practice under PGD'. *(Comment: I think this is specifically needed here, despite the box including 'training' running on the left hand side of the figure.)* | Thank you for your comment. Wording was considered by the NICE editorial team.<br>The GDG agreed that training and competency was relevant to all parts of the PGD process and the figure reflects this. |
| 16 | North West London Hospitals NHS Trust | 3.1 | 17 | 2 | Addition: '…in place, to ensure appropriate use of the PGD/s'. | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 17 | North West London Hospitals NHS Trust | 3.1 | 17 | 15 | Addition'…. Should be identified and corrected when organisations…..' | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 18 | North West London Hospitals NHS Trust | 3.1 | 18 | 14 | Addition… 'Great care, including taking advice from a consultant microbiologist….' | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 19 | North West London Hospitals NHS Trust | 3.1 | 18 | 19 | *Comment: My understanding is that the law only allows 'supply or administration' under a PGD, and does not allow subsequent dosage adjustment. This paragraph is not clear. It implies that adjustment is possible under a PGD, but that the GDG is not recommending it.*<br>*I would re-write the paragraph:* | Thank you for your comment. This section has been reworded following further discussion by the GDG. |

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| | | | | | 'The GDG recognised that specifying a dosage range so the health professional could select the correct dose for a patient was appropriate in a PGD.<br>Although the law allows supply or administration under a PGD, it does not allow dosage adjustment without supply at the time of the adjustment.<br>Therefore the GDG noted that dose adjustments should not be made under a PGD when a medicine is already in a patient's possession unless this was specified at the point of supply.<br>In addition, the GDG did not consider frequent individual adjustment of dosage using a PGD to represent good practice and agreed that prescribing or a PSD would be a more appropriate option'. | |
| 20 | North West London Hospitals NHS Trust | 3.1 | 19 | 3 | *Comment: Historically contrast media have frequently been used with no prescription or other legal authorisation. The reality is that PGDs may provide a much safer way than previous systems to ensure that appropriate patient factors are taken into consideration prior to administration of the contrast media. In many situations there is no resource* | Thank you for your comment. The relevant text has been amended to reflect this comment.<br><br>The GDG discussed and agreed that prescribing or a PSD remains the preferred option for the majority of care. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety, and there are clear governance arrangements and accountability. |

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| | | | | | *to allow doctors to assess individual patients and prescribe for them.*<br>*An alternative might be the use of a patient specific direction in the form of a list of patients, signed off by a prescriber. It is unlikely that the prescriber would have the time to check the patients individually. Hence in order to ensure patient safety, it would be necessary for the protocol to include a checklist to be used by the health professional prior to the administration of the contrast media. This would be very similar to the use of a PGD, and would not have any significant advantage over a PGD. (In a PGD any patient that did not fit the inclusion criteria would be referred to a doctor).*<br>***In conclusion,*** *it is unrealistic that all contrast media can be prescribed individually for patients, and hence the use of PGDs is likely to provide safer care than many previous systems. Perhaps Trusts should be advised to do a risk assessment and record the outcome if they decide to continue to use a PGD.* | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination in line with legislation and local governance arrangements. |
| 21 | North West London Hospitals NHS Trust | 3.1 | 20 | 32 | Box 4. Delete 'In a particular setting'. I don't think this adds anything, and I had to read it several times to work out what it was saying. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 22 | North West | 3.1 | 21 | 2 | Comment: Should this be | Thank you for your comment. Recommendations will be |

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| | London Hospitals NHS Trust | | | | 'Recommendation 2.1' or '3.1'? | included in section 2 and therefore the numbering is consistent with NICE style. |
| 23 | North West London Hospitals NHS Trust | 3.1 | 21 | 15 | Revised wording: 'Consider investing in the training of additional prescribers and redesigning services if necessary, as part of a wider development or review of local medicines policy'. | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 24 | North West London Hospitals NHS Trust | 3.1 | 21 | 19 | Revised wording '……registered health professionals who are included in the list of professionals who can legally supply and/or administer medicines using a PGD.' | Thank you for your comment. The relevant text has now been amended to reflect this comment, hyperlink added to legislation. |
| 25 | North West London Hospitals NHS Trust | 3.1 | 22 | 10 | Additional wording: 'Consider including an antimicrobial in a PGD only in exceptional circumstances, and after consultation with local microbiologists. Ensure that its use is clinically essential and will not jeopardise local and national strategies to combat antimicrobial resistance'. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[1] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 26 | North West London Hospitals NHS Trust | 3.2 | 25 | 1 | Comment: I would agree in principle with all that follows about how to ensure that PGDs are not used inappropriately. However, reading the recommendations through, there is | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |

[1] The Health Protection Agency is now part of Public Health England.

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| | | | | | the risk that a very bureaucratic process is set up. Within our organisation, we have a formal process where a proposal form is submitted to the Drugs and therapeutics Committee prior to the writing of a PGD. However, most of the points listed are covered prior to submission of the proposal by informal discussion with appropriate staff. We have not yet needed patient or commissioner involvement.<br><br>Hence I would add to the first 2 and 5th bullet points:<br><br>'where appropriate, seeking views of stakeholders….'<br>'where appropriate, gathering intelligence….' | |
| 27 | North West London Hospitals NHS Trust | 3.2 | 27 | 6 | Addition: 'Ensure a multidisciplinary PGD approval group, or subcommittee of an appropriate existing medicines management group…' | Thank you for your comment. The relevant text has now been amended to reflect this comment. Details of the group are for local consideration and implementation. |
| 28 | North West London Hospitals NHS Trust | 3.3 | 30 | 19 | Addition: 'See Section… for potential routes of authorisation of the PGDs.' *Comment: This Scenario is not helpful without identifying the solution at this point.* | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |
| 29 | North West London Hospitals NHS Trust | 3.3 | 30 | 23 | Addition: 'See Section… for potential routes of authorisation of the PGDs.' *Comment: This Scenario is not helpful without identifying the solution at this point.* | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |

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| 30 | North West London Hospitals NHS Trust | 3.3 | 30 | 25 | Reworded:' A provider organisation, (such as an NHS trust and or an independent provider organisation), may develop and authorise its own PGDs to provide an NHS-commissioned service, *(Comment: Original wording not clear).* | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 31 | North West London Hospitals NHS Trust | 3.3 | 32 | 9 | *Paragraphing. Comment: 2 ideas are included in this paragraph. It needs to be split:*<br>'The GDG concluded that it was good practice for commissioning and provider organisations to collaborate when developing PGDs'.<br>Split here:<br>'The PGD working group should be separate from……' | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 32 | North West London Hospitals NHS Trust | 3.3 | 32 | 11 | Punctuation (Comma added): 'The PGD working group should be separate from, but would need to liaise with, the PGD approval group (see section 3.2).' | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 33 | North West London Hospitals NHS Trust | 3.3 | 32 | 27 | Addition:' ……..should usually be consistent with the summary of product characteristics (SPC).<br>Exceptions are where the medicine is being used off-label (see recommendation 2.1.8). | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 34 | North West London Hospitals NHS Trust | 3.4 | 36 | 19 | *Comment: This paragraph is about development of the PGD, not about who signs it off. It is not necessary here. It could be moved to section 3.3. However, for clarity, if it is retained,* | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | | | | | *then the line in my next comment should be included, requiring that the representative of the professional group should also signing the PGD.* | |
| 35 | North West London Hospitals NHS Trust | 3.4 | 36 | 22 | Addition: '……should also be involved. The GDG considered it good practice that this person should also sign the PGD.' (See section 3.3*).* *Comment: See my comment above about deleting or moving this paragraph*. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 36 | North West London Hospitals NHS Trust | 3.4 | 37 | 19 | Addition:'…..appropriate people and authorising body after review…' | Thank you for your response. 'Appropriate people' would include the person signing on behalf of the authorising body. |
| 37 | North West London Hospitals NHS Trust | 3.4 | 37 | 28 | *Comment: Split this paragraph. There are 2 points here*<br>- *Appropriate people are responsible for the PGD.*<br>- *The PGD may be being used within a separate organisation.*<br>'When the PGD has been signed by the appropriate people and is authorised for use, clear local arrangements are needed that outline the ownership of, and responsibility for, delivering the service.'<br>Split here:<br>'The PGD may need to be 'adopted' by the provider organisation(s) if they have not been involved……..' | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 38 | North West London Hospitals | 3.4 | 38 | 17 | Addition:'…the most up to date version. It is good practice that the | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out |

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| | NHS Trust | | | | posting on the intranet highlights the fact that PGDs may only be used by eligible trained and authorised professionals. The heading to the site might include wording such as: 'Patient Group Directions (PGDs) must only be used by ***Specified REGISTERED*** HEALTH CARE PROFESSIONALS who have been ***SPECIFICALLY*** trained and ***PERSONALLY AUTHORISED*** to work under the PGD'. *Explanation: There are normally no specific restrictions to the use of policies which are posted on trust intranets. There is a risk that if PGDs are freely available on trust intranets, staff who do not understand PGDs may decide to use them, without understanding the restrictions that apply to them.* | key principles. Details of the process are for local consideration and determination. |
| 39 | North West London Hospitals NHS Trust | 3.4 | 38 | 27 | Addition: 'The GDG agreed that provider organisations should designate, and keep a record of, an appropriate person (for example, a clinical supervisor, line manager or GP) to be responsible for authorising these health professionals' within each service or clinical area.' | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 40 | North West London Hospitals NHS Trust | 3.4 | 41 | 6 | Addition:'…… Identify an appropriate person who is responsible for ensuring this occurs, and that the use of PGDs is restricted to suitably | Thank you for your comment. This has been considered in section 3.7 of the guidance. |

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| | | | | | trained and competent health professionals'. | |
| 41 | North West London Hospitals NHS Trust | 3.5 | 43 | 13 | Addition:<br>The law requires that supply under a PGD should not be delegated. However, it is good practice, in accordance with trust medicines polices, that a second person should check the issue of medication, particularly where PGDs are used in busy areas, such as urgent care centres. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |
| 42 | North West London Hospitals NHS Trust | 3.5 | 44 | 9 | *Comment: It is not routine practice that batch numbers are recorded of all parenteral medicines administered on hospital wards. (Batch numbers are recorded for vaccines and blood products on wards).Why are PGDs different?* | Thank you for your comment. The relevant text has been amended to reflect this comment. |
| 43 | North West London Hospitals NHS Trust | 3.5 | 46 | 26 | *Comment: It is not routine practice that batch numbers are recorded of all parenteral medicines administered on hospital wards. (Batch numbers are recorded for vaccines and blood products on wards).Why are PGDs different?* | Thank you for your comment. The relevant text has been amended to reflect this comment. |
| 44 | North West London Hospitals NHS Trust | 3.6 | 50 | 20 | Addition: '….including, where appropriate, patients or their carers'.<br>*Comment: In many cases, it is clear that a PGD is appropriate and the inclusion of this recommendation may frequently result in a 'box-ticking 'exercise, slowing down the process* | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | | | | | *and with no benefit to patient care. It may be difficult to identify patients, and where there are no suitable alternatives to a PGD, (e.g. school immunisations), it may be inappropriate to ask the opinion of patients, who may find it difficult to grasp the legal concept of a PGD.* | |
| 45 | North West London Hospitals NHS Trust | 3.7 | 55 | 23 | Addition: 'Relevant clinical knowledge, or experience of working in the clinical speciality or service where the PGD is to be used<br>*Comment: The pharmacist may not have experience of actually working in the clinical speciality, but may have appropriate clinical knowledge.*<br>***Examples:***<br>*- immunisation and family planning, where pharmacists do not work directly within the services, but do have relevant clinical expertise,*<br>*- medical information pharmacists, who provide clinical checks, and sign a range of PGDs, but don't work within any particular speciality.* | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 46 | North West London Hospitals NHS Trust | 3.7 | 56 | 19 | *Comment: Recommendation 2.7.6 is Not very clear.*<br>*Is this what is meant?*<br>'Ensure staff using PGDs receive appropriate training and competency assessments, and that these assessments are repeated when a PGD is re-authorised, or changes are made | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |

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| | | | | | to the PGD, or when there are any clinical concerns relating to the member of staff.' | |
| 47 | North West London Hospitals NHS Trust | 3.8 | 58 | 21 | *Comment: It has proved very difficult to comply with the requirement to reconcile stocks included in the HSC 2000/026. It is my understanding that very few trusts and services do fill this obligation.*<br>***Question**: Is it a legal requirement? Can the GDG consider whether it is appropriate?*<br>*It is effectively requiring that medication used under a PGD is treated in the same way as a Controlled Drug. This is very difficult in services such as urgent care centres, where PGDs are used alongside nurse and doctor prescribing. Many organisations have taken the view that this is adding unhelpful record keeping that is more likely to detract from good patient care and patient records. The energy involved in checking errors where staff have forgotten to record issues is likely to be out of proportion to the benefit from keeping these type of records.*<br>*It would be very helpful if this could be revised, and that NICE could recommend that such record keeping is only implemented when it would be appropriate to the needs of a service* | Thank you for your comment. The Health Service Circular (HSC 2000/026) states that 'there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis' (see section 3.5). The GDG agreed this reflects good practice.<br><br>All records and documentation relating to PGDs should comply with information governance arrangements outlined in the Department of Health's Code of practice on records management (2006), for example, data protection, confidentiality and duration records should be securely stored. |

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| | | | | | *and the patient, or, indeed, omit it entirely. See below:*<br>***Suggested rewording, omitting the reference to the HSC:***<br>'**Organisational records**<br>The GDG acknowledged the importance of maintaining, storing and archiving appropriate organisational records.<br>There must be a secure system for managing the storage and issue of medicines in accordance with trust or organisational medicines polices.<br>All records and documentation relating to PGDs…….. | |
| 48 | North West London Hospitals NHS Trust | Appendix A | 65 | 11 | *Comment: The section on 'Dispensing' may be misinterpreted as it states that there is no legal distinction between dispense and supply, and yet under a PGD, a POM must be administered by the person who assessed the patient, and there can be no delegation.*<br>**Is this clearer?**<br>Addition:' ……. There is no legal distinction between 'dispense' and 'supply'. However, 'supply ' under a PGD must be by the same health professional that assessed the patient under a PGD' | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 49 | North West London Hospitals NHS Trust | Appendix A | 67 | 15 | Addition:'…….to a named patient, or list of named patients' | Thank you for your comment. Wording was considered by the NICE editorial team. |

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| 50 | Aylesbury & Chiltern CCGs (previously NHS Buckinghamshire) | General | | | The purpose of this document is to advance our understanding of the processes that should be followed in the development and approval of PGDs, particularly relating to the new NHS organisational structure.<br>It is good to have a process laid out and many of the details included are clear, however there needs to be more clarity regarding the responsibility for authorising individual PGDs. For example if PH in the local authority commission a service from GPs or Community pharmacies who is responsible for writing the PGD and who should authorise?<br><br>The document relies heavily on hyperlinks to web pages, but many of the hyperlinks lead to information that has not been updated or pages that have moved, so it is impossible to follow up the information.<br><br>There are many links to primary legislation which is not easy to interpret. Clear interpretation of the legislation is needed. | Thank you for your comment. This has been considered in section 3.4 of the guidance.<br><br>Thank you for your comment. The hyperlink has now been amended to reflect this comment.<br><br>Thank you for your comment. Section 1.6 covers the relevant legislation. Wording was considered by the NICE editorial team. |
| 51 | York Teaching Hospitals NHS Foundation Trust | 1.6 | 11 | 21 | It would be useful to have further comments re: labelling of PGDS e.g. minimum requirements in addition to MHRA website | Thank you for your comment. There is a hyperlink for further information about this topic. |
| 52 | York Teaching | 1.6 | 11 | 28 | I think this statement is slightly | Thank you for your comment. The relevant text has now |

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| | Hospitals NHS Foundation Trust | | | | confusing and I'm not sure how this could be implemented in practise. The HCP who is signed to the PGD must issue the treatment to the patient (in addition to administer) therefore how would a prescription charge be obtained from the patient?<br>Also there is an issue re: contraception and sexual health PGDS that are both exempt from charges. | been reworded to reflect this comment. |
| 53 | York Teaching Hospitals NHS Foundation Trust | 3.1 | 1 | 16 | Box re: alternative influenza vaccination e.g. PSD for a practise nurse. This may result in delay of treatment for patient and nurses just asking the GP to write the treatment without appropriate assessment of the patient. | Thank you for your comment. Details of the process are for local consideration and determination. |
| 54 | York Teaching Hospitals NHS Foundation Trust | 3.1 | 18/19 | 17 | Or not be able to delegate the issue or administration of that PGD treatment to another individual. | Thank you for your comment. Delegation is not permitted in legislation. |
| 55 | York Teaching Hospitals NHS Foundation Trust | 3.1 | 20 | 4 | Self-administered medicines would this not be an exclusion for a PGD? | Thank you for your comment. Box 3 lists those clinical situations when PGDs need to be considered carefully, which may include injectable preparations for self-administration. |
| 56 | York Teaching Hospitals NHS Foundation Trust | 3.4 | 38 | 30 | Appropriate documentation may be better worded as sign the individual PGD. | Thank you for your comment. Individual PGDs are not signed in some circumstances. |
| 57 | York Teaching Hospitals NHS Foundation Trust | 3.5 | 44 | 5 | How the patient meets the criteria for the PGD may be worded as reason for treatment –I just wondered if staff would list a full criteria list? | Thank you for your comment. Criteria listed in section 3.5 is for monitoring and evaluation purposes, not for inclusion or exclusion criteria of supply or administration. |
| 58 | York Teaching Hospitals NHS | 3.7 | 55 | | All boxes for knowledge and experience should also state | Thank you for your comment. This has been included in Box 7 which highlights the knowledge, skills and/or |

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| | Foundation Trust | | | | knowledge and understanding of the legal framework for PGD use. | expertise for all people involved with PGDs. |
| 59 | York Teaching Hospitals NHS Foundation Trust | 4.3 | 65 | 11 | It should reinforce that only the health care professional signed onto the PGD can dispense or issue that PGD treatment and this cannot be delegated. | Thank you for your comment. The relevant text has now been removed to reflect this comment. |
| 60 | York Teaching Hospitals NHS Foundation Trust | 4.3 | 68 | 6 | Treatment is not prescribed via a PGD but is issued within the legal framework of PGDS | Thank you for your comment. This is consistent with the content of the guidance. |
| 61 | York Teaching Hospitals NHS Foundation Trust | | | | Although not covered within the NICE documentation I think it should be mentioned how staff sign back onto a renewed PGD that they are already signed onto-which PGD takes precedence and is there a time frame for staff to sign up to this?. | Thank you for your comment. Organisational governance arrangements for PGDs are for local consideration and determination. Arrangements will vary depending on how services are commissioned and provided and what resources are available.<br>See recommendation 2.6.7 for information. |
| 62 | Red Box Healthcare Ltd | General | | | 1. Legislation does not state that PGDs are required to include how and how often practitioners are required to train, nor is there a requirement in legislation that PGDs state which body will administer and implement a PGD, nor how the use of PGDs will be audited. PGDs can be written and signed without these and other relevant contextual elements being included. The NICE draft guidance addresses these elements. We suggest NICE guidance recommends that the authors and signatories of PGDs specify these elements at the time PGDs are written, if necessary in the | Thank you for your comment. Legislation has been considered in section 1.6 'Legal framework governing the use of PGDs' of the guidance. |

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| | | | | | form of addendums. We feel consideration should be given to these elements at the time PGDs are written and signed, as they are integral to the application of PGDs and they have a bearing on other elements which are included in PGDs as legislative requirements. | |
| 63 | Red Box Healthcare Ltd | General | | | 2. We feel guidance should make reference to the features required of administrative systems employed to implement PGDs.<br><br>There are software systems in use which enable PGDs to be used by community pharmacists. The use of such systems would help to ensure many of the recommendations of the draft guidance are met, particularly in the areas:<br><br>2.5 Using Patient Group Directions<br>2.6 Reviewing and updating Patient Group Directions<br>2.7 Training and competency<br>2.8 Organisational governance<br><br>The features of such systems include the following:<br><br>● 'PGD leads' register organisations responsible for administering the use of PGDs. Practitioners register as | Thank you for your comment. The GDG agreed that in many cases a recommendation could not explicitly state which individual person or organisation was responsible for implementing the recommendation. Arrangements will vary depending on how services are commissioned and provided and what resources are available. When the GDG agreed that a responsible individual person or organisation could be identified, this is clear within the recommendation. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |

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| | | | | | individuals and link themselves to their organisation. Both 'PGD leads' and practitioners have their own secure log in.<br>• The authors of a PGD and/or the body responsible administering the use of a PGD put together online training packages for each PGD, including support documents such as background medical and therapeutics information, patient information leaflets, 'quick guides' for practitioners, and patient assessment forms. All these documents are online pages which form part of a training package. The pages can be downloaded and printed as required.<br>• Prior to being authorised to use each PGD, practitioners are required to pass an online questionnaire. This questionnaire tests a practitioner's knowledge base and some aspects of competency.<br>• The authority to use each PGD is assigned to each practitioner for a limited to time, after which practitioners are required to re-train and re-pass an online questionnaire. Email reminders are sent to practitioners when their authority to use each PGD is expiring.<br>• 'PGD leads' and those with | |

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| | | | | | 'administrator access' are able to log-in to see the details of each practitioner linked to their organisation, including which PGD practitioners are authorised to use and when practitioner re-training is required.<br>• Practitioners apply PGDs by completing patient assessment forms. The inclusion and exclusion criteria specified by a PGD are assessed during the process of completing the assessment form.<br>• Completed assessment forms are a record of PGD use, including medicine supplied and name of the supplying practitioners. The form is evidence of compliance with the specifications of the PGD.<br>• Completed forms can be audited for quality and outcomes.<br>• PGD training material and supporting support documents can be updated as required; ensuring the version online is always the latest version. | |
| 64 | Ambulance Pharmacists Network | 1.5 | 6 | 18 | Not an exemption, but legislation does not apply to the administration of non-parenteral medicines. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 65 | Ambulance Pharmacists Network | 1.6 | 9 | 13 | Change "ambulance paramedic" to paramedic, as these clinicians work in a range of environments | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| 66 | Ambulance Pharmacists Network | 3.4 | 36 | 6 | We think more explicit guidance on the adoption of PGDs by commissioned services needs to be more explicit. Responsibilities for training, competence and so on. | Thank you for your comment. Training and competency has been considered in section 3.7 of the guidance. |
| 67 | Ambulance Pharmacists Network | 3.4 | 38 | 22 | As for 3.4/36/6 and needs to be linked explicitly with governance arrangements. | Thank you for your comment. Unfortunately, the point of this comment is not clear. Governance arrangements for PGDs are covered in section 3.8 of the good practice guidance. |
| 68 | Ambulance Pharmacists Network | 43 | 3.5 | 22 | We thought it may be useful to suggest invoicing of the fee as an option (passive) | Thank you for your comment. Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a **supply** of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are **administered** under a PGD. The method of collection is for local consideration and determination. |
| 69 | Whitstable Medical Practice | General | | | With the large number of new local commissioning organisations, there is a real danger of duplication of effort in the production and authorisation of PGDs, with consequent significant cost. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 70 | Whitstable Medical Practice | 3.1 | 22 | | Recommendation 2.1.11 -Agree with reserving antimicrobials to clinically essential situations.<br>However, whereas a prescriber could offer a 'delayed' prescription, as a safety net, (consistent with NICE guidance), PGDs currently do not allow such flexibility, and an initial recommendation to 'watch and wait' requires a further consultation and assessment, with attendant costs to | Thank you for your comment to support the recommendation. |

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| | | | | | services and patients. | |
| 71 | Whitstable Medical Practice | 3.2 | 27 | | Recommendation 2.2.3 PGD approval groups – it is unclear as to whether a 'confederation of CCGs' could pool resources to establish such a group with delegated responsibility to act on behalf of member CCGs. This would seem advantageous in reducing costs and clarification on this point would be welcomed. | Thank you for your comment. Organisational governance arrangements for PGDs are for local consideration and determination. Arrangements will vary depending on how services are commissioned and provided and what resources are available. |
| 72 | Whitstable Medical Practice | 3.6 | 48 | 20 | An extension of the current 2y then review would significantly reduce the costs of production and authorisation of PGDs, and could be done without adverse impact on patient safety for instance by alignment with Product Licence renewal. | Thank you for your comment. No response required. |
| 73 | Whitstable Medical Practice | 3.6 | 49 | 14 | Significant changes to Product Licences require action to amend PGDs, as do changes to existing NICE guidance, or other nationally recognised guidance (such as Primary Care Guidance on antibacterials). It would be most helpful to task a suitable organisation on behalf of the NHS to prompt that existing PGDs should be considered for review in light of 'x change to SPC, new NICE guidance , new recommended best practice etc.<br>By way of example – Paracetamol children's doses changes were notified by MHRA ahead of changes to manufacturer's product labels, which | Thank you for your comment. This is outside the scope of this good practice guidance. The good practice guidance states that the process should allow for an unscheduled review of a PGD earlier than the designated review date. |

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| | | | | | allowed good time to amend existing PGDs and have them authorised and ready to use to coincide with availability of new stock.<br>A significant change to the advice on interaction between oral contraceptives and antibiotics (from the Faculty of Reproductive and Sexual Health) was less widely notified, despite having significant impact on existing clinical practice and advice for patients. | |
| 74 | Whitstable Medical Practice | 3.7 | 53 | 19 | Training and assessment of competency -Refers to the 'absence of a comprehensive suite of nationally produced educational materials' – it would be helpful to ensure consistency across all service providers, that a nationally recognised training organisation such as CPPE, or Skills for Health, be commissioned to produce a minimum skill set, which can then be supplemented by locally delivered-service specific training.. | Thank you for your comment. No response required. |
| 75 | South East Health Ltd | 2.1.11 | 22 | 10 | Use of antimicrobials will never be 'exceptional' as PGDs have to be the supply vehicle of choice in the majority of Walk-in Centres, Minor Injury Units, Genito-urinary and Out-of-hours services where services are nurse/paramedic led and not NMPs. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[2] guidance<br>• a local specialist in microbiology has agreed that |

[2] The Health Protection Agency is now part of Public Health England.

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| | | | | | NMP numbers are still very low and recent NHS changes will not support further training in the short term. | a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 76 | South East Health Ltd | 2.1.12 | 22 | 15 | Warfarin is a common PGD medicine where provision is in nurse/pharmacist led community settings. Dosing is according to protocol/software and PGD provides a legal supply route. | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants. |
| 77 | South East Health Ltd | 2.1.12 | 22 | 17 | High risk – either specify or delete as the term is subjective unless related to the referenced document. Opiates are listed in this document but no specification as to injectable, schedule 2, does it mean all opiates? | Thank you for your comment. This section has been reworded following further discussion by the GDG. |
| 78 | South East Health Ltd | 2.3.2 | 34 | 8 | Involvement of a microbiology specialist will be unlikely for most provider organisations, as the specialist will be 'drowned' by requests from plurality of providers. Alternatively suggest reference to HPA and local guidance with specialist input if the PGD wishes to deviate from accepted guidance. | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 79 | Northern Eastern and Western Devon CCG | 3 | 14 | All | Flow chart very useful | Thank you for your positive comment supporting the guidance. |
| 80 | Northern Eastern and Western Devon CCG | General | | | ? requires a section to include frequently asked questions | Thank you for your comment. This is outside the scope of this good practice guidance. Please see the national PGD website for further information |

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| | | | | | | (www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/). |
| 81 | Leeds Community Healthcare NHS Trust | 3.1 | 15 | | Lack of funding and staff commitment may have contributed to the unnecessary or inappropriate development of PGDs - This is not always practical in some services where only one product would ever be used under a PGD. It would not be appropriate or cost effective for someone to do the prescribing course in these circumstances. | Thank you for your comment. The GDG discussed settings using a narrow range of drugs and agreed that this does not exclude prescribing as an option for supplying and/or administering medicines (particularly when medicines are considered to be 'higher risk'). The GDG felt that prescribing would be a more appropriate option. See section 3.1. If drugs in a PGD are used infrequently, a PGD is not the most appropriate method of medicines supply. See sections 2.6 and 3.6. Details of the process are for local consideration and determination. |
| 82 | Leeds Community Healthcare NHS Trust | 3.1 | 16 | 1 | We are pleased you have acknowledged that a PSD is s suitable way for District Nurses to deliver flu vaccinations. The Medicines Management Team at LCH was met with a degree of antagonism from the PCT and HPA when we adopted this approach rather than a PGD last year. | Thank you for your positive comment supporting the guidance. |
| 83 | Leeds Community Healthcare NHS Trust | 3.1 | 19 | 8 | We are pleased that you have acknowledged that more than one medicine could be included in a PGD for managing a single condition, if appropriate. | Thank you for your comment. No response required. |
| 84 | Leeds Community Healthcare NHS Trust | 3.1 | 21 | | Recommendation 2.1.6 – PGDs must only be used in organisations and services that are legally eligible to use them within the NHS. Could you please provide further clarity in NHS organisations offering a private service are eligible to use PGDs within that service? E.g. A Travel Health | Thank you for your comment. This is outside the scope of the guidance. |

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| | | | | | Vaccination Service. | |
| 85 | Leeds Community Healthcare NHS Trust | 3.2 | 25 | 23 | Appeals process published on website – should this be an intranet or public facing internet site? Placing on the latter would seem to have little value to the public. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 86 | Leeds Community Healthcare NHS Trust | 3.2 | 25 | 25 | Composition of PGD approval group – This structure seems too prescriptive especially within a community services organisation. There should be more flexibility of who to approve. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 87 | Leeds Community Healthcare NHS Trust | 3.2 | 26 | 9 | It would be useful to add that whilst one PGD should in most cases work across all teams there may be circumstances where more than one PGD would be appropriate because the contents of the document would differ sufficiently that to include them in one single document might be a cause of confusion. E.g. EHC supplied by different services. | Thank you for your comment. The GDG agreed that a single PGD in a patient group covering different services in 1 organisation would in most circumstances be more appropriate. The GDG concluded that operating a PGD approval group may help to reduce unnecessary duplication of PGDs. The process would be for local consideration and determination. |
| 88 | Leeds Community Healthcare NHS Trust | 3.2 | 27 | | Recommendation 2.2.3 – question the value of the last two points – engaging with the public (would any of the public be interested to comment to make this a prudent use of resources) and liaising with commissioners (once they have commissioned a service we should decide how to provide as long as we satisfy that it is legal and ethical). | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. The GDG agreed that either the commissioner or provider organisation may have responsibility for developing the PGD. This will be for commissioners and providers to consider and determine locally (see section 3.8). |
| 89a | Canterbury and Coastal CCG | 1.6 | 8 | 13 | The clarification on organisations who can sign off PGDs is welcome as the | Thank you for your comments. Authorisation of PGDs is specified in legislation (see |

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| | | | | | role of the primary care organisation in the ratification of PGD document has caused problems over recent years and this widens the number of organisations able to undertake this function.<br><br>There are a number of advantages to specifying that the provider for services should be able to undertake authorization of their own PGDs if required:<br><br>1) Equity of support for providers-The cost of producing, administering and ensuring the required governance is in place is significant. PGDs are not the only option for providers but do enable staff without a prescribing qualification to provide a service. It is therefore the providers choice if they wish to fund the provision of PGDs or train staff to the required qualification<br><br>2) Maintains the separation of functions between commissioners and provider-The organisation signing the PGD takes on additional responsibilities on behalf of the Healthcare Professional working under the PGD. If the CCG signs the documents they are taking on responsibilities which would normally | section 1.6).<br>Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies.<br><br>The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination in line with legislation and local governance arrangements. |

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| | | | | | lie with the provider.<br><br>3) Sustainable-Authorization of PGDs requires certain signatures. If the CCG is providing PGDs but has a vacancy in the specified post, they may be unable to fulfill this function. This may cause a difficult contractual situation where the provider requires the document to deliver the contracted service but the CCG cannot legally provide the PGD | |
| 89b | Canterbury and Coastal CCG | 1.6 | 8 | 13 | The majority of PGD documents are required in minor injury services and our CCG may consider specifying that providers must be organised in a way to comply with DH regulations and be able to sign off their own PGDs or use staff who are qualified prescribers (for the reasons above) to remove the requirement for the CCG to produce PGDs. | Thank you for your comment.<br>Authorisation of PGDs is specified in legislation (see section 1.6). |
| 89c | Canterbury and Coastal CCG | 1.6 | 8 | 13 | It is unlikely GP practices would be capable of writing and ratifying their own PGDs but for the reasons above it would be preferable for alternative organisations than the commissioning organisations to provide PGDs for GP practices and other independent contractors. | Thank you for your comment.<br>Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 89d | Canterbury and Coastal CCG | 1.6 | 8 | 13 | Would it be possible for the regulations to allow for a commissioning organisation to approve a provider working under an | Thank you for your comment this is for local consideration and determination.<br><br>Following publication of the draft guidance, the GDG have |

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| | | | | | agreed formal framework to produce PGDs (including the ratification signatures) on behalf of the commissioning organisations for independent contractors to use for NHS services? The framework agreement could be subject to regular review and dependent on annual reports but the onus on writing the document, ratifying distribution and audit would be the responsibility of a separate provider not the commissioning organisation. Independent contractors could purchase access to the PGDs if required or alternatively use staff trained as prescribers. There are a number of companies who product PGDs on a private basis for non NHS services and this seems an option that could be considered for the NHS if the legislation allowed. | been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 90 | St George's Healthcare NHS Trust – Community Services | 1.6 | 9 | 28 | Must be named, competency assessed and authorised to practice | Thank you for your comment. The wording provided in the guidance is that taken from legislation. |
| 91 | St George's Healthcare NHS Trust – Community Services | 3.1 | 15 | 19 | The preferred way for patients to receive medicines is for an appropriately qualified healthcare professional to prescribe for an individual patient on a one-to-one basis. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| 92 | St George's Healthcare NHS Trust – Community Services | 3.1 | 18 | 27 | General: I think the statement needs clarification i.e. PGD's cannot be used where dose adjustments are required | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 93 | St George's Healthcare NHS Trust – Community Services | 2.1.11 | 22 | | General: Need to consider Walk-In Centres/UCC with autonomous practitioners and not all Independent Prescribers, appropriate to use if inclusion/exclusion criteria specific enough. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[3] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 94 | St George's Healthcare NHS Trust – Community Services | 3.2 | 26 | 11 | General: Excellent idea that a single PGD covering different services in a single organisation would be in most circumstances appropriate. Build on a resource PGD library, accessed by 'Read Only' on the intranet for consideration to avoid duplication. | Thank you for your comment. No response required. |
| 95 | St George's Healthcare NHS Trust – Community Services | 3.3 | 33 | 6 | Should have an expiry date of 2 years unless there is clear clinical evidence emerging requiring an earlier change in practice. | Thank you for your comment. The GDG agreed that it may be appropriate to update the PGD less frequently than every 2 years. In other circumstances, a planned review period of less than 2 years may be necessary but a maximum expiry should be 3 years from the date the PGD |

[3] The Health Protection Agency is now part of Public Health England.

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| | | | | | | was authorised.<br>The GDG agreed that the process should also allow for an unscheduled review of a PGD earlier than the designated review date. The relevant text has now been reworded to reflect this comment. |
| 96 | St George's Healthcare NHS Trust – Community Services | 3.5 | 44 | 7 | The batch number and expiry date should be recorded for all medications issued along with vaccines, blood-derived …… | Thank you for your comment. The relevant text has been amended to reflect this comment. |
| 97 | St George's Healthcare NHS Trust – Community Services | 3.6 | 50 | 2.6.3 | General: Clinical evidence to support the PGD should be listed in the specific PGD references. | Thank you for your comment. This has been considered in section 3.3 of the guidance. |
| 98 | St George's Healthcare NHS Trust – Community Services | 3.8 | 58 | 9 | And identifies common themes of areas for further development. | Thank you for your comment. This has been considered in section 3.7 of the guidance. |
| 99 | Diabetes Education and Management Group (part of The British Dietetic Association) | General | | | The BDA would like to thank you for the opportunity to respond to this consultation. | Thank you for your positive comment supporting the guidance. |
| 100 | Diabetes Education and Management Group (part of The British Dietetic | 3 | 19 | 8 | This appears to be contradictory. The recommendation says that PGDs should ideally be for single medications; however it then goes on to say that there could be groups of medications. The recommendation | Thank you for your comment. The GDG found evidence that more than 1 medicine **could** be included in a PGD. However, the GDG agreed that good practice was likely to be represented by including a single medicine. It recognised that including more than 1 medicine may be appropriate in some circumstances, provided all legal |

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| | Association) | | | | appears to be neither broad nor specific and would therefore be difficult to interpret in practical terms. Our view is that it would be unrealistic and unmanageable to recommend single medications. We would like to suggest that the guideline could specify groups/classes of medications e.g. oral hypoglycaemics (any). | requirements were included for each drug. The GDG concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis. |
| 101 | Diabetes Education and Management Group (part of The British Dietetic Association) | 3 | 20 | 8 | Can there be further clarity on terminology used e.g. what they consider to be complex long term conditions.<br>As an additional option to the list we would like to suggest – situations where the medication is closely related to diet e.g. Phosphate Binders and Pancreatic Enzyme Replacement Therapy (PERT e.g. Creon) | Thank you for your comment. The relevant text has now been reworded to reflect this comment.<br>The good practice guidance does not aim to provide an exhaustive list of situations which may arise when considering medicines to be included in a PGD. |
| 102 | Diabetes Education and Management Group (part of The British Dietetic Association) | 3 | 22 | 2.1.12 | Recommendation 2.1.12. We wanted to query why insulin is considered high risk. Would any medication in an inappropriate dose be high risk? Almost all Summary of Product Characteristics have death as a potential outcome of inappropriate dosing, therefore would insulin be more high risk than giving a potassium supplement. | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |
| 103 | Diabetes Education and Management Group (part of | 3 | 22 | 2.1.13 | This recommendation suggests that a PGD should not be used to make dose adjustments when a medicine is in a patient's possession and recommends | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |

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| | The British Dietetic Association) | | | | alternative options be used in Box 4 P20 line 8. However there are no other options available or suggested for key regulated healthcare professionals to access as an alternative. | |
| 104 | Diabetes Education and Management Group (part of The British Dietetic Association) | 3.2 | 24 | 12 | "clinical lead" is referred to in the text. We would like to see further clarity on who are considered to be clinical leaders. | Thank you for your comment. This is for local consideration and determination. |
| 105 | Diabetes Education and Management Group (part of The British Dietetic Association) | General | | | There is widespread custom and practice that healthcare professionals (who are legally able to function under PGD's) are using protocols safely and effectively, to facilitate dose adjustment for example for patients enrolled on the DAFNE programme – even though there is no legal framework for this. These protocols have been developed using the PGD template with as much, if not more, evidence as required for a PGD. It also requires MDT consultation/working group and established governance arrangements, consistent with requirements for PGD approval. We would strongly recommend that this process for PGD's could be extended to include dose adjustment. This would provide a legal framework for current practice further strengthening | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |

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| | | | | | safe and effective regulated practice. | |
| 106 | Diabetes Education and Management Group (part of The British Dietetic Association) | General | | | The latest diabetes update from Diabetes UK suggests there is now a level 3 qualification on the Qualification Credit Framework, which allows for competence based insulin administration by care workers. We have concerns about how this fits with this guideline. | Thank you for your comment. Administration of medicines should be in accordance with legislation. Legislation does not enable care workers to use PGDs. |
| 107 | Diabetes Education and Management Group (part of The British Dietetic Association) | General | | | Key to progression of professions and practice in terms of safe effective medicines management, by key healthcare professionals, for the benefit of patients, is the generation of robust evidence. How can this evidence base be generated if this document does not provide national guidance as to best practice in the absence of a legal framework. | Thank you for your comment. Section 1.6 of the good practice guide details the legal framework governing the use of PGDs. Recommendations have been based on legislation and the best available evidence. |
| 108 | East and South East Specialist Pharmacy Services | 1.5 | 6 | 8-16 | As currently written it is not clear that a patient specific direction written by a prescriber is also prescribing but not on a prescription. The person writing the patient specific direction still has responsibility for clinical assessment etc.<br>Section could be slightly expanded. | Thank you for your comment. Patient Specific Directions are outside the scope of this good practice guidance. There is a hyperlink for further information from the MHRA about this topic. |
| 109 | East and South East Specialist Pharmacy Services | 3.1 | 18 | 5 | Off label use. In exceptional circumstances.<br>This could mean either exceptional in the big scheme of medicines and PGDs or exceptional in relation to a specific PGD. | Thank you for your comment. The relevant text has now been amended to reflect this comment to provide clarity. |

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| | | | | | For some PGDs every use would be off label and therefore not exceptional<br><br>This should be clarified further | |
| 110 | East and South East Specialist Pharmacy Services | 3.1 | 19 | 19 | I agree that referencing the fact that P medicines are available via pharmacies is valid, especially as this is usually cheaper than the prescription charge. However an additional statement is needed stating that a PGD may be appropriate for a P medicine where a) the patient is exempt from prescription charges and b) in settings where access to a retail pharmacy may be limited i.e. in-patient settings, care homes and custodial settings. | Thank you for your comment. Further information can be found on the hyperlink provided on 'To PGD or not to PGD' in the good practice guidance. |
| 111 | East and South East Specialist Pharmacy Services | 3.1 | 20 | Box 2 | An additional bullet point for use of PGDs for minor ailment/triage clinics where this maximises the use of skill mix in a care setting where the use of non-medical prescribers is unavoidably low. I understand the sentiment that prescribers should be encouraged and used where possible but for many provider organisations this is a longer term strategy and PGDs provide a safe and effective solution for maximising skill mix and patient access to minor ailments. | Thank you for your comment. Minor ailments would be covered within bullets 2 and 3 of box 2. The setting alone should not determine the need for a PGD. |
| 112 | East and South East Specialist Pharmacy Services | 3.2 | 25 | 20 | The use of appeals process appears to add another layer of bureaucracy to an already cumbersome process. If the submission process is robust would it | Thank you for your comment. The GDG agreed that an appeals process for decisions made by a medicines decision-making group reflects good practice. |

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| | | | | | be needed? In practice this may be onerous. | |
| 113 | East and South East Specialist Pharmacy Services | 3.2 | 25 | 2 | Seeking stakeholder engagement from patients seems rather impractical and probably unlikely to happen in practice | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 114 | East and South East Specialist Pharmacy Services | 3.2 | 28 | 6 | There is an assumption all areas have all encompassing formularies. Although recommended in practice do formularies exist everywhere and do they contain this level of detail contained? | Thank you for your comment. The NHS standard contract requires all providers of NHS services to comply with NICE technology appraisals and to publish their local formularies. NICE issued good practice guidance on Developing and updating local formularies in December 2012. |
| 115 | East and South East Specialist Pharmacy Services | 3.3 | 20 | Box 5 | There needs to be complete clarity as to the developing and authorising body for Public Health programmes where responsibility for delivery of these programmes rests with Public Health England and/or NHS England. For example immunisation programme delivery (where high volumes of PGDs are used in GP practices and other settings) is now the responsibility of NHS England. To support clarification it would be helpful to add an additional scenario to cover immunisation programmes such as child immunisations which are commissioned through NHS England in partnership with Public Health England. There should be clarity around the organisation responsibilities for the production and governance of PGDs for childhood | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies.<br><br>NHS England has published some emerging scenarios for nationally commissioned immunisation and vaccination programmes following consultation of the draft guidance. The guidance has been updated to reflect this comment. |

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| | | | | | immunisation programmes and other services commissioned by NHS England (e.g. prescribed services in specialised commissioning)<br>A further scenario should be added to cover Public Health England services such as sexual health programmes (e.g. EHC, Chlamydia), flu programmes (e.g. flu vaccines) and smoking cessation (e.g. NRT). | |
| 116 | East and South East Specialist Pharmacy Services | 3.3 | 32 | 30 | Following SPC is not applicable for example when following JCVI advice for immunisations. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 117 | East and South East Specialist Pharmacy Services | 3.3 | 34 | Recommendations box | Based on the statement about commissioner and provider collaboration on page 32, I suggest that an additional recommendation about collaboration is included relating to this. Otherwise this aspect may get lost when commissioners and/or external authorising bodies develop the PGDs. The function of accessing expertise for PGD development is the main element that makes this collaboration required, especially for smaller providers. | Thank you for your comment. The GDG discussed and agreed that collaboration between commissioners and providers is a theme that is considered throughout the guidance, and is for local consideration and determination. |
| 118 | East and South East Specialist Pharmacy Services | 3.4 | General comment | Omission within the section | Current advice for custodial settings such as prisons has been that the prison governor or chief police officer has needed to sign PGDs as part of the authorisation. This is shown here: http://www.mhra.gov.uk/Howweregul | Thank you for your comment. This is outside the scope of this good practice guidance. A hyperlink to the MHRA guidance has been added for further information. |

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| | | | | | ate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheprivatesector/index.htm . The consultation document does not include guidance on authorisation for these settings. Please can the guidance be extended to include the advice about these settings so that appropriate authorisation and signatories can be maintained or set up in the new NHS structures? | |
| 119 | East and South East Specialist Pharmacy Services | 3.5 | 44 | Bullet point 5 | I agree that it is important for the documentation/patient record to identify who has issued the medicine using a PGD. However the need for a signature is not necessary where a clinical IT system is used to record the supply. This is because the clinical system will be logged into by the user and thus there is an automatic record of who issued the medicine. The consultation which resulted in the issue of the medicines under PGD along with details of the medicine supplied is what should be recorded in the IT system in these circumstances. A common solution used by providers to ensure consistency for this is the use of a specific PGD-based template.<br><br>For paper-based documentations of | Thank you for your comment. Electronic signatures can be used when signing a PGD, providing guidance issued by the Department of Health is followed. Governance processes would be for local consideration and determination. |

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| | | | | | care (i.e. in the absence of an IT record), then I agree that the name and signature of the person issuing the medicine under PGD should be recorded along with the written details/outcomes of the episode of care relating to this supply. | |
| 120 | East and South East Specialist Pharmacy Services | 3.5 | 46 | 2.5.5 | When medicines are supplied by PGD a PIL is a requirement.<br>In practice following administration is this really achievable? | Thank you for your comment. The GDG agreed this represents good practice. |
| 121 | East and South East Specialist Pharmacy Services | 3.7 | 52 | Paragraph 5 line 4 | The example of training to administer an injection is flawed as the function/competencies of physically administering a medicine are separate from the competencies to assess the patient for the need of the injection. Using a PSD in this case requires competency in the former but not the latter. Using a PGD requires competency in both. The following is a suggested way of including a similar example*: For example, health professionals who had not completed appropriate training on assessing the appropriateness of an injection may be legally able to administer it under a PGD (i.e. they have been trained to administer the injection), but the GDG did not consider a PGD to be an appropriate option without successful completion of additional training on* | Thank you for your comment. This section has been reworded following further discussion by the GDG. |

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| | | | | | *patient assessment. Prescribing or a Patient Specific Direction (PSD) should be used until the appropriate patient assessment training* ***and relevant medicines administration training*** *has been completed*. | |
| 122 | East and South East Specialist Pharmacy Services | 3.8 | 57/58 | Patient Safety Incidents section | I agree that reporting and actions resulting from Patient Safety Incidents needs to be included. However in order to clarify that this section relates to those incidents relating to PGD supply/administration (i.e. within the scope of the guidance) can I suggest the section is reworded to make it clearer that incidents relating to PGD use should be integrated and included in the organisation's processes for handling patient safety incidents for all organisations involved in developing and authorising PGDs. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 123 | East and South East Specialist Pharmacy Services | 3.8 | 59 | Bullet point 1 | As above this bullet point can be focussed on PGDs by changing it to:<br><br>*Patient safety incidents, such as medication errors, near misses and suspected adverse events that occur where a PGD was used as part of the episode of care.*<br><br>This is also relevant for recommendation 2.84 on page 60. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 124 | East and South East Specialist | 3.8 | 59 | Bullet point 2 | In addition the Terms of Reference (ToR) of the PGD approval and PGD | Thank you for your comment. This has been considered in section 3.3 of the guidance. Relevant text has now been |

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| | Pharmacy Services | | | | working group (or ToR of a group which takes on this function such as a Drug and Therapeutics committee) are needed. This is because the PGD approval and working group processes need to align with organisational structures and accountability. The members should also declare any conflicts of interest (which they may have already completed for other functions they deliver in the organisation).<br><br>This is also relevant for recommendation 2.84 on page 60. | amended to reflect this comment. The GDG agreed the PGD working group would not require Terms of Reference, although the roles and responsibilities of each person, how they work together to develop the PGD and how the group operates should be determined locally and clearly defined. |
| 125 | East and South East Specialist Pharmacy Services | 4.3 | 62/63 | Last paragraph on page 62 and first two paragraphs on page 63 | I agree that the guidance doesn't fully cover the arrangements needed for these different settings. See my comment on section 3.4. The Secure Environment Pharmacists Group and East and South East Specialist Pharmacy services will be able to help you in identifying and guiding providers and commissioners in the practical interpretation of this guidance for custodial settings. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 126 | East and South East Specialist Pharmacy Services | Glossary | 65 | Second paragraph: Definition of dispense | I disagree that "dispense" involves giving the medicine to the patient. "Dispense" is to make up (i.e. package and label) the medicine prior to administration or supply. The use of dispense to describe handing over a medicine to a patient is the main | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | | | | | source of confusion in medicines handing functions and responsibilities, especially within the nursing profession. Please consider adjusting this definition as follows:<br><br>*To make up, (i.e. package and/or label) a clinically appropriate medicine, prior to supply for self-administration or administration by another, usually a health professional. In the case of POMs, dispensing must be in response to a legally valid prescription. There is no legal distinction between 'dispense' and 'supply'*. | |
| 127 | East and South East Specialist Pharmacy Services | Overall | All | All | Overall this is a very well written guidance document that once finalised will provide an essential core up to date guide on how to handle the use of PGDs within the legislation. It covers all aspects of PGD handling in a logical systematic way providing an easy to read document. This is particularly commendable given the complexity of the use of PGDs in all the different provider and commissioning bodies. | Thank you for your positive comment supporting the guidance. |
| 128 | Bristol Clinical Commissioning Group | 1.4 | 5 | 13 | It may be useful to clarify that PGDs are not the main route of medication supply for a service, with the use of non-medical prescribers being a preferred and so PGDs should be used as opportunistic aids to help medication supply. | Thank you for your comment. This has been considered in section 1.5 of the guidance. |

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| 129 | Bristol Clinical Commissioning Group | 1.5 | 6 | 31 | In an emergency and under certain conditions “as defined in the Medicines Act” a pharmacist…. | Thank you for your comment. Wording was considered by the NICE editorial team. There are hyperlinks for further information about this topic. |
| 130 | Bristol Clinical Commissioning Group | 3.1 | 17 | 30 | Maybe also mention social enterprises, as many community provider organisations have become social enterprises. | Thank you for your comment. The GPG provides examples which are not exhaustive. |
| 131 | Bristol Clinical Commissioning Group | 3.1 | 18 | 21 | Paragraph states that frequent individual adjustments to dose were not good practice, would be good to include examples such as warfarin adjustment due to changing INR or changes to insulin dose. The paragraph following this mentions dose adjustments should not be made unless specified at the point of supply – this is a little confusing following the previous paragraph. | Thank you for your comment. The relevant text has been amended to reflect this comment. |
| 132 | Bristol Clinical Commissioning Group | 3.1 | 19 | 12 | Guidance states that more than 1 medicine may be appropriate in some circumstances. There is the issue of potentially confusing this with mixing medicines. The mixing of medicines is not allowed under current PGD arrangements and should be done by a prescriber, or a combination medication chosen so no mixing required. | Thank you for your comment. This has been considered in section 1.6 of the guidance |
| 133 | Bristol Clinical Commissioning Group | 3.1 | 20 | 20 | Box 3 “the medication is an injectable preparation for self-administration” – possibly re-word or expand as would a prescription with full counselling may be a better option with better | Thank you for your comment. The GDG agreed that PGDs should be considered carefully when a medicine is an injectable preparation for self- administration. Alternatives to PGDs should be used when managing long-term conditions or when the medicine needs frequent |

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| | | | | | governance? This could potentially be a group of complex patients? | dosage adjustments, or frequent or complex monitoring. |
| 134 | Bristol Clinical Commissioning Group | 3.1 | 22 | 18 | In recommendation 2.1.12 – would it be useful to mention unstable patients in the patient the list? | Thank you for your comment. The PGD must list all exclusion criteria which relates to the medicine being supplied or administered under the PGD, in line with legislation. |
| 135 | Bristol Clinical Commissioning Group | 3.1 | 22 | 1 | Section 2.1.8 –"Consider informing the patient or their carer that the use is "off-label". Should this be "inform the patient" instead of consider so that the patient is able to give full informed consent. If they are not aware of the off-label nature the patient won't be fully informed? | Thank you for your comment. The updated GMC good practice guidance on prescribing and managing medicines and devices considers that in some circumstances it may not be practical or necessary to draw attention to the licence. All individual health professionals using PGDs should refer to their standards of practice for clarity. The relevant text has been amended to reflect this comment. |
| 136 | Bristol Clinical Commissioning Group | 3.4 | 37 | 26? | People authorising PGDs need to have understanding of the drug and condition PGD is referring to, but also about the service it is aimed at. | Thank you for your comment. This has been considered in section 3.7 of the guidance. |
| 137 | Bristol Clinical Commissioning Group | 3.5 | 43 | 11 | The appendix on Page 64 discussed an appropriately labelled pack; this relates to the section on p43, it would be good if the appendix made clear that appropriate labelling applies to all medication supplied to a patient not just prescription only medicines but pharmacy medicines as well? It would be useful if included examples of recommended labelling? | Thank you for your comment. Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGDs. The MHRA can provide further information on labelling requirements. |
| 138 | Bristol Clinical Commissioning Group | 3.5 | 44 | 16 | Whether patient consent was obtained in line with DOH - It would be good to also add that good practice suggests documenting Fraser competency assessment in children under 16years. | Thank you for your comment. This is included in the DH guidance on consent. |

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| 139 | Bristol Clinical Commissioning Group | 3.6 | 49 | 1 | "The process for reviewing and updating a PGD should include a literature search to identify new evidence". This may be dependent on capacity of the PGD team. Often a review of local and national guidance is most useful to ensure the PGD information is clinically accurate and up to date. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 140 | Bristol Clinical Commissioning Group | general | | | Reinforce in the "3.7 Training and competency" section that not all situations/patients will meet the specific inclusion criteria of a PGD and so providers will need to have agreed processes of how they deal with these situations perhaps obtain a PSD from a prescriber, link with a prescriber for a prescription or signpost to another service. The provider should be aware of local alternative services. Although briefly mentioned in this section it could be expanded and reinforced. | Thank you for your comment. This has been considered in sections 1.6 and 3.5 of the guidance. |
| 141 | Bristol Clinical Commissioning Group | 3.4 | 36 | 4 | Should the word "than" be "that" | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 142 | Bristol Clinical Commissioning Group | general | | | Perhaps clarify section around collating prescription charges as this can be an area of difficulty and confusion. | Thank you for your comment. The relevant text has now been amended to reflect his comment. See section 1.6. Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a **supply** of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are **administered** under a PGD. |
| 143 | Bristol Clinical | general | | | Overall, relatively easy to read and | Thank you for your positive comment supporting the |

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| | Commissioning Group | | | | understand, good to have one document with all guidance in. | guidance. |
| 144 | North Somerset Clinical Commissioning Group | 1.5 | 7 | 6 | It may be useful to also strongly clarify that the purpose of PGD is **not**:<br>* To allow an organisation to avoid investing in the training and development of staff to become Non-Medical Prescribers.<br>* To allow services to avoid the cost of employing a non-medical prescriber<br>* To allow services to avoid service re-design which could improve services for patients. | Thank you for your response. The guidance states the purpose of a PGD.<br>The GDG found evidence that the majority of clinical care involving supplying and/or administering medicines should be provided on an individual, patient-specific basis (see section 1.5). The GDG was aware of PGDs being used to deliver a service when independent prescribing, supplementary prescribing or a Patient Specific Direction (PSD) would be a more appropriate option, for example when prescribers were not available at the required time. |
| 145 | North Somerset Clinical Commissioning Group | 1.5 | 6 | 29 | In an emergency and under certain conditions “as defined in the Medicines Act” a pharmacist…. Could this sentence be added in as there are non-negotiable conditions to consider | Thank you for your comment. Wording was considered by the NICE editorial team. There are hyperlinks for further information about this topic. |
| 146 | North Somerset Clinical Commissioning Group | 1.6 | 11 | 27 | Can practical examples of how and when payment can be collected be provided? | Thank you for your comment. Implementation is outside the scope of this good practice guidance. |
| 147 | North Somerset Clinical Commissioning Group | 1.6 | 11 | 27 | Please discuss where this money should end-up within the NHS. Should the money be used as an income for the NHS organisation who have issued a contract to provide these services? or should it be re-directed to a central NHS location? And is there a legal issue if the money is not collected e.g. fraud or is collection optional? | Thank you for your comment. This is outside the scope of this good practice guidance. It is a legal requirement to obtain prescription charges from eligible patients who are not exempt. The legislation can be found here. |
| 148 | North Somerset Clinical | 3.1 | 17 | 29 | Maybe also mention social enterprises, as many community provider | Thank you for your comment. The GPG provides examples which are not exhaustive. |

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| | Commissioning Group | | | | organisations have become social enterprises. | |
| 149 | North Somerset Clinical Commissioning Group | 3.1 | 18 | 17 | The paragraph states “specifying a dosage range so the health professional could select the correct dose for a patient was appropriate in a PGD.” Please include an example e.g. does it mean different doses of amoxicillin liquid for children at different ages. E.g. Different doses of steroid injection for physiotherapists to inject different volumes into different joints. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 150 | North Somerset Clinical Commissioning Group | 3.1 | 18 | 21 | The paragraph states that frequent individual adjustments to dose were not good practice. It would be good to include examples such as warfarin adjustment due to changing INR or changes to insulin dose. The paragraph following this mentions dose adjustments should not be made unless specified at the point of supply – this is very confusing following the previous paragraph. Could this be expanded to more clearly explain the situation? | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants. This section has been reworded following further discussion by the GDG. |
| 151 | North Somerset Clinical Commissioning Group | 3.1 | 19 | 12 | Guidance states that more than 1 medicine may be appropriate in some circumstances. There is the issue of potentially confusing this with mixing medicines. The mixing of medicines is not allowed under current PGD arrangements and should be done by a | Thank you for your comment. This has been considered in section 1.6 of the guidance |

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| | | | | | prescriber, or a combination medication chosen so no mixing required. | |
| 152 | North Somerset Clinical Commissioning Group | 3.1 | 19 | 12 | I would disagree with the GDG's view that more than one medicine may be appropriate in certain circumstances. I feel only one drug should be included per PGD; this is because PGDs should not a used as a means of deciding which treatment should be used, but as a means of supplying the most appropriate treatment option. | Thank you for your comment. The relevant text has been reworded to reflect this comment. The GDG found evidence that more than 1 medicine **could** be included in a PGD. However, the GDG agreed that good practice was likely to be represented by including a single medicine. It recognised that including more than 1 medicine may be appropriate in some circumstances, provided all legal requirements were included for each drug. The GDG concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis. |
| 153 | North Somerset Clinical Commissioning Group | 3.1 | 20 | 4 | Box 3 "the medication is an injectable preparation for self-administration" – possibly re-word or expand as would a prescription with full counselling may be a better option with better governance? This could potentially be a group of complex patients? | Thank you for your comment. The GDG agreed that PGDs should be considered carefully when a medicine is an injectable preparation for self- administration. Alternatives to PGDs should be used when managing long-term conditions or when the medicine needs frequent dosage adjustments, or frequent or complex monitoring. |
| 154 | North Somerset Clinical Commissioning Group | 3.1 | 20 | 8 | Box 4 – Could management of long-term conditions be included. Requests for a B12 PGD's come around regularly but it has never been felt this is an appropriate use of a PGD and currently the box reads that it is not recommended to use a PGD if the condition is complex. | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 155 | North Somerset Clinical Commissioning Group | 3.1 | 22 | 13 | In recommendation 2.1.12 – would it be useful to mention unstable patients in the patient the list? | Thank you for your comment. The PGD must list all exclusion criteria which relates to the medicine being supplied or administered under the PGD, in line with legislation. |

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| 156 | North Somerset Clinical Commissioning Group | 3.1 | 22 | 1 | Section 2.1.8 –"Consider informing the patient or their carer that the use is "off-label". Should this be "inform the patient" instead of consider so that the patient is able to give full informed consent. If they are not aware of the off-label nature the patient won't be fully informed? | Thank you for your comment. The updated GMC good practice guidance on prescribing and managing medicines and devices considers that in some circumstances it may not be practical or necessary to draw attention to the licence. All individual health professionals using PGDs should refer to their standards of practice for clarity. The relevant text has been amended to reflect this comment. |
| 157 | North Somerset Clinical Commissioning Group | 3.4 | 37 | 26 | People authorising PGDs need to have understanding of the drug and condition PGD is referring to, but also about the service it is aimed at. | Thank you for your comment. This has been considered in section 3.7 of the guidance. |
| 158 | North Somerset Clinical Commissioning Group | 3.4 | 38 | 4 | Could an example of adoption also be given for national retail pharmacy chains and the need for a pharmacy PGD adoption process? | Thank you for your comment. Details of the process are for local determination and implementation. |
| 159 | North Somerset Clinical Commissioning Group | 3.5 | 42 | 5 | Could an example be given that pharmacists need to be approved to work under the PGD by their employing organisation? | Thank you for your comment. This has been considered in section 3.4 of the guidance. |
| 160 | North Somerset Clinical Commissioning Group | 3.5 | 42 | 15 | Which organisations….should it be the employer of the health professional providing training? Or the organisation with whom the provider has the contract with who need to provide the training e.g. the CCG, NHS commissioning board. Please clarify who is responsible or should this be locally agreed via a contract? | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 161 | North Somerset Clinical Commissioning Group | 3.5 | 43 | 10 | The appendix on page 64 discussed an appropriately labelled pack; this relates to the section on page 43, it would be good if the appendix made | Thank you for your comment. Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGDs. The MHRA can provide further information on labelling requirements. |

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| | | | | | clear that appropriate labelling applies to all medication supplied to a patient not just Prescription Only Medicines but Pharmacy 'P' medicines as well? What about GSL medicines? It would be useful if it included examples of recommended labelling for the different product types POM, P, GSL | |
| 162 | North Somerset Clinical Commissioning Group | 3.5 | 43 | 10 | The 'appropriately labelled pack' definition on page 64 says the medicine will **usually** have been over labelled by a licensed manufacturing unit. Please could it be defined as to when over labelling by a licensing manufacturing unit is not required by law. | Thank you for your comment. Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGDs. The MHRA can provide further information on labelling requirements. |
| 163 | North Somerset Clinical Commissioning Group | 3.5 | 44 | 16 | Whether patient consent was obtained in line with DOH - It would be good to also add that good practice suggests documenting Fraser competency assessment in children under 16years. | Thank you for your comment. This is included in the DH guidance on consent. |
| 164 | North Somerset Clinical Commissioning Group | 3.6 | 49 | 1 | "The process for reviewing and updating a PGD should include a literature search to identify new evidence". This may be dependent on capacity of the PGD team. Often a review of local and national guidance is most useful to ensure the PGD information is clinically accurate and up to date. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 165 | North Somerset Clinical Commissioning | general | | | Reinforce in the "3.7 Training and competency" section that not all situations/patients will meet the | Thank you for your comment. This has been considered in sections 1.6 and 3.5 of the guidance. |

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| | Group | | | | specific inclusion criteria of a PGD and so providers will need to have agreed processes of how they deal with these situations perhaps obtain a PSD from a prescriber, link with a prescriber for a prescription or signpost to another service. The provider should be aware of local alternative services. Although briefly mentioned in this section it could be expanded and reinforced. | |
| 166 | North Somerset Clinical Commissioning Group | 3.4 | 36 | 4 | Should the word “than” be ”that” | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 167 | North Somerset Clinical Commissioning Group | general | | | The document feels very much aimed at authors and groups developing or updating PGD’s PGD rather than PGD users. | Thank you for your comment. The GPG applies to all individuals and organisations involved with PGDs. |
| 168 | North Somerset Clinical Commissioning Group | general | | | I believe people using PGD’s would also like more practical examples of what is expected of them when using PGD’s. For example How they should practically use PGD’s during a consultation, information about best practice regarding documentation and audit, Information about their governance responsibilities such as diagnostic skills, and also practical examples for the different clinical settings in which PGD’s may be used e.g. GP surgery, minor injuries, A&E, contraceptive clinics etc. I know some of this is available in the NPC 2009 | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |

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| | | | | | document on PGD's but it would be useful to have this best-practice guidance updated and incorporated into this NICE guidance so that those using PGD's have a reason to refer to the NICE guidance. | |
| 169 | North Somerset Clinical Commissioning Group | general | | | This guidance adds only a little extra knowledge for people who regularly develop PGD's. | Thank you for your comment. No response required. |
| 170 | North Somerset Clinical Commissioning Group | general | | | The guidance does bring much information into one place which is very helpful and does clarify best-practice for governance structures. | Thank you for your positive comment supporting the guidance. |
| 171 | North Somerset Clinical Commissioning Group | general | | | The guidance does not assist in clarifying areas of long-term concern/uncertainty such as the legal view of over-labelling | Thank you for your comment. Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGDs. The MHRA can provide further information on labelling requirements. |
| 172 | Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust | 3.1 | 19 | 3 - 7 | Changes in working arrangements in many radiology departments makes prescribing impractical, especially out-of-hours where many departments are outsourcing and the radiologist is based in another part of the country. The alternative would be for on on-call doctor with no knowledge of contrast media to blindly prescribe in accordance with protocol. Radiographers at least have knowledge of contrast media and therefore are more "qualified" to assess patients for suitability in accordance with defined PGD. | Thank you for your comment. The relevant text has been amended to reflect this comment.<br><br>The GDG discussed and agreed that prescribing or a PSD remains the preferred option for the majority of care. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety, and there are clear governance arrangements and accountability. |

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| | | | | | Radiographers are currently unable to become prescribers.<br>We believe PGDs for contrast media have been developed in an effort to improve governance arrangements where practice has previously not been compliant with any legal form of prescribing.<br>We feel that the panel should consult specifically with radiology departments as to the impact before they are to highlight as an example of bad practice | |
| 173 | Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust | 3.2 | 26 | 13 | Different PGDs for the same medicines are often required to reflect differences in staff competency and exclusion/inclusion criteria for a given scenario. | Thank you for your comment. The GDG agreed that a single PGD in a patient group covering different services in 1 organisation would in most circumstances be more appropriate. The GDG concluded that operating a PGD approval group may help to reduce unnecessary duplication of PGDs. The process would be for local consideration and determination. |
| 174 | Brook Advisory | | 14 | | Figure 1 helpful overview of the process | Thank you for your comment. The flowchart is intended to summarise the PGD process clearly and concisely, and does not consider the entirety of local arrangements. Some of these may vary in different organisations. |
| 175 | Brook Advisory | Box 7 | 55 | | Very useful tool for clarifying roles and responsibilities | Thank you for your positive comment supporting the guidance. |
| 176 | Brook Advisory | General | | | Extremely useful guidance which discusses each stage of the PGD process, really helpful inserting the links to the relevant national guidance. Although this is still in draft format I found this very useful whilst currently reviewing and amending PGDs for the | Thank you for your positive comment supporting the guidance. |

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| | | | | | organisation, cross checking the PGD contents, establishing organisational guidance for PGD use and the subsequent process of presenting them to a local commissioner. | |
| 177 | Northern Devon Healthcare NHS Trust | 1.3 | 4 | N/A | **PGDs for Privately Provided Services:** Outside of the scope of the guidance, but could a sentence be included regarding the legality of privately provided services? i.e. does the legislation apply to NHS services only? | Thank you for your comment. This section has been reworded following further discussion by the GDG. The scope of the guidance however cannot be changed. |
| 178 | Northern Devon Healthcare NHS Trust | 1.4 | 5 | 1 | **Link to Health Service Circular (HSC 2000/026):** Link navigates to DH website, which then directs to the National Archives page for DH website, and is difficult to navigate / locate reference.<br>Consider replacing with direct link to document, which would be quicker: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 179 | Northern Devon Healthcare NHS Trust | 1.5 | 7 | 26 / 27 | **Link to Health Service Circular (HSC 2000/026:** as above | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 180 | Northern Devon Healthcare NHS Trust | 1.5 | 7 | footer | **Link to Health Service Circular (HSC 2000/026:** as above | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 181 | Northern Devon Healthcare NHS Trust | 1.5 | 5 | 11 | Link to Crown Report: As above – takes several clicks to get to the report via archive page dh.gov.uk. Please | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |

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| | | | | | include direct link, as quicker: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4077153.pdf | |
| 182 | Northern Devon Healthcare NHS Trust | 1.5 | 6 | 24 | **Link to parenteral medicines:** Could the list be included in the Guidance, as an Appendix, as this is commonly referred to, and these meds do not require PGDs? | Thank you for your comment. The hyperlink provides information directly from the legislation. |
| 183 | Northern Devon Healthcare NHS Trust | 1.6 | 8 | 2 | **Link to 'legislation was amended':** link to legislation without further information takes time to find relevant Schedule / paragraph. If links to legislation are to be included, could more detail to the Schedule / Paragraph also be included, to aid locating reference (or expand in text – paragraph 2, page 8 summary is clear). | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 184 | Northern Devon Healthcare NHS Trust | 1.6 | 8 | 14 / 15 | **'Legislation':** This is the Human Medicines Regulations 2012, but there is no link. Suggest either stating Human Medicines Regulations 2012 or link from the word 'Legislation'. | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 185 | Northern Devon Healthcare NHS Trust | 1.6 | 8 | N/A | **Paragraph 2 and bullet points paragraph 5:** repeat each other. Maybe combine? | Thank you for your comment. Unfortunately, the point of this comment is not clear. |
| 186 | Northern Devon Healthcare NHS Trust | 1.6 | 10 | 11 | **After '….may be considered':** suggest adding 'in clearly defined situations' | Thank you for your comment. The relevant text has now been amended to reflect this comment |
| 187 | Northern Devon Healthcare NHS | 3 | 13 | 8 | **Bullet point 'authorising PGDs':** Suggest differentiating between | Thank you for your comment. Wording is consistent with legislation. Different terminology may exist locally. To |

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| | Trust | | | | '**Ratifying'** PGDs (following development by group / individuals requiring PGD) – when PGD is signed by pharmacist, doctor/dentist; and **Authorising** PGDs – which is when PGD is authorised to be used by the Organisation / Authorising Body. | avoid confusion and misinterpretation, for the purpose of the guidance this is all considered as part of the authorising process. |
| 188 | Northern Devon Healthcare NHS Trust | 3 | 14 | N/A | **Algorithm / flow chart:** as comments above – suggest after Stakeholder engagement, amend text box wording from '*Authorisation* by doctor (or dentist), pharmacist and other professional groups representative' to '*Ratification'*. | Thank you for your comment. Wording is consistent with legislation. Different terminology may exist locally. To avoid confusion and misinterpretation, for the purpose of the guidance this is all considered as part of the authorising process. |
| 189 | Northern Devon Healthcare NHS Trust | 3 | 15 | N/A | **Algorithm / flow chart:** text box 'communication and dissemination' – consider adding 'training and assessment of competency to work under PGD'. | Thank you for your comment. The GDG agreed that training and competency was relevant to all parts of the PGD process and the figure reflects this. Details are outlined in section 3.7. |
| 190 | Northern Devon Healthcare NHS Trust | 3 | 15 | N/A | **Algorithm / flow chart:** text box 'Review and updating' – an arrow needs to go back up to Stakeholder engagement with note, to start review the process as detailed in the text boxes below. | Thank you for your comment. The flowchart is intended to summarise the PGD process clearly and concisely, and does not consider the entirety of local arrangements. Some of these may vary in different organisations. |
| 191 | Northern Devon Healthcare NHS Trust | 3 | 14, 15 | N/A | **Considering the need for a Patient Group Direction:** Does the GDG have a view regarding which groups within organisations can decide whether a new PGD is needed? What are the governance considerations for the developing organisation / authorising body? Suggested minimum | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. See section 3.2 for details on obtaining agreement to develop a PGD. |

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| | | | | | membership of a development & ratification group would be helpful. | |
| 192 | Northern Devon Healthcare NHS Trust | 3.1 | 20 | Box 3 | **Box 3 title:** Clinical situations when PGDs need to be carefully considered carefully: ADD: "and use in exceptional, clearly justified situations" | Thank you for your comment. Alternative options to PGDs for certain clinical situations have been listed in box 4. |
| 193 | Northern Devon Healthcare NHS Trust | 3.1 | 20 | Boxes 3 & 4 | **Boxes 3& 4 content:** move bullet point in Box 4 "an antimicrobial is needed (this may be appropriate in some circumstances, such as chlamydia treatment in a sexual health clinic" to Box 3 (as a PGD should always be considered as a last option according to algorithm, page 14, when other methods of administration / supply are not possible, according to service requirements / commissioning arrangements). Page 22 Recommendation 2.1.11 already states that antimicrobials may be included in a PGD in exceptional circumstances (see previous comment). | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 194 | Northern Devon Healthcare NHS Trust | 3.1 | 20 | Box 4 | **Box 4 title:** This could be worded more strongly to say "Clinical situations when PGDs are not appropriate" | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 195 | Northern Devon Healthcare NHS | 3.1 | 22 | 10, 11, 12 | **Recommendation 2.1.11:** Following end of sentence "…. To combat | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be |

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| | Trust | | | | antimicrobial resistance." ADD "ensuring PGDs are in line with Joint Formulary recommendations, taking association with *C. difficile* risk into account. | included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[4] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 196 | Northern Devon Healthcare NHS Trust | 3.2 | 24 | 9, 10, 12, 16, 22, 24 | **Terminology: PGD approval group:** Suggest this is changed to PGD Ratification Group, as per previous comments above, to differential between ratification and authorisation on behalf of an authorising body. | Thank you for your comment. Different terminology may exist locally. To avoid confusion and misinterpretation, for the purpose of the guidance this is all considered as part of the authorising process. |
| 197 | Northern Devon Healthcare NHS Trust | 3.3 | 31 | 14,15 | **PGD Working Group membership:** The doctor/dentist and pharmacist signing the PGD MUST be part of the group developing the PGD (take the work 'ideally' out of the two bullet points).<br>It may not be possible to have a specialist with appropriate expertise (such as specialist in GUM medicine / sexual health / microbiologist) present at meetings of the PGD working group, but we accept that these specialists need to be consulted / involved as part | Thank you for your comment. This is not required by current legislation.<br>The roles and responsibilities of each person and how they work together to develop the PGD should be determined locally and be clearly defined. |

[4] The Health Protection Agency is now part of Public Health England.

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| | | | | | of the development process, which would be minuted. | |
| 198 | Northern Devon Healthcare NHS Trust | 3.3 | 33 | 3 | **Referencing evidence:** The recommendation is that all evidence is referenced – this is appropriate and good practice. However, to include the evidence as an appendix would potentially make the document very large and unwieldy, and is unnecessary – this could be recorded in the development group minutes. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 199 | Northern Devon Healthcare NHS Trust | 3.4 | 36 | 3 | **Commissioner / Provider governance responsibilities:** The document states that where the provider is the authorising body, the commissioning organisation is responsible for ensuring governance arrangements are in place. Surely, the responsibility for governance in this case lies with the authorising body, not with the commissioning organisation? Could this be clarified? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 200 | Northern Devon Healthcare NHS Trust | 3.4 | 36 | 19 | **Signing of PGDs by doctor/dentist and pharmacist:** Document says "when possible" a doctor/dentist and pharmacist should be involved in developing the PGD. If these practitioners are taking responsibility for signing the PGD, they would have to also be involved in the development – remove the "when possible". | Thank you for your comment. The GDG agreed that members of the PGD working group developing a PGD should include:<br>• a lead author<br>• a doctor (or dentist)<br>• a pharmacist<br>• a representative of any other professional group who will practise under the PGD, such as a nurse.<br>The GDG recognised that in some organisations, particularly larger organisations, these members may not be the same people who sign the PGD as part of the |

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| | | | | | | authorisation process (see section 3.4). However, in other organisations, such as in small organisations with fewer resources, the PGD may be signed by the same people who were involved in developing the PGD.<br>The relevant text has been amended to reflect this comment. |
| 201 | Northern Devon Healthcare NHS Trust | 2.5.6 | 46 | 13 | **Collection of prescription fees:** Should this be part of good practice guidance? The document describes some of the barriers to collecting prescription fees, such as the administrative burden. It should be left up to local decision-makers to agree on if or how prescription fees are collected – there may be circumstances where collection of prescription fees is not appropriate (e.g. would it be ethical to deny treatment if patient presenting is unable to pay?) | Thank you for your comment. The relevant text has now been amended to reflect his comment. See section 1.6. Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a **supply** of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are **administered** under a PGD. |
| 202 | Northern Devon Healthcare NHS Trust | 2.5.7 | 47 | 1 | Consider adding something about Gillick / Fraser competence in here. | Thank you for your comment. A hyperlink has been added providing further information about this topic. |
| 203 | Northern Devon Healthcare NHS Trust | 2.6.5 | 50 | 21 | **Expiry date of PGDs:** Should be 2 years. - agreeing on a "case-by-case" basis does not provide sufficient safeguards. Although PGDs should be reviewed before the expiry if there are changes, a minimum review period of 2 years builds a safety net into the system that would otherwise not be there. | Thank you for your comment. The GDG discussed this and agreed in some circumstances it may be appropriate to update the PGD less frequently than every 2 years, provided processes are in place to allow for unscheduled review prior to the review date. |
| 204 | Northern Devon Healthcare NHS | 3.7 | 55 | | **Box 7 Pharmacist signing a PGD: bullet point 3:** A pharmacist involved | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |

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| | Trust | | | | in the development (and signing) of a PGD is unlikely to have "Experience of working in the clinical specialty or service where the PGD is to be used". For this Trust, this could include Minor Injury Units, GUM/Sexual Health Services, Vaccination clinics (e.g. influenza), Physiotherapy, and emergency care. The pharmacist needs to work closely with a practitioner working in the service and have a working understanding of the service, but not direct experience of working in the clinical specialty, as this would be impossible to meet. | |
| 205 | Northern Devon Healthcare NHS Trust | 3.7 | 55 | | **Box 7 People authorising named health professionals to practice under the PGD:** In addition to the three bullet points listed, the authorising person also needs to have responsibility (professional or managerial) for the staff being authorised to work to the PGD. | Thank you for your comment. The GDG agreed this person may not have managerial responsibilities. |
| 206 | Northern Devon Healthcare NHS Trust | general | | | **Governance framework within which PGDs are used:** For some services, such as the management of minor ailments / services provided via minor injury units (MIUs), a clear framework is needed for staff to operate via a PGD. For example, the treatment of infections via MUIs by the provision of | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[5] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented |

[5] The Health Protection Agency is now part of Public Health England.

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| | | | | | advice and possibly the administration and/or supply of items via PGD must be carefully managed. The mechanism used within this Trust is by the use of Clinical Treatment Protocols, which appropriately trained staff work to, which clearly link to PGDs for specific indications (e.g. Protocol for managing presenting with possible/suspected meningococcal disease, linked to PGD for the appropriate antibiotic treatment, according to local formulary/microbiology advice). | • use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. |
| 207 | Northern Devon Healthcare NHS Trust | general | | | **Term "PGD approval group":** As per previous comments - Suggest this is changed to PGD Ratification Group, as per previous comments above, to differential between ratification and authorisation on behalf of an authorising body. | Thank you for your comment. Wording was considered by the NICE editorial team. Different terminology may exist locally. To avoid confusion and misinterpretation, the terms used for the purpose of the guidance are included in the glossary. |
| 208 | Northern Devon Healthcare NHS Trust | general | | | **Recommendations**: would be clearer if split into groups for Providers and Commissioners or Both Commissioners and Providers. | Thank you for your comment. The GDG agreed that in many cases a recommendation could not explicitly state which individual person or organisation was responsible for implementing the recommendation. Arrangements will vary depending on how services are commissioned and provided and what resources are available. When the GDG agreed that a responsible individual person or organisation could be identified, this is clear within the recommendation. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 209 | Northern Devon Healthcare NHS | General | | | **Algorithm:** would be clearer if split into responsibilities for Providers and | Thank you for your comment. Formatting options limit this. Responsibilities may vary depending on how services |

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| | Trust | | | | Commissioners or Both Commissioners and Providers. | are commissioned and provided and what resources are available. |
| 210 | Northern Devon Healthcare NHS Trust | general | | | **Complex contracting arrangements between providers (+/- commissioners):** The guidance does not appear to cover situations where one NHS provider is commissioned / contacted by another (NHS Provider or Non-NHS provider of NHS services) to undertake PGD development on that Provider's behalf. What would the governance requirements be in such situations? This is not clear from the guidance or flowchart on P14. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 211 | Northern Devon Healthcare NHS Trust | general | | | **Links to other websites / sources of information**: Guidance forms a useful summary of legislative requirements for PGD development. Therefore, are all links to other sources of information absolutely necessary? It might be more helpful for resources and links to be listed on NELM website instead (e.g. legislation, MHRA information), which would be referenced in guidance. | Thank you for your comment. The NeLM website no longer exists. It is NICE style to reference relevant text using hyperlinks. |
| 212 | Northern Devon Healthcare NHS Trust | general | | | **Links to documents:** navigation to / back from links is not consistent – preferred option to link directly to document and then to link back to the page in PGD navigated from (most link back to the front page of the PGD document – it is time consuming to then scroll back through and find the | Thank you for your comment. This is outside the scope of this good practice guidance. The links have been set up by the publishing team at NICE. The electronic format on publication will be different to that during consultation. |

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| | | | | | page in the document).<br>(The **'Legislation'** link on page 9 works as described above) | |
| 213 | Northern Devon Healthcare NHS Trust | general | | | **Collection of the NHS prescription changes for items supplied via PGD to patients who are not eligible for free prescriptions:** Could a statement about the position for this be included in the guidance? | Thank you for your comment. The relevant text has now been amended to reflect his comment. See section 1.6. Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a **supply** of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are **administered** under a PGD. |
| 214 | Northern Devon Healthcare NHS Trust | general | | | Clearly differentiate between the use of SHOULD and MUST within the guidance. 'Should' often seems to be used when 'must' may be appropriate. (e.g. page 45 Recommendation 2.5.3: health professionals should: not delegate their responsibility. The 'should' needs to be a 'must'). | Thank you for your comment. When the term 'must' is used in the guidance, this is required by legislation. When the GDG agreed the evidence represented good practice 'should' is used. |
| 215 | Leeds North Clinical Commissioning Group | 3.1 | 18 | 13 | Section also needs to include a statement around inappropriate antibiotic prescribing leads to avoidable healthcare associated infections. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 216 | Leeds North Clinical Commissioning Group | 1.6 | 10 | 1 | The section on controlled drugs is very confusing in respect of what is or is not allow. | Thank you for your comment. The relevant text has now been amended and format altered to reflect this comment. |
| 217 | Leeds North Clinical Commissioning Group | 1.6 | 10 | 2 | Suggest putting the word excludes in bold to help clarification | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 218 | Leeds North Clinical | 1.6 | 10 | 14 | The statement except for treating addiction may be better replaced with | Thank you for your comment. The relevant text has now been amended and format altered to reflect this |

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| | Commissioning Group | | | | – The use of these drugs for the treatment of addition remains excluded. | comment. |
| 219 | Leeds North Clinical Commissioning Group | 1.6 | 10 | 19 | The statement “except anabolic steroids…..etc” may be better replaces with “However, anabolic steroids and any injectable preparation used for treating addiction remain excluded.” | Thank you for your comment. The relevant text has now been amended and format altered to reflect this comment. |
| 220 | Leeds North Clinical Commissioning Group | 3.5 | 44 | 14 | Within the patient consent section does there need to be a section about consenting to information being passed the patients normal health care professional, such as general practioner, to ensure they have a full medical history of the patients treatment or some statements about the patients responsibility to inform their General practioner. | Thank you for your comment. Whether patient consent to treatment was obtained should be considered and documented in line with the Department of Health’s advice on consent (2009). |
| 221 | Bridgewater Community Healthcare NHS Trust | 1.4 | 5 | 9 | Should it read Registered Health Professionals? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 222 | Bridgewater Community Healthcare NHS Trust | 1.6 | 9 | 13 | What about paramedics working in other areas? E.g. Walk In Centres | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 223 | Bridgewater Community Healthcare NHS Trust | 1.6 | 11 | 3 | What about Non-Medical Prescribers? | Thank you for your comment. The wording provided in the guidance is that taken from legislation. |
| 224 | Bridgewater Community Healthcare NHS | 3.1 | 19 | 16 | What about paracetamol? E.g. In Walk in Centres | Thank you for your comment. The GDG agreed that local policies would be more appropriate when a PGD is not necessary, with the employing organisation retaining legal |

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| | Trust | | | | | responsibility for the actions of its employees. See 'To PGD or not to PGD' for further information. |
| 225 | Bridgewater Community Healthcare NHS Trust | 3.1 | 19 | 23 | What kind of local policies? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 226 | Bridgewater Community Healthcare NHS Trust | 3.1 | 22 | 2.1.9 | What about immunisations? | Thank you for your comment. The relevant text now been amended to reflect this comment. |
| 227 | Bridgewater Community Healthcare NHS Trust | 3.3 | 32 | 27 | What about immunisations being used outside SPC on recommendations from the Joint Vaccination Committee? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 228 | Bridgewater Community Healthcare NHS Trust | 3.3 | 33 | 6 | Should there be a recommended maximum time limit? | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 229 | Bridgewater Community Healthcare NHS Trust | 3.4 | 37 | 13 | What if a provider organisation crosses multiple CCGs and authorises its own PGDs is CCG approval still needed? | Thank you for your comment. In these circumstances, if the provider is an authorising body, the commissioning organisation does not legally need to authorise the PGD for the provider. However the GDG recognised in some circumstances, the provider organisation may not be legally able to authorise their own PGDs if they are not listed as an authorising body in the legislation. PGDs developed for use across several CCGs would need to be authorised within each CCG. This has been considered in section 3.3, box 6 of the guidance. |
| 230 | Bridgewater Community Healthcare NHS Trust | 3.5 | 46 | 2.5.7 | Should concurrent medication be documented as being checked for interactions? | Thank you for your comment. This should be included within the exclusion criteria |
| 231 | Bridgewater | 3.6 | 50 | 2.6.5 | Include a maximum time without | Thank you for your comment. Details of the process of |

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| | Community Healthcare NHS Trust | | | | updating | review are for local consideration and determination |
| 232 | Bridgewater Community Healthcare NHS Trust | 3.7 | 55 | | Box 7 People in the PGD Working Group should also consider local and national guidance and local policies | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 233 | Bridgewater Community Healthcare NHS Trust | | 65 | 1 | Delegation – does this exclude supervising administration during post registration training? E.g. immunisation | Thank you for your comment. Delegation is not permitted in legislation. |
| 234 | Bridgewater Community Healthcare NHS Trust | General | | | Sets out a coherent plan for organisations using PGDs to follow | Thank you for your positive comment supporting the guidance. |
| 235 | Marie Curie Cancer Care | General | | | Although Marie Curie's exposure to Patient Group Directions (PGDs) is currently only limited, we anticipate working more with PGDs in the future. Overall, we think that the approach of the NICE good practice guidance on PGDs is very comprehensive. | Thank you for your positive comment supporting the guidance. |
| 236 | Marie Curie Cancer Care | General | | | The Patient Group Directions Good Practice Guide is an important document which provides an excellent framework to assist with the development of PGD's, and comprehensive guidance to ensure robust governance. This, utilised in conjunction with the Legal Exemptions in an Emergency List of Medications can ensure that PGDs are not developed unnecessarily. | Thank you for your positive comment supporting the guidance. |

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| 237 | Marie Curie Cancer Care | General | | | We think that PGDs have an important role in end of life care, to ensure patient receive timely and appropriate interventions in the absence of Patient Specific Directions, allowing Marie Curie registered nurses, working out of hours, the ability to administer medicines to alleviate common symptoms experienced at the end of life and allow terminally ill patients to be pain free in their last days.<br>PGDs that have been developed for medicines to treat confusion/agitation, nausea, anxiety/terminal restlessness and respiratory secretions help Marie Curie nurses to improve the quality of service they provide to patients and carers with palliative care needs. | Thank you for your comment. No response required. |
| 238 | Marie Curie Cancer Care | 3.8 | | | We think that the recommendation of organisational PGDs would reduce duplication of efforts and ensure consistency across all services. However the need/ value of PGDs may differ across our different services (Hospices, MCNS Core Service, MCNS Fast Track, MCNS Rapid Response, MCNS Multi-patient Visit, MCNS Out of Hours Services etc.) and any organisational PGDs would have to meet all four nations' regulatory requirements as MCCC deliver services in the 4 nations. | Thank you for your comment. This is outside the scope of this good practice guidance. |
| 239 | Marie Curie | 3.8 | | | Organisational PGDs would work very | Thank you for your comment. This is outside the scope of |

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| | Cancer Care | | | | well in some situations, for example where there is UK guidance/ agreement regarding best practice and therefore MCCC could develop a national PGD for use in MCCC Hospices or other MCCC services (e.g. for instillagel, or flumazenil). However a Charity wide generic Symptomatic Relief PGD would prove more challenging in light of the differences in ratified symptom management guidelines across the UK (both medication and dose) that our services work to 'as per service level agreements' and therefore Symptomatic Relief PGDs would have to be local rather than national. | this good practice guidance. |
| 240 | Marie Curie Cancer Care | General | | | We think that legislative changes, planned to ensure that Clinical Commissioning Groups, NHS England and local authorities are able to authorise Patient Group Directions (PGDs), are essential. It is also critical that transitional arrangements are made to ensure that PGDs can continue to be used in the short term, while the new arrangements are put in place.<br><br>(The issue arises because the bodies that are legally able to authorise PGDs - Primary Care Trusts, Health Authorities and Strategic Health | Thank you for your comment. Details of legislative changes are outside the scope of this good practice guidance. |

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| | | | | | Authorities – ceased their existence on 1 April 2013; so their PGDs will no longer be valid in England.) | |
| 241 | Marie Curie Cancer Care | General | | | We think that the recommendations in general are very clear and help making a complex process comprehensible. | Thank you for your positive comment supporting the guidance. |
| 242a | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | The need for Patient Group Directions has arisen because primary and secondary care is still working under out-of-date medicines legislation, for example the need in emergency situations and clinical areas such as obstetrics in hospitals arise because the law is too slow to match practice. | Thank you for your comment. Legislative changes are outside the scope of this document. |
| 242b | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | Whilst the introduction to this section describes the various legal options for prescribing, supplying and administering medicines it should highlight changes that allow for non-medical prescribing. PGDs, in whatever clinical setting, should become the exception rather than the norm. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 242c | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | Further, PGDs should not be used to supply or administer medicines on an infrequent or exceptional basis except as a consequence of an untoward effect in certain clinical situations e.g. if an endoscopist is not a non-medical prescriber he/she may be authorised to use a PGD for midazolam as this is used frequently for a pre-defined patient group and the endoscopist has competence and familiarity, but the | Thank you for your comment. The GDG discussed settings using a small number of medicines and agreed that this does not exclude prescribing as an option for supplying and/or administering medicines (particularly when medicines are considered to be 'higher risk'). The GDG felt that prescribing would be a more appropriate option. See section 3.1. If drugs in a PGD are used infrequently, a PGD is not the most appropriate method of medicines supply. See sections 2.6 and 3.6. Details of the process are for local consideration and determination. |

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| | | | | | endoscopist would also require a PGD for flumazenil to treat rare over-sedation.<br><br>In the above example however, as the health professional only uses three or four medicines it may be argued that independent prescribing status would be inappropriate if these products are used infrequently and in this situation a PGD would be more appropriate (as it would contain all of the exclusion criteria, dose limits, cautions and other precautionary requirements, and the development process ensures that the accountabilities are scrutinised and judged 'consistent with professional working relationships') but with a 'limit' placed on the number of medicines a registered practitioner can supply or administer products under a PGD. | |
| 242d | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | We therefore believe that:<br>The 'exceptions' should be explicitly framed and the alternatives clearly identified | Thank you for your comment. No further action required. This is covered within the guidance. See section 1.5. |
| 242e | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | PGDs are used to help in situations where a health professional knows will arise but the patient is not known in advance. However, if the health professional does know about the patient in advance then they should know how they can appropriately | Thank you for your comment. The GDG agreed that the definition of a PGD should not be interpreted as indicating that the patient should not be identified. Patients may or may not be known to the service.<br><br>PGDs will include patient inclusion and exclusion criteria. Patients who do not meet criteria should be managed as |

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| | | | | | manage the situation and the exceptions to that management | detailed in the individual PGD. |
| 243f | Guild of Healthcare Pharmacists | 3.1 Recommendation 2.1.1 | 21 | 2 | There should be a minimum number of packs that are supplied by a service as this would ensure that there was on-going competency by practitioners working under this directive | Thank you for your comment. The frequency of PGDs being used is included within the guidance. See section 3.6. The frequency of use would be considered when reviewing the PGD, to determine whether the PGD remains the most appropriate option to deliver the service and would be for local consideration and determination. See section 3.6. |
| 242g | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | There should be a minimum number of packs that are supplied by a service as this would ensure that there was on-going competency by practitioners working under this directive. This would not affect emergency situations as this would be administration of medicines only | The GDG agreed that organisational governance arrangements for PGDs are for local consideration and determination. Arrangements will vary depending on how services are commissioned and provided and what resources are available. |
| 242h | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | Should there be more than one choice of medicine for a condition this should be exceptional and clearly linked to the alternative PGD. An example would be the use of erythromycin for soft tissue infections in patients allergic to penicillin | The GDG agreed that a single medicine should be included within a PGD. A 'suite' of PGDs may exist for multiple treatment options, for example for oral contraceptives. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[6] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6). |
| 242i | Guild of Healthcare | 1.5 | 5 | 16 | If there are numerous similar products for a condition this suggests complex | Thank you for your comment. The guidance clearly states that the majority of clinical care involving supplying |

[6] The Health Protection Agency is now part of Public Health England.

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| | Pharmacists | | | | clinical management that should be undertaken by patient specific directives. It may be more appropriate (similar to patient specific directives) to have a prescriber taking specific clinical responsibility for the PGD with another senior medical practitioner taking clinical corporate responsibility for the appropriate use. This would ensure ownership | and/or administering medicines should be provided on an individual, patient-specific basis (see section 1.5). Even in circumstances when it may be legally possible, the GDG agreed that a PGD may not be the preferred and safest approach to individual situations of providing patients with the medicine(s) they need. |
| 242j | Guild of Healthcare Pharmacists | 1.5 | 5 | 16 | If packs of medicines for supply are 'fully labelled' and negate the ability to change directions in situations that allow for variable doses, this suggests complexity and should be dealt with by patient specific directions. Only the name and date should be added to a pack over-labelled for supply by a person authorised to work under a PGD. | Thank you for your comment. Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGDs. The MHRA can provide further information on labelling requirements. |
| 243a | Guild of Healthcare Pharmacists | 3.1 Recommendation 2.1.1 | 21 | 2 | PGDs should only be used for distinct patient episodes. The first question to ask is - can the authorisation to supply or administer a medicine be undertaken on a patient specific basis? | Thank you for your comment. The relevant text has now been amended to reflect this comment.<br>The GDG agreed that these factors should be considered when 'considering the need' for a PGD. |
| 243b | Guild of Healthcare Pharmacists | 3.1 Recommendation 2.1.1 | 21 | 2 | Should there be more than one choice of medicine for a condition this should be exceptional and clearly linked to the alternative PGD | Thank you for your comment. This is covered in the guidance, see section 3.5. |
| 243c | Guild of Healthcare Pharmacists | 3.1 Recommendation 2.1.1 | 21 | 2 | Where there are numerous similar products for a condition this should be undertaken by patient specific directives. A prescriber should take | Thank you for your comment. The GDG discussed and agreed that, in general, the need for a PGD in a specific clinical situation should be considered locally. A comprehensive approach should include reviewing the |

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| | | | | | specific clinical responsibility for the PGD with another senior medical practitioner taking clinical corporate responsibility for the appropriate use | care pathway and exploring **all** the options for prescribing, supplying and/or administering medicines, see section 3.1. |
| 243d | Guild of Healthcare Pharmacists | 3.1 Recommendation 2.1.1 | 21 | 2 | If packs of medicines for supply are 'fully labelled' and negate the ability to change directions in situations that allow for variable doses, this should be dealt with by patient specific directions. Only the name and date should be added to a pack over-labelled for supply by a person authorised to work under a PGD. | Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGDs. The MHRA can provide further information on labelling requirements. |
| 244a | Guild of Healthcare Pharmacists | 3.1 Recommendation 2.1.2 | 9 | 6 | Patient Group Directions, in whatever clinical setting, should become the exception rather than the norm. The 'exceptions' should be explicitly framed and the alternatives clearly identified. If a health professional knows about the patient in advance then he/she should know how to appropriately manage the situation and also the exceptions to that management. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 244b | Guild of Healthcare Pharmacists | 3.1 Recommendation 2.1.2 | 9 | 6 | PGDs should not be used to supply or administer medicines on an infrequent or exceptional basis except as a consequence of an untoward effect in defined clinical situations. | Thank you for your comment. The frequency of PGDs being used is included within the guidance. See section 3.6. The frequency of use would be considered when reviewing the PGD, to determine whether the PGD remains the most appropriate option to deliver the service and would be for local consideration and determination. |
| 244c | Guild of Healthcare | 3.1 Recommendation | 9 | 6 | If a non-medical prescriber uses a medicine infrequently a PGD would be | Thank you for your comment. The frequency of PGDs being used is included within the guidance. See section |

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| | Pharmacists | 2.1.2 | | | more appropriate but with a 'limit' placed on the number of medicines a registered practitioner can supply or administer products under a PGD. | 3.6. The frequency of use would be considered when reviewing the PGD, to determine whether the PGD remains the most appropriate option to deliver the service and would be for local consideration and determination. |
| 245 | Guild of Healthcare Pharmacists | 1.6 | 9 | 10 | The list of Health Professionals eligible to use PGDs should include 'Pharmacy Technicians'. The clinical roles of pharmacy technicians in NHS hospitals has developed in recent years therefore adding these registered health professionals to the list would enhance patient care by improving access to appropriate medicines and reducing delays in treatment. The skills of these individuals would also be maximised. | Thank you for your comment. This would require an amendment to legislation and is outside the scope of this guidance. The list of healthcare professions eligible to use PGDs is clearly stated in legislation and does not currently include pharmacy technicians. |
| 246 | Guild of Healthcare Pharmacists | 1.6 | 10 | 23 | If a PGD includes multiple clinical indications for the named medicine and authorises specific health professionals to use the product for a specific indication, the PGD should include a clear statement at the outset indicating which health professionals may supply or administer the medicine for each indication. | Thank you for your comment. The wording provided in the guidance is that taken from legislation (Human Medicines Regulations 2012) and outlines this detail. See section 3.5. |
| 247 | Guild of Healthcare Pharmacists | 3.5 | 42 | 9 | Although this section mentions that health professionals have a professional responsibility to work within their competency and undertake appropriate professional development, there should also be a statement (to stress) that they are also | Thank you for your comment. This is reflected in the guidance. |

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| | | | | | accountable for their actions when making a decision to supply or administer a medicine under a PGD | |
| 248 | Sheffield Clinical Commissioning Group | General | | | This GPG is welcome, particularly at a time when changes to the NHS organisation have resulted in uncertainty to the roles and responsibilities of the various bodies | Thank you for your positive comment supporting the guidance. |
| 249 | Sheffield Clinical Commissioning Group | 1.6 | 8 | 27 | The term "independent medical agency" is used here as one of the bodies that can authorise PGD. This term is then defined in the appendix A as an agency that includes the provision of services by medical practitioners. It would be helpful to clarify whether GP practices, who are registered with the CQC as primary medical services providers and who are contracted to provide an NHS service, are included or excluded from this group | Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 250 | Sheffield Clinical Commissioning Group | 1.6 | 9 | 3 | Does treatment of disease/disorder/injury also include prevention of disease e.g. immunisation, antibiotic prophylaxis? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 251 | Sheffield Clinical Commissioning Group | 3.3 | 30 | 6 | The CDG discussed evidence that the commissioning organisation may or may not be the body that develops the PGD. A number of scenarios are subsequently described. It would be helpful if the guidance included more discussion on this. It may be a contentious issue between the | Thank you for your comment. Details of the process are necessarily for local consideration and determination based on organisational structure and service delivery. |

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| | | | | | commissioner and provider as development of PGD requires resources | |
| 252a | Sheffield Clinical Commissioning Group | 3.4 | 36 | 6 | CCGs are membership organisations with each GP practice being a member. If the GP practice cannot authorise PGDs, is it possible for the CCGs to authorise PGDs on behalf of their member practices for services that are not commissioned by the CCG. For example, vaccination and immunisations are commissioned by NHS England. The area office may not have the resources or personnel to develop and authorise the PGDs to deliver these. | Thank you for your comment. CCGs are authorising bodies as listed in legislation.<br>NHS England has published some emerging scenarios for nationally commissioned immunisation and vaccination programmes following consultation of the draft guidance. The guidance has been updated to reflect this comment.<br><br>Adopting PGDs within the service is included in the guidance. See section 3.4. |
| 252b | Sheffield Clinical Commissioning Group | 3.4 | 36 | 6 | Is the CCG able to authorize the PGDs that are then adopted by each GP practice? | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 253 | Sheffield Clinical Commissioning Group | 3.5 | 44 | 11 | A signature, which may be electronic, is detailed as part of the record of supply/administration. At GP practices, on the GP computer clinical system, the signature is not usually recorded. The login to the system is individual, usually via a smartcard, and the patient record details the name and status of the person supplying or administering the medicine under the PGD. This has been considered by the PCT as sufficient for governance purposes | Thank you for your comment. Electronic signatures can be used when signing a PGD, providing guidance issued by the Department of Health is followed. Governance processes would be for local consideration and determination. |

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| | | | | | without the need to add an electronic signature. Consideration of this by the CDG would be appreciated. | |
| 254 | North East Ambulance Service NHS Foundation Trust | 1.5 | 6 | 24 | It is not so much a legal 'exemption' but that the restriction imposed by section 58(2)(b) (restriction on administration) does not apply to the administration to human beings of specific medicinal products for parenteral administration where the administration is for the purpose of saving life in an emergency. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 255 | North East Ambulance Service NHS Foundation Trust | 1.6 | 9 | 13 | 'Paramedics' is the recognised Registered Health Care Professional title. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 256 | North East Ambulance Service NHS Foundation Trust | 3.4 | 36 | 6 | Some more detail could be included outlining how the limits set by the legislation on who can authorise PGDs may be overcome if a private organisation is commissioned to provide a service to NHS organisation(s) (e.g. private ambulance service) or a stand alone charity ambulance service such as an Air Ambulance who may currently use PGDs. | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 257 | North East Ambulance Service NHS Foundation Trust | 3.4 | 39 | 3 | More detail could be provided such as a template to map the required governance arrangements when the authorising body is not the employing organisation. | Thank you for your comment. Details of the process are necessarily for local determination and implementation. |
| 258 | North East | 3.5 | 43 | 22 | More detail about possible options | Thank you for your comment. Details of the process are |

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| | Ambulance Service NHS Foundation Trust | | | | highlighting those with a low administrative burden would be welcome. | necessarily for local consideration and determination in accordance with legislation. |
| 259 | North East Ambulance Service NHS Foundation Trust | 3.7 | 54 | 8 | While some of the skills in the 'Local decision-making competency framework' are applicable to the needs of the PGD approval group, the emphasis of this document is 'decisions about funding' and many of the skills are appropriate for that role, while the emphasis in the development and approval of PGDs is more about patient safety, and evidence and clinical evaluation. A detailed 'PGD Competency Framework' similar to that for local decision making would be very welcome. | Thank you for your comment. NICE implementation team have identified that a PGD competency framework to support implementation of the guidance would be a useful tool. This will be developed following guidance publication. |
| 260 | Glaxosmithkline UK Ltd. | General | General | General | The Good Practice Guidance document is a valuable resource which will support consistency in development and communication of PGDs.<br><br>There is a need to make sure that the guidelines are consistent to the regulations by the MHRA in relation to the use of PGDs as well.<br><br>We believe that there is a significant gap at present where the scope of the document does not address the provision of non-NHS reimbursed services using PGDs in non-NHS | Thank you for your comment. The GDG identified this issue and co-opted an MHRA representative on to the GDG to ensure the guidance is consistent with MHRA regulations.<br><br>The provision of non-NHS commissioned services is outside of the scope of the guidance. |

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| | | | | | settings by health care professionals. We believe the principles are cross cutting and should be included within the scope of this document. These organisations provide a significant contribution to the management of non-urgent care services to the general public and increasing access (due to the extended hours pharmacies provide and number of locations) to specific services (ie influenza vaccination) for those recommended the vaccine. The use of PGDs is a critical element in the delivery of these services. | |
| 261 | Glaxosmithkline UK Ltd. | 1.4 | 5 | 10 | The current definition of a PGD is limited to those patients who require 'treatment' for a condition and does not allow room for prophylaxis where patients/public could be completely healthy such as in the case of vaccines. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 262 | Glaxosmithkline UK Ltd. | 1.5 | 6 | 8-29 | The guidelines should take into account the extensive use of PGDs within the private healthcare sector for prophylactic treatment such as that used in private pharmacies for delivery of influenza vaccines to those currently not included within NHS reimbursed groups and private travel vaccination clinics. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 263 | Glaxosmithkline UK Ltd. | 1.6<br>3.4 | 8<br>36 | 16-17;24-25<br>6-9 | Although currently beyond the scope of this document at present, clarity is required as to whether a PGD requires | Thank you for your comment. This is outside the scope of this good practice guidance. |

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| | | | | | authorisation from an 'authorising body' should the service that is being provided be purely private ie private travel vaccination clinics | |
| 264 | Glaxosmithkline UK Ltd. | 3.1 | 16 | 1 | Box 1 which provides options for supplying and/or administering influenza vaccines does not take into account the extensive use of PGDs by community pharmacists in the delivery of non-NHS commissioned enhanced services. | Thank you for your comment. This is outside the scope of this good practice guidance. |
| 265 | Glaxosmithkline UK Ltd. | 3.1 | 17 | 20 | The document currently does not include the use of PGDs to provide non-NHS funded care which is currently where there is the greatest level of ambiguity and the current draft guidelines provide very little clarity on this aspect. | Thank you for your comment. This is outside the scope of this good practice guidance. However, wording has been amended to provide clarity on this issue in the good practice guidance. |
| 266 | Glaxosmithkline UK Ltd. | 3.4 | 37 | 13-15 | National pharmacy chains which provide a specific NHS/non-NHS service may develop PGDs for use across multiple sites across the country. In this circumstance, would the national pharmacy chain require approval by authorising bodies of each local area or would a single approval be adequate nationally. | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 267 | Glaxosmithkline UK Ltd. | 3.6 | 49 | 15-16 | There are currently a number of PGD templates circulating on NHS intranet and external sites which are adopted by provider organisations following inclusion of local guidelines. In this circumstance, we would expect the | Thank you for your comment. NICE implementation team have identified that a PGD template document to support implementation of the guidance would be a useful tool. This will be developed following guidance publication. |

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| | | | | | 'lead author' referred to within the draft guidelines to be the individuals adopting the templates rather than the authors of the original template. This is not completely clear in this statement. | |
| 268 | Glaxosmithkline UK Ltd. | 1.6<br>3.6 | 9<br>49 | 28-29<br>19-20 | As individuals eligible to use the PGD have to be named within a PGD, it would be useful to provide clarity as to how organisations can handle the addition or removal of eligible health care professionals from the PGD in a practical and pragmatic fashion especially in locations such as community pharmacies where there is a high degree of flux. There are also implications on this aspect when the document requires reviewing and updating regularly. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |
| 269 | Northampton General Hospital NHS Trust | 3.1 | 15 | 10 | Have a PGD for neutropenic sepsis when insufficient Drs available to ensure treatment is not delayed | Thank you for your comment. The GDG discussed settings using a narrow range of drugs and agreed that this does not exclude prescribing as an option for supplying and/or administering medicines (particularly when medicines are considered to be 'higher risk'). The GDG felt that prescribing would be a more appropriate option. See section 3.1. If drugs in a PGD are used infrequently, a PGD is not the most appropriate method of medicines supply. See sections 2.6 and 3.6. Details of the process are for local consideration and determination. |
| 270 | Northampton General Hospital NHS Trust | 3.1<br>2.1.8 | 18<br>21 | 5<br>25 | Wording of 'exceptional' misleading or misinterpreted as a PGD should support medicines that are regularly used for an indication even though off | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| 271 | Northampton General Hospital NHS Trust | 3.1<br>2.1.11 | 18<br>22 | 15<br>9 | Disagree-PGDs are used in A&E and are essential to support patient waiting times for minor infections, they reflect the antimicrobial guidelines in the Trust and are developed with a microbiologist-expect advice so although they are not 'absolutely essential' they are an excellent tool as there are insufficient Drs to prescribe and very competent registered nurses practitioners to enable them to be supplied or administered. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[7] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 272 | Northampton General Hospital NHS Trust | 3.1<br>2.1.12 | 18<br>22 | 28<br>19 | Disagree-We have used them to manage warfarin supply by anticoagulant nurses to start patients on warfarin as they provide a useful framework for training and competency, inclusion/exclusion criteria so we disagree that this outweighs the benefits. Not practical to have clinics managed by Drs so dose adjustments are included in the PGD | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants. |
| 273 | Northampton General Hospital NHS Trust | 2.2.2 | 27 | 5 | Makes sense to have a PGD group to consider the need for a PGD before it is developed | Thank you for your comment. No response required. |
| 274 | Northampton General Hospital NHS Trust | 2.2.3 | 27 | 9 | Think this is excessive and not practical. There are already many governance groups and it would be | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local |

[7] The Health Protection Agency is now part of Public Health England.

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| | | | | | difficult to resource from current staff, could be part of medicines management committee or authorising group responsibilities. Why should the public be engaged? | consideration and determination. |
| 275 | Northampton General Hospital NHS Trust | 2.2.6 | 28 | 28 | Not feasible to consider the public's views on individual PGDs. PALS officer on authorising committee will represent patient's views. | Thank you for your comment. Details for patient involvement are for local consideration and determination. |
| 276 | Northampton General Hospital NHS Trust | 2.3.1 | 34 | 1 | The PGD working group will be variable depending on the specialist area. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 277 | Northampton General Hospital NHS Trust | 2.3.3 | 34 | 10 | Should have been considered in the proposal but will require consultation when being developed for the staff and area it is developed for. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |
| 278 | Northampton General Hospital NHS Trust | 3.3 | 33 | 6 | Agree that expiry date should be more flexible; consider a maximum interval to be specified. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 279 | Northampton General Hospital NHS Trust | 2.4.3 | 40 | 5 | The legal requirement is to have a Doctor to sign but these are often the very people who have no clear line of responsibility of what or why they sign the PGD. Asking them to have competency training will be a barrier to implementing PGDs in very useful situations. Should this be the clinical lead of the directorate area, i.e. still a Dr but more specified. | Thank you for your comment. Details of training and implementation are for local consideration and determination. See section 3.7 for details on training and competency. |
| 280 | Northampton General Hospital NHS Trust | 2.4.6 | 40 | 15 | Disagree-legislation does not specify that an individual should sign the PGD. A clinical governance lead is a member of the authorising body and when | Thank you for your comment. Legislation states that the PGD must be signed on behalf of the authorising body. Evidence suggests that a clinical governance or patient safety lead in an NHS organisation would usually be |

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| | | | | | ratified has 'signed' the PGD by having a statement that this has been ratified by the authorising body i.e. Medicines Management committee. The individual signing this for every PGD ,every time is not practical or manageable. | responsible for signing PGDs on behalf of the authorising body. This person has responsibility for ensuring PGDs are developed in line with legislation (see section 1.6) and local organisational policies and governance arrangements, with full consideration of the service in which the PGD is to be used. |
| 281 | Northampton General Hospital NHS Trust | 2.4.9 | 41 | 9 | Once a PGD is developed it is difficult for an organisation to keep records of all HCP who practice under a PGD | Thank you for your comment. The GDG agreed this recommendation reflects good practice. |
| 282 | Northampton General Hospital NHS Trust | 2.5.3 | 45 | 18 | Not always their responsibility to know alternatives as they do not show this competency, and they should refer to Dr | Thank you for your comment. Health professionals who are eligible to work under a PGD have a professional responsibility to work within their competency and undertake appropriate professional development in order to work safely with PGDs as part of their professional practice. |
| 283 | Northampton General Hospital NHS Trust | 2.5.5. | 46 | 10 | PILs when supplied not when administered | Thank you for your comment. The GDG agreed it was good practice to provide a patient information leaflet when a medicine is administered using a PGD, although this is not required by legislation. The relevant text has now been amended to reflect this comment. |
| 284 | Northampton General Hospital NHS Trust | 2.7.1 | 56 | 1 | How can you identify these senior people? | Thank you for your comment. Details of senior individuals are for local consideration and determination. Guidance on knowledge, skills and experience is provided in section 3.7. |
| 285 | Northampton General Hospital NHS Trust | 2.7.2 | 56 | 4 | Disagree- the benefit of this is questionable and may waste valuable time and resources. | Thank you for your comment. The relevant text has now been amended to reflect this comment. The GDG concluded that training and assessment of competency is essential to reduce variation and deliver safe and effective services where PGDs are used. |
| 286 | Northampton General Hospital NHS Trust | 2.8.5 | 60 | 13 | Who is to monitor and what should be monitored and why? Not enough guidance supplied for results of | Thank you for your comment. This is outside the scope of this good practice guidance. Details of the process are for local consideration and determination. |

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| | | | | | monitoring and evaluation | |
| 287 | Northampton General Hospital NHS Trust | General | | | This is a comprehensive review of PGDs used in many clinical situations, guidance is required to clarify how PGDs should be developed and implemented. The recommendations try to address all organisational issues e.g. funding and resources but some recommendations are overly demanding and create an industry in itself. There are positive aspects to be taken from this but there is a danger of it becoming too prescriptive. | Thank you for your comment. No response required |
| 288 | Hywel Dda Health Board | 3.4 | 36 | 19 | Our current process is that the lead author, doctor and pharmacist involved in developing the PGD are named on the PGD. The PGD is then checked (Quality Assured) by the PGD Working Group (including nurses, health visitors and pharmacist) before signing for authorisation by the Head of Pharmacy & Medicines Management, HB Director and Relevant Professional Lead. | Thank you for your comment. No response required. |
| 289 | Department of Health | 1.3 | 4 | | DH-MPI acknowledges that the main focus of the good practice guide is on supporting NHS organisations (including non-NHS bodies delivering NHS services). However, the existing PGD guide advises that those non-NHS bodies able to use PGDs should aim to follow that guidance as well. Our view is that the GPG should continue to | Thank you for your comment. This section has been reworded following further discussion by the GDG. The scope of the guidance however cannot be changed. |

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| | | | | | advise that it is relevant to non-NHS users as well. This supports patient safety. | |
| 290 | Department of Health | 1.5 | 6 | 1 | Replace 'allow' with 'enable'. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 291 | Department of Health | 1.5 | 6 | 3 | Replace 'allow' with 'enable' | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 292 | Department of Health | 1.5 | 7 | 7 | Not sure what 'evidence' was considered here. DH-MPI's view is that there should just be a clear statement of the preferred position i.e. ' The majority of clinical care should be provided on an individual, patient-specific basis' . The current PGD guidance document supports this position by reference to the legislation governing the use of medicines, which is designed to protect patient safety, being ' … built around this traditional model of prescribing'. This should be the default position – with other mechanisms being considered where they offer advantages, without compromising patient safety. | Thank you for your comment. This section has been reworded following further discussion by the GDG. |
| 293 | Department of Health | 1.5 | 7 | 13 | '….where it is consistent with appropriate professional relationships and accountability.' We recognise that this is established wording taken from HSC 2000/026, but question whether it is clear to users what this means? We would like to suggest '…..where there are clear arrangements for clinical governance, training and review.' as | Thank you for your comment. The GDG discussed the HSC 2000/026 wording. The relevant text has now been reworded to reflect this comment. |

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| | | | | | alternative wording. | |
| 294 | Department of Health | 1.6 | 8 | 6 | Replace ‘effect’ with ‘effectiveness’. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 295 | Department of Health | 3.1 | 17 | 14 | Suggest revised wording as follows: ‘Such practice is illegal ~~Because this is not within the legal requirements for PGDs~~, and the GDG agreed that organisations should aim ~~this use should be~~ to identify~~ied~~ any such illegal activity as part of the ~~when organisations~~ development or review of their strategic medicines policy.’ | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 296 | Department of Health | 3.1 | 18 | 12 | Following recent concerns expressed by the UK Chief Pharmaceutical Officers and discussions with community pharmacy representatives concerning the growing threat from antimicrobial resistance, we suggest the following revised wording on the use of PGDs for supply of antibiotics:<br><br>‘Antimicrobial resistance is a public health matter of major importance and health care providers need to ensure that they do not jeopardise strategies to combat this threat. The UK Chief Pharmaceutical Officers’ shared view is that PGDs are not, in the main, appropriate mechanisms for the supply of antibiotics. PGDs should not be used for this purpose without the fully documented support of a local NHS microbiologist, and unless | Thank you for your comment. This section has been reworded to reflect this comment following further discussion by the GDG. |

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| | | | | | there is a clearly defined clinical need. Even where these requirements are met, the use of PGDs for supply of antibiotics should be monitored robustly and reviewed regularly.' | |
| 297 | Department of Health | 3.1 | 19 | 23 | Amend 'policies' to read 'protocols'? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 298 | Department of Health | Recommendation 2.1.8 | 22 | 1 | Suggest that this needs to be clearer i.e. that patients <u>should</u> be informed of any off-label use. | Thank you for your comment. The updated GMC good practice guidance on prescribing and managing medicines and devices considers that in some circumstances it may not be practical or necessary to draw attention to the licence. All individual health professionals using PGDs should refer to their standards of practice for clarity. |
| 299 | Department of Health | Recommendation 2.5.3 | 45 | 17 | Some of the recommendations listed <u>must</u> rather than should be complied with. This needs to be made clear. | Thank you for your comment. When the term 'must' is used in the guidance, this is required by legislation. The term 'should' is used when the GDG agreed the evidence represented good practice. |
| 300 | Department of Health | 1.3 | 4 | | Our advice is that Non NHS bodies using PGDs for non NHS purposes should be strongly encouraged to follow this guidance. | Thank you for your comment. This section has been reworded following further discussion by the GDG. The scope of the guidance however cannot be changed. |
| 301 | Department of Health | 1.4 | 5 | 9 | It should say, "by named authorised **regulated** health professionals | Thank you for your comment. Thank you for your comment. The relevant text has now been amended. |
| 302 | Department of Health | 1.5 | 5 | 24 | Add, "dispensing doctors" after, " A pharmacist | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 303 | Department of Health | 1.5 | 6 | 23 | Would it be helpful to include what happens during a pandemic – national protocols are developed authorised on behalf of relevant Ministers. But these are used only for antiviral medicines. Presumably for all other medicines the normal regulations apply? | Thank you for your comment. This is covered within the guidance (reference to pandemic disease). The guidance does not cover systems and process used during periods of pandemic disease, but links are provided for further information. |
| 304 | Department of | 1.5 | 7 | 9 | Add, "supplementary" after | Thank you for your comment. The relevant text has now |

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| | Health | | | | "independent" | been amended to reflect this comment. |
| 305 | Department of Health | 3.1 | 15 | 12 | Add, "or supplementary" after independent | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 306 | Department of Health | 3.1 | 15 | 14 | Should say…."barriers to developing **non-medical** independent and **supplementary** prescribing | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 307 | Department of Health | 3.1 | 16 | 24 | - add, "non-medical;" before, "independent" prescribing | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 308 | Department of Health | 3.1 | 17 | 4 | - add, "non-medical;" before, "independent" prescribing | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 309 | Department of Health | 3.1 | 17 | 8 | Add, "named" before, "registered health professionals" | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 310 | Department of Health | 3.1 | 18 | 16 | There should be a sentence added which states that PGDs for antimicrobials should only be developed with the agreement of the local consultant microbiologist | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 311 | Department of Health | 3.1 | 18 | 22-24 | Not sure what this is trying to portray | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 312 | Department of Health | 3.1 | 18 | 28 | What is meant by, "complex medicine" – For example, in the case of warfarin there is very clear objective guidance which allows the dose of warfarin to be adjusted using INR readings. The new models of delivery have revolutionised the lives of people who need regular monitoring, much easier. If such patients now need to go to a hospital or a GP practice to see a GP every time the doses needs monitoring adjusting, is going to result in a huge | Thank you for your comment. The relevant text has been reworded to reflect this comment.<br>The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |

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| | | | | | amount of inconvenience for patients. | |
| 313 | Department of Health | 3.1 | 22 | Recommendation 2.1.11 | Add, the use of a PGD for antimicrobials must have the involvement and agreement of the local consultant microbiologist | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[8] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 314 | Department of Health | 3.1 | 22 | Recommendation 2.1.12 | Disagree about including warfarin for reasons stated above | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |
| 315 | Department of Health | 3.1 | 22 | Recommendation 2.1.13 | Not sure what this is trying to portray | Thank you for your comment. The relevant text has been amended to reflect this comment.<br>The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |
| 316 | Department of Health | 3.1 | 22 | Recommendation 2.1.14 | To add, “ideally a separate PGD should be developed for each medicine” | Thank you for your comment. The GDG concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis. |
| 317 | Department of Health | 3.2 | 25 | 2 | Whilst, in principle. The idea of having patients/public involved in the | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation |

[8] The Health Protection Agency is now part of Public Health England.

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| | | | | | development of PGDs is a great one, is this always going to be practical and or deliverable? | of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 318 | Department of Health | 3.2 | 25 | 9-11 | Not sure what this Is trying to say | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 319 | Department of Health | 3.2 | 25 | 31 | Should the professional group who will be administering the medicines be represented e.g. nurses? | Thank you for your comment. Membership of the group is for local consideration and determination. |
| 320 | Department of Health | 3.2 | 29 | Recommendation 2.2.6 | Does it need to have a bullet point that states that even if a PGD exists, that does not mean that the named health professional is bound to administer the medicine? The HP has to work within their scope of practice and if they don't feel competent to administer or supply the medicines as laid out in the PGD, they can say No. | Thank you for your comment. This has been considered in section 3.5 of the guidance. |
| 321 | Department of Health | 3.3 | 31 | 16 | Should this say, "antimicrobial" rather than antibacterial? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 322 | Department of Health | 3.4 | 35 | 11 | WE disagree that there is increasing use of independent providers e.g. community pharmacists using PGDs. CPs have been using PGDs for several years now. Also, whilst they are independent contractors, they are contracted to provide NHS services. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 323 | Department of Health | 3.4 | 35 | 15-16 | We are not sure why the lines of accountability between the provider and commissioning organisation are at risk of becoming blurred. | Thank you for your comment. The GDG discussed how NHS changes are altering the way healthcare is delivered. These changes may affect governance arrangements between organisations in relation to PGDs. |
| 324 | Department of Health | 3.4 | 37 | 23-24 | Might be better to replace "competency" with , "that they are competent to do so" | Thank you for your comment. Wording was considered by the NICE editorial team. |

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| 325 | Department of Health | 3.4 | 41 | Recommendation 2.4.10 | Should it say at the end, “and signed off by each organisation?” | Thank you for your comment. This is included within the text. Detail of the process for local adoption is for local consideration and determination with the commissioner and provider. |
| 326 | Department of Health | 3.5 | 42 | 25 | It may be helpful to add, “and also the professional needs to act within his/her competence and may decide that they are not competent to supply the medicine. | Thank you for your comment. This is stated in section 3.5 of the GPG as ‘health professionals have a professional responsibility to work within their competency and undertake appropriate professional development in order to work safely with the PGD as part of their professional practice’. Health professionals should be assessed as competent and authorised to practice. |
| 327 | Department of Health | 3.5 | 43 | 19 and 26 | Replace “fees” with “charges” | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 328 | Department of Health | 3.5 | 46 | Recommendation 2.5.6 | Replace “fees” with “charges” | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 329 | Department of Health | 3.7 | 53 | 1, 11, 17 and 18 | Is it really going to require additional training for senior professionals on the PGD approval group? If they are able to prescribe then we would have thought they are able to oversee the development and sign off of PGDs. Is it a realistic requirement? | Thank you for your comment. The GDG agreed that appropriate training, regular re-training and assessment of competency was needed for all people involved with PGDs, particularly if and when their roles and responsibilities change. |
| 330 | Department of Health | 3.7 | 54 | 10 | As above | Thank you for your comment. The GDG agreed that appropriate training, regular re-training and assessment of competency was needed for all people involved with PGDs, particularly if and when their roles and responsibilities change. |
| 331 | Department of Health | 3.7 | 55 | Box 7 | Is it necessary for the Doctor and person signing the PGD to have experience working in a local medicines decision-making group? That may limit the number of people able to carry out this role. | Thank you for your comment. The GDG agreed this reflects good practice. The doctor signing the PGD would need to have experience of the organisational local medicines decision-making process. A senior doctor and pharmacist should have this experience. The GDG agreed people in specific roles require additional specialised |

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| | | | | | | knowledge, skills and/or expertise dependent on their role which is detailed in the guidance. This may need to be sourced or commissioned from outside the organisation. This is for local consideration and determination. |
| 332 | Department of Health | 3.7 | 56 | Recommendation 2.7.3 | Is comprehensive training for **ALL practical and deliverable?** | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 333 | Pharmacy Voice Limited | General | | | The judicious use of PGDs supports patient choice and access to self-care, without compromising quality or safety or undermining the traditional route of initiation and supply. There have been many benefits to date, for example, the supply of emergency hormonal contraception (EHC) through pharmacies under PGD arrangements has helped prevent many unplanned pregnancies. Community pharmacy NHS flu vaccination services can improve access to people that GP-led services find problematic, including those in the under 65 “at risk” groups. Community pharmacies are open for longer hours than GP surgeries and the network more geographically accessible. The public access community pharmacies more often than any other health profession and staff can initiate immediate vaccination for eligible patients attending the pharmacy for any | Thank you for your comment. No response required. |

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| | | | | | reason, when a visit to the surgery may require a special trip. Community pharmacy flu vaccination services have enabled flu vaccination targets to be met in areas where previously they have not been met. | |
| 334 | Pharmacy Voice Limited | General | | | We see significant benefits to independent prescriber status, but this is unlikely to provide an immediate alternative to PGD provision in many circumstances. We do not think any studies been carried out into the cost effectiveness of using independent prescribers compared with the supply of POM medicines via PGD. | Thank you for your comment. No response required. |
| 335 | Pharmacy Voice Limited | General | | | PGDs used in community pharmacy enable the supply of a POM (prescription only medicine) without a prescription. However, the existence of a PGD does not mean supply is the only point of the process. Those for whom supply is not appropriate will be given advice on the best course of action, including signposting to an appropriate health care provider. The most effective PGDs allow pharmacists to directly refer patients, for example, to a sexual health clinic or an out of hours service. | Thank you for your comment. No response required. |
| 336 | Pharmacy Voice Limited | General | | | PGDs are used to improve patient access to necessary healthcare. This includes choice of provider as well as location. Supply via a PGD from a | Thank you for your comment. No response required. |

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| | | | | | pharmacist may be chosen because:<br>• It is a preferred option e.g. the supply of EHC (some teenagers would worry about being seen at or going to the doctors by family or friends)<br>• It offers timely access, particularly when time may be critical e.g. EHC or minor ailment services, or hepatitis vaccine being administered to substance misusers, when the pharmacist can remind them when each vaccination is due as they collect their substitute opioid.<br>• There may be less perceived stigma attached than, for example, attending a GUM clinic e.g. Chlamydia test and treat<br>• In some areas the use of NHS PGDs for the supply of travel medicines or erectile dysfunction can free GP resources for more complex care.<br>• It improves choice and/or facilitates self-care: some patients choose to be vaccinated against flu even though they are not a target individual. They may choose a | |

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| | | | | | pharmacy offering a private PGD as their provider. If this prevents them becoming infected then demand for NHS services may be reduced. | |
| 337 | Pharmacy Voice Limited | General | | | The judicious use of PGDs can also reduce GPs' workload, to enable them to have more time to treat those with more complex needs. Provision of an antibiotic by pharmacists to appropriate patients suffering with UTI could save a GP visit in three quarters of patients (*Management of urinary tract infection symptoms in patients attending community pharmacies: influence of patient group directions* J L Booth Pharmaceutical Public Health NHS Greater Glasgow & Clyde 2012) | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[9] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 338 | Pharmacy Voice Limited | 3.1 | 15 | | The introduction of legislation to allow pharmacists to become independent prescribers was welcomed by the profession. However, the opportunities for community pharmacists to become independent prescribers and use those skills for the benefit of patients and the public have been limited. This is due to a number of factors, which include the cost of training but more importantly the difficulty of finding training | Thank you for your comment. This is outside the scope of this good practice guidance. |

[9] The Health Protection Agency is now part of Public Health England.

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| | | | | | placements and mentors, and then the lack opportunity to practise, or obtain funding from an NHS organisation for a service. Most community pharmacists practising as independent prescribers are GP surgery-based and funded by the GP practice. This does not offer the opportunities for pharmacists or the improvement to patient access to services originally hoped for, and the opportunity to free up GPs to manage complex cases or services moved from hospital to primary care is also limited. | |
| 339 | Pharmacy Voice Limited | 3.1 | 15 | | As an alternative to PGDs, commissioners (CCGs and Local Authorities) should assess the need for independent prescribers (probably through the Pharmaceutical Needs Assessments) and facilitate delivery by co-ordinating and funding a training plan through the Local Education and Training Board (Health Education England). | Thank you for your comment. This is outside the scope of this good practice guidance. |
| 340 | Pharmacy Voice Limited | 3.1 | 15 | | The judicious use of PGDs can be used to help commissioners identify elements of the population who need an accessible service, and target locations where that need is greatest eg PGDs supporting contraceptive services. | Thank you for your comment. No response required. |
| 341 | Pharmacy Voice Limited | 3.1 | 15 | | If, as now, the number of community pharmacists trained as independent prescribers remains low, it will be | Thank you for your comment. Details of the process are necessarily for local consideration and determination. |

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| | | | | | difficult for commissioners to find qualified pharmacists in the areas of need. | |
| 342 | Pharmacy Voice Limited | 3.1 | 15 | | Providing additional knowledge and skills for pharmacists to supply via a PGD is quick and relatively simple; distance learning can be used for knowledge components or service familiarisation, though a face to face element may be required for soft skills. | Thank you for your comment. No response required. |
| 343 | Pharmacy Voice Limited | 3.1 | 15 | | A pharmacist must have been on the GPhC register for a minimum of two years before commencing training. This could prove problematic for commissioners, and lead to a reduction in services for patients and the public if independent prescribers were the sole route to supply. | Thank you for your comment. This is outside the scope of this good practice guidance. |
| 344 | Pharmacy Voice Limited | 3.1 | 15 | | An independent prescribing course costs approximately £2000 (without backfill) and represents a significant time commitment. Course duration is variable, but includes a minimum of 90 hours face to face practice under the supervision of a designated medical practitioner and about 400 hours study. Many pharmacists cite the difficulty in find a GP trainer as a barrier to undertaking the course. | Thank you for your comment. This is outside the scope of this good practice guidance. |
| 345 | Pharmacy Voice Limited | 2.1.11 | 22 | | Judicious supply of antibiotics via PGD can not only improve the health of the patient but also reduce risk to the local population e.g. in *Chlamydia* | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best |

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| | | | | | screening, the provision of an appropriate antibiotic following a positive screen via a PGD is justified, improves access and shortens the patient journey. Some NHS areas commission travel health services, in areas of need. Doxycycline is included in some PGDs for prevention of malaria. | clinical practice, such as Public Health England[10] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 346 | Pharmacy Voice Limited | 3.2 | 24 | | We agree that PGDs take considerable development and suggest after approval of the use of a PGD in a particular circumstance, the appropriate PGD should be available on the PGD website so a local PGD development group can use this as the basis for their own PGD. | Thank you for your comment. The GDG agreed that organisations considering adapting an existing PGD should be assured that robust and transparent processes were followed in the development of the original PGD. Any organisation adapting an existing PGD for authorisation and use in their own organisation takes full responsibility and accountability for the content of the PGD. Details of the process are for local consideration and implementation. |
| 347 | Pharmacy Voice Limited | 3.2 | 24 | | Use of an existing PGD will not only save commissioners resource, but will be simpler and safer in operation than may be the case now, where slightly different PGDs can operate in the same location, or where pharmacists working across localities have to use different PGDs for the provision of the same medicine. | Thank you for your comment. The GDG agreed that organisations considering adapting an existing PGD should be assured that robust and transparent processes were followed in the development of the original PGD. Any organisation adapting an existing PGD for authorisation and use in their own organisation takes full responsibility and accountability for the content of the PGD. Details of the process are for local consideration and implementation. |
| 348 | British Medical Association | General | | | We agree that it is important that good practice guidelines are introduced for the development and | Thank you for your comment. The good practice guidance is produced in line with NICE methodology. The GDG are aware of the complexity in this area. The GDG agreed that |

[10] The Health Protection Agency is now part of Public Health England.

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| | | | | | authorisation of patient group directions (PGDs), however we are disappointed in the guidelines proposed. We feel that the recommendations are onerous and complicated, and that this complexity and the desire to cover all possibilities weakens the guidelines | the recommendations reflect good practice. |
| 349 | British Medical Association | General | | | We strongly recommend that general practices are included in the bodies that can develop PGDs, especially given that even private healthcare organisation are now able to do so. | Thank you for your comment. This is included within the guidance. |
| 350 | British Medical Association | 1.6 | 11 | 3 | We would like to make clear that, even further than advice, certain conditions (e.g. erectile dysfunction) require tests and investigation before prescribing, and that these conditions should not be subject to PGDs. Equally, in other conditions, the frequency of prescribing symptomatic treatment (such as short-acting beta agonists for asthma) can suggest the need to progress to more intensive treatment, and again these conditions should be excluded (a view supported by boxes 2, 3 and 4 on page 20 of the consultation). | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 351 | British Medical Association | 3.7 | 52 | | Given our recommendation that general practices are included in the bodies which can develop PGDs, we are concerned about the recommendations for training. Within | Thank you for your comment. The GDG concluded that training and assessment of competency is essential to reduce variation and deliver safe and effective services where PGDs used. The HSC 2000/026 states that 'a senior person in each profession should be designated with the |

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| | | | | | general practice the majority of health care professionals have easy access to advice from senior staff, should this be required. In recent years there has been an increase in attempts to impose unnecessary training on competent practice staff, when it should be the responsibility of GPs to determine the training needs of the staff in their practice. | responsibility to ensure that only fully competent, qualified and trained professionals operate within directions.' |
| 352 | The British Dietetic Association | General | | | The BDA would like to thank you for the opportunity to respond to this consultation. | Thank you for your positive comment supporting the guidance. |
| 353 | The British Dietetic Association | 3 | 19 | 8 | This appears to be contradictory. The recommendation says that PGDs should ideally be for single medications; however it then goes on to say that there could be groups of medications. The recommendation appears to be neither broad nor specific and would therefore be difficult to interpret in practical terms. Our view is that it would be unrealistic and unmanageable to recommend single medications. We would like to suggest that the guideline could specify groups/classes of medications e.g. oral hypoglycaemics (any), Phosphate Binders (any). | Thank you for your comment. The GDG found evidence that more than 1 medicine **could** be included in a PGD. However, the GDG agreed that good practice was likely to be represented by including a single medicine. It recognised that including more than 1 medicine may be appropriate in some circumstances, provided all legal requirements were included for each drug. The GDG concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis. |
| 354 | The British Dietetic Association | 3 | 20 | 8 | Can there be further clarity on terminology used e.g. what they consider to be complex long term conditions. | Thank you for your comment. The relevant text has now been reworded to reflect this comment.<br>The good practice guidance does not aim to provide an exhaustive list of situations which may arise when |

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| | | | | | As an additional option to the list we would like to suggest – situations where the medication is closely related to diet e.g. Phosphate Binders and Pancreatic Enzyme Replacement Therapy (PERT e.g. Creon) | considering medicines to be included in a PGD. |
| 355 | The British Dietetic Association | 3 | 22 | 2.1.12 | Recommendation 2.1.12. We wanted to query why insulin is considered high risk. Would any medication in an inappropriate dose be high risk? Almost all Summary of Product Characteristics (SPCs) have death as a potential outcome of inappropriate dosing, therefore would insulin be more high risk than giving a potassium supplement. | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |
| 356 | The British Dietetic Association | 3 | 22 | 2.1.13 | This recommendation suggests that a PGD should not be used to make dose adjustments when a medicine is in a patient's possession and recommends alternative options be use in Box 4 P20 line 8. However there are no other options available or suggested for key regulated healthcare professionals to access as an alternative. | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |
| 357 | The British Dietetic Association | 3.2 | 24 | 12 | "clinical lead" is referred to in the text. We would like to see further clarity on who are considered to be clinical leaders. | Thank you for your comment. This is for local consideration and determination. |
| 358 | The British Dietetic Association | General | | | There is widespread custom and practice that healthcare professionals (who are legally able to function under PGD's) are using protocols safely and | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |

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| | | | | | effectively, to facilitate dose adjustment for example for patients enrolled on the DAFNE programme – even though there is no legal framework for this. These protocols have been developed using the PGD template with as much, if not more, evidence as required for a PGD. It also requires MDT consultation/working group and established governance arrangements, consistent with requirements for PGD approval. We would strongly recommend that this process for PGD's could be extended to include dose adjustment. For example in dietetic practice, advanced Dietitians dose adjust medication as an integral part of practice (via protocol) i.e. renal dietetics and phosphate binder, Cystic Fibrosis and pancreatic enzyme replacement therapy. This would provide a legal framework for current practice further strengthening safe and effective regulated practice. | |
| 359 | The British Dietetic Association | General | | | The latest diabetes update from Diabetes UK suggests there is now a level 3 qualification on the Qualification Credit Framework, which allows for competence based insulin administration by care workers. We have concerns about how this fits with this guideline. http://aimawards.org.uk/wp- | Thank you for your comment. Administration of medicines should be in accordance with legislation. Legislation does not enable care workers to use PGDs. |

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| | | | | | content/uploads/units/aim_units/Safe%20Administration%20of%20Medication%20and%20Monitoring%20Techniques%20L3%20CV5.pdf | |
| 360 | The British Dietetic Association | General | | | Key to progression of professions and practice in terms of safe effective medicines management, by key healthcare professionals, for the benefit of patients, is the generation of robust evidence. How can this evidence base be generated if this document does not provide national guidance as to best practice in the absence of a legal framework. | Thank you for your comment. Section 1.6 of the good practice guidance details the legal framework governing the use of PGDs. Recommendations have been based on legislation and the best available evidence. |
| 361 | Royal College of Nursing | General | General | | The Royal College of Nursing welcomes proposals to develop this guidance. It is timely. | Thank you for your positive comment supporting the guidance. |
| 362 | Royal College of Nursing | 1.4 | 5 | 1 | Link to HSC Circular broken | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 363 | Royal College of Nursing | 1.5 | 5 | 13 | It reads as though the footer is part of the main body of the text, f | Thank you for your comment. The format was considered by the NICE editorial team. |
| 364 | Royal College of Nursing | 1.6 | 8 | 14 | Link to national PGD website broken | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 365a | Royal College of Nursing | 1.6 | 8 | 22 | Lack of clarity here, implications is that the authorising body authorise PGDs on behalf of their commissioned services. Not clear from this if a CCG authorises PGDs for use in their member practices (they don't actually commission these services) | Thank you for your comment. This has been considered in section 3.4 of the guidance. |
| 365b | Royal College of Nursing | 1.6 | 8 | 22 | Section3.3 Box 5 Scenario 1 implies that CCGs can authorise PGDs for GP | The relevant text on commissioning of services has now been amended to reflect this comment. |

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| | | | | | practices. | |
| 366 | Royal College of Nursing | 1.6 | 9 | 41 | Sentence feels 'wordy' suggest the following instead 'Legislation permits the following registered health care professionals to supply or administer medicines against a patient group direction' | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 367 | Royal College of Nursing | 1.6 | 9 | 48 | 'Nurse' should be replaced with 'registered nurse'<br>Only the title 'registered nurse' is regulated, anyone can use the title 'nurse' | Thank you for your comment. The wording has been amended to reflect this comment. |
| 368 | Royal College of Nursing | 1.6 | 9 | 83 | Can the some of the list of items below be represented in a PGD as hyperlinks to the electronic version of the Green book? If so which ones? | Thank you for your comment. Criteria required for inclusion in PGDs is stated in legislation. |
| 369 | Royal College of Nursing | 1.6 | 10 | 84 | Suggest replacing 'the period during which the direction is to have effect' with 'the commencement and expiry date of the PGD'. There has been confusion in the past around review dates vs expiry dates and currency validity of PGD. | Thank you for your comment. Wording was considered by the NICE editorial team. The wording provided in the guidance is that taken from The Human Medicines Regulations 2012. |
| 370 | Royal College of Nursing | 2 | 12 | all | Not clear if section 3's content will be transposed into section 2. Drafting note not clear | Thank you for your comment. The recommendations included in section 3 (Evidence and recommendations) will also be included in section 2 (Recommendations) on final publication. |
| 371 | Royal College of Nursing | 3 | 13 | 10 | Suggest changing 'training and competency' to 'competence and on-going training' to reflect a continuous cycle of training in terms of PGDs, | Thank you for your comment. Wording was considered by the NICE editorial team. See recommendation 2.7.5. |
| 372 | Royal College of Nursing | 3 | 14 | Figure 1 | Box 1 needs expanding on, consider inserting '**TO PGD OR NOT TO PGD? –** | Thank you for your comment. The guidance is published in electronic format, therefore only a hyperlink to the |

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| | | | | | **That is the question. A guide to choosing the best option for individual situations' document** | summary title used. See NICE style guide. |
| 373 | Royal College of Nursing | 3 | 16 | 13 | 'National PGD website tools' link does not take reader to page | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 374 | Royal College of Nursing | 3.1 | 16 | 14 and 15 | 'To PGD or not to PGD' link is broken | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 375 | Royal College of Nursing | 3.1 | 16 and 17 | 21 to 24 | These sentences feel too loose in terms of good governance perhaps the following wording could be used 'In circumstances when there are insufficient prescribers, the GDG accepted that PGDs may be needed as an interim option while independent prescribing is developed, however this should be in exceptional circumstance only' | Thank you for your comment. The GDG agreed that governance arrangements would need to be in place (see section 3.8) if PGDs may be needed as an interim option while independent prescribing is developed. Section 3.1 clearly states that PGDs should not be seen as a direct substitute for independent prescribing. |
| 376 | Royal College of Nursing | 3.1 | 19 | 102-104 | Acknowledge that a PGD for GSL is not needed but need to add some more detail as to what local arrangements should be. Suggest 'local polices which give robust guidance on supply and administration in terms of conditions patient group and route should be implemented and ratified for use by non-prescribing Health Professional' | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 377 | Royal College of Nursing | 31. | 21 | Recommendation 2.1.3 | Link to PGD website tools broken | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 378 | Royal College of Nursing | 3.2 | 27 | Recommendation 2.2.1 | Suggest adding a recommendation EITHER<br>a) 'Authorising bodies (CCGs, LAs and NHS CB) must ensure if they are to commission | Thank you for your comment. This has been considered in sections 3.3 and 3.4 of the guidance. |

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| | | | | | services that use PGDs they have adequate personal and governance arrangement in place to authorise and / or develop their provider PGDs'.<br>OR<br>b) Any authorising organisation can authorise and / or develop any providers PGD, irrespective of the provider being commissioned directly by that authorising organisation, provided the provider and authorising organisations establish robust governance arrangements between them and follow all best practice guidance in relation to PGD development and authorisation | |
| 379 | Royal College of Nursing | 3.3 | 30 | Box 5 Scenario 1 | Please confirm if this means a CCG can authorise PGDs for use in their member practices | Thank you for your comment. As scenario 1 states in box 6 of the good practice guidance, CCGs can develop and authorise PGDs for use in their member practices. |
| 380 | Royal College of Nursing | 3.3 | 32 | 38 | 'Good practice for commissioning and provider organisations to collaborate when developing PGDs' Does this mean only providers and commissioners who have a direct commissioning /provider relationship work together on a PGD. Need to clarify if GP surgeries are to work with NHS England, to develop and authorise their PGDs or can GP surgeries work | Thank you for your comment. The GDG discussed evidence that the commissioning organisation may, or may not be the organisation that develops the PGD and a number of scenarios may exist (outlined in box 6) where PGDs are developed from collaboration between different organisations.<br><br>NHS England has published some emerging scenarios for nationally commissioned immunisation and vaccination programmes following consultation of the draft guidance. |

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| | | | | | with any authorising organisation? | |
| 381 | Royal College of Nursing | 3.4 | 37 | 42, | link to guidance issued by DGH , does not take you to that page | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 382 | Royal College of Nursing | 3.4 | 38 | 78-79 | The sentence which says 'For example, a lead GP could authorise' can this be changed to 'a competent senior health professional could authorise'. Job title does not assume competence in field specific medicine supply and /or administration | Thank you for your comment. This is only provided as an example and a GP would be an appropriate person to undertake this role. |
| 383 | Royal College of Nursing | 3.6 | 48 | 5-6 | Are commissioners responsible for all their providers PGDs? Same issue as before in terms of providers commissioned directly or any commissioner and any provider | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 384 | Royal College of Nursing | 3.7 | 52 | 4 | PGD website link broken | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 385 | Royal College of Nursing | 3.8 | 60 | Recommendation 2.8.5 | Can the words 'including regular audit' be added to this recommendation | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 386 | Primary and Community Care Pharmacy Network (PCCPN) | 1.4 | 5 | 4 | Link to circular no longer valid | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 387 | Primary and Community Care Pharmacy Network (PCCPN) | 1.4 | 5 | 8 | The guidance should make it clear that the PGD is a legal document rather than just by implying this | Thank you for your comment. The GDG agreed that 'legal framework' was appropriate terminology. |
| 388 | Primary and Community Care Pharmacy Network (PCCPN) | 1.5 | 6 | 8-16 | As currently written it is not clear that a patient specific direction written by a prescriber is also prescribing but not on a prescription. The person writing the patient specific direction still has responsibility for clinical assessment | Thank you for your comment. Patient Specific Directions are outside the scope of this good practice guidance. There is a hyperlink for further information from the MHRA about this topic in the guidance. |

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| | | | | | etc.<br>Section could be slightly expanded. | |
| 389 | Primary and Community Care Pharmacy Network (PCCPN) | 1.6 | 7 | 26-27 | Link to circular now no longer valid | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 390 | Primary and Community Care Pharmacy Network (PCCPN) | 1.6 | 8 | 23 | Should now read NHS England? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 391 | Primary and Community Care Pharmacy Network (PCCPN) | 1.6 | 11 | 17 | Should this read “arrangements for referral for medical or dental advice”? Dentist can sign a PGD and for some PGDs a dental referral would be more appropriate. | Thank you for your comment. The wording provided in the guidance is taken from legislation. |
| 392 | Primary and Community Care Pharmacy Network (PCCPN) | 3.1 | 15 | 3 | There is an emphasis on commissioners and providers.<br>This division is not apparently applicable to NHS trusts using PGDs. | Thank you for your comment. Unfortunately, the point of this comment is not clear. NHS trusts are provider organisations and are listed in the legislation as an authorising body. The commissioners for NHS trusts are clinical commissioning groups or NHS England. |
| 393 | Primary and Community Care Pharmacy Network (PCCPN) | 3.1 | 17 | 17 | Link no longer valid | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 394 | Primary and Community Care Pharmacy Network (PCCPN) | 3.1 | 18 | 5 | Off label use in exceptional circumstances.<br>This could mean either exceptional in the big scheme of medicines and PGDs or exceptional in relation to a specific PGD.<br>For some PGDs every use would be off label and therefore not exceptional | Thank you for your comment. The relevant text has now been amended to reflect this comment to provide clarity. |

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| | | | | | This should be clarified further | |
| 395 | Primary and Community Care Pharmacy Network (PCCPN) | 3.1 | 19 | 16 | Use of PGD for supply of P medicines which is appropriate for urgent and immediate supply when the patient does not have access to a registered pharmacy. This is not clear from document.<br><br>Most Trust's will have developed protocols for the administration or supply of GSL medicines for urgent immediate use. This could be mentioned as a good practice point. | Thank you for your comment. The GDG agreed that local policies would be more appropriate when a PGD is not necessary, with the employing organisation retaining legal responsibility for the actions of its employees. See 'To PGD or not to PGD' for further information. |
| 396 | Primary and Community Care Pharmacy Network (PCCPN) | 3.1 | 20 | 8 Box 4 | 3rd bullet point an antimicrobial is needed Clarify that a PGD (rather than this )may be appropriate in some circumstances, such as chlamydia treatment in a sexual health clinic However see also comment below re recommendation 2.1.11 | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[11] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 397 | Primary and Community Care Pharmacy | 3.1 | 22 | Recommendation 2.1.11 | Antibiotic PGDs to be used in exceptional circumstances.<br>If the PGD has a microbiologist | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when: |

[11] The Health Protection Agency is now part of Public Health England.

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| | Network (PCCPN) | | | | involved in the development or follow local antimicrobial guidelines then the PGD will be following guidelines. The statement would affect the working of, for example, walk in centres , specialist sexual health clinics, urgent treatment centre, minor injury unites etc. | • clinically essential and clearly justified by best clinical practice, such as Public Health England[12] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 398 | Primary and Community Care Pharmacy Network (PCCPN) | 3.2 | 25 | 20 | The use of appeals process appears to add another layer of bureaucracy to an already cumbersome process. If the submission process is robust would it be needed? In practice this may be onerous. | Thank you for your comment. GDG agreed that an appeals process for decisions made by a medicines decision-making group reflects good practice. |
| 399 | Primary and Community Care Pharmacy Network (PCCPN) | 3.2 | 25 | 2 | Seeking stakeholder engagement from patients and the public seems rather impractical and probably unlikely to happen in practice<br>Seeking stakeholder view from commissioning may also not be practical unless it is being used to build the PGD into clinical pathways or service specification | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 400 | Primary and Community Care Pharmacy Network (PCCPN) | 3.2 | 28 | 6 | Recommendation 2.2.4. Bullet point 8 (line 6): There is an assumption all areas have all encompassing formularies. Although recommended in practice do formularies exist | Thank you for your comment. The NHS standard contract requires all providers of NHS services to comply with NICE technology appraisals and to publish their local formularies. NICE issued good practice guidance on Developing and updating local formularies in December |

[12] The Health Protection Agency is now part of Public Health England.

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| | | | | | everywhere and do they contain this level of detail? | 2012. |
| 401 | Primary and Community Care Pharmacy Network (PCCPN) | 3.3 | 31 | 10-14 | In some organisations the PGD working group will not be those signing off the PGD for the organisation as recommended in section 3.3. It may be better to have the people with the correct expertise develop and the assurance provided to the authorisers. Suggest removing ideally those signing the PGD. Also suggest that reference is made to what is legally required. | Thank you for your comment. The relevant wording has been amended to reflect this comment. |
| 402 | Primary and Community Care Pharmacy Network (PCCPN) | 3.3 | 31 | 15-16 | For some trusts/organisations an agreement from a specialist in microbiology will be sought but often that is the extent of it – not formally part of the work group and not signing the PGDs. Would it be possible to amend the text so that input from for example an antimicrobial pharmacist would be acceptable? Also PGDs for antimicrobials should be in line with local formulary. These PGDs are often used in urgent treatment centres and minor injury units. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[13] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 403 | Primary and Community Care Pharmacy Network (PCCPN) | 3.3 | 32 | 30 | Following SPC is not applicable for example when following JCVI advice for immunisations. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

[13] The Health Protection Agency is now part of Public Health England.

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| 404 | Primary and Community Care Pharmacy Network (PCCPN) | 3.3 | 33 | 1-2 | Unclear why a literature search is required to assess relevance and validity? | Thank you for your comment. The GDG discussed and agreed that the process for developing a PGD should include conducting an appropriate literature search as good practice. The evidence identified should then be evaluated to assess its relevance and validity. |
| 405 | Primary and Community Care Pharmacy Network (PCCPN) | 3.4 | 37 | 3-7 | Change this to "In some organisation this person is often a member…."<br>There are NHS organisation where the senior clinical governance lead is a director who may not be part of any medicines related decision group but be responsible for the overall (clinical) governance of the organisation/NHS Trust. | Thank you for your comment. This is for local consideration and determination. |
| 406 | Primary and Community Care Pharmacy Network (PCCPN) | 3.5 | 46 | 2.5.5 | When medicines are supplied by PGD a PIL is a requirement.<br>In practice following administration is this really achievable? | Thank you for your comment. The GDG agreed this represents good practice. |
| 407 | Primary and Community Care Pharmacy Network (PCCPN) | 3.6 | 48 | 17 | Link no longer valid | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 408 | Primary and Community Care Pharmacy Network (PCCPN) | 3.7 | 52 | 10 | Link no longer valid | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 409 | Primary and Community Care Pharmacy Network (PCCPN) | 3.7 | 53 | 30 | Is clinical knowledge a professional standard? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 410 | Primary and Community Care | 3.7 | 55 | Box 7 | "Pharmacist signing a PGD: Experience of working in the clinical speciality or | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |

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| | Pharmacy Network (PCCPN) | | | | service where the PGD is to be used". This may be difficult to achieve for some PGDs as some services using PGDs do not have direct pharmacist input. In practice the senior pharmacist may cover a large clinical area within an organisation e.g., family planning, minor injury units and vaccines used by school nurses. For example, this could make it difficult for pharmacists working for CCGs to sign PGDs. | |
| 411 | Primary and Community Care Pharmacy Network (PCCPN) | 3.7 | 56 | 1 -2 | Recommendation 2.7.6. This implies that there should be training delivered and a 'test' set post-training to ensure competency. Suggest rewording to reflect what is said in main text. | Thank you for your comment. The GDG discussed the evidence and agreed that appropriate training, regular re-training and assessment of competency was needed for all people involved with PGDs, particularly if and when their roles and responsibilities change. |
| 412 | Primary and Community Care Pharmacy Network (PCCPN) | 3.8 | 58 | 19 | Link no longer valid | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 413 | Primary and Community Care Pharmacy Network (PCCPN) | Appendix A | 67 | 10 | Link no longer valid | Thank you for your comment. The hyperlink has now been amended to reflect this comment. |
| 414a | Primary and Community Care Pharmacy Network (PCCPN) | General | | | The process being proposed appears to be very bureaucratic and prescriptive. Whilst we don't want to see PGDs being used without good governance in place the proposals are very controlling and don't allow for the necessary flexibility. NICE should be recommending that robust governance | Thank you for your comment. The purpose of the good practice guidance was to set out key principles. The GDG agreed the recommendations reflect good practice. In many cases a recommendation could not explicitly state which individual person or organisation was responsible for implementing the recommendation. Arrangements will vary depending on how services are commissioned and provided and what resources are available. The GDG |

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| | | | | | arrangements are in place, understood, followed and monitored. What these arrangements are should be up to the organisation. There is concern that because NICE recommends organisations will be expected to do, as with other NICE recommendations.<br>For example<br>• Some organisations may not have an approval group but it would be for the chief or senior pharmacist for the appropriate directorate to decide.<br>• Due to practical problems e.g. person responsible for reviewing a PGD off on long term sick it may be necessary to extend a PGD beyond its expiry date – this should be possible with local agreement<br>• Already PGD process in some places is overly time consuming and cumbersome and the process takes months due to fixed meeting dates of the various committees needed to approve the different stages. Organisations should have the flexibility to be able to make their processes more responsive. | agreed that a responsible individual person or organisation could be identified and this is clear within the recommendation. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 414b | Primary and Community Care Pharmacy Network (PCCPN) | General | | | **Private sector**<br>We would like to see mention of individual / small groups of healthcare professionals e.g. nurses who are | Thank you for your comment. Private practice is outside of the scope of the guidance. The good practice guidance states that a range of organisations and services can currently use PGDs to provide **NHS-funded care.** The lists |

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| | | | | | employed in the private sector doing NHS work such as vaccines in boarding schools. At present seems to assume private sector will have a contract to provide major health services e.g. acute care, hospice<br>Some more specific examples would help especially in relation to Social Enterprises or Community Interest Companies.<br>The use of language with regard to the private sector developing their own PGDs for NHS patients less than clear. One of the reasons for some of the confusions is that CQC and medicines act do not share common vocabulary.<br><br>Also further examples where e.g., where three different providers have been commissioned to deliver a service in partnership (e.g., acute trust, community trust and a private provider). | and examples provided are not intended to be exhaustive. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 414c | Primary and Community Care Pharmacy Network (PCCPN) | General | | | **Audit**<br>There is little mention of Audit and there should be both audit of the PGD processes and audit of the use of the PGDs to ensure robust practice. Audits are part of a robust governance framework. Perhaps some examples of audit tools might be useful. | Thank you for your comment. Section 3.8 of the good practice guidance highlights the importance of monitoring and evaluation of PGDs. |
| 415 | Oxleas NHS | 3.1 | 20 | 33 | There may be some situations (when | Thank you for your comment. The GDG discussed this |

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| | Foundation Trust | | | | the diagnosis is not in doubt) when prompt initiation of antimicrobials under PGD would be advantageous, with the benefits of initiating antimicrobials outweighing any potential risks to the patient waiting to consult a prescriber.<br><br>We wonder if more clarity can be given to the use of antimicrobials in PGDs as there appears to be a contradiction in the existing statements. The advice in box 4, p.20, <clinical conditions when *alternative options* to PGDs should be used> list antimicrobials. However, recommendation 2.1.11, p.22 states <consider including an antimicrobial in a PGD only in exceptional circumstances. Ensure that its use is clinically essential and will not jeopardise local and national strategies to combat antimicrobial resistance>, implying that antimicrobials may be used.<br><br>We wonder if listing antimicrobials within box 3, p.20, <examples of clinical situations when PGDs need to be *considered carefully*> would be more consistent with recommendation | issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[14] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |

[14] The Health Protection Agency is now part of Public Health England.

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| | | | | | 2.1.11 and the comment on p.18 (3rd bullet point). | |
| 416 | Oxleas NHS Foundation Trust | 3.7 | 53 | 26 | Box 6 implies that *all* those involved with PGDs require <knowledge, skills, and expertise> in the below:<br>• Information technology—we think this is dependent on local systems and how practitioners access PGDs and the supporting information, so not always relevant to all<br>• Records management, including version control—again, dependent on local processes; in particular version control may be needed by those authoring PGDs but not necessarily for those working under them<br><br>And thus that these skills are required by those working *under* PGD as well as those authoring PGDs—we wonder if this is necessary. It may be clearer to simply state that this knowledge is only required by those writing or preparing PGDs. | Thank you for your comment. The GDG considered the evidence and agreed that for any person involved with PGDs will need the knowledge, skills and expertise in the specific areas listed in box 7 of the good practice guidance. |

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| 417a | Oxleas NHS Foundation Trust | 3.7 | 55 | 7, 9, 13, 17, 21 | p. 55, box 7, the knowledge, skills and expertise of those involved in specific PGD roles:<br><br>**People working in the PGD working group**—we wonder why all members of a PGD working group need to have 'knowledge, skills, and expertise' in <medicines management systems, such as safe storage, packing and labelling> when a member of the team must include a pharmacist, who could be considered the expert in this area. Depending on the definition of 'knowledge, skills, and expertise', it may be impractical for all the different professions who make up the group to meet this requirement; having at least one member of the group that has the knowledge and skills needed should be sufficient. | Thank you for your comment. The GDG agreed this reflects good practice. |
| 417b | Oxleas NHS Foundation Trust | 3.7 | 55 | 7, 9, 13, 17, 21 | Box 7 also states that both the **Doctor (or dentist)** and **Pharmacist** members need to have:<br>• Relevant specialist clinical and pharmaceutical knowledge, including national guidance and policy<br>• Experience of working in the clinical speciality or service where the PGD is to be used<br>Again, it is felt that it may be impractical to expect both of these | Thank you for your comment. The GDG agreed this reflects good practice and is for local consideration and determination. |

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| | | | | | roles to meet this criteria; locally it is expected that a professional lead from each of the services that will use the PGD will also co-author the document to contribute the specialist knowledge needed and have the experience of working in the speciality to guide on practical issues. We do not feel that having more than one author with specialist knowledge is necessary, particularly for medicines used within the terms of their product licence. | |
| 417c | Oxleas NHS Foundation Trust | 3.7 | 55 | 7, 9, 13, 17, 21 | In summary, we would suggest that box 7 is revised to list the core knowledge and skills that is expected within the PGD working group instead of specifying them in particular roles. Therefore, providing the *group* has all the necessary skills they can then proceed in the development of the PGD in the knowledge that they have the expertise between them, namely:<br>• Knowledge of PGD legal framework<br>• Relevant clinical knowledge<br>• Relevant pharmaceutical knowledge<br>• Knowledge of the service | Thank you for your comment. The GDG discussed and concluded that the authorising body should have clear governance arrangements in place to ensure that people in the PGD working group have the necessary knowledge, skills and expertise to develop PGDs The relevant text has been amended to reflect this comment. |
| 418 | Oxleas NHS Foundation Trust | 3.3 | 31 | 14, 16 , 17 | There is ambiguity in the term 'signing off' which suggests authorisation, and 'signing' as in writing your name to denote authorship. We suggest that the members that have written the | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | | | | | PGD should 'sign' the direction, rather than 'sign off' the direction, which would be the action of the person authorising the PGD on behalf of the organisation. This would then be consistent with terminology used in recommendation 2.3.1, p.34 | |
| 419 | Oxleas NHS Foundation Trust | 3 | 14 | Figure 1 | Box 5 <Establish PGD working group><br>Box 7 <Authorisation by doctor (or dentist), pharmacist and other professional group representative><br><br>HSC 2000/026 states that legislation requires that the patient group direction *must* be signed by a doctor (or dentist) and pharmacist both of whom *should* have been involved in developing the direction. Box 7 as it stands does not indicate that the doctor (or dentist) and pharmacist has taken part in the development of the direction, unless 'authorisation' has been taken to mean writing, in which case 'authoring' may be more appropriate.<br>To remove the ambiguity, we would suggest that box 5 should read 'Establish a PGD working group which includes a doctor (or dentist), pharmacist, and other professional group representatives'; box 7 should read 'The doctor (or dentist), pharmacist, and other professional | Thank you for your comment. The flowchart is intended to summarise the PGD process clearly and concisely, and does not consider the entirety of local arrangements. Some of these may vary in different organisations. The relevant text in section 3.3 has now been amended to include reference to HSC to reflect this comment. |

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| | | | | | group representatives who have authored the PGD will sign the finished direction'.<br><br>The above should also be clarified in section 3.3 p.31. | |
| 420 | Oxleas NHS Foundation Trust | 3.4 | 37 | 16 | There is ambiguity over the term 'electronic signatures'. Signatures need to be visible on the completed PGD. Electronic signatures obtained when a user logs onto an IT system, and may not be visible on the final document, would not be suitable. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 421 | Oxleas NHS Foundation Trust | 3.5 | 44 | Bullet point 5 | In contrast to the comment above, the need for a 'signature' is not necessary when a clinical IT system is used to record the supply or administration of medicine under PGD; the user who has issued the medicine will be recorded securely on the system, but not necessarily as their actual 'signature'. | Thank you for your comment. Electronic signatures can be used when signing a PGD, providing guidance issued by the Department of Health is followed. Governance processes would be for local consideration and determination. |
| 422 | Somerset Clinical Commissioning Group | General | | | GPG repeatedly refer to 'the legislation' or to 'guidance' without being specific making identification and verification of GPG statements difficult. Recommend that proper references are included to make document robust. | Thank you for your comment. Hyperlinks to the relevant legislation are provided, in line with NICE style for an electronic document. |
| 423 | Somerset Clinical Commissioning Group | General | | | The draft guidance appears to be predominantly weighted towards secondary care development and use. Practical implications of implementing the recommendations in a primary | Thank you for your comment. This has been written to provide guidance on the principles for all who are involved with PGDs, including commissioners and providers, who provide NHS-commissioned services. Many non-secondary care scenarios are included within |

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| | | | | | care environment, especially in light of the recent NHS reforms, appear not have been considered fully. | the guidance. |
| 424 | Somerset Clinical Commissioning Group | General | | | The GDG refer to 'original intention' of PGDs (page 18) with respect to some aspects of PGD use, however, there is no systematic examination of all of the 'original intentions' and whether these intentions are still valid, and if not the evidence and thinking behind why the original intentions need to be superseded. Some of the GDG recommendations may considered to be at odds with some of what may be considered by some to be the original intentions of PGDs e.g. a framework for rapid response to legally supply of medicines without the need for a PSD; the authorisation process proposed (Section 3.4), although robust, will in some circumstances prevent rapid responses to emerging issues in healthcare through the bureaucratic process required to adhere to the proposed recommendations. | Thank you for your comment. The GDG agreed that the 'original intention' of PGDs did not include medicines needing frequent dosage adjustments, or frequent or complex monitoring. The GDG supported the original intention and agreed that the risks of using these medicines in a PGD outweighed the benefits and alternative options should be used. |
| 425 | Somerset Clinical Commissioning Group | 1.5 | 6 | 15 | PSDs are written instruction for a specific patient in medical and non-medical prescribing in both independent and supplementary activities. PSDs are not an exclusive activity to independent prescribers as implied. Please refer to the MHRA FAQ on PSDs: | Thank you for your comment. The relevant text has now been reworded to reflect this comment and a hyperlink to the MHRA guidance added. |

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| | | | | | http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/Frequentlyraisedissues/PatientSpecificDirections/index.htm | |
| 426 | Somerset Clinical Commissioning Group | 1.5 | 6 | 19 | Other groups may also requisition drugs by means of a signed order e.g. masters of ships | Thank you for your comment. The relevant text has now been amended to reflect this comment. A full list of exemptions is included in The Human Medicines Regulations 2012. See section 1.5. |
| 427 | Somerset Clinical Commissioning Group | 3.1 | 18 | 20 | Prescribing and PSD are essentially the same activity. | Thank you for your comment. No response required. |
| 428 | Somerset Clinical Commissioning Group | 3.1 | 18 | 24 | Evidence of the 'original intention' assertion should be presented or referenced accurately. | Thank you for your comment. This was discussed and agreed by the GDG. |
| 429 | Somerset Clinical Commissioning Group | 3.1 | 18 | 25 | There may be circumstances where it is appropriate for complex medicines to be supplied or administered under a PGD. Relevant competencies of practitioners using the PGD would have to be assured. | Thank you for your comment. The GDG discussed settings using a small number of medicines and agreed that this does not exclude prescribing as an option for supplying and/or administering medicines (particularly when medicines are considered to be 'higher risk'). The GDG felt that prescribing would be a more appropriate option. See section 3.1. If drugs in a PGD are used infrequently, a PGD is not the most appropriate method of medicines supply. See sections 2.6 and 3.6. Details of the process are for local consideration and determination. |
| 430 | Somerset Clinical Commissioning Group | 3.1 | 19 | 9 | Clarification of GDG definition of a 'single medicine' is needed. Single medicine could mean a single drug but in multiple forms e.g. pessary and cream | Thank you for your comment. The relevant text has been reworded to reflect this comment.<br>The GDG found evidence that more than 1 medicine **could** be included in a PGD. However, the GDG agreed that good practice was likely to be represented by including a single medicine. It recognised that including more than 1 medicine may be appropriate in some circumstances, provided all legal requirements were included for each |

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| | | | | | | drug. The GDG concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis. |
| 431 | Somerset Clinical Commissioning Group | 3.1 | 19 | 11 | Where evidence supports the use of multiple medicines to treat a single condition it could be considered more appropriate to have one PGD for all the medicines required to treat the condition. | Thank you for your comment. The GDG concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis. |
| 432 | Somerset Clinical Commissioning Group | 3.1 | 19 | 15 | Differences between the marketing authorisation between medicines marketed under different legal categories (POM, P and GSL) exist and need to be highlighted. Such differences may necessitate a PGD for an off-label use of a P or GSL medicine. Financial consequences to the NHS of using P or GSL versions of a POM medicine also need to be considered. | Thank you for your comment. Definitions of 'prescription-only medicine', 'pharmacy medicine' and 'general sales list' are included in the glossary of the guidance.<br>The decision to develop a PGD should be based on clinical reasons rather than finance and this is reflected in the recommendations. |
| 433 | Somerset Clinical Commissioning Group | 3.1 | 20 | 19 | Self-administration injections are becoming more common and manufacturers have addressed many of the issues that may previously have affected self-administration of parenteral medicines. | Thank you for your comment. No response required. |
| 434 | Somerset Clinical Commissioning Group | 3.1 | 20 | 23 | Evidence and best practice supports the treatment of a range of conditions with multiple medicines or forms of a medicine. | Thank you for your comment. Unfortunately, the point of this comment is not clear. |
| 435 | Somerset Clinical Commissioning Group | 3.1 | 20 | 31 | Suggest replace "used" with "considered more appropriate" | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 436 | Somerset Clinical | 3.1 | 20 | 32 | Second bullet point: this is the role of | Thank you for your comment. The relevant text has now |

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| | Commissioning Group | | | | the PGD exclusion criteria | been amended to reflect this comment. |
| 437 | Somerset Clinical Commissioning Group | 3.1 | 20 | 34 | We disagree: it may be appropriate if in full consultation with prescribing committees and local microbiology service and infection control. Role of inclusion and exclusion criteria to mediate antimicrobial stewardship - PGD criteria can also mandate that supplies are notified to other relevant clinicians involved in the patients care. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[15] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 438 | Somerset Clinical Commissioning Group | 3.1 | 21 | 12 | Differences between the marketing authorisation between medicines marketed under different legal categories (POM, P and GSL) exist and need to be highlighted. Such differences may necessitate a PGD for an off-label use of a P or GSL medicine. Financial consequences to the NHS of using P or GSL versions of a POM medicine also need to be considered. | Thank you for your comment. Definitions of 'prescription-only medicine', 'pharmacy medicine' and 'general sales list' are included in the glossary of the guidance.<br>The decision to develop a PGD should be based on clinical reasons rather than finance. |
| 439 | Somerset Clinical Commissioning Group | 3.1 | 21 | 22 | Recommendation implies that PGDs can only be used for the provision of services for the provision of NHS provided care. A number of PGDs are currently in use for private services | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. The relevant text has now been amended to reflect this |

[15] The Health Protection Agency is now part of Public Health England.

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| | | | | | that are outside the NHS. Clarification of the legal basis of this statement is needed. Recommendation 2.1.6 appears to be contradicted by the definition of activities allowed by Independent medical agencies in Appendix A (page 65). | comment. |
| 440 | Somerset Clinical Commissioning Group | 3.1 | 21 | 28 | Guidance from the GDG on the definition or meaning of "exceptional" would be useful. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 441 | Somerset Clinical Commissioning Group | 3.3 | 31 | 13 | Guidance from the GDG on the definition of "lead author" and their role in the PGDs development would be useful. | Thank you for your comment. The roles and responsibilities of each person and how they work together to develop the PGD should be determined locally and clearly defined. |
| 442 | Somerset Clinical Commissioning Group | 3.3 | 31 | 17 | The only professional groups that must sign-off a PGD to fulfil legal criteria are a doctor or dentist *and* a pharmacist. Other professional groups are not required; however, it could be considered best practice to include evidence of professional leadership from a member of that professional group to by whom the PGD will be used to encourage engagement within that group as to the validity of the PGD. | Thank you for your comment. This has been considered in section 3.4 of the guidance. |
| 443 | Somerset Clinical Commissioning Group | 3.3 | 31 | 20 | PGD use in primary care where multiple independent contractors may be providing a service would make it impossible to include all persons responsible for training and competencies of the professionals using the PGDs. | Thank you for your comment. It is the responsibility of the provider to ensure staff using PGDs are trained and competent to use them. |

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| 444 | Somerset Clinical Commissioning Group | 3.4 | 35 | 2 | Evidence to support the assertion "that the legislation requires" should be presented or referenced accurately; especially with reference to employing organisations are responsible for authorisation of employed healthcare professionals. | Thank you for your comment. Hyperlinks to the relevant legislation are provided, in line with NICE style for an electronic document. |
| 445 | Somerset Clinical Commissioning Group | 3.4 | 35 | 21 | Any individual or organisation can develop a PGD, however, only certain organisations can authorise a PGD. Clarification of the differences is required. | Thank you for your comment. This has been considered in section 3.3 of the guidance. The scenarios in box 6 clarify this. |
| 446 | Somerset Clinical Commissioning Group | 3.4 | 37 | 16 | Accurate referencing to the guidance referred to is required: the link is not specific enough to enable readers to locate the guidance on electronic signatures. | Thank you for your comment. A hyperlink has been added for clarity. |
| 447 | Somerset Clinical Commissioning Group | 3.4 | 40 | 10 | It would be useful if the GDG gave guidance on the responsibilities and accountabilities of the authorising signatories to the authorising body. | Thank you for your comment. This has been considered in section 3.4 of the guidance. |
| 448 | Somerset Clinical Commissioning Group | 3.4 | 41 | 7 | A reference to when the authorising body is not the employing organisation of the employing organisation should be included. Guidance on the governance arrangements in such situations would also be useful. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 449 | Somerset Clinical Commissioning Group | 3.5 | 43 | 10 | Evidence to support the assertion packs of medicines should not be broken down into smaller units should be presented or referenced accurately. Community Pharmacies can split packs for dispensing against prescriptions, | Thank you for your comment. The GDG reviewed the evidence and noted that legislation does not cover splitting of packs by community pharmacists when supplying medicines under a PGD. |

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| | | | | | however, whether the legislation allows splitting of packs for supply under PGDs or not needs to be clarified in the GDG guidance. | |
| 450 | Somerset Clinical Commissioning Group | 3.5 | 46 | 7 | See previous comment regarding of splitting of packs by registered community pharmacies. | Thank you for your comment. Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGDs. The MHRA can provide further information on labelling requirements. |
| 451 | Somerset Clinical Commissioning Group | 3.6 | 50 | 12 | We would consider that a literature search is only required if other authoritative guidance (e.g. NICE guidance) is lacking or out of date. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 452 | Somerset Clinical Commissioning Group | 3.7 | 52 | 25 | See previous comments relating to differences between 'prescribing' and 'PSDs' | Thank you for your comment. No response required. |
| 453 | Somerset Clinical Commissioning Group | 3.7 | 55 | 14 | Re: 'clinical speciality' experience; May require authoring doctor to be different for different PGDs covering different specialities. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 454 | Somerset Clinical Commissioning Group | 3.7 | 55 | 22 | Re: 'clinical speciality' experience; may require authoring pharmacist to be different for different PGDs covering different specialities and may exclude any pharmacist from signing off some PGDs for specialties where pharmacist would only dispense the medicines and have may have no other experience of the service or speciality. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 455 | Somerset Clinical Commissioning Group | 3.7 | 55 | 28 | The only professional groups that must sign-off a PGD to fulfil legal criteria are a doctor or dentist *and* a pharmacist. Other professional groups are not required; however, it could be | Thank you for your comment. This has been considered in section 3.4 of the guidance. |

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| | | | | | considered best practice to include evidence of professional leadership from a member of that professional group to by whom the PGD will be used to encourage engagement within that group as to the validity of the PGD. | |
| 456 | Somerset Clinical Commissioning Group | 3.7 | 55 | 32 | Local medicines decision –making groups are small committees and seek representation from a range of specialities but this may not be comprehensive. Therefore, this condition may be mutual exclusive of the previous point requiring a "specialist practitioner in the clinical speciality" | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 457 | Somerset Clinical Commissioning Group | 3.7 | 55 | 41 | PGD use in primary care where multiple independent contractors may be providing a service would make it impossible to include all persons responsible for training and competencies of the professionals using the PGDs. | Thank you for your comment. This has been considered in section 3.4 of the guidance. Details of training and assessment of competency is for local consideration and determination. |
| 458 | Somerset Clinical Commissioning Group | 3.8 | 60 | 8 | Clarification of who has to comply with the CQC standards is needed. | Thank you for your comment. The GDG agreed that in many cases a recommendation could not explicitly state which individual person or organisation was responsible for implementing the recommendation. Arrangements will vary depending on how services are commissioned and provided and what resources are available. When the GDG agreed that a responsible individual person or organisation could be identified, this is clear within the recommendation. Implementation of the recommendations is for local consideration and |

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| | | | | | | determination and outside the scope of this guidance. |
| 459 | Somerset Clinical Commissioning Group | 3.8 | 60 | 27 | The requirement for maintaining a record of the signatures of members of the PGD working group is not needed and irrelevant. Minutes or other records of actual or virtual meetings of the PGD working group would suffice. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 460 | Somerset Clinical Commissioning Group | Appendix A | 65 | 11 | GDG should clarify the differences between dispensing and supply for the purpose of the guidance although it is recognised that there no legal distinction there is a distinction in practical terms. | Thank you for your comment. The relevant text has now been removed to reflect this comment. |
| 461 | Somerset Clinical Commissioning Group | Appendix A | 65 | 16 | Definition needs clarification | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 462 | Somerset Clinical Commissioning Group | Appendix A | 65 | 17 | An accurate reference to corroborate the assertion that legislation allows IMAs to develop and authorise PGDS. | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 463 | Somerset Clinical Commissioning Group | Appendix A | 65 | 19 | Definition contradicts Recommendation 2.1.6 (page 21) which appears to state that PGDs can only be used for NHS services. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 464 | Somerset Clinical Commissioning Group | Appendix A | 67 | 14 | Incorrect statement: All medical and non-medical prescribers can issue PSDs (e.g. independent *and* supplementary prescribers) | Thank you for your comment. Supplementary prescribers can issue PSDs in the secondary care setting, as set out in legislation, provided this is under an agreed patient-specific clinical management plan Writing a PSD is a form of prescribing. |
| 465 | Somerset Clinical Commissioning | Appendix A | 68 | 5 | Prescribing is not limited to medicines and may include appliances, medical | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | Group | | | | devices, activities and counselling etc. | |
| 466 | Somerset Clinical Commissioning Group | Appendix A | 68 | 6 | Recommend deletion of 'usually but not necessarily a POM' – reference to medicine would be sufficient. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 467 | Somerset Clinical Commissioning Group | Appendix A | 69 | 7 | Recommend that administration and dispensing are both forms of supply is included. | Thank you for your comment. Administration is not a form of supply. |
| 468 | NHS England | General | | | The document is very repetitive and is quite confusing to read particularly for audiences less familiar with PGDs. Assume the constant reference to the GDG understood this, or reviewed this information, etc. throughout the document will be removed. Should be sufficient to put a couple of pages at the front or back saying what process the GDG used to arrive at this guidance, as they have on page 62. By removing the constant references to what the GDG did you could reduce the document by 30%. | Thank you for your comment. NICE style and formatting on the NICE website will be different when published. |
| 469 | NHS England | General | | | NHS Commissioning board should say NHS England. | Thank you for your comment. Text has been added to reflect this. |
| 470 | NHS England | 1.5 | 6 | 5 | There should be reference to where supply of medicines from mass prophylaxis distribution centres fits in with this guidance | Thank you for your comment. This is covered within the guidance (reference to pandemic disease). The guidance doesn't cover systems and process used during periods of pandemic disease, but links are provided for further information. |
| 471 | NHS England | 1.6 | 10 | 23 | Information to be included in a PGD. This section merely lists what the legislation sets out as the requirements for information to be included. However in best practice | Thank you for your comment.<br>Section 1.5 includes information to be included in a PGD (as set out in legislation). Any additional details to be included in a PGD are for local determination and implementation. |

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| | | | | | guidance, we think this section could be expanded and cover the following:-<br>- Instances where additional information may be included (or recommendation that organisations should limit the information solely to the legal requirements).<br>- This is important, because many PGDs do contain significant amounts of other information – e.g. training and competency requirements.<br>- The tendency of some organisations to include non-clinical reasons for excluding patients;<br>The tendency for some PGDs to include "cautions" when it is unlikely to be practicable for the person using the PGD to be able to access the information to make a decision. This is particularly common in PGDs for community pharmacists, where it is virtually impossible to make a decision on a caution without access to the patient's notes. An example of this was for seasonal flu vaccination and patients with degenerative diseases of the CNS. Many PGDs have included this group with the caution that their condition needed to be reviewed on a case by case basis. It would be rare | Considering the need for a PGD includes clinical situations in which PGDs may be appropriate. The GDG agreed that where uncertainty remains about the differential diagnosis, particularly when further investigations or diagnostic tests are needed, for example erectile dysfunction that alternatives to PGDs should be used. See section 3.1. This section has been reworded following this discussion by the GDG. |

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| | | | | | that a community pharmacist could do that | |
| 472 | NHS England | 1.6 | 11 | 27 | Standard prescription charge rules, this section is different from the guidance received for the setting up and running a mass antibiotic collection centre. There is no prescription charge mentioned in the MADC guidance. Should there be some specific reference to MADC or other Mass Prophylaxis Distribution Centres and how this differs from PGDs | Thank you for your comment. This is covered within the guidance (reference to pandemic disease). See section 1.5. |
| 473 | NHS England | 3.1 | 18 | 12 | Caution on antibiotics on PGDs. We are aware that some PGDs for minor ailments include antibiotics. We welcome the strong wording on this page, which needs to be drawn to the attention of those organisations commissioning Minor Ailment Schemes that use PGDs for antimicrobials. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[16] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 474 | NHS England | 3.1 | 19 | 8 | Relating to the inclusion of more than 1 medicine within a PGD. We are concerned that in such a scenario, where cautions or exclusions relate to | Thank you for your comment. The GDG found evidence that more than 1 medicine **could** be included in a PGD. However, the GDG agreed that good practice was likely to be represented by including a single medicine. It |

[16] The Health Protection Agency is now part of Public Health England.

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| | | | | | 1 medicine in a PGD but not the other(s) that this could lead to confusion. Further guidance should be given about the limited circumstances when it may be appropriate to have a PGD for more than one medicine. | recognised that including more than 1 medicine may be appropriate in some circumstances, provided all legal requirements were included for each drug. The GDG concluded that the risks and benefits of including more than 1 medicine in a PGD should be carefully considered on a case-by-case basis. |
| 475 | NHS England | 3.1 | 19 | 15 | Reference to GSL or P medicines being included in a PGD. We are aware of some examples of this where the decision to develop at PGD for a medicine is done purely on cost grounds – i.e. that the POM medicine is cheaper than the P medicine. Our view is that a decision to develop a PGD should be on clinical reasons rather than budgetary. | Thank you for your comment. Definitions of 'prescription-only medicine', 'pharmacy medicine' and 'general sales list' are included in the glossary of the guidance. |
| 476 | NHS England | 3.2 | 24 | 9 | Not very easy to find out who the authorising body is, should be clearer with list in the glossary | Thank you for your comment. The glossary entry has been amended to reflect this comment. |
| 477 | NHS England | 3.2 | 25 | 1 | It is not very practical to seek views from the public, other than patients, for the development of PGDs | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 478 | NHS England | 3.2 | 25 | 25 | PGD approval group. Bearing in mind local authorities will also be able to authorise PGDs, the proposed structures of PGD approval group need to recognise organisational structures and staff within Local Authorities | Thank you for your comment. The GDG discussed and indicated that the PGD approval group should include specific people however the composition of the group is for local consideration and determination. |
| 479 | NHS England | 3.3 | 30 | 5 | The draft guidance does not provide sufficient guidance about the circumstances when the provider should approve the PGD and when the | Thank you for your comment. Details of the process are necessarily for local consideration and determination based on organisational structure and service delivery. |

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| | | | | | commissioner should approve the PGD. This is an area of contention and requires more clarity about who should have responsibility and in what circumstances. The governance arrangements particularly around staff competency etc. needs to be more clearly set out | |
| 480 | NHS England | 3.3 | 33 | 1 | Seems rather excessive to suggest doing a full literature search to develop a PGD. Would be more appropriate to suggest ensuring NHS evidence is checked for best practice guidance and up to date information about use of medicine e.g. from SPC is used | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 481 | NHS England | 3.4 | 36 | 1 | The guidance is rather vague on recommendations for organisational sign off. We would like to see a more specific recommendation that a designated person in the organisation is given responsibility by the board to give organisational sign off and that this person should be the person responsible for clinical quality / patient safety in the organisation. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 482 | NHS England | 3.4 | 38 | 11 | Up to date PGDs must be available to those staff using them – this is rather unclear in this section, but says so clearly in other parts of the guidance. This is not consistent with elsewhere in the document. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 483 | NHS England | 3.6 | 49 | 1 | Not sure the proposed system for | Thank you for your comment. The GDG concluded that all |

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| | | | | | reviewing PGDs will actually work. Sounds fine and very reasonable, but unlikely to be followed in practice – also comments related to section 3.3. page 33 relevant | organisations with responsibility for PGDs should establish and manage a work programme for reviewing, updating and re-authorising PGDs within the legal requirements. |
| 484 | NHS England | 3.8 | 58 | 16 | The guidance should include a statement about responsibility for maintaining an up to date record of those staff authorised and competent to use the PGD, and that this is included within local PGD governance processes | Thank you for your comment. This has been considered in recommendation 2.8.7 of the guidance. Details of the process are for local consideration and determination |
| 485 | NHS South London Commissioning Support Unit | General | | | The document is well laid out and provides clear guidance on the points that need to be taken into consideration when developing PGDs. It also provides a useful summary of PGD legislation. | Thank you for your positive comment supporting the guidance. |
| 486 | NHS South London Commissioning Support Unit | General | | | It may be useful to provide more guidance on how PGDs will be approved in practice for organisations such as the Local Authorities or the NHS Commissioning Board who may have the expertise available (or commissioned) but may not have the equivalent of a medicine-decision making body in their governance arrangements. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |
| 487 | NHS South London Commissioning Support Unit | 1.6 | 11 | 18 | Should the duration for keeping these records be specified? (as noted on page 17 of the National Prescribing Centre (2009) PGD document i.e. 8 years for adults, and for children, until | Thank you for your comment. This has been considered in section 3.8 of the guidance. |

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| | | | | | the child is 25 years old or for 8 years after a child's death) | |
| 488 | NHS South London Commissioning Support Unit | 3 | 14 | Figure 1 | We think that in practice the PGD approval group will need to closely link with the authorising body (it may not be the same body) and that this should be demonstrated on this flow-chart (it is mentioned in the text) | Thank you for your comment. The flow chart has now been amended to reflect this comment. |
| 489 | NHS South London Commissioning Support Unit | 3.1 | 17 | 3 | The NHS Commissioning Board and the Local Authority won't have medicine policies; therefore it is unclear how they would be able to develop their local independent prescribing. | Thank you for your comment. Organisations may need to develop or review their strategic medicines policy to develop independent prescribing locally until national policies/strategies are developed. |
| 490 | NHS South London Commissioning Support Unit | 3.2 | 24 | 9 | Again, we feel that this guidance suggests that the PGD approval group is separate to the authorising group. In practice, we don't know of any organisation in which the PGD approval group is separate from the authorising group | Thank you for your comment. The guidance states that the **PGD working group** is separate from, but would need to liaise with, the PGD approval group. The glossary in the good practice guidance provides the information required. |
| 491 | NHS South London Commissioning Support Unit | 3.2 | 25 | 2 | While theoretically, seeking the views from patients and the public is a good idea; in practice, we felt that it may not be practical and are unaware of anywhere that this currently happens. | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 492 | NHS South London Commissioning Support Unit | 3.3 | 31 | 9 | We feel that face to face meetings within a multi-disciplinary group are extremely useful As such; we would recommend that PGD working groups should be encouraged to have at least one face to face meeting. | Thank you for your comment. The GDG agreed it would be for local consideration and determination. |
| 493 | NHS South London | 3.4 | 38 | 16 | We feel that there is a risk in publishing the signed final versions of | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | Commissioning Support Unit | | | | PGDs on the intranet, as it could lead to people, who don't understand PGD legislation, to print them off and use them outside of the prescribed governance. | |
| 494 | NHS South London Commissioning Support Unit | 3.5 | 43 | 25 | Arrangements for the collection of appropriate fees does not appear to be included in the criteria for considering if a PGD is appropriate (page 25) | Thank you for your comment. The GDG agreed that the recommendation reflects good practice. |
| 495 | NHS South London Commissioning Support Unit | 3.5 | 46 | 22 | Documenting **how** they met the criteria of the PGD – we feel this is impractical, as some PGDs may have a lot of inclusions | Thank you for your comment. The GDG agreed this represents good practice. |
| 496 | NHS South London Commissioning Support Unit | 3.5 | 47 | 1 | We would expect that consent would always need to be obtained; as such we suggest that 'whether' could be changed to 'how' patient consent was obtained | Thank you for your comment. Whether patient consent to treatment was obtained should be considered and documented in line with the Department of Health's advice on consent (2009). |
| 497 | NHS South London Commissioning Support Unit | 3.7 | 55 | 23 | We think 'clinically competent pharmacist', rather than a 'pharmacist with experience of working in the clinical speciality or service' would be more suitable wording. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 498 | NHS South London Commissioning Support Unit | 3.7 | 55 | 33 | Experience of working in local medicines decision group – how does this relate to Local Authorities (see comment on section 3.1) | Thank you for your comment. The GDG agreed people in specific roles require additional specialised knowledge, skills and/or expertise dependent on their role which is detailed in the guidance. This may need to be sourced or commissioned from outside the organisation. This is for local consideration and determination. |
| 499 | NHS South London Commissioning | 3.7 | 55 | 16 | Role section – nil noted regarding the ability of the people assessing the competency of the health | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | Support Unit | | | | professionals they are authorising. | |
| 500 | NHS South London Commissioning Support Unit | 3.8 | 57 | 25 | Patient safety incidents – it may be helpful to suggest how Local Authorities could manage this | Thank you for your comment. Implementation is outside the scope of this good practice guidance. |
| 501 | NHS South London Commissioning Support Unit | 4 | 62 | 8 | Appendix B should read Appendix C | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 502 | NHS South London Commissioning Support Unit | 4 | 62 | 11 | Appendix C should read Appendix D | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 503 | Royal College of Physicians & Surgeons Glasgow (Faculty of Travel Medicine) | General | | | Whilst the Executive Board of the Faculty of Travel Medicine would agree with the majority of the recommendations made in the consultation, we would like to make the following comments in respect of **vaccines** & **malaria chemoprophylaxis** currently used in the provision of travel health: | Thank you for your comments. Please see individual responses to 504 - 510. |
| 504 | Royal College of Physicians & Surgeons Glasgow (Faculty of Travel Medicine) | General | | | We feel strongly that PGD's should be used not only by NHS organisations & services but also by independent contractors providing travel health services to the general public and specific groups of travellers: this would include private travel clinics, pharmacies, OH settings, schools, general practice and the MoD | Thank you for your comment. This is outside the scope of this good practice guidance. Further information can be found on the MHRA website. |
| 505 | Royal College of Physicians & | General | | | PGD's related to the provision of travel health should be standardised across | Thank you for your comment. This is outside the scope of this good practice guidance. Further information can be |

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| | Surgeons Glasgow (Faculty of Travel Medicine) | | | | the NHS and all independent contractors regardless of their status across all four home countries e.g. privately financed primary care service contracted to provide services on behalf of the NHS | found on the MHRA website.<br>Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 506 | Royal College of Physicians & Surgeons Glasgow (Faculty of Travel Medicine) | General | | | Centrally generated PGD's should be available for both "NHS" and "non-NHS" vaccines | Thank you for your comment. NHS England has published some emerging scenarios for nationally commissioned immunisation and vaccination programmes following consultation of the draft guidance. The guidance has been updated to reflect this comment. |
| 507 | Royal College of Physicians & Surgeons Glasgow (Faculty of Travel Medicine) | General | | | PGD's relating to the provision of travel health should be written by a central vaccine specialist team, to include a Travel Health accredited specialist, who would be responsible for the regular review & update of the PGD's: this could be applicable to accredited specialist teams within the devolved administrations | Thank you for your comment. This is outside the scope of this good practice guidance. Further information can be found on the MHRA website. |
| 508 | Royal College of Physicians & Surgeons Glasgow (Faculty of Travel Medicine) | General | | | This central team should devolve responsibility for training in the appropriate use of PGD's by registered accredited health care professionals | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 509 | Royal College of Physicians & Surgeons Glasgow (Faculty of Travel Medicine) | General | | | Local devolved PGD groups should be responsible for maintaining a register of those PGD's implemented in their area, and should have the authority to request a register from local organisations or contractors, of those individuals using PGD's | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |
| 510 | Royal College of | General | | | The Board feel that PGD's will be | Thank you for your comment. This is outside the scope of |

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| | Physicians & Surgeons Glasgow (Faculty of Travel Medicine) | | | | required for the foreseeable future but that the current fragmented system impacts on the safe and legal provision of vaccines to travellers both within NHS and independent contractor services in all four home countries. | this good practice guidance. |
| 511 | Kettering General Hospital NHS Foundation Trust | General | | | The guidance strongly reinforces the principle that clinical care should be provided on an individual, patient-specific base by a prescriber; the purpose of PGDs is expanded on; this is welcomed. | Thank you for your positive comment supporting the guidance. |
| 512 | Kettering General Hospital NHS Foundation Trust | General | | | The publication of NICE guidance to highlight the legal framework around PGDs and the importance of robust governance is very welcome and timely. Experience in our Trust is that there is a discernible trend to develop and use of PGDs to manage planned care, and consideration of alternative mechanisms for supply / administration is not undertaken willingly. PGDs are sometimes seen as a means of role enhancement of practitioners over patient benefit; though it can indeed be an appropriate way of developing skills in some areas, prior to becoming an independent prescriber.<br>It is often difficult to engage managers, clinicians and practitioners in discussion of the impact of PGDs on | Thank you for your positive comment supporting the guidance. |

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| | | | | | financial resources and service provision. We have practitioners who 'treasure' their PGDs because of the robust governance framework developed by Pharmacy, rather than explore more appropriate non-medical prescriber roles, while others see our local PGD policy as unnecessarily bureaucratic.<br>This guidance should help those with the task of developing PGDs make our case to the Trust at the highest level when necessary. | |
| 513 | Kettering General Hospital NHS Foundation Trust | General | | | The lists of recommendations for each stage in the development of a PGD are very helpful in principle. | Thank you for your positive comment supporting the guidance. |
| 514 | Kettering General Hospital NHS Foundation Trust | General | | | The definition of a PSD has not been clarified, as suggested in the 'Review of Medicines Legislations: Informal consultation on the provisions for PGDs and other matters' dated 22/10/2011. A PSD allows the sale or supply of the medicine for a specific individual in a hospital setting. Directions for administration are legally only required if the medicine to be supplied is a POM for parenteral use. A PGD is defined in HSC 2000/026 as 'written instructions for the supply or administration of *medicines* to groups of patients who may not be individually identified before presentation for treatment'. There is | Thank you for your comment. The focus of this good practice guidance is PGDs. Definitions of other legal options for prescribing, supplying and administering medicines including PSDs are included in the glossary.<br><br>Thank you for your comment. GSL and P medicines can be supplied without the need for a PGD. The GDG agreed that local policies would be more appropriate when a PGD is not necessary, with the employing organisation retaining legal responsibility for the actions of its employees. See 'To PGD or not to PGD' for further information.<br><br>The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and |

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| | | | | | no clarification whether the PGD legislation applies only to medicines that are POMs. So, what is the basis for requiring a PGD for administration of a non-parenteral POM, but not a P or GSL medicine *(see also 'To PGD or not to PGD)?* There is also no clarification on why 'supply' means only 'supply to take home' in the 'To PGD or not to PGD' scheme.<br>I raise this point because the draft guidance recommends that directions for administration of <u>P</u> medicines (where supply of TTA pack is not required) should be removed from all PGDs and covered separately by a Trust protocol. We have to date included P medicines (except on midwives PGD) to take advantage of robust governance framework afforded by PGDs and to comply with our Trust Administration of Medicines Policy, which states 'Patients (and their carers where appropriate) will have their medicines prescribed at times when they are needed and administered in a safe way. This policy will ensure that medicines are handled safely and appropriately to enable medicines to be taken safely.]<br>Clearly, for all POMs, instructions to supply and administer have become inseparable on a PSD in a hospital | determination. |

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| | | | | | setting and it makes sense to require regulation of administration of non-parenteral POMs under a PGD. But should this not apply to P medicines too? Allowing administration of P meds under a Trust protocol would be inconsistent with our Administration of Medicines Policy and there is a risk that the governance framework will be less rigorous than that in place for PGDs. In the course of the business of a hospital, P medicines may be supplied to a patient for the purpose of being administered to a particular person in accordance with the written directions of a prescriber *(from: Medicines, Ethics & Practice, RSPGB July 2010).* 'Supply' is defined in the draft guidance as 'To provide a medicine to a patient or carer for administration' i.e. not just supply *to take home*. So, in a hospital setting can 'administration' of a P medicine not already in a patient's possession really be considered as a procedure independent of supply? If a PGD is needed for supply of a P medicine, it must be needed for administration too as you cannot administer without supplying the medicine first. In a hospital setting either a prescriber or other HCP will be taking the decision that a P (or even a GSL) medicine is | |

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| | | | | | appropriate for treating a specific condition/symptom in a specific patient and will need to supply it – this is a different scenario to a patient selecting the medicine in a retail Pharmacy (or other retail outlet for GSL medicine) and surely should have a more rigorous control than a Trust protocol. | |
| 515 | Kettering General Hospital NHS Foundation Trust | General | | | The issue of saline flushes (medicines) presented in a non-POM formulation needs to be addressed. Although legally these may be administered by HCA under a local protocol, surely this is not the spirit of Medicines Act legislation; this practice is also incongruous in the context of the findings / recommendations of the Francis Report. A formal position on the administration of Medical Gases would also be welcome – our Medicines Management policies require that these are prescribed or administered under a PGD rather than administered under a local protocol. | Thank you for your comment. This is outside the scope of this good practice guidance. |
| 516 | Kettering General Hospital NHS Foundation Trust | 3.1 | 21 | 1 | Recommendation 2.1.1 Barriers to implementation – engaging clinicians and managers in discussion about resources to train independent / supplementary prescribers. We acknowledge that PGDs may be used in the interim while non-medical prescribers are trained – we require | Thank you for your comment. No response required. |

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| | | | | | this concession while discussion around anticoagulation service is re-configured; currently the clinics are led by clinical nurse specialists working under a PGD. | |
| 517a | Kettering General Hospital NHS Foundation Trust | 3.1 | 22 | 15-18 | Recommendation 2.1.12 page 22<br>Do not include complex medicines requiring frequent dosage adjustments such as warfarin.<br>Do not include medicines needing frequent or complex monitoring<br>Do not include high-risk meds<br><br>I would agree. Although in principle we have a robust governance framework for some PGDs (e.g. the VKA/enoxaparin PGD), there are practical problems with implementing it, and therefore I would support the NICE guidance. For example, I have highlighted in my annual assessment report to the anticoagulation department the need for a complete set of Trust-approved policies / protocols to support all the procedures/processes included in the PGD, but this has not been achieved by the nursing team due to lack of time. Many protocols are 'verbal' - the nurses know what to do. The lead clinician is aware of these issues. | Thank you for your comment. No response required. |
| 517b | Kettering General Hospital NHS | 3.1 | 22 | 15-18 | For existing PGDs there is no time-limited requirement or mechanism for | Thank you for your comment. No response required. |

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| | Foundation Trust | | | | checking the decision to treat 'standard' patients, dosing adjustments for the length of supply made (if dose is variable), there is no protocol for dose adjustment made by the nursing team, other than an annual audit check of a sample of 10 patients from each practitioner (performed this year by lead clinician. This does present a risk to patients. | |
| 517c | Kettering General Hospital NHS Foundation Trust | 3.1 | 22 | 15-18 | Decisions about 'complex' patients are all reviewed by consultants. Although I agree with NICE recommendations, we will have to continue with this PGD as an interim measure until nurses can complete an independent prescriber course and the service can be re-designed. | Thank you for your comment. No response required. |
| 518 | Kettering General Hospital NHS Foundation Trust | 3.1 | 22 | 15-18 | Recommendation 2.1.11 page 22 Consider including an antimicrobial in a PGD only in exceptional circumstances.<br><br>We have antibiotics on A&E PGD to treat bites etc., antibiotic choices/dosages are compliant with Trust policy. This would seem to be an appropriate use of the PGD - otherwise service re-design would be required if insufficient (non) medical prescribers are available - some emergency care | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[17] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this |

[17] The Health Protection Agency is now part of Public Health England.

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| | | | | | nurses are independent prescribers | comment. |
| 519 | Kettering General Hospital NHS Foundation Trust | 3.2 | 24 | 2-5 | If relevant paperwork is completed and presenter describes the service need for a PGD at the authorising body, then there should be no need for initial discussion before planning to do a PGD. It may be at the peril of those preparing a PGD where consideration that the organisation may not feel a PGD is needed in that area, and further approval is not granted in the authorising body | Thank you for your comment. Unfortunately, the point of this comment is not clear. The flowchart (figure 1) is intended to summarise the PGD process clearly and concisely, and does not consider the entirety of local arrangements. Some of these may vary in different organisations. See sections 3.1 and 3.2. |
| 520 | Kettering General Hospital NHS Foundation Trust | 3.2 | 26 | 6-8 | We agree with the recommendation to include service commissioner and finance lead on PGD approval group, but anticipate barriers to implementation because of difficulty in recruiting these individuals to the group. To date it has been difficult to engage managers / clinicians / practitioners in discussion around financial considerations and service provision to support PGDs.<br>One suggestion could be that the committee authorising group (that has approval to ratify PGDs in the organisation) has the adequate representation of those mentioned above and that signatures are obtained in that meeting. | Thank you for your comments. Details in relation to engagement with suggested individuals on the PGD approval group is for local consideration and determination |
| 521 | Kettering General Hospital NHS Foundation Trust | 3.2 | 26 | 9 | Multiple PGDs operating in several clinical areas is discouraged in the draft consultation. This makes sense | Thank you for your comment. The GDG agreed that a single PGD in a patient group covering different services in 1 organisation would in most circumstances be more |

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| | | | | | when considering rationalisation of management of several documents by Pharmacy, but has disadvantages when looking at management of practitioner competencies and evaluation/monitoring of the PGD – this is easier when managed by leads within each separate clinical group than by one individual PGD Practitioner Lead acting across many clinical areas. | appropriate. The GDG concluded that operating a PGD approval group may help to reduce unnecessary duplication of PGDs. The process would be for local consideration and determination. |
| 522 | Kettering General Hospital NHS Foundation Trust | 3.2 | 27 | 5-9 | Recommendation 2.2.2 – There is no reason why the approval group and the authorising group cannot be the same group. This is not made explicit in the document | Thank you for your comment. Further information can be found in the glossary of the good practice guidance. |
| 523 | Kettering General Hospital NHS Foundation Trust | 3.2 | 28 | 15 | Recommendation 2.2.5 PGD approval group should ensure adequate resources for service delivery: Barrier to implementation – must be included in Terms of Reference of approval group if the group is not specifically for discussion and approval of PGDs. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of implementation are necessarily for local consideration and determination. |
| 524a | Kettering General Hospital NHS Foundation Trust | 3.2 | 28 | | Recommendation 2.2.5 page 28 Responsibility of the PGD approval (and authorising body) is to ensure adequate resources, such as finance, training, medicines procurement and diagnostics are available for service delivery. | Thank you for your comment. The relevant text has now been amended to reflect this comment. Implementation of the recommendations is for local consideration and determination. |
| 524b | Kettering General Hospital NHS Foundation Trust | 3.2 | 28 | 526 | Several recent examples illustrate difficulties in discharging this responsibility, including: | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or |

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| | | | | | 1. Anticoagulant VKA / enoxaparin PGD - medicine supply is not as cost effective as it could be (nurses have no time to review this); service workload / staffing is critical; no easy mechanism to levy charges for medicines supplied etc. – The approval body should have the power and representation (including governance leads) to ensure this or control service provision problems when they develop; The approval body should reject re-approval or development of certain PGDs in future. The Trust would need to understand that the service needs the proper financial support etc. if the PGD is to continue operating (but see above for comment on 'high risk' meds not being suitable for inclusion on a PGD).The NPC competency framework requires that PGD practitioners know how to get support for the resolving service issues...this support has not been forthcoming from senior service managers, despite lead clinicians being aware of issues. | complex monitoring for example anticoagulants or insulin. |
| 524c | Kettering General Hospital NHS Foundation Trust | 3.2 | 28 | 526 | 2. Proposed NOAC PGD. The experience with delivering the anticoagulant service under the VKA/enoxaparin PGD needs to be borne in mind when considering the proposal to develop a PGD for NOACs. | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants or insulin. |

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| | | | | | These need proper financial input. | |
| 525 | Kettering General Hospital NHS Foundation Trust | 3.3 | 31 | 7 | Process for developing PGDs 'PGD working group should include a doctor and pharmacist – ideally the people signing off the PGD'. As pharmacists are often the 'gate keepers' for PGDs then a pharmacist with relevant experience in the clinical area and/or knowledge and experience in PGDs should be involved. | Thank you for your comment. The roles and responsibilities of each person and how they work together to develop the PGD should be determined locally and be clearly defined. |
| 526 | Kettering General Hospital NHS Foundation Trust | 3.4 | 36 | 13 | People signing the PGD When signing…should be undertaken by senior professionals… Does this allow room for not involving people of sufficient seniority in writing the PGD? Does the term 'senior' need defining further? As pharmacists are often the 'gate keepers' for PGDs then a pharmacist with relevant experience in the clinical area and/or knowledge and experience in PGDs should be involved | Thank you for your response. The GDG agreed senior professionals would need to **authorise** the PGD, individuals involved in **developing** the PGD would be determined locally. Section 3.7 provides details on training and competency for those developing and using the PGD. The relevant text has now been amended to reflect this comment. |
| 527 | Kettering General Hospital NHS Foundation Trust | 3.4 | 40 | 5 | Recommendation 2.4.2 Address barriers that may delay authorising PGDs, such as lack of leadership and ownership, lack of understanding of legislation and governance requirements – these problems exist in our organisation! Face-to-face meetings with key personnel will be the only way of ensuring awareness of NICE recommendations and the impact on PGDs in each Trust – emails are not read, and therefore relying on | Thank you for your comment. Details of the process are for local determination and implementation. |

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| | | | | | this is ineffective governance; this will have an impact on workload and will need support for resources from the authorising body (Acute Trust in our case). This work will likely fall to Pharmacy; resourcing time for this task will be a challenge. | |
| 528 | Kettering General Hospital NHS Foundation Trust | 3.4 | 38 | 5 | Do CCGs need to authorise a PGD if the Trust as provider feels a PGD is an appropriate mechanism for delivering a commissioned service? | Thank you for your comment. This has been considered in section 3.3, box 6 of the guidance. |
| 529 | Kettering General Hospital NHS Foundation Trust | 3.4 | 40 | 27 | Recommendation 2.4.6. …Identify the appropriate individual who is to sign the PGD on behalf of the authorising body. The guidance lacks clarity on how many people, and at what level in the organisation, should be involved. The Medical Director on behalf of the authorising body signs every PGD. However, who is best place to take responsibility for the governance of the PGDs? Who is best placed to provide service support and resolve issues? Currently, either the Directorate or CMT/CBU/Division managers are named on a PGD as authorising its use in the Directorate/CMT … but they don't sign the PGD. We ask the Directorate or Clinical Management Team Managers to confirm they authorise the PGDs for use in there and to accept 'ownership' of the PGD, but these managers do not | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |

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| | | | | | sign the PGD. We have put in place a process for discussion and approval at CMT governance committees prior to being signed off by the approval body. The process of collecting signatures after a PGD has discussed and approved by the approval body is lengthy. In addition to the Medical Director and Chair of MMC, the Head of Nursing, the Chief Pharmacist and the PGD Lead Pharmacist sign. We allow for a PGD to be approved at MMC (our approval body) meeting in first week of the month in which the PGD expires, allowing up to 3 weeks to gather signatures before the expiry date, but this does not always happen in time. Trusts (authorising bodies) will need to embrace the legislation and enable signatures to be gathered more swiftly. | |
| 530 | Kettering General Hospital NHS Foundation Trust | 3.4 | 41 | 4 | Recommendation 2.4.8 Dissemination of PGD. Commitment of Trust to resourcing the time needed for this role. This task is undertaken by the Pharmacy Department in our Trust, but it is not clear how this should be funded by the Trust. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 531 | Kettering General Hospital NHS Foundation Trust | 3.4 | 41 | 12 | Recommendation 2.4.9 A senior, responsible person from each service is identified to authorise named registered HCPs to practice under the PGD – we have had experience of a | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |

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| | | | | | PGD with a large number of practitioners where the senior person could not demonstrate in the annual audit that all practitioner competencies were up to date (if any of them). Governance issues prevail when the number of practitioners authorised to practice under one PGD is large. We have also had three examples in the past year where the senior person responsible for authorising practitioners has left the clinical area / Trust and failed to arrange for a replacement. Despite governance framework being in place, senior personnel ignore procedures. If signatures are to continue to be required by Director of Nurse (for example), then it will be the responsibility of this individual to ensure that those (nurses) named have the necessary competencies. | |
| 532 | Kettering General Hospital NHS Foundation Trust | 3.4 | 41 | 14 | Recommendation 2.4.9 Maintenance of a PGD register and administration of the PGD development and review process needs to be properly resourced and funded. These tasks are organised by the Pharmacy Department in our Trust, but it is not clear how this should be funded by the Trust, for example reduction of administrative support staff means that much administrative work falls on | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |

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| | | | | | to Pharmacists in addition to development / review / training work. | |
| 533 | Kettering General Hospital NHS Foundation Trust | 3.5 | 46 | 16 | Recommendation 2.5.6 Collecting charges for medicines supplied as TTAs under PGDs in a hospital setting; PGD practitioners are not well placed to collect charges; experience with pre-pay machines has been poor (expensive to implement and maintain, prone to vandalism); patients could be invoiced by the Finance Department…but will they pay? The use of tokens purchased at Reception prior to OP appointment is used in other areas to purchase e.g. scan images…but this may not be appropriate to PGDs e.g. unknown whether a patient will receive a TTA; could ask patient to pay at Cashier's Office – will they?<br>The suggestion of collecting charges will generate a completely new level of bureaucracy that the NHS is completely riddled with already. | Thank you for your comment. The relevant text has now been amended to reflect his comment. See section 1.6. Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a **supply** of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are **administered** under a PGD. |
| 534 | Kettering General Hospital NHS Foundation Trust | 3.6 | 48 | 15 | We already allow a 6-month time frame for review of existing PGDs and still have problems with getting some of them reviewed before the expiry date is reached. Barrier: a lack of commitment to prioritising this work by PGD practitioner leads and clinicians and managers. | Thank you for your comment. The GDG agreed review and updating should start **at least** 6 months before the expiry date of the PGD to allow sufficient time to complete the process. |

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| | | | | | This is to be raised in the education and training package | |
| 535 | Kettering General Hospital NHS Foundation Trust | 3.6 | 48 | 28 | Work plan to review /update / re-authorise PGDs is in place, but is under-resourced in current financial climate. Also encountered problems where PGD Practitioner Lead Author does not flag up change in practice requiring earlier review of PGD. | Thank you for your comment. This is outside the scope of this good practice guidance. |
| 536 | Kettering General Hospital NHS Foundation Trust | 3.7 | 53 | 17 | We agree that a 'training needs assessment' is necessary, but this will need commitment to PGDs from the Trust and adequate resourcing. | Thank you for your comment. Details of the process are for local consideration and determination. |
| 537 | Kettering General Hospital NHS Foundation Trust | 3.7 | 55 | 19 | Pharmacist signing a PGD – Trusts may not have a pharmacist with experience of working in the clinical specialty or service where the PGD is to be used – is it sufficient to be able to determine the care pathway with the practitioner so that all medicine management issues are considered, in the context of the PGD legislation and pharmaceutical issues? Suitable training packages should be available for all staff new to PGDs and should then direct these to further resources | Thank you for your comment. The relevant text has now been reworded to reflect this comment. Details of training packages needed are for local consideration and determination. |
| 538 | Kettering General Hospital NHS Foundation Trust | 3.7 | 56 | 9 | Recommendation 2.7.3 Many barriers to implementation could be overcome with better training. However, recruitment of individuals to the PGD approval body, to the working group or as signatories will be more difficult; the requirement to undergo training | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |

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| | | | | | will require support of approval body to ensure that individuals comply with requirements (i.e. no training – no PGD). Revision of the practitioner training package, development of a new training package and materials for others will require the commitment of the Trust to provide the resources and a realistic attitude to the support required. | |
| 539 | Kettering General Hospital NHS Foundation Trust | 3.7 | 56 | 14 | Recommendation 2.7.4 'Ensure adequate education materials are available…' The lack of national standard for training / competency assessment materials will lead to variable standards across Trusts, though the NPC PGD 2009 competency framework is very useful. | Thank you for your comment. NICE implementation team have identified that a PGD competency framework document to support implementation of the guidance would be a useful tool. This will be developed following guidance publication. |
| 540 | Kettering General Hospital NHS Foundation Trust | 3.8 | 57 | 16 | Clarity is required (or is this for each CCG and provider to decide?) around the relationship between CCG and Trust as provider, in relation to how much involvement the CCG has in how a service is delivered by the Trust. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 541 | Kettering General Hospital NHS Foundation Trust | 3.8 | 57 | 21 | 'The GDG agreed that in order to ensure governance arrangements are followed, a designated person in each organisation should have overall organisation ability' Not clear where this person should be drawn from within the organisation? | Thank you for your comment. Governance arrangements are for local consideration and determination. The guidance states that in an authorising body, this is likely to be the person authorising PGDs on behalf of the organisation, such as the clinical governance or patient safety lead. |
| 542 | Greater East Midlands (GEM) | General | | | This guidance is practical, provides some clear direction and would be | Thank you for your positive comment supporting the guidance. |

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| | Commissioning Support Unit | | | | positive to support new and evolving organisations. | |
| 543 | Greater East Midlands (GEM) Commissioning Support Unit | Recommendation 2.1.6 | 21 | | Add in link for listing of organisations and services that are legally eligible to use PGDs | Thank you for your comment. Organisations that are legally eligible to use PGDs are included in section 3.1 of the guidance. |
| 544 | Greater East Midlands (GEM) Commissioning Support Unit | Recommendation 2.1.8 | 22 | | Prescribers are required to inform the patient when a medicine is being used off-label: instead of 'consider' should this be worded more strongly to bring in line with expectations for prescribers?<br>Non-medical prescribers are required to discuss 'off label' prescribing decisions with the patient. | Thank you for your comment. The updated GMC good practice guidance on prescribing and managing medicines and devices considers that in some circumstances it may not be practical or necessary to draw attention to the licence. All individual health professionals using PGDs should refer to their standards of practice for clarity. |
| 545 | Greater East Midlands (GEM) Commissioning Support Unit | Recommendation 2.1.10 | 22 | | Consider adding in link to which CDs are not legally permitted | Thank you for your comment. A table has now been added to reflect this comment. |
| 546 | Greater East Midlands (GEM) Commissioning Support Unit | 3.2 | 24 | 7 | 'examples of a number of proposal forms being used for this purpose' – it would be useful for example forms to be included as they may be useful to adopt/adapt for local use | Thank you for your comment. The NICE implementation team have identified that a PGD template/PGD competency framework document to support implementation of the guidance would be a useful tool. This will be developed following guidance publication. |
| 547 | Greater East Midlands (GEM) Commissioning Support Unit | 3.3 | 33 | 5 | To include 'evidence' in the PGD itself may make the PGD too large a document and unwieldy – our experience has been that the bigger the PGD document is the less likely it is to read and/or referenced during clinical care. There is a need for balancing the amount of information contained within the document with | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | | | | | the size of the document itself to make it user-friendly and allow it to serve its purpose successfully. Suggest that most 'evidence' would be best placed as referenced only rather than including directly in the PGD itself. | |
| 548 | Greater East Midlands (GEM) Commissioning Support Unit | 3.3 | 33 | 6/7 | Consider making a good practice recommendation around 2 year expiry, even though this is not a legal requirement, as this paragraph may be interpreted as supporting a longer than 2 year review date. | Thank you for your comment. The GDG agreed that it may be appropriate to update the PGD less frequently than every 2 years. In other circumstances, a planned review period of less than 2 years may be necessary but the GDG agreed that a maximum expiry should be 3 years from the date the PGD was authorised. |
| 549 | Greater East Midlands (GEM) Commissioning Support Unit | 3.4 | 37 | 14 | It would be useful for there to be guidance on this. If a CCG can develop a PGD for use by other CCGs, or if a CSU were to develop a PGD for use by a number of CCGs, what guidance is there on the authorisation? The guidance issued earlier this year indicated that the authorising organisation will need a formal process within their relevant clinical governance structure – what might this arrangement look like? | Thank you for your comment. Organisational governance arrangements for PGDs are for local consideration and determination. Arrangements will vary depending on how services are commissioned and provided and what resources are available. |
| 550 | Greater East Midlands (GEM) Commissioning Support Unit | Recommendation 2.4.1 | 40 | | Could a link be added here to allow appropriate authorising bodies to be easily identified?<br>Thinking particularly about getting clarity on the independent providers and CQC registration etc. | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies. |
| 551 | Greater East Midlands (GEM) Commissioning | Recommendation 2.5.3 | 45 | 5 | 'ensure no exclusion criteria are present' – the meaning of this is not clear and could be misinterpreted – | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | Support Unit | | | | consider re-wording – PGDs do include exclusion criteria this we think is referring to making sure the patient is not excluded under those criteria. | |
| 552 | Greater East Midlands (GEM) Commissioning Support Unit | 3.6 | 48 | 8 | A good practice recommendation that supports PGDs not being 'rubber stamped' with a new expiry date just to get around the expiry date would be useful. A full review and re-authorisation should be carried out. | Thank you for your comment. This has been considered in section 3.6 of the guidance. |
| 553 | Central London Community Healthcare NHS Trust | 1.5 | 6 | 29 | Emergency supply; the paragraph implies that a patient can be supplied POM at their request from the pharmacy: the Medicines , Ethics & Practice (MEP)states that one of the conditions the patient's request has to fulfil is that the medicine they are requesting has been previously prescribed by the doctor. The patient is currently on the medication. It can only be supplied if the conditions set in MEP are met. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 554 | Central London Community Healthcare NHS Trust | 1.6 | 10 | 30 | The "product may be sold" in the paragraph is misleading as PGD legislation allows supply but not sale. | Thank you for your comment. The wording provided in the guidance is that taken from legislation. |
| 555 | Central London Community Healthcare NHS Trust | 1.6 | 11 | 19 | MHRA legislation states that records must be kept for audit purposes. As a result majority of the PGDs have an audit section in their template. This enables the group to identify the appropriate audits whist drawing up the PGD. | Thank you for your comment. This is not included within current legislation. The GDG agreed that it was good practice to undertake monitoring and evaluation (see section 3.8). |

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| | | | | | For 'Good Practice' the other sections that will be appropriate are:<br>Storage of medicines<br>Staff training & Competences | |
| 556 | Central London Community Healthcare NHS Trust | 3.1 | 17 | 14 | The paragraph is confusing; is the recommendation that Healthcare assistants and students can be identified as PGD users and be allowed to work under the PGD provided it is addressed under strategic medicines policy? Is the suggestion that local protocols can override the medicines and PGD legislation? | Thank you for your comment. The relevant text has now been reworded to reflect this comment. Policies or protocols cannot override legislation. |
| 557 | Central London Community Healthcare NHS Trust | 3.2 | 27 | 18 | Recommendation 2.2.3: Would public and patients' views be relevant to all proposals for PGDs or in certain circumstances. E.g. if a diabetes consultant identifies that there is a need for a PGD for the service, should they seek input from public /patient view? | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 558 | Central London Community Healthcare NHS Trust | 3.4 | 46 | 16 | Recommendation 2.5.6: it would be helpful to have guidance as to what the service should do when the patient is exempt; in pharmacies the patient is requested for their exemption certificate which is recorded in their patient records. Should the same happen in services? If they do not have the certificate on them, how does the service verify. This is an enquiry that comes up regularly in context of NHS fraud. | Thank you for your comment. The relevant text has now been amended to reflect his comment. See section 1.6. Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a **supply** of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are **administered** under a PGD. |

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| 559 | Central London Community Healthcare NHS Trust | 3.6 | 50 | 21 | Recommendation 2.6.5- The statement implies that expiry date is flexible. It would be helpful to have clarity e.g. 2 years and less if appropriate. | Thank you for your comment. The text has been amended to reflect this comment. Details of the process of review are for local consideration and determination |
| 560 | National Travel Health Network and Centre | 1.3 | 4 | 17-24 | It seems that this guidance does not apply to independent providers providing private healthcare – is this the case? If so could this be made explicit and could an explanation/link be provided about what the process should be for these groups | Thank you for your comment. This section has been reworded following further discussion by the GDG. The scope of the guidance however cannot be changed. |
| 561 | National Travel Health Network and Centre | 1.5 | 6 | 22 | Does this exemption also apply to Occupational health schemes that have been commissioned for NHS services? | Thank you for your comment. An FAQ on the national PGD website clarifies this comment and can be found here. |
| 562 | National Travel Health Network and Centre | 1.4 | 13-14 | 5 | Some may find this statement a bit confusing | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 563 | National Travel Health Network and Centre | General | General | General | **the practical value of the guidance and provisional recommendations**<br>Anticipate will be a very useful resource. Clarifies many areas. Recommendations add weight particularly relating to competencies/CPD issues | Thank you for your positive comment supporting the guidance. |
| 564 | National Travel Health Network and Centre | General | General | General | **how easy the recommendations will be to implement**<br>Will there be any measure of consistency within PGDs<br>Do these recommendations give us scope as a National body to develop | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance |

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| | | | | | PGDs (we have been asked so many times) | |
| 565 | Royal Pharmaceutical Society | General | | | **Practical Value of the Guidance:**<br>We believe the guidance is well developed and provides a sensible, well-reasoned piece of Good Practice Guidance and overall we support the recommendations within the consultation paper.<br>As a GB organisation we are however unclear of the status of this guidance in the devolved countries and are cautious of having 3 differing pieces of "good practice guidance" for pharmacists to adhere too. | Thank you for your positive comment supporting the guidance.<br><br>Thank you for your comment. Unfortunately it is not clear which 3 differing pieces of 'good practice guidance' this comment refers to. The NICE good practice guidance replaces the National Prescribing Centre – Patient Group Directions (2009) guide. |
| 566a | Royal Pharmaceutical Society | General | | | **General comments :**<br>**Pharmacist prescribers**<br>We believe PGDs have been a useful mechanism in allowing access to medicines, particularly in "see and treat" services e.g. emergency hormonal contraception / stop smoking services. There is clear evidence of patient benefit in continuing with this legal mechanism. We are however cautious that PGDs are not over used and welcome the guidance support that PDGs are only one route of supply of medicine. | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 566b | Royal Pharmaceutical | General | | | We strongly support the development of Pharmacist independent prescribers | Thank you for your comment. No response required. |

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| | Society | | | | (IP) as a preferred route of access to medicines, as this route would provide a more holistic prescribing model. We would therefore advocate that where new services are being developed the use of pharmacist prescribers is considered first and as part of the process of PGD development. Additionally if IP services is the preferred option but is not developed due to constraints then this evidence is gathered and reported back to the commissioning body so they can look at the workforce development issues within their organisation. | |
| 566c | Royal Pharmaceutical Society | General | | | **Use of PDG's**<br>When PDGs are developed to support access to medicines through new services in the community, we strongly support the use of this good practice guidance. We believe there must be a robust system of governance, accountability and audit to ensure patient safety is not compromised by the demand for access to medicines as part of newer services delivered in the community.<br>In some circumstances patients may wish for a quick supply route of medicines but this may not be appropriate or within their best interests to avoid a full consultation with a medicinal or independent | Thank you for your comment. No response required. |

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| | | | | | prescriber. All new services that use PGDs as the supply model should ensure patient safety is at the centre and the risks verses benefits are considered. | |
| 566d | Royal Pharmaceutical Society | General | | | **Organisational and structural changes in the NHS and PGD authorisation**<br>The NHS across GB is constantly evolving to ensure it is suitable to deliver health services, and PGD authorisation, accountability and audit process must be flexible enough to accommodate these changes, but also be robust enough to ensure true accountability.<br>There must be a 'one stop' website that updates any guidance and templates in light of changes and provides a gold standard resource to aid new organisations to develop quality PGDs that put patient safety first. | Thank you for your comment. The National PGD website provides further information, examples and templates. |
| 567 | Royal Pharmaceutical Society | 2.1.7 | 21 | | **Unlicensed medicines**<br>Whilst we agree that in principle unlicensed medicines should not be supplied/administered under a PGD, we would support their use when it is justified by best clinical practice, or an off label use is required by necessity. The one notable example being, Tuberculin PPD (Mantoux test). Tuberculosis services all use the | Thank you for your comment. Legislation requires that unlicensed medicines must not be included in a PGD. |

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| | | | | | unlicensed Mantoux, and as such have to use Patient Specific Directions (PSDs) not PGDs as a means of supplying the test. The use of PSDs is not appropriate in this instance as it is not always possible for prescribers to individually assess each patient and we would therefore ask for this exception to be noted within the guidance, and consideration of off- label use justified by best clinical practice. | |
| 568 | Cambridgeshire Community Services NHS Trust | 2.5.4 | 46 | | Recommendation 2.5.4 – Please clarify what is meant by splitting packs e.g. is it permissible to remove tablets that are excess to requirements? | Thank you for your comment. The GDG was aware that legislation enables pharmacists to split original packs when dispensing a medicine against a prescription. However, the GDG agreed that **all** health professionals supplying medicines under a PGD should not split original packs into smaller units.<br>This section has been reworded following further discussion by the GDG. |
| 569 | Cambridgeshire Community Services NHS Trust | 3.7 | 55 | 2 | Box 2 &3. Bullet 2 for Dr and pharmacist signing PGDs. What is meant by ' Experience of working at a level of responsibility appropriate to the role' Please clarify | Thank you for your comment. Wording was considered by the NICE editorial team. |
| 570 | Cambridgeshire Community Services NHS Trust | 3.7 | 55 | 2 | Box 2 Bullet 3 Dr. ''Experience of working in the clinical speciality or service where the PGD is to be used'' – how does this work for a nurse led service where there is no doctor working in the service? | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |
| 571 | Cambridgeshire Community | 3.7 | 55 | 2 | Box 3 Pharmacist Bullet 3. ''Experience of working in the clinical speciality or | Thank you for your comment. The relevant text has now been reworded to reflect this comment. |

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| | Services NHS Trust | | | | service where the PGD is to be used''. A pharmacist may work with a speciality or service but not in it. E.g. Minor Injuries Units. | |
| 572 | Faculty of Sexual and Reproductive Healthcare (RCOG) | 3.1 | 18 | 12 | The document highlights caution with regard to the use of antimicrobials under PGD; however this is common place within sexual health services. There is some reference to Chlamydia treatment later in the document but PGDs are often used for STI treatment in Community settings very appropriately. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[18] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. The relevant text has now been amended to reflect this comment. |
| 573 | Faculty of Sexual and Reproductive Healthcare (RCOG) | 3.3 | 31 | 15 | The document states that a consultant microbiologist should always be involved during the writing of PGDs for antimicrobials. This may be a difficult resource to access for some community providers and is this essential particularly when the medication prescribed is in accordance with national guidelines and standards e.g. treatment for Chlamydia, Herpes etc. | Thank you for your comment. The GDG discussed this issue and concluded that antimicrobials should be included in a PGD only when:<br>• clinically essential and clearly justified by best clinical practice, such as Public Health England[19] guidance<br>• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented<br>• use of the PGD is monitored and reviewed regularly (see section 3.6).<br>Chlamydia screening is considered an example of appropriate use of antimicrobials for supply under a PGD. |

[18] The Health Protection Agency is now part of Public Health England.
[19] The Health Protection Agency is now part of Public Health England.

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| 574 | Faculty of Sexual and Reproductive Healthcare (RCOG) | 1.3 | 8 | 21 | The Faculty notes that local authorities are authorising bodies. A number of Local Authorities do not have doctors in Public health who are in a position to sign off PGDs and would question who would have this responsibility in this case | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are necessarily for local consideration and determination. |
| 575 | Faculty of Sexual and Reproductive Healthcare (RCOG) | Box 7 | 55 | | The specialist doctor responsible for developing the PGD should ideally be a local clinician | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 576 | Central Manchester University Hospitals NHS Foundation Trust | General | | | The guidance reflects quite closely the organisational approach to PGDs at CMFT and would be an excellent resource to support the development of sound practice in new organisations or where a new PGD Lead is in post. | Thank you for your positive comment supporting the guidance. |
| 577 | Central Manchester University Hospitals NHS Foundation Trust | General | | | It seems that this guidance does not fully replace the 2009 NPC Guide. Having more up to date information, it may cause confusion where there are differences. Are there plans to update the 2009 NPC Guide? | Thank you for your comment. The PGD good practice guidance will replace the 2009 NPC guide. The National PGD website will provide further information and FAQs. |
| 578 | Central Manchester University Hospitals NHS Foundation Trust | General | | | The lack of 'approved' or sample templates feels to be a missed opportunity to provide a useful resource. | Thank you for your comment. The NICE implementation team have identified that a PGD template would be a useful tool to support implementation of the guidance. This will be developed following guidance publication. |
| 579 | Central Manchester University | 1.6 | 10 | 18 | Exceptionally confusing wording through use of double and triple negative | Thank you for your comment. The relevant text has now been amended and format altered to reflect this comment. |

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| | Hospitals NHS Foundation Trust | | | | | |
| 580 | Central Manchester University Hospitals NHS Foundation Trust | 1.6 | 10 | 23 | Although it is not a legal requirements, details relating to storage of the medicine, before and after supply, are considered necessary within this organisation, particularly with regard to maintenance of cold chain. Although this information is contained in the organisational Medicines Policy, it is considered a useful opportunity to reinforce storage requirements in relation to particular products, e.g. vaccines. | Thank you for your comment. The relevant text has now been amended (see section 3.5) to reflect this comment. |
| 581 | Central Manchester University Hospitals NHS Foundation Trust | 3.1 | 19 | 23 | Does this paragraph relate to all of the previous paragraphs? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 582 | Central Manchester University Hospitals NHS Foundation Trust | 3.1 | 20 | | Box 4 lists warfarin as being unsuitable for supply under PGD, but I have worked in and now oversee an anticoagulant clinic both of which used PGDs for initial supply of warfarin without any clinical incidents. It is labelled for use according to directions in the anticoagulant record, just as it would be if prescribed by the GP/consultant and reduces the risk of patients taking any doses in advance of receiving formal counselling. | Thank you for your comment. The GDG agreed that alternatives to PGDs should be used when the medicine needs frequent dosage adjustments, or frequent or complex monitoring for example anticoagulants. |
| 583 | Central Manchester | 3.2 | 26 | 11 | Complex statement – can it be reworded to clarify? | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | University Hospitals NHS Foundation Trust | | | | | |
| 584 | Central Manchester University Hospitals NHS Foundation Trust | 3.7 | 55 | | This is a very useful table and could be used as a basis for extending the NPC competence framework to include roles other than the practitioner. Might this be a future project along with review of the NPC Guide to practical application of this guidance? | Thank you for your positive comment supporting the guidance. NICE implementation team have identified that a competency framework document to support implementation of the guidance would be a useful tool. This will be developed following guidance publication. |
| 585 | Central Manchester University Hospitals NHS Foundation Trust | 3.8 | 59 | 3 | This implies that the PGD approvals group must meet, but at CMFT we use a virtual format and have found this to be a more reliable and efficient way of ensuring timely consideration of PGDs. It is specifically stated that this would be acceptable for working groups and should also be considered an option for approvals groups. Also mentioned under recommendation 2.8.6 | Thank you for your comment. This has been considered in section 3.3 of the guidance. Relevant text has now been amended to reflect this comment. |
| 586 | Secure Environments Pharmacist Group | 1.5 | 6 | 8-16 | As currently written it is not clear that a patient specific direction written by a prescriber is also prescribing but not on a prescription. The person writing the patient specific direction still has responsibility for clinical assessment etc. Section could be slightly expanded. | Thank you for your comment. Patient Specific Directions are outside the scope of this good practice guidance. There is a hyperlink for further information from the MHRA about this topic. |
| 587 | Secure Environments Pharmacist Group | 3.1 | 18 | 5 | Off label use. In exceptional circumstances. This could mean either exceptional in the big scheme of medicines and PGDs or exceptional in relation to a specific | Thank you for your comment. The relevant text has now been amended to reflect this comment to provide clarity. |

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| | | | | | PGD.<br>For some PGDs every use would be off label and therefore not exceptional<br><br>This should be clarified further | |
| 588 | Secure Environments Pharmacist Group | 3.1 | 19 | 19 | I agree that referencing the fact that P medicines are available via pharmacies is valid, especially as this is usually cheaper than the prescription charge. However an additional statement is needed stating that a PGD may be appropriate for a P medicine where a) the patient is exempt from prescription charges and b) in settings where access to a retail pharmacy may be limited i.e. in-patient settings, care homes and custodial settings. Where GSLs are needed then protocols enabling the supply rather than PGDs can be used. | Thank you for your comment. Further information can be found on the hyperlink provided on 'To PGD or not to PGD' in the good practice guidance. |
| 589 | Secure Environments Pharmacist Group | 3.1 | 20 | Box 2 | An additional bullet point for use of PGDs for minor ailment/triage clinics where this maximises the use of skill mix in a care setting where the use of non-medical prescribers is unavoidably low. I understand the sentiment that prescribers should be encouraged and used where possible but for many provider organisations this is a longer term strategy and PGDs provide a safe and effective solution for maximising skill mix and patient access to minor ailments. | Thank you for your comment. Minor ailments would be covered within bullets 2 and 3 of box 2. The setting alone should not determine the need for a PGD. |

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| 590 | Secure Environments Pharmacist Group | 3.2 | 25 | 20 | The use of an appeals process appears to add another layer of bureaucracy to an already cumbersome process. If the submission process is robust would it be needed? In practice this may be onerous. | Thank you for your comment. The GDG agreed that an appeals process for decisions made by a medicines decision-making group reflects good practice. |
| 591 | Secure Environments Pharmacist Group | 3.2 | 25 | 2 | Seeking stakeholder engagement from patients seems rather impractical and probably unlikely to happen in practice | Thank you for your comment. The GDG agreed the recommendations reflect good practice. Implementation of the recommendations is for local consideration and determination and outside the scope of this guidance. |
| 592 | Secure Environments Pharmacist Group | 3.2 | 28 | 6 | There is an assumption all areas have all encompassing formularies. Although recommended in practice do formularies exist everywhere and do they contain this level of detail contained? | Thank you for your comment. The NHS standard contract requires all providers of NHS services to comply with NICE technology appraisals and to publish their local formularies. NICE issued good practice guidance on Developing and updating local formularies in December 2012. |
| 593 | Secure Environments Pharmacist Group | 3.3 | 20 | Box 5 | There needs to be complete clarity as to the developing and authorising body for Public Health programmes where responsibility for delivery of these programmes rests with Public Health England and/or NHS England. For example immunisation programme delivery (where high volumes of PGDs are used in GP practices and other settings) is now the responsibility of NHS England. To support clarification it would be helpful to add an additional scenario to cover immunisation programmes such as child immunisations which are commissioned through NHS England in partnership with Public Health | Thank you for your comment. Following publication of the draft guidance, the GDG have been made aware that the MHRA are currently reviewing legislation relating to the authorisation of PGDs by independent medical agencies.<br><br>NHS England has published some emerging scenarios for nationally commissioned immunisation and vaccination programmes following consultation of the draft guidance. The guidance has been updated to reflect this comment. |

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| | | | | | England. There should be clarity around the organisation responsibilities for the production and governance of PGDs for childhood immunisation programmes and other services commissioned by NHS England (e.g. prescribed services in specialised commissioning)<br>A further scenario should be added to cover Public Health England services such as sexual health programmes (e.g. EHC, Chlamydia), flu programmes (e.g. flu vaccines) and smoking cessation (e.g. NRT). | |
| 594 | Secure Environments Pharmacist Group | 3.3 | 32 | 30 | Following SPC is not applicable for example when following JCVI advice for immunisations. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 595 | Secure Environments Pharmacist Group | 3.3 | 34 | Recommendations box | Based on the statement about commissioner and provider collaboration on page 32, I suggest that an additional recommendation about collaboration is included relating to this. Otherwise this aspect may get lost when commissioners and/or external authorising bodies develop the PGDs. The function of accessing expertise for PGD development is the main element that makes this collaboration required, especially for smaller providers. | Thank you for your comment. The GDG discussed and agreed that collaboration between commissioners and providers is a theme that is considered throughout the guidance, and is for local consideration and determination. |
| 596 | Secure Environments Pharmacist Group | 3.4 | General comment | Omission within the section | Current advice for custodial settings such as prisons has been that the prison governor or chief police officer | Thank you for your comment. This is outside the scope of this good practice guidance. A hyperlink to the MHRA guidance has been added for further information. |

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| | | | | | has needed to sign PGDs as part of the authorisation. This is shown here: http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheprivatesector/index.htm . The consultation document does not include guidance on authorisation for these settings. Please can the guidance be extended to include the advice about these settings so that appropriate authorisation and signatories can be maintained or set up in the new NHS structures? | |
| 597 | Secure Environments Pharmacist Group | 3.5 | 44 | Bullet point 5 | I agree that it is important for the documentation/patient record to identify who has issued the medicine using a PGD. However the need for a signature is not necessary where a clinical IT system is used to record the supply. This is because the clinical system will be logged into by the user and thus there is an automatic record of who issued the medicine. The consultation which resulted in the issue of the medicines under PGD along with details of the medicine supplied is what should be recorded in the IT system in these circumstances. A common solution used by providers to ensure consistency for this is the | Thank you for your comment. Electronic signatures can be used when signing a PGD, providing guidance issued by the Department of Health is followed. Governance processes would be for local consideration and determination. |

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| | | | | | use of a specific PGD-based template.<br><br>For paper-based documentations of care (i.e. in the absence of an IT record), then I agree that the name and signature of the person issuing the medicine under PGD should be recorded along with the written details/outcomes of the episode of care relating to this supply. | |
| 598 | Secure Environments Pharmacist Group | 3.5 | 46 | 2.5.5 | When medicines are supplied by PGD a PIL is a requirement.<br>In practice following administration is this really achievable? | Thank you for your comment. The GDG agreed this represents good practice. |
| 599 | Secure Environments Pharmacist Group | 3.7 | 52 | Paragraph 5 line 4 | The example of training to administer an injection is flawed as the function/competencies of physically administering a medicine are separate from the competencies to assess the patient for the need of the injection. Using a PSD in this case requires competency in the former but not the latter. Using a PGD requires competency in both. The following is a suggested way of including a similar example*: For example, health professionals who had not completed appropriate training on assessing the appropriateness of an injection may be legally able to administer it under a PGD (i.e. they have been trained to administer the injection), but the GDG did not consider a PGD to be an* | Thank you for your comment. This section has been reworded following further discussion by the GDG. |

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| | | | | | *appropriate option without successful completion of additional training on patient assessment. Prescribing or a Patient Specific Direction (PSD) should be used until the appropriate patient assessment training* ***and relevant medicines administration training*** *has been completed.* | |
| 600 | Secure Environments Pharmacist Group | 3.8 | 57/58 | Patient Safety Incidents section | I agree that reporting and actions resulting from Patient Safety Incidents needs to be included. However in order to clarify that this section relates to those incidents relating to PGD supply/administration (i.e. within the scope of the guidance) can I suggest the section is reworded to make it clearer that incidents relating to PGD use should be integrated and included in the organisation's processes for handling patient safety incidents for all organisations involved in developing and authorising PGDs. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |
| 601 | Secure Environments Pharmacist Group | 3.8 | 59 | Bullet point 1 | As above this bullet point can be focussed on PGDs by changing it to:<br><br>*Patient safety incidents, such as medication errors, near misses and suspected adverse events that occur where a PGD was used as part of the episode of care.*<br><br>This is also relevant for recommendation 2.84 on page 60. | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| 602 | Secure Environments Pharmacist Group | 3.8 | 59 | Bullet point 2 | In addition the Terms of Reference (ToR) of the PGD approval and PGD working group (or ToR of a group which takes on this function such as a Drug and Therapeutics committee) are needed. This is because the PGD approval and working group processes need to align with organisational structures and accountability. The members should also declare any conflicts of interest (which they may have already completed for other functions they deliver in the organisation).<br><br>This is also relevant for recommendation 2.84 on page 60. | Thank you for your comment. This has been considered in section 3.3 of the guidance. Relevant text has now been amended to reflect this comment. The GDG agreed the PGD working group would not require Terms of Reference, although the roles and responsibilities of each person, how they work together to develop the PGD and how the group operates should be determined locally and clearly defined. |
| 603 | Secure Environments Pharmacist Group | 4.3 | 62/63 | Last paragraph on page 62 and first two paragraphs on page 63 | I agree that the guidance doesn't fully cover the arrangements needed for these different settings. See my comment on section 3.4. The Secure Environment Pharmacists Group and East and South East Specialist Pharmacy services will be able to help you in identifying and guiding providers and commissioners in the practical interpretation of this guidance for custodial settings. | Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of the process are for local consideration and determination. |
| 604 | Secure Environments Pharmacist Group | Glossary | 65 | Second paragraph: Definition of dispense | I disagree that "dispense" involves giving the medicine to the patient. "Dispense" is to make up (i.e. package and label) the medicine prior to administration or supply. The use of | Thank you for your comment. The relevant text has now been amended to reflect this comment. |

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| | | | | | dispense to describe handing over a medicine to a patient is the main source of confusion in medicines handing functions and responsibilities, especially within the nursing profession. Please consider adjusting this definition as follows:<br><br>*To make up, (i.e. package and/or label) a clinically appropriate medicine, prior to supply for self-administration or administration by another, usually a health professional. In the case of POMs, dispensing must be in response to a legally valid prescription. There is no legal distinction between 'dispense' and 'supply'*. | |
| 605 | Secure Environments Pharmacist Group | Overall | All | All | Overall this is a very well written guidance document that once finalised will provide an essential core up to date guide on how to handle the use of PGDs within the legislation. It covers all aspects of PGD handling in a logical systematic way providing an easy to read document. This is particularly commendable given the complexity of the use of PGDs in all the different provider and commissioning bodies. | Thank you for your positive comment supporting the guidance. |