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Edition Number 7

Quality in Practice
Guidance for Dispensing Practices in England, Scotland and Wales

Introduction


This new, seventh edition of the dispensing guidance aims to reflect the changing environment in which dispensing practices operate. In response to members’ requests since the 2012 update, information relating to Controlled Drugs has been given its own specific section, and new sections have been added to provide information on preparing the dispensary for an inspection by the Care Quality Commission (CQC) and implementing a successful home delivery service.

Keeping this guidance up to date is no mean feat, and so our thanks go to the DDA Board and its associates, who have helped in the production of this edition. Particular thanks must go to DDA website journalist Ailsa Colquhoun for her help in updating this edition, and to Brian Brown, National Medicines Manager, Medicines Optimisation Team at CQC, for his comments and assistance. Dr Malcolm Ward, whose work on earlier editions of the DDA dispensing guidance still proves invaluable.

We aim to keep this guidance under constant review to keep pace with legislative and service delivery changes, and we welcome your help in alerting us to any updates, errors or omissions. Please send these to: office@dispensingdoctor.org

The guidance will be posted in the members' section of the website, at www.dispensingdoctor.org along with any subsequent revisions.

Over the years, the DDA dispensing guidance booklet has become a valuable tool for all those who are involved in dispensing by doctors. Please take the time to read it carefully, bringing the relevant points to the attention of your dispensing team.

Dr Richard West MBE
Chairman
The Dispensing Doctors’ Association
Historical Context

There are around 1,200 dispensing practices in the UK, supplying pharmaceutical services to almost four million of their 8.7 million registered patients.

The rules governing who may or may not receive dispensing services have changed little in the last century; it was Lloyd George’s administration that decided that, in rural areas, where patients lived more than a mile from their nearest pharmacy, an exception must be made to the tenet that “doctors prescribe and pharmacists dispense” and they could ask their doctor to dispense directly to them.

Medicine and technology have come a long way since 1911 and the boundaries between pharmacy and medicine have become less rigid; not only do doctors dispense, but increasingly, pharmacists prescribe. So the old tenet is no longer valid.

If we want to retain the ability to provide the dispensing services that our patients value so highly, then it is essential that those services are of the highest quality.

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Definitions
Chapter 1: The prescription

1.1 Checking for prescribing errors

Even the best prescriber makes mistakes, and that applies across the whole host of prescribers, whether medical (GPs, doctors, consultants) or non-medical (pharmacists, nurses, dentists, podiatrists, radiographers, etc). The dispensary, therefore, fulfils a very important double-checking role, even when the doctor’s prescribing expertise is extensive and very familiar, to ensure that the right patient gets the right drug, in the right quantity, and in the right dose and strength – every time a drug is dispensed.

The Patient Safety Observatory report identifies the following medication errors as the most common:

• **Wrong dose, strength or frequency of medicine**
• **Omitted medicine**
• **Wrong medicine.**

**Source:** Patient Safety Observatory report. Safety in doses [online] available from: www.nrls.npsa.nhs.uk/resources/search-by-audience/community-pharmacy-staff/?entryid45=59822&p=3

Two groups of patients are commonly associated with medication errors:

• Patients with known allergies to certain medicines, particularly to antibiotics
• Children, particularly, aged up to four years. The commonest problems are in dose calculation (including 10-fold errors) and particular medicines (gentamicin).

If you are the dispenser and still in doubt, refer back to the prescriber.
If you are the prescriber then ask a colleague.

NHS Commissioning Board Special Health Authority offers a wealth of good advice on preventing medication errors. The seven key actions to improve medication safety are:

1. Increase reporting and learning from medication incidents and identify actions against local risks in an annual medication report
2. Implement and audit NPSA safer medication practice recommendations – see link below for more information
3. Improve staff skills and competences
4. Minimise dosing errors, by providing information, training and tools for staff to make calculations of doses easier, and target efforts towards high-risk areas (such as children) and high-risk drugs (such as insulin)
5. Ensure medicines are not omitted, by identifying current levels of omitted medicines and target areas for action (for instance, anticoagulation or other high-risk medication), reviewing medicine storage and medication supply chains
6. Ensure the correct medicines are given to the correct patients by improving packaging and labelling of medicines, and supporting local systems that make it harder for staff to select wrong medicines or give medicines to wrong patients.

7. Improve recording of patient allergies, and raise awareness amongst staff of high-risk products and the importance of knowing the patient’s allergy status.

More information
NHS Commissioning Board Special Health Authority medication safety resources [online] available from: www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/

1.2 Signing the prescription

Thanks to the use of computerised systems in general practice, prescriptions are generally transmitted electronically to the dispensary. Provided the software safeguards are in place to prevent someone other than the doctor issuing a prescription, the Medicines Act definition of an “electronic prescription” is satisfied, and a handwritten signature is not required prior to dispensing to comply with the criminal law. The Care Quality Commission has agreed that while this practice potentially does not comply with regulations, it is “modern good practice”.

The regulator of GPs additionally offers the following pragmatic guidance:

Acute/consultation prescriptions
Ideally prescriptions should be printed in the consultation room and signed at the time. If this is not the case, there needs to be a robust process in place to ensure that prescriptions are usually signed at the end of the same day. There should also be a robust system to verify the accuracy of the supply. This provision does not apply to prescriptions for controlled drugs.

For information relating to CDs see section 4.4.

Repeat prescriptions
These should be signed before medicines or appliances are supplied to the patient – and ideally before the dispensing takes place. On occasions where this is not possible, the procedure to follow should be supported by a practice protocol and a clear audit trail.

Schedule 6 of the 2013 NHS Pharmaceutical Services regulations (as amended) modifies the terms of service of dispensing doctors to:
• Exempt personally administered items from the requirement to record any order before the drugs or appliances are dispensed
• State that dispensing doctors must not unreasonably refrain from issuing a prescription form for dispensing at a pharmacy, if the patient so requests.

The legislation also intends that the pharmaceutical terms of service of dispensing doctors will become the terms of service of their primary medical services contract with the NHS, and so become enforceable under that contract. This aims to pacify those respondents to the consultation who commented that dispensing doctors should be subject to the same performance sanctions regime as pharmacists and dispensing appliance contractors.

More information

1.3 Prescriptions for pharmaceutical ‘specials’

Due to their cost, pharmaceutical ‘specials’ should only be prescribed after extensive consideration of the patient’s pharmaceutical needs, comprising the following step-wise approach:

1. Consider referral to speech and language therapy for a swallowing screening assessment. Speech and language therapists may be able to recommend simple interventions to help patients swallow
2. Medication review to check that medication is still required
3. Use a licensed medicine in a suitable formulation - consider changing the drug or formulation taking into consideration possible differences in bioavailability and ingredients
4. Use a licensed medicine in an unlicensed manner. Prescribers must be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative that does not require manipulation. A written direction must be documented in the patient's care plan
5. Use an unlicensed special. Special-order liquid medicines are unlicensed and can be expensive.

The prescription for the special should define exactly what the medicine should consist of (the formulation). Prescribers are advised to specify a batch-produced formulation, where possible.
More information


More information on endorsing and procuring specials can be found in Sections 1.6 and 3.4.

1.4 Understanding prescription charges

In England, from April 2015, the charge is £8.20 for each prescription item, preparation or type of appliance including each anklet, legging, knee cap, below knee, above knee or thigh stocking.

Unless a completed declaration of entitlement to exemption or remission is made on the prescription form, a charge is payable for each drug or appliance supplied, including each piece of elastic hosiery.

Elsewhere in the UK (Wales, Scotland and Northern Ireland) prescriptions are free.

More information


Single or multiple charges
Part XVI of the Drug Tariff for England, Section 11, Notes on charges payable, lists the rules which govern single and multiple prescription charges.

A single charge is payable where:

- The same drug or preparation is supplied in more than one container
- Different strengths of the same drug are ordered as separate items on the same prescription form
- More than one appliance of the same type (other than hosiery) is supplied
- A set of parts making up a complete appliance is supplied
- Drugs are supplied in powder form with a solvent separate for subsequent admixing
• A drug is supplied with a dropper, throat brush or vaginal applicator
• Several flavours of the same preparation are supplied.

Multiple prescription charges are payable where:
• Different drugs, types of dressings or appliances are supplied
• Different formulations or presentations of the same drug or preparation are prescribed and supplied
• Additional parts are supplied together with a complete set of apparatus or additional dressing(s) together with a dressing pack
• More than one piece of elastic hosiery is supplied.

Charge exemptions
The list of exemptions to the prescription charge, now payable in England only, is extensive.

Provided that the appropriate declaration is received, a charge is not payable for drugs or appliances, including elastic hosiery, supplied for:

• Children aged under 16
• Young people aged 16, 17 or 18 in qualifying full-time education
• People aged 60 and over
• People holding a valid exemption certificate, which is issued to:
  • Expectant mothers
  • Women who have borne a child or women who have given birth to a child in the last 12 months
  • People suffering from the following specified conditions who have a valid exemption certificate:

  I. permanent fistula (for example, caecostomy, colostomy, laryngostomy or ileostomy) requiring continuous surgical dressing
  II. a form of hypoadrenalism (for example, Addison's Disease) for which specific substitution therapy is essential
  III. diabetes insipidus and other forms of hypopituitarism
  IIII. diabetes mellitus, except where treatment is by diet alone
  V. hypoparathyroidism
  VI. myasthenia gravis
  VII. myxoedema (that is, hypothyroidism requiring thyroid hormone replacement)
  VIII. epilepsy requiring continuous anti-convulsive therapy
  IX. continuing physical disability which means they cannot go out without the help of another person
  X. cancer - for further information about the exemption for cancer please see the Drug Tariff for England and Wales.
• War pensioners holding a War Pension exemption certificate for prescriptions needed for treating their accepted disablement
• People who have purchased a Prescription Prepayment Certificate (PPC), which is valid at the point of dispensing
• Contraceptive substances, drugs used for contraceptive purposes, and listed contraceptive appliances
• Medication administered personally by a GP
• People in receipt of certain State benefits
• People named on, a valid NHS Tax Credit Exemption Certificate
• People named on a valid HC2 certificate (help with healthcare costs)
• Released prisoners who present an FP10 or FP10 (MDA) will not have to pay a prescription charge for any item on that form if the following applies:
  I. ‘HMP’, the prison name, address and the prison telephone number is printed in the box provided for the practice address on the front of the form, with the prescribing code and responsible Primary Care Trust code
  II. The patient does not have to sign the declaration, but should print their name and address if different from the front of the form. Should the patient be homeless the use of ‘No Fixed Abode’ is acceptable in part 3 of the form.

Exemption certificates only apply to charges for NHS prescriptions but they cover all prescriptions, not just those for the exempting condition.

Pending receipt of an exemption certificate, patients should ask the dispenser for an NHS receipt (FP57) (which is also a refund claim form) when they pay a prescription charge.

Medical exemption
Patients diagnosed with one of the qualifying conditions for medical exemption, who are aged 60 or and over are exempt from NHS prescription charges on age grounds and do not need to apply for a medical exemption certificate.

However, patients who are exempt because they are receiving a relevant benefit, for example the universal credit, may wish to apply for a medical exemption certificate so they are covered if their financial circumstances change.

Applications for medical exemption for all patients, including cancer patients, are made to, and exemption certificates issued by, the NHS Business Services Authority (BSA). Certificates run for five years and are in respect of all NHS prescriptions, not just those for the exempting medical condition.

Certificates can be used until the end date shown. A reminder will be issued automatically and the certificate may then be renewed if the qualifying
conditions still apply. Certificates do not have to be returned if the patient’s condition changes. They should be returned on the death of the patient so the system may be noted and no reminders sent.

Application forms FP92A are only available for NHS use. They are normally purchased and distributed by NHS England. They have been revised to include cancer patients.

If a patient receiving private treatment has an NHS doctor, they may apply for exemption if the doctor has access to records to enable him/her to confirm the patient’s statement.

**More information**


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### 1.5 Obtaining patient declarations

To secure exemption of or remission from prescription charges when presenting an FP10 prescription form for dispensing, the patient, or a patient representative must complete the declaration on the back of the prescription form.

If a charge is paid, patients or their representatives should sign the prescription form to declare this. Charges are retained by the dispensing practice whose payment for provision of pharmaceutical services will then be adjusted accordingly.

**Managing declarations**

Dispensary staff are reminded that they must ask for proof of exemption on every occasion. If this evidence is not available, dispensers should mark the evidence not seen box on the reverse of the prescription.

Patients should be advised that claims for exemption from prescription charges may be subject to post-payment verification checks, which are administered locally by the local area team. If it is found that prescription charge exemption has been claimed incorrectly by the patient or their representative, the patient may be asked to pay the original charge, plus a penalty charge in accordance with the Health Act 1999.

Practices also have a vested interest in ensuring that exemption declarations are made correctly: prescription forms submitted for reimbursement without a completed reverse declaration will be considered a chargeable item, the prescription ‘switched’ to the chargeable bundle, and a deduction will be made from the practice’s remuneration. The only exceptions are computer-generated prescriptions for patients with the relevant age exemptions, and those for personally administered items.

Therefore, before submission, practices must make every effort to ensure the patient or patient’s representative has filled in and signed the prescription
charge declaration. However, dispensing practices are not expected to be confrontational and if no evidence is seen, they should tick the box in the right hand corner of the reverse of the prescription form to say so.

**Off-site deliveries**

When an item is delivered to a patient outside the surgery, the practice must make every reasonable effort to obtain a signed declaration from the patient regarding their status for paying the prescription charge.

**Patient representative’s liability**

However, there will be occasions when repeat prescriptions are delivered to points outside the surgery, or for example for collection from village shops in rural areas. Where a patient is exempt from charges and it is not practical for the patient to sign the form, dispensing staff or the doctor may act as the patient’s representative and fill in and sign the declaration on the patient’s behalf. However, they should only do so when there is absolutely no doubt as to the claimed exempt status. The representative who signs on the patient’s behalf will be held jointly and severally liable by the NHS counter fraud authorities for any incorrect claim made.

**More information on the transit of medicines off-site is included in Section 2.10 of this Guidance.**

**Contraceptives**

In some circumstances, contraceptive products will attract a prescription charge, so the script must be endorsed to show whether a charge has been levied.

An example is co-cyprindiol (Dianette/Clairette/Acnocin/Diva/Cicafem) which is prescribed both as a contraceptive pill and as a specific treatment for acne.

When used for acne only, a prescription charge is due. When used for contraception the prescription form needs to be endorsed by the prescriber with the female gender symbol, ♂, OC or CC to qualify for prescription fee exemption. Patients should also sign the contraceptive exemption declaration on the reverse of the form.

**Governance**

The practice must ensure they have collected charges where appropriate and keep accurate monthly records of:

- The total number of exempt items, and prescription forms dispensed
- The total number of ‘paid for’ items and forms dispensed
- The total amount of fees collected: this should equal the total number of fee-paid items multiplied by the current prescription fee
- The total number of items and forms covered by pre-payment certificates.
Before submission, FP10s should be checked to ensure the declarations have been filled in and signed, except for those relating to personally administered items and computer-generated prescriptions exempted on age criteria. It may be helpful to ask the prescriber to write exempt items such as the contraceptive pill and personally administered items on separate FP10s, to reduce the administration of tallying and recording charged and exempt items on the Prescription Pricing Authority submission document (form FP34D). Practices should also check that the prescriber code matches the form type (eg, Nurse prescribers may not use doctors’ prescription forms, and vice versa).

**Planned exemption checks**

As this guide went to press (September 2015), the Department of Health was in the process of implementing plans that by 2018 will enable all NHS dispensing contractors (community pharmacies and dispensing practices) to have access to an electronic database to check a patient’s prescription charge exemption status.

The plans require dispensing staff to verify a patient’s entitlement to free NHS prescriptions against a national database at the point of dispensing.

When details of the planned arrangements are available, the DDA will ensure that the practical implications for dispensing staff are considered. Dispensary staff should check DDA Online for more information on these plans, as this becomes available.

**Wales:** In Wales, there is no longer any requirement for a patient or their representative to sign the declaration on the reverse of a WP10 to be exempt from paying a prescription charge.

**Scotland:** Even though prescriptions (GP10) are free, the patient/patients representative is required to sign the reverse of the script at Part B as confirmation that the item(s) have been dispensed.
1.6 Endorsing the prescription

To ensure that the practice is paid correctly for the prescriptions it dispenses, the prescription must be correctly endorsed. Prescription pricing departments cannot read practices’ minds - only the prescription endorsement in front of them - particularly, as pricing is now done using computer scanners.

Drugs to be reimbursed only in certain circumstances

Some drugs can only be prescribed and dispensed on the NHS in some circumstances. The endorsement is your claim that these circumstances have been met. There are two main endorsements to consider:

- Advisory Committee on Borderline Substances (ACBS)
- Selected List Scheme (SLS).

Most computer systems provide automated ACBS and SLS endorsement, and the prescriber – not the dispenser – should ensure this endorsement is applied.

The Drug Tariff should always be consulted if there is any doubt as to the reimbursement status of a drug.

The Tariffs can be found at:


ACBS (Advisory Committee on Borderline Substances)

Certain foods and toilet preparations have characteristics of drugs. The circumstances in which such substances may be regarded as drugs, and therefore, supplied to NHS patients, are decided by the Government body, the Advisory Committee on Borderline Substances. To verify that the item is being prescribed for a medical condition, prescriptions must be endorsed ‘ACBS’.

Examples of items requiring ACBS endorsement include: gluten-free foods for coeliac disease, food supplements such as Fortisip and Ensure, complete food preparations such Nutrison, topical preparations such as E45 emollient bath oil and total UV block preparations.

More information

Part XV of the Drug Tariff for England and Wales
Part 12 of the Drug Tariff for Scotland
MIMS [online] from: [www.mims.co.uk](http://www.mims.co.uk)
BNF Appendix 7 [online] from: [www.bnf.org](http://www.bnf.org)
SLS (Selected List Scheme)
The SLS comprises ‘black’ and ‘grey’ lists. Drugs on the black list may not be supplied on the NHS, while drugs on the ‘grey list’, may be supplied on the NHS only for specific medical conditions. The endorsement SLS verifies that these circumstances have been met. Practices are reminded that in England, in 2014, the National Health Service (General Medical Services Contracts) (Prescription of drugs etc.) (Amendment) Regulations 2014, removed generic ingredient sildenafil from Part XVIIIA and B of the Drug tariff (the Black and Grey Lists) and removed the NHS prescribing restrictions for sildenafil (NB: and other generic drugs used in ED). However, branded Viagra remains on the grey list.

Wales and Scotland
As this guide went to press (September, 2015) in Wales and Scotland, NHS prescribing restrictions on sildenafil remain in place, although since April 2013 GPs in Wales may prescribe sildenafil for a wider group of patients who are experiencing severe distress as a result of their condition. In Scotland men diagnosed as suffering severe distress because of their impotence may access sildenafil through the hospital service.

More information

The National Health Service (General Medical Services Contracts) (Prescription of drugs etc.) (Amendment) Regulations 2014 available [online] from: http://www.legislation.gov.uk/uksi/2014/1625/regulation/1/made


Part XVIII of the Drug Tariff for England
Part 12 of the Drug Tariff for Scotland

Endorsements related to reimbursement
The requirements for endorsing prescriptions in relation to reimbursement are set out in the Drug Tariffs.

England and Wales
For a generic product listed in Part VIIIA or Part VIIIB of the Drug Tariff, reimbursement is based on the Drug Tariff price. The only endorsement that may be required is the pack size where there are multiple pack sizes listed.
For example where the pack used is 56 and the quantity supplied is 28 the fraction 28/56 should be written in the endorsement column.

**For a generic product which is not listed in Part VIII A of the Drug Tariff, reimbursement is based on the manufacturer’s list price of the endorsed product.**

Endorsement of the brand name is therefore required as well as the pack size where multiple pack sizes of the product are available. If no brand exists, then an endorsement of manufacturer/supplier is required. If the product is less common the net price before discount and ex VAT should also be endorsed. Please note that it should be clear whether the price endorsed is for the prescribed quantity or for the full pack size used.

**Other common endorsements**

**Broken bulk**

‘Broken bulk’ allow dispensers to claim for reimbursement of the full minimum quantity obtainable from a supplier or manufacturer of a product, even if the patient only requires a smaller quantity (as indicated on the prescription form). This provision only applies to those products where the minimum quantity obtained cannot be readily dispensed for another patients during the next six months – in fact, any subsequent prescription submitted within the following six months for the same item in any quantity up to the quantity already reimbursed will be deemed to have been supplied from the remaining original quantity, and will not be reimbursed. Exceptions to the broken bulk entitlement are listed in the Drug Tariffs.

The endorsement is: **BB**

**Out of Pocket expenses (OOP)**

A 50p threshold for claims applies, and entire claims will be paid (no deductions).

To make claims for Out of Pocket Expenses (OOP) as described in Part II, Clause 12 of the Drug Tariff, practices should endorse prescriptions ‘XP’ or ‘OOP’ along with details of the claim, eg, carriage, P&P. Please make sure that details of the claim are directly adjacent to the item for which you are making the claim otherwise the claim may not be reimbursed (for example, if the details are added next to a prescribed item for which OOP is not allowed). You do not need to claim OOP against all items on that particular form unless expenses have been separately incurred for each item. There is no longer any need to total and submit the OOP claim on the submission form. These prescriptions should be separated from the bulk of prescriptions.

**More information**

NHS BSA quarterly hints and tips bulletins available [online] from: [http://www.nhsbsa.nhs.uk/3191.aspx](http://www.nhsbsa.nhs.uk/3191.aspx)
Specials

England and Wales
Reimbursement prices for commonly-prescribed specials are included in Part VIIIIB of the Drug Tariff for England and Wales.

Items not included in Part VIIIIB will be reimbursed according to how the item has been obtained.
Where the item has been obtained from a manufacturer holding a MHRA specials licence, reimbursement will be made according to the price endorsed by the contractor.

Endorsement required
The price endorsed should be the actual invoice price paid by the dispensing practice less any discount or rebate linked to the procurement of the item (irrespective of when the discount is received). The dispensing doctor discount recovery rate (clawback) will be applied, as set out in the NHS GMS Statement of Financial Entitlements (SFE).

Contractors are reminded that the endorsement should also include:

- The manufacturer's/importer's licence number
- The batch number of the unlicensed medicine.

Where the special has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, by the contractor or by a third party, the contractor shall endorse the names, quantities and cost of the ingredients used in preparing the special.

Remuneration
Dispensing practices in England and Wales are paid a £20 fee for dispensing any special. The fee must be claimed by endorsing XP on the prescription, together with the amount claimed: £20.

This is set out in the paragraphs of the Drug Tariff ‘Arrangements for payment for all other specials and imported unlicensed medicines’ and ‘Endorsement requirements above Part II Clause 9’.

Each £20 claimed must then be included on the FP34D submission documents sent to the NHSBSA. Further guidance is included on the reverse of the FP34D document.

More information
Scotland

Streamlined arrangements for the reimbursement of non-Part 7S/U items in Scotland came into effect from September 1, 2015 and these allow Scottish dispensaries to dispense non-Part 7 S/U items without seeking prior authorisation from the health board in the following two scenarios:

- Authorisation was obtained for patient prescription within last 12 months with less than 20% price variation from original authorisation
- Preparation is available from an NHS manufacturing unit within Scotland/ England/ Wales.

The new arrangements are contained in a Generic Framework for Specials Authorisation Process across Scotland, which also details the process for health board authorisation of non-Part 7 products not covered by the framework’s arrangements, and the process for recovery by health boards of unauthorised expenditure.

Remuneration

For items not listed in Part 7, the contractor or the contractor’s representative must endorse the invoice price less discount and prescriber’s details, and where possible, stamp, date, initial and endorse the Certificate of Analysis (COA)/Certificate of Conformity (COC) or invoice (where COA/C is not available). To receive the fixed non-Part 7S handling charge, practices should endorse ‘hc’. If other OOP expenses apply (including wholesaler handling charges) endorse as postage and packing costs (pp).

More information


At-a-glance prescription endorsement guide: England and Wales

<table>
<thead>
<tr>
<th>Prescribed Product</th>
<th>Dispensing Endorsements required for reimbursement</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Tariff Part VIII generic medicinal product</td>
<td>None required</td>
<td>Only required if more than one pack size listed in Part VIII</td>
</tr>
<tr>
<td>Proprietary or branded medicinal product</td>
<td>None required</td>
<td>Only required if more than one pack size listed in manufacturers price list</td>
</tr>
<tr>
<td>Non-Part VIII generic medicinal product</td>
<td>Yes</td>
<td>See above</td>
</tr>
<tr>
<td>Drug Tariff Part IX generic medical device</td>
<td>None required</td>
<td>Only required if more than one pack size listed in Drug Tariff Part IX</td>
</tr>
<tr>
<td>Part IX Proprietary or branded medical device</td>
<td>None required</td>
<td>Only required if more than one pack size listed in Drug Tariff Part IX</td>
</tr>
</tbody>
</table>
### Other endorsements

<table>
<thead>
<tr>
<th>Category</th>
<th>Uses and Restrictions</th>
<th>Endorsement Requirement</th>
</tr>
</thead>
</table>
| Broken bulk                       | For products not likely to be readily dispensed over the next six months. Exceptions apply | BB  
The pack size supplied must also be endorsed                                               |
| Hosiery                           | Sufficient information about the product being dispensed is needed.                     | compression class article style quantity knit  
If appropriate made to measure eg, Class2, Thigh Length, 2 stockings, Circular Knit          |
| Not Dispensed                     | Where an item has not been dispensed the prescribed product name should be scored out and an ND endorsement made immediately adjacent to the prescribed product name. | ND  
Dispenser is also required to score out item in prescribed area                            |
| Price                             | For less common products (other than unlicensed specials and imports) and for certain appliances, the total net price for the prescribed quantity (before discount and ex VAT) should be endorsed on prescriptions. For unlicensed medicines not listed in Part VIIIB (England and Wales) the total net price for the prescribed quantity (after any discount or rebate and ex VAT) should be endorsed on prescriptions. If the price endorsed relates to the price of the pack size this should be clearly endorsed. | IP  
£p (before discount and ex VAT)                                                          |
| Trusses                           | Single or double, and side if single. Position, eg. Inguinal, Scrotal Type, eg. Spring truss, Elastic band truss. | single double position type                                                               |
| Unlicensed specials and imported products | Products not listed in Part VIIIB (England and Wales) should be endorsed with manufacturer/supplier and net price (after any discount or rebate and ex VAT). | net price (after discount or rebate and ex VAT) if appropriate                           |
Useful further endorsing guidance
NHS BSA dispensing endorsing guidance for dispensing practices available [online] from:
http://www.nhsbsa.nhs.uk/PrescriptionServices/1119.aspx

PSNC guide to prescription endorsement available [online] from:
http://psnc.org.uk/dispensing-supply/endorsement/endorsement-guidance/

Scotland

Probable endorsements:
The four boxes on the pink GP10 prescription form, in the right hand column, represent the pack size boxes. All other endorsements should be printed under the four boxes for each item on the prescription. The only data included in the box should be the pack size in numeric quantity only. Please do not enter units of measure such as `g’ or `ml’.

Pack endorsement: The pack endorsement is used to indicate the size of pack used to dispense the quantity. Under the pricing rules, the Scottish pricing authority, Practitioner Services Division assumes that you are using the most economical pack sizes available. However, for many products different pack sizes are available. If the pack size you are using differs from the most economical pack size, you will need to add a pack size endorsement to determine payment.
Pack of 28 will be denoted as: 28

Quantity supplied (if not as prescribed): If in dispensing a product, you have to change the quantity so that it differs from the prescribed quantity, an endorsement should be added to show the quantity change.
A quantity change may be required where the prescriber prescribes an amount which cannot be dispensed exactly, due to the nature of the pack. The quantity change allowed is related to the size and number of packs available, and is subject to PSD rules.
Denote 60 quantity supplied as: 60

Manufacturer: To ensure accurate payment for items prescribed generically which are not in the Drug Tariff, you should provide the name of the manufacturer. In the absence of an endorsement you will be paid from a pecking order from an agreed list.
Invoice price endorsement
The endorsement is SP, followed by the NHS net cost price, excluding VAT, in format ‘pppp’. The claim below is for £4.58. An invoice should be submitted as evidence of the claim, but the price claimed must be declared on the prescription form or no payment will be made.
Example: SP 458

Out of pocket expenses
Where additional expenses have been incurred in obtaining supplies of a drug other than items in Parts 2-7 and 9 of the Scottish Drug Tariff, payment of the amount incurred will be made if the contractor submits a claim. You should provide evidence of cost, including the nature of the expense, and the value claimed. Where the invoice covers more than one prescription form, Out of pocket expenses should be claimed on one occasion only. The endorsement is: XP and the cost must be stated in the format pppp.
Example: For out of pocket expenses of £7.95, the endorsement is: XP 795

Items in short supply
Where a dispensing practice is unable to obtain an item listed in Part 13 of the Scottish Drug Tariff, at the price listed in the Tariff, they should endorse the prescription with the manufacturer/brand and the net cost price excluding VAT. A copy of the invoice should be paper-clipped to the prescription.

More information
1.7 Submission for pricing

Hospital prescriptions

Some hospitals do not provide outpatient dispensing services but instead issue the patient with a FP10 (HP) prescription (England), WP10HP (Wales) or HBP (Scotland). If the patient is on your dispensing list, you may dispense this medicine to him/her.

In England, Scotland, and Wales dispensing practices may also dispense for their dispensing patients prescriptions generated by dentists and by an out of hours service.

Payment for hospital-generated prescriptions

FP10 (HP) or equivalent prescriptions can be submitted for payment by general practices using the normal payment submission routes. FP10 (HP) or equivalent prescriptions should not be transcribed onto practice prescription forms as this will result in the drug costs being attributed to the practice rather than the hospital. The same applies to prescriptions issued by dentists.

England

FP10s should be sorted into patient charge group: exempt, paid, paid at the previous year’s rate. Each group should be segregated and secured with a plastic band.

Within each group, prescriptions should be sorted in the order below:

- Resubmitted forms from previous month/s
- Forms FP10MDA by prescriber surname – to be sorted open and flat
- Forms FP10D
- Forms FP10P/SS with relevant practitioner indicator by prescriber surname, eg, PN=Practice Nurse, CN= Community Nurse
- Forms FP10P/SS with supplementary prescriber (SP) indicator by prescriber surname
- Forms FP10SS/NC Hospital forms
- All other FP10 forms by prescriber surname.

Dispensing contractors must send in the pink FP34D Submission Document declaration form when making monthly claims for reimbursement and remuneration, and a FP34D Appendix form for high volume personally administered vaccine items.

More information

NHS BSA information. Sending in your reimbursement and remuneration claim – declaration forms available [online] from:

http://www.nhsbsa.nhs.uk/2473.aspx
Wales:
Contractors are asked to separate exempt prescriptions into two groups before submission for pricing:

**Group 1:** Those that can be priced automatically  
**Group 1a:** Those prescriptions that need to be priced by an operator  
**Group 2** Patient charge has been levied

Separating scripts into Group 1 and Group 1a

**Group 1 (to be automatically priced)**
This group should only include regular (WP10SS, WP10IPSS, WP10SPSS & WP10PN) exempt prescriptions which have been dispensed as prescribed and where there is no additional claim or endorsement added i.e. where you would be happy for an automated system to pay you for the prescription as it has been prescribed.

**Group 1a (to be passed to an operator for review and pricing)**
Group 1a should include all of the remaining exempt prescription forms. This group will include all of the remaining prescription form types and any prescription forms where changes or additional endorsement has been necessary i.e. an exception applies.

**Group 1a would therefore include the following:-**

**Exceptions:**
- Broken Bulk claimed
- Dispensed quantity is different to that prescribed
- Out of Pocket Expenses claim
- Item not dispensed
- Local special scheme endorsed (eg, WRS)
- Additional items claimed (eg, droppers)
- NCSA or NCSO items
- Generically prescribed but branded drug indicated on prescription
- Hand written amendment has been made to prescribed information

**Other Prescription Forms:**
- Resubmissions
- WP10HP(AD) (Hospital CD instalment)
- WP10MDA (GP CD instalment)
- All other non standard WP10 forms including Repeat dispensing forms
- All WP10 equivalents eg, England FP10 series forms
In Wales the submission document is the WP34D. Personally administered items can be submitted online.

More information
NHS Wales Primary Care Services information. Submitting your dispensing account available [online] from:
http://www.primarycareservices.wales.nhs.uk/submitting-your-dispensing-account-1

Scotland
Scotland’s Practitioner Services Division requires the submission document, the yellow GP34A, to be completed with the following information:

- Dispensing month
- Date of dispatch
- Contractor code
- Practice Name and address including postcode
- Practice stamp
- VAT registration number
- Signature of Doctor
- Forms and items as exempt - please align to the left.

It is important that the figures detailed on the GP34A declaration agree with the forms being submitted on that occasion.

More information
Scotland’s Practitioner Services Division. Information for dispensing doctors available [online] from:
http://www.psd.scot.nhs.uk/professionals/pharmacy/information-for-dispensing-doctors.html
Prescription handling tips

<table>
<thead>
<tr>
<th>Glue:</th>
<th>Avoid sticking a label on the prescription during the dispensing process. Residual glue can jam the high speed scanners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removable items:</td>
<td>Avoid using tape, pins, paperclips, staples or post-it notes, as these have to be manually removed</td>
</tr>
<tr>
<td>Stamping:</td>
<td>Take care when stamping and endorsing prescriptions not to obliterate the age and date of birth box on the front of the prescription form. Difficult to read age/DOB information could lead to the prescription being switched from exempt to chargeable</td>
</tr>
<tr>
<td>Endorsing:</td>
<td>Endorse legibly and clearly, using only the minimum amount of information required. As far as possible, keep endorsements within the left-hand margin of the prescription form. Printed endorsements that are faint or out of line with the prescribed product information risk being referred back. There should not be a gap between consecutive item endorsements. Please ensure that items are separated, and that it is clear where one endorsement ends and another starts</td>
</tr>
</tbody>
</table>

1.8 Understanding the schedule of payments

Since the introduction of new automated prescription scanning equipment in England, prescription pricing accuracy has emerged as an area of concern. All practices, irrespective of location, are advised to check carefully their schedule of payments, particularly for discrepancies relating to prescription charges and expensive items. If you believe that there is a significant discrepancy over reimbursement of a particular bundle you may arrange for the bundle to be sent by the pricing authority to your primary care organisation/health board for inspection. The pricing authorities cannot return individual prescription forms for retrospective correction.

To help identify discrepancies relating to prescription charges, practices should keep detailed monthly records of:

- The total number of exempt prescription forms dispensed including a record of the number of items covered
- The total number of ‘paid for’ items dispensed and the number of related forms
- The total amount of fees collected: this should equal the total number of fee-paid items multiplied by the current prescription fee
- The total number of items and forms covered by pre-payment certificates.

England and Wales

NHS Prescription Services produces electronic payment schedule data (called 'electronic FP34 data') which contractors can use instead of receiving a paper copy. It is not a like for like replacement of the paper version and practices will
need to develop their own IT solution to allow them to read and manipulate the data as it is not readily exported to Microsoft Excel.

Schedules can be received in conjunction with the paper FP34 and a 12-month history is maintained. At an agreed time, the NHS Prescription Services will stop sending paper FP34s.

An example Schedule file is available at: http://www.ppa.org.uk/systems/sys_main_fp34.htm

**More information**


**Scotland**

Information on dispensing related payments due to Scottish practices is issued each month by the Practitioner Services Division in the form of a Summary of Payments and an attached A3 payment breakdown document. Contractors should pay particular attention to the sections covering deductions and VAT, particularly on Personally Administered items. Payments are made three months in arrears.

### 1.9 Private sales

Under the provisions of The Medicines Act 1968 any doctor can supply, on a private basis, all classes of medicines, including those on the General Sales List, Pharmacy List (P) medicines and Prescription-only Medicines.

All patients have a right to ask for a private prescription, however, an NHS practice may not demand or accept a fee for the provision of a service that constitutes treatment, for a prescription or for the supply of any drug, medicine or appliance except in the circumstances set out in clause 484 of the GMS contract (similar restrictions apply in PMS contracts). Private prescriptions for treatment/s other than the exceptions listed above must be directed to a pharmacy for dispensing.

A GP’s NHS contract strictly limits the private supply of medicines to:

1. Private patients, who can be supplied with any required medication from the practice
2. NHS patients of the practice:
   - for treatment consisting of an immunisation for which no NHS remuneration is payable, and which is requested in connection with travel abroad
   - for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in his possession solely in
anticipation of the onset of an ailment or occurrence of an injury while he is outside the United Kingdom but for which he is not requiring treatment when the medicine is prescribed

− if the patient is a dispensing patient of the practice and the medicine cannot be prescribed on the NHS – ie, it is listed in Schedule 1 (the ‘black list’) of the NHS (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 or in Schedule 2 (SLS – the ‘grey list’) for which the patient does not meet the requirements for provision under the NHS. (Clause 484.11)

− for prescribing or providing drugs for malaria chemoprophylaxis.) (Clause 484.12).

The transaction should always be regarded as dispensing a prescription-only medicine and a full record made accordingly and it is suggested that the charge should take account of:

• The cost of the drug
• An on-cost element
• VAT
• A dispensing fee.

For NHS patients of the practice the charge cannot include any fee for the act of private prescribing. The exception to this rule is for prescribing, on a private basis, anti-malarial drugs for travel abroad. Specific provision has been made for this in the GMS contract (clause 484.12).

**Over-the-counter General Sales List (GSL) and Pharmacy medicine (P) items**

Since there is no statutory distinction between POMs, P-list and General Sales list items supplied by doctors, dispensing doctors may not sell to their NHS patients any OTC items that are available on NHS prescription, eg, aspirin, or paracetamol. Such items must be prescribed using an NHS prescription form, and the appropriate prescription charge paid. As a ‘blacklisted’ medicine, Panadol, however, can be supplied privately.

Our legal advice is that a dispensing practice can dispense privately for their NHS patients only those items that are blacklisted and only if the patient is a dispensing patient (clause 484.11).

A strict interpretation of clause 483 would preclude a practice from charging a fee for use of credit or debit cards to pay prescription charges.

**Contract clause 483**

483. The Contractor shall not, either itself or through any other person, demand or accept from any patient or its representative a fee or other
remuneration for its own or another’s benefit 483.1 for the provision of any treatment whether under the Contract or otherwise, or 483.2 for any prescription or repeat prescription for any drug, medicine or appliance, except in the circumstances set out in clause 484.

1.10 Vaccinations/antivirals

Vaccines

England and Wales: Practices are reminded that centrally procured vaccines sourced using ImmForm should not generate an NHS prescription and reimbursement request. These forms should be used to only to reimburse the practice for payment for vaccines that are classed as for personal administration and where the vaccine has been purchased by the practice.

Practices incorrectly accounting for vaccines should email NHS BSA Prescription Services for a payment adjustment.

E: nhsbsa.repricingrequest@nhs.net

Public Health Wales Vaccine Preventable Disease Programme (VPDP) available [online, access to the NHS Wales network is required to view] from: http://howis.wales.nhs.uk/immunisation

Scotland: Centrally procured vaccines should be obtained using the stock order (GP10a) system. The GP10 prescription and reimbursement request should only be issued to reimburse the practice for payment for vaccines that are classed as for personal administration and where the vaccine has been purchased by the practice.


Flu pandemics

The UK Health and Social Care Influenza Pandemic Preparedness and Response document 2012 provides guidance on operational aspects of pandemic response in the health and social care sectors throughout the UK. This should be read in conjunction with the UK Influenza Pandemic Preparedness Strategy 2011.

The strategy outlines the principle of rapid access to antiviral medicines, antibiotics and healthcare. This principle allows the supply of antiviral medicines at premises that are not a registered pharmacy, and as such, enables dispensing doctors to dispense pandemic related supplies to non-dispensing list patients.

In the event of a pandemic, antiviral medicines may be supplied on the basis of an authorisation voucher for children under 13 years of age or the right hand side of the FP10 or equivalent for patients aged 13 or over.
This guidance, despite its England-specific references, is said to be generally applicable for Scotland and Wales, but in the event of an actual pandemic, contractors are advised to contact Public Health England/health board as arrangements may be subject to change. As this guide went to press (September, 2015), a Scotland-specific version of the UK guidance was under development.

More information

1.11 Record-keeping
All items dispensed must be properly recorded and all records kept for at least 11 years.

Specials
Where there is a Certificate of Analysis (COA)/Certificate of Conformity (COC) for the special, the contractor must stamp, date, initial and endorse the COA/COC with the invoice price less discount, plus the prescriber’s details, and submit these monthly to the NHS England area team/health board. Where a COA/COC is unavailable, the invoice should be endorsed as above, and submitted to the relevant primary care organisation.

The following records must be kept for five years:

- The source of the special or imported unlicensed product
- The person to whom and the date on which the special or imported unlicensed product was sold or supplied
- The prescriber’s details
- The quantity of each sale or supply
- The batch number of the special.
Chapter 2: The dispensing process

2.1 Staff training and development

In August 1998 the Court of Appeal confirmed that it is lawful for dispensing GPs to delegate to employed staff the act of dispensing medicines for their patients. The DDA encourages and promotes dispenser training. All staff should be adequately trained for all the tasks they are required to perform as part of their job. They should be involved in CPD and encouraged to keep up to date.

**Qualifications and standards**

There are currently no compulsory qualifications for dispensers in general practice. In order to be eligible for the Dispensary Services Quality Scheme (England and Wales) payments all current staff must have a qualification equivalent to a Level 2 Certificate in Pharmacy Service Skills (NVQ) (QCF). This qualification offers skills in teamwork, health and safety, preparation and issuing of prescribed medicines and the ordering, receipt and storage of pharmaceutical stock.

A higher level of qualification, the Level 3 Diploma in Pharmacy Service Skills (NVQ) (QCF) is now available to dispensing practices, giving dispensers skills in accuracy checking, giving pharmaceutical information and advice, assisting in the validation of prescriptions and the counselling of patients, and making more effective contributions to patients’ medication use reviews (DRUMs).

**Registering as a pharmacy technician**

It will be helpful for practices to understand the requirements for dispensing staff who wish to register as a pharmacy technician. Staff may apply to register as a pharmacy technician if they have:

- Approved qualifications (competency and knowledge qualifications) and meet the work experience requirements
- They are an EEA national with an EEA pharmacy technician qualification.

The qualifying period of work experience comprises two years’ relevant work-based experience in the UK under the supervision, direction or guidance of a pharmacist to whom the technician pre-registrant has been directly accountable for not less than 14 hours per week. During these two years, the technician pre-registrant must have completed at least 1,260 hours of work experience (excluding sickness absence, maternity leave and holidays) and at least 315 hours of work experience in each year.

From July 1st, 2011 it has been mandatory for pharmacy technicians to register with the General Pharmaceutical Council to practise in England, Scotland and Wales. Employers of pharmacy technicians must satisfy themselves that those working within their organisation are appropriately trained and registered.
Only those on the GPhC’s register can work as, or call themselves, a pharmacy technician.

**Apprenticeships**

**England:** Fully funded Advanced Apprenticeships are available to candidates aged between 16-18 years who meet the Skills Funding Agency eligibility criteria. There is an employer contribution required for candidates aged over 19.

The Advanced Apprenticeship programme consists of the BTEC Level 3 Diploma in Pharmaceutical Science (QCF), Level 3 Diploma in Pharmacy Service Skills (NVQ) (QCF) (formerly NVQ 3 Pharmacy Services Evidence Collection), Functional Skills Level 2 in Maths and English and Employee Rights and Responsibilities Workbook.

**Eligibility**

- Candidates must live in England and have either been a resident in the UK and Islands for 3 years prior to enrolment, or have been a national of the European Union for 3 years
- Candidates cannot be in full time education, must be aged 16 years old or above and must be provided with a contract of apprenticeship employment
- A minimum hourly rate of £3.30 is applied for all apprentices in the first year of their apprenticeship. Salary must meet the Minimum Wage Regulations thereafter
- Apprentices must work for a minimum of 16 hours a week. It is anticipated that all employed apprentices will be engaged in working and learning for a minimum of 30 hours per week.

Apprenticeship candidates will complete the Level 2 Certificate in Pharmacy Service Skills (NVQ) (QCF), Level 2 Certificate in Pharmaceutical Science (knowledge) (QCF) and Functional Skills Level 1 in Maths and English.

Advanced apprenticeship candidates will complete the Level 3 Diploma in Pharmacy Service Skills (NVQ) (QCF), BTEC Level 3 Diploma in Pharmaceutical Science (knowledge) (QCF) and Functional Skills Level 2 in Maths and English.

Employers are advised to check current apprenticeship arrangements in England, as their need arises, as the arrangements in England were under review as this guide went to press.

**Wales:** Fully funded Level 2/3 apprenticeships are available to candidates aged 16-24 years. Full funding for employers offering Level 4+ apprenticeship training is available to candidates of any age.

Further employer incentive programmes include:

- Jobs Growth Wales Scheme (JGWS) allows employers to offer fully funded six-month work experience placement)
Young Recruits Programme (JGWS follow on apprenticeship funding).

More information

Scotland: Funding is available for the employer when taking on an apprentice. Each local authority has incentives to help the employer with wage costs. Contact your local authority for more information. With regards to training, Skills Development Scotland contributes funding towards the training costs, and priority funding is given to 16-19 year olds.

More information


Careers Wales website information available [online] from: www.careerswales.com. Tel: 0800 028 4844

Skills Development Scotland website information available [online] at: https://www.ourskillsforce.co.uk/modern-apprenticeships/
Tel: 0800 783 6000

Appraisal
Annual staff appraisals are both good practice, and a requirement for both the DSQS and Quality and Outcomes Framework (QOF) payments.

2.2 Standard Operating Procedures

Standard operating procedures (SOPs) are defined as ‘detailed written instructions to achieve uniformity of the performance of a specific function’ and should be produced for each dispensing activity in the dispensary. They form part of the DSQS and they contribute to patient safety.

Writing an SOP
SOPs should be specific to the practice and should set out in writing what
should be done, when, where and by whom. They must be reviewed and updated at least once every 12 months, and whenever dispensing procedures are amended. A written audit trail of amendments should be maintained.

More information


2.3 The dispensing process

Most dispensing practices will be fully computerised and this is strongly recommended in the interests of patient safety, providing an audit trail, and saving staff time.

The dispensing process involves six basic stages:

- Prescription interpretation
- Avoiding picking errors
- Containers
- Labelling
- Checking
- Supply to patient.

Interpretation

The dispensary’s task is to supply the item in accordance with the prescriber’s instructions, which should state:

- The drug
- The strength
- The quantity
- The correct form.

Dispensers should also consider whether the right drug has, in fact, been prescribed. Any doubts or queries should be referred back to the prescriber (see section 1.1). For this reason, dispensers should have easy access to a doctor at all times during the working day, either in person, by computer email messaging or by telephone. Though training and the use of standard operating procedures, dispensary staff should be clear when, and in what situations they need to seek advice from the prescribing GP.
2.4 Avoiding picking errors

From June 2012 the key functions and expertise for patient safety developed by the National Patient Safety Agency (NPSA) have transferred to the NHS Commissioning Board Special Health Authority.

This organisation reports that over 80% of dispensing errors are picking errors. These errors involve the selection of the wrong strength or formulation of the correct medicine, or the wrong medicine completely.

A number of factors are associated with an increased risk of picking errors:

- Not being able to find medicines (illogical or chaotic stock organisation)
- Cluttered and overstocked storage (refrigerators, CD cabinet and shelving)
- Inadequate attention markers for drugs with similar names
- Staff fatigue
- Interruptions.

According to the NHSCB SHA, the risk of picking errors may be decreased through good dispensary design, and the use of automation (robots).

More information

NHSCB SHA guide. Design for patient safety guide to the design of the dispensing environment available [online] from:

http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/

2.5 Containers

All dispensed medication must be supplied in an appropriate container (eg, bottle, box, etc). Blister packs or special containers should not routinely be repackaged.

If a medicines is repackaged, suitable containers for medicines include:

- Small glass or plastic tablet bottles
- Brown glass bottles for liquid medication for internal use
- Ribbed brown glass bottles for liquid medication for external use
- Cartons or bags for blister-packed oral dosage forms
- Jars for dispensing of topical preparations
- Dropper bottles.

Liquid medicines in small doses

It is no longer appropriate to dilute liquid medicines. Where doses of less than 5ml are required an oral dosage syringe should be supplied. The patient or the patient’s representative should be advised how to use the syringe.
Child resistant packaging

It is good practice to dispense medication in child-resistant packaging. The Medicines and Healthcare products Regulatory Agency notes:

- Child-resistant packaging is legally required only for medicines which contain aspirin, paracetamol and those which contain more than 24mg of elemental iron.
- Medicines containing dosulepin are required by virtue of the marketing authorisation to be supplied to the market in packs which have been shown to be child resistant.

The relevant regulations are: The Medicines (Child Safety) Regulation 2003 number 2317 [SI 2003/2317] available [online] at:

Dispensers should also consider the following exceptions to supply using a CRC:

- Specific request - the patient, carer or representative requests a container that is not child resistant, perhaps due to difficulty in opening a CRC. A poster near the dispensary will help to advise patients of this right of request. The request may be met by supplying a compliance aid or non-CRC lid.
- Original pack - there may be reasons underpinning why the medicine should remain in the original container. Medicines requiring specific containers are indicated with a black square.
- No CRC exists for a particular liquid medicine.

Where appropriate, the patient should be counselled and advised to keep medicines away from the reach and sight of children.

Monitored Dosage Systems

Since their UK introduction in 1989, monitored dosage systems (MDS) have become an accepted way of helping patients to medicines compliance. Department of Health guidance on assisted administration of medicines concludes they are a useful way of supporting around one in two people requiring assistance with their medicines use.

However, dispensing practices must consider the liability issues of MDS: drug licence holders are not obliged to produce stability data for the use of their drug in a compliance aid, and without this, drugs are not licensed for use in this situation. Therefore, the decision to fill an MDS is effectively dispensing the medicines ‘off-licence’, placing the resulting liability on the prescriber for that action.

As with other unlicensed medicines, off-licence prescribing should only be done in agreement with the patient/carer or when a ‘best interests’ decision has been taken. MDS should not be used when patients’ use of medicines is supported by a paid care worker.
The final decision to include or exclude a drug from a compliance aid is therefore left up to the dispensary. Factors that may influence this decision include: previous practice/experience with the drug and any supplier information on the chemical and physical properties of the drug, eg, hygroscopicity and light sensitivity.

A seven or 28-day prescription may prompt the decision to supply a medicine in an MDS. The NHS takes the position that seven-day prescriptions should only be issued when it is in the best interests of the patient to receive medication in seven-day cycles. As well as those with varying prescriptions, this may include patients such as: vulnerable patients, the elderly or addicts, who cannot cope with larger quantities of medication for a month.

For workload related issues, the dispensary may decide to supply four weeks’ supply at a time, but in four separate cassettes. In this instance, only one prescription should be issued to cover the month’s supply. This is a matter of probity based on the principle that the dispensing fee relates to the physical act of dispensing the quantity of medication detailed on the prescription.

**More information**


**Choosing the Right MDS: factors to consider:**

- Does it accommodate all the doses needed throughout the day?
- Is it easy for the patient or carer to use?
- Are the dosage instructions, time and patient details clearly visible?
- Are the medicines clearly identified on the tray?
- Is the system tamper-evident?
- Can individual doses be removed to take on days out? If so, are their instructions/patient details on each individual dose to maintain continuity of compliance?
- Does it have any features to combat MRSA such as antimicrobial packaging?
- Does it accommodate all tablets and capsules, including hygroscopic.
2.6 Labelling

The Medicines Act 1968 specifies that the following information must appear on the label of every dispensed item, even if the patient is supplied with more than one container of the same medication:

- The name of the patient
- The name and address of the surgery/pharmacy supplying the medication
- The date of dispensing: this should be the date on which the supply is actually dispensed. Labels should not be printed in advance.
- Directions for use should include:
  - the number of tablets to be taken (eg, one tablet to be taken)
  - the frequency of dosage (eg, three times a day)
  - any qualifying information (eg, when required for the relief of pain).
  - specific instructions. Avoid phrases such as: ‘as directed’ or ‘as before’, or Latin terms
- The words “Keep out of the reach of children”
- For medicines for external use, the words “For external use only”.

It is also considered good practice to include on every dispensed label:

- The name and strength of the medication
- The form of the medication (eg, tablets, capsules, syrup, etc)
- The quantity dispensed clear, comprehensive and legible. Latin abbreviations should not be used
- Specific dosage instructions (eg, one tablet to be taken three times a day)
- Any relevant cautionary and advisory labels (See BNF Appendix 3).

Other labelling considerations

- Positioning: Labels must not obscure any information on the bottle or packet
- Inner containers: Inner containers should also be labelled, as the outer packaging may be discarded in use
- Handwritten labels: for patient safety reasons, handwritten labels are not recommended
- Cautions: Where the number of cautionary and advisory labels exceeds the space on the label, a second label may be needed. In the absence of computer-generated warnings, a range of supplementary warning labels should be available
Medicines dispensed out-of-hours: Medicines dispensed out-of-hours are not exempt from legal requirements. A pre-printed label carrying the doctor's name and address should be used. All handwritten labels should comply with the legal requirements above.

Additional patient information: Supply as required.

2.7 Checking

Before supplying the medicine to the patient, the dispensary must ensure no dispensing errors have occurred. Misreading the prescription is the most common reason why dispensing errors occur. Therefore, all dispensary tasks (drug selection and labelling) should be checked against the original prescription. A good checklist will include the following checks:

**Checklist 1: Looking at the original prescription, have you dispensed?**

- ✓ The right drug
- ✓ The right strength
- ✓ The right form
- ✓ The right quantity
- ✓ A medicine with an adequate shelf-life

Medicines should not be dispensed if they are out of date or are likely to go out of date before the quantity supplied is used, e.g., a six month supply of oral contraceptive pills with an expiry date for 3 months' time. Out-of-date stock should be quarantined, and destroyed.

**Please see section 3.5 for more information on medicines disposal.**

**Checklist 2: Looking at the original prescription, does the label include?**

- ✓ Correct, specific directions
- ✓ The correct patient's name
- ✓ The correct date of dispensing
- ✓ The relevant cautionary or advisory labels
- ✓ The name of practice supplying the medication.

**Checklist 3: Have you?**

- ✓ Used an appropriate container
- ✓ Recorded who dispensed and who checked the items
- ✓ A small, adhesive check slip can be incorporated either as part of the main label or as a small, separate additional label. The initials of the relevant staff will provide an audit trail of the dispensing process.
Cross-checking

Where two members of staff dispense together, the checking procedure should involve each staff member checking the other. Where a single member of staff dispenses alone, extreme care should be taken by the individual to ensure that everything is double-checked prior to being issued to the patient. Electronic checking systems using bar codes are ideal for this.

2.8 Dispensing audit

Dispensing errors or near-misses should be audited for learning purposes. They should also be reported to the NHS National Learning and Reporting Service [online] at: http://www.nrls.npsa.nhs.uk/

A successful audit will result in the following:

- Full details of errors occurring during the dispensing process will be recorded
- Dispensary staff should be aware of and able to address, the stage/s of dispensing and circumstances where errors most commonly occur
- Dispensary staff should be aware of, and able to address the type/s of errors that most commonly occur
- Dispensary staff should be aware of, and able to address, the causes of errors that most commonly occur
- Dispensary staff should be aware of, and able to address, the frequency with which they make errors
- Staff will be able to identify appropriate preventative action in response to dispensing errors.
## Type of error

### 1. Labelling Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong drug/form on label</td>
<td>wrong drug name or form on label (e.g., ointment instead of cream)</td>
</tr>
<tr>
<td>Wrong strength on label</td>
<td>e.g., 25mg instead of 50mg on label</td>
</tr>
<tr>
<td>Wrong directions on label</td>
<td>Eg, one three times a day instead of One twice a day</td>
</tr>
<tr>
<td>Wrong patient name on label</td>
<td>Do not include examples of spelling mistakes</td>
</tr>
<tr>
<td>Wrong quantity on label</td>
<td>e.g., 28 tablets instead of 56 tablets on label</td>
</tr>
<tr>
<td>Wrong label on container</td>
<td>Labels swapped with those belonging to another drug or patient</td>
</tr>
</tbody>
</table>

### 2. Selection Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong drug/form selected</td>
<td>Incorrect drug or form dispensed</td>
</tr>
<tr>
<td>Wrong strength selected</td>
<td>e.g., 25mg instead of 50mg dispensed</td>
</tr>
<tr>
<td>Wrong quantity counted</td>
<td>e.g., 28 tablets instead of 56 tablets dispensed</td>
</tr>
</tbody>
</table>

### 3. Bagging Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong name on bag</td>
<td>Do not include examples of spelling mistakes</td>
</tr>
<tr>
<td>Wrong address on bag</td>
<td>Do not include examples of spelling mistakes</td>
</tr>
<tr>
<td>Item omitted from bag</td>
<td>e.g., two items in bag instead of three items</td>
</tr>
<tr>
<td>Extra item in bag</td>
<td>e.g., an extra item from another patient is included in the bag</td>
</tr>
</tbody>
</table>

### Common causes of errors include:

- Labelling errors: Typing mistakes, incorrect selection form the computer and using the previous drug/dose on PMR
- Medicine picking errors
- Interruptions
- Novice staff
- Time of day (changing performance levels over time).

## 2.9 Issuing medicines to patients

### Patient counselling

Counselling should be built into the consultation process by the GP and the practice nurse. At the end of the process, patients should know what their
medicines/appliances and inhalers are for, and how they should be taken/used.

Dispensers may have a role in double-checking that the patient has understood and assimilated this information, and should understand what to do if any further information is required. If an unlicensed medicine has been dispensed, staff should take extra care to ensure that the patient is aware of that fact, and knows what to do if they have any problems.

A suitable area should be available to allow patients to discuss matters with dispensary staff in private.

An SOP may be written to cover the referral of patient queries back to the GP.

**Patient information leaflets**

Since 1999 all medicines should be supplied with an approved patient information leaflet (PIL). Where original packs have to be broken, for example, when a shorter course of an antibiotic is indicated than provided in the original pack, then the patient information leaflet should be photocopied or a copy downloaded from the manufacturer’s website.

Similarly, when there has to be a change in the form or dosage of the medication, an explanation should be given to the patient both verbally and in the form of a suitable written instruction.

**Other good practice**

**Storage:** A supervised and secure space should be designated for dispensed medicines until they are collected.

**Bag label:** Dispensed medicines/items should be issued in a paper or plastic bag properly labelled with the patient’s name and address.

**Identity check:** On collection, the patient’s name, address and date of birth should be checked from the label on the bag.

**Additional patient support:** Patients may also benefit from colour-coded highlights on their prescription items to help them differentiate between similarly packaged items.

### 2.10 Transit of medicines

**Home delivery**

Offering patients the opportunity to have their medicines delivered to their home can be of great benefit, particularly to those who are too frail or ill to collect their prescriptions. It’s important that you factor delivery drivers into your staff training and development plans. Delivery drivers are the face of the dispensary to housebound patients and others who choose the service, and it’s important that high standards of professionalism and safety are met with each delivery: when providing medicines via a delivery service patients or their...
carers still need to know how to use the medication safely, effectively and appropriately and check that they are not experiencing adverse effects or compliance difficulties.

A standard operating procedure should be put in place to ensure that dispensary staff, including the staff member with courier duties, follow a procedure which enables the safe, effectively and timely supply of medicines, while also safeguarding confidential information about the medication that a patient is taking. This should state when the scheduled delivery/ies will take place.

**The delivery driver should also have a current DBS check.**

Resources to support a home delivery service, including a template letter of patient authorisation, are available to DDA members from the DDA Member Resources section of the DDA’s website.

**Vehicle ownership**

Deliveries can be made by staff using their own cars (with suitable insurance - see below) or in a practice-owned vehicle. If your practice decides to use its own vehicle, you have two basic choices: Buy or lease. Which option makes better sense for your practice depends on how long you plan to keep the vehicle and how many miles it will typically be driven.

Consider carefully the cost, including tax advantages for each option. Consult your accountant for the best advice.

**Vehicle insurance**

The practice must also ensure that delivery vehicles have the appropriate insurance as standard car insurance will only cover the driver for domestic use and commuting back and forth to work.

Staff or practices should contact their insurer to discuss individual requirements, as there is a wide range of business use policies to choose from, including:

- **Business use (class 1)** - Cover for the main driver in connection with their work for driving to different sites that aren't their normal place of work. A spouse may also be covered for business use but other named drivers may not be.

- **Business use (class 2)** - Usually covers the policyholder and a named driver for business use, although some insurers may stipulate that the two must work in the same occupation.

**More information**

Delivery to a remote site for collection

When dispensed medicines are delivered to remote villages for later distribution to patients by a designated responsible person, (eg, the post-mistress/master):

- It is recommended that, wherever possible, a lockable transport container is used
- All dispensed items should be firmly sealed with staples or adhesive tape to maintain patient confidentiality and the integrity of dispensed items
- The bag should be labelled only with the name and address of the patient and the name, address and telephone number of the issuing doctor
- The designated responsible person should take care to store prescription items in a location where security and confidentiality can be assured
- The designated responsible person should properly identify the patient or the patient’s representative.

Collection book: A collection book could accompany all sealed packages dispatched to the remote distribution point and, if all parties are willing, could record:

- The date when the medication was dispatched
- The name and address of the patient
- The signature/ initial of the dispenser dispatching the medication
- The date on which the medication was collected
- The signature of the patient or patient’s representative collecting the medication.

The contents of this collection book must be considered as containing confidential patient information, and the designated responsible person should be advised to treat and store it as such.
The doctor’s bag - general guidance

For GPs on home visits, the choice of what to include in the GP's bag is determined by the medical conditions likely to be met; the medicines the GP is confident in using; the storage requirements, shelf-life and costs of such treatments; the extent of ambulance paramedic cover, and the proximity of the nearest hospital. Practice protocol should make clear who will maintain the bag, in particular, checking medicines’ expiry dates: the practice or the individual GP.

2.11 Patient data confidentiality

Dispensary staff, including couriers, should be made aware that the patient medication record is confidential, and that data should not be disclosed to anyone without the consent of the GP and, where relevant, the patient.

The current Department of Health guidance on patient data confidentiality can be found in 'Confidentiality and Disclosure of Information: General Medical Services (GMS), Personal Medical Services (PMS), and Alternative Provider Medical Services (APMS), Code of Practice', published on 24 March 2005.

Within a GP practice, this guidance clearly limits the dissemination of patients’ health and personal information. The key phrase is: ‘need to know basis’. In summary, information can only be shared if:

- The patient has given their explicit consent, preferably in writing
- Sharing the information is necessary for medical purposes and is shared by a health professional.

In exceptional circumstances, for example, when it is in the public interest, it may become necessary for the practice to disclose confidential or sensitive information.

More information

When designing or improving your dispensary layout, it is important to consult your dispensers as well as your architect. Dispensers will feel far happier working in an environment that has been planned taking into consideration their views.

Particular consideration should be given to: safety, hygiene, security, comfort, lighting, temperature control (<25°C), ventilation and space. The overall design layout should facilitate the flow of the dispensing process, and maximise patient safety.

### 3.1 Location of equipment

Dispensaries require a lot of equipment. When designing the dispensary, thought should be given to the layout of commonly used equipment, to ensure workflow remains logical, and to reduce staff fatigue - both of which are important for patient safety.

**The following equipment is usually required:**

- Computer terminal
- Printers for scripts and labels
- Scanner (eg, for computerised CD invoices)
- Barcode scanner
- Photocopier
- Shredder
- Telephone(s)/fax
- Designated fridge with effective temperature regulation and thermometer for the storage of appropriate medicines, eg, vaccines (2–8°C)
- CD cupboard
- Electronic pill counter
- Back-up triangular, manual pill counter
- Panic button for staff, connected to main security system or separate alarm.
- Lockable security hatch
- Chair(s), perhaps of the swivel type, with adjustable height to ensure optimum staff comfort/good posture
- Short stepladder for accessing higher shelves
- Storage for consumables and small equipment: labels, bags, bottles, spoons, oral syringes, measuring cylinders, monitored dose system consumables
• Designated stainless steel sink, preferably double, with draining board
• Hand-washing and drying facilities
• Bottle washing and drying facilities if undertaken
• Notice board
• Reference books: Drug Tariff, BNF, MIMS and Dispensing Guidelines
• Waste bins: for clinical waste and for general waste
• Till/cash tin, debit/credit card machine.

### 3.2 Key design features

**Easy cleaning:** Particularly of the work surfaces, floors and sink area

**Space:** the dispensary should be designed with an adequate walkway. This should be kept free from clutter

**Flooring:** should be non-slip, and anti-fatigue

**Lighting:** Ideal choices include contrast lighting that minimises shadows, incorporating natural lighting where possible

**Confidential area:** a nearby area/room should be designated for private patient counselling

**Security:** the practice should have lockable windows and a security alarm. The dispensary door should have a five-lever mortice lock. Other security features include: window security bars, a lockable security hatch, and staff panic button

**Ventilation and temperature control:** The correct operating temperature of a dispensary is below 25°C and functional dispensary room thermometers should be in place. Good practice dictates the use of multiple thermometers with valid calibration certificates that are replaced annually. A daily record of minimum and maximum room temperatures should be in place. These records should be backed up every night (if electronic), be retained for two years, and be available for audit.

Any deviations in temperature should be reported to the dispensary manager on that day.

Where items have been stored in adverse conditions then the stability of the product must be considered in light of the duration of time the product was exposed to adverse temperatures:

• Contact the manufacturer for further information
• Medicines considered unstable must be written off and disposed of following the DDA SOP: The safe and effective disposal of medications.

**Work surfaces:** There should be plenty of space to facilitate methodical working

**Sink area:** tiled splash backs are preferable to allow for easy cleaning. High rotating mixer hot and cold taps with lever handles are ideal for the needs of the dispensary.
Standing work (dispensing) should be performed at kitchen worktop height (90cm)

**Office area:** To reduce distractions, another risk factor for error, the computer and telephone should be located separate to the dispensing workbenches. Desk height (76cm) is appropriate for tasks that are usually done seated

**Shelving:** space allocation should be determined by the practice’s likely dispensing volumes and stock control efficiency, plus consideration of good item separation and ease of access (patient safety considerations). Central column-type shelving provides good access and space economy. The top shelf should, ideally, be eye-level for reasons of safety and ease of access

**Other storage:** Allow sufficient space for the storage of tote boxes, measuring devices, extemporary dispensing equipment and consumables (labels, bottles, etc, dressings and appliances

**Designated area for returned or waste medicines.**

**More information**


### 3.3 Good housekeeping

**Expire dates:** A standard operating procedure should be in place to ensure that stock is date-checked every three months, that stock is rotated correctly and that measures are in place to reduce wastage caused by expired stock, as well as the likelihood of a customer receiving expired stock.

**More information**


**The fridge:** The dispensary refrigerator should be designated for cold chain items (products requiring refrigeration). The refrigerator should be equipped with a maximum–minimum thermometer. Temperatures should be monitored at least twice weekly and recorded in a book designated for that purpose. Checking the fridge temperature on Fridays and Mondays will help identify and resolve any problems occurring over the weekend. The range of temperatures within the fridge should not fluctuate outside the range between 2°C and 8°C.
Counting equipment: Medicines should not be handled directly during the dispensing process. This can be avoided by counting using either a counting triangle or an electronic counter.

Avoiding cross-contamination: Cross-contamination from one medicine to another can occur. This is particularly hazardous if dispensing cytotoxic drugs, but can also be problematic with steroids and antibiotics. Designating dispensary equipment and regular cleaning can help avoid cross-contamination. Disposable drugs should be worn if dispensing cytotoxic drugs.

Staff cleanliness and hygiene: Dispensary hygiene can be improved through the use of:
- Alcohol hand-rubs
- Protective clothing
- The use of waterproof dressings on cuts and abrasions
- A ban on eating or drinking in the dispensary.

3.4 Procuring medicines

EU Directive 85/374/EEC 25.7.1985 requires that a supplier of a product must be able to identify the manufacturer in order to escape liability in the event of product failure. It also states that product liability holds until 10 years after the date of manufacture.

By implication, this Directive requires all dispensing contractors to ensure that all dispensed items can be linked with the manufacturer. The DDA advises that practices should record the patient name, batch number, supplier and manufacturer for every item dispensed, using either a computerised or paper-based system. Invoices should be kept for a minimum of 11 years.

Failure to record any details could render a dispensing practice liable in the event of a claim over a faulty product where the manufacturer is untraceable.

Specials

Special medicines can be very expensive (several hundred pounds for one bottle). As a matter of good practice, dispensing contractors should ensure they source non-Tariff medicines at a reasonable price. If a practice does not operate a specials formulary, this may involve obtaining quotes from a number of suppliers.

The following should inform the choice of Special supplied:
- The quality of the formulation: Dispensing contractors should specify to the supplier exactly what they require. The formulation should be chosen so that it delivers the following requirements as fully as possible:
- Safety: none of the excipients constitute a hazard to the patient
- Bioequivalence: in terms of efficacy with the alternative licensed medicine or a known bioavailability so the dosage can be adjusted
• **Stability**: A known stability profile for all ingredients within the shelf life attributed to the product

• **Patient acceptability**: The medicine is acceptable to the patient (eg, texture, taste, absorption characteristics, dose volume).

**The quality of the manufacturing process**

The manufacturer should be chosen on the basis they:

• Possess a pharmaceutical manufacturing license for the activity they are being asked to undertake

• Use Good Manufacturing Practice (GMP) processes

• Label and package the product in accordance with latest guidelines

• Provide supporting governance documentation of quality (described below)

• Provide a rapid delivery service.

**The quality of the product**

Dispensing contractors should not assume any aspect of quality and take all reasonable steps to ensure that the product supplied:

• Is of a suitable standard, ie, checking strength, formulation and excipients.

• Comes with a:

  I. **certificate of analysis (COA)**: A certificate of analysis should be available for any batch manufactured special and is evidence that critical parameters have been confirmed by retrospective physical, chemical or microbiological assay of a sample of the final product

  II. **or a Certificate of conformity (COC)**: A certificate of conformity is a signed statement by the manufacturer that they believe the product complies with the purchaser’s specification

• Is pharmaceutically appropriate and suitable for the patient

• Has evidence to support the labelled shelf life of the product

• Ideally comes with an information leaflet although this is not yet a legal requirement.

**Previous supplies**

Dispensing contractors should check if the patient has had the product supplied before (eg, by questioning the patient or asking to see the product for labelling information). If so, attempts should be made to establish the previous source of the product and continue to access it from the same supplier. This will improve the likelihood of clinical equivalence and continuity of care, minimising the risk of new side effects and adverse reactions due to different formulations.
When prescribing a pharmaceutical special there is a possibility that it will have a very short expiry - sometimes as low as seven days. Prescribers need to be aware that if this is the case they may need to prescribe four prescriptions for a month's supply of the pharmaceutical special.

Dispensing contractors should consider the amount prescribed in the light of expiry date information and contact the prescriber if necessary to:

- Adjust the quantity prescribed should the amount on the prescription lead to wastage
- Minimise the need for patients to request repeat prescriptions less than monthly, arrange for more than one prescription to be written to allow the supply to the patient for several times during a month.

Patient information
Dispensing contractors are likely to be the last point of contact with the patient prior to the unlicensed special being administered. The dispensary should check that the patient is aware they have been supplied an unlicensed medicine.

More information

Counterfeit medicines
The World Health Authority defines counterfeit medicines as those medicines that are “deliberately and fraudulently mislabelled with respect to identity and / or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging”.

Counterfeit medicines can harm patients in two ways:

- Improper treatments are a risk to public health, either through increased disease transmission or through the development of antibiotic resistance
- The credibility of a national healthcare system can be harmed if counterfeit medicines get into the legitimate supply chain, which may lead to patients becoming irrationally fearful of legitimate treatments.

The Yellow Card scheme now supports the reporting of all suspected problems or incidents to all healthcare products, including counterfeit or quality concerns, and not just suspected side effects to medicines.

Dispensing practices can make a report at:

✓ Web: [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)
Dispensing contractors are also advised to:

- Await MHRA instructions – conducting unilateral action may prove ill-advised, unnecessary, confusing and counter-productive
- If a drug alert and recall notice is received, be prepared to:
  - check the current stock held in the dispensary and return any potential counterfeit medicines in line with guidance issued
  - if possible, interrogate the PMR systems to reveal which individual patients are on that particular medicine and when it was dispensed
  - contact those patients who have been supplied with that particular medicine within the suggested timeframe to check on their medication.

If a patient is concerned that they have a counterfeit medicine then dispensing staff should make a record of this (ideally, recording patient contact details, reason for patient's suspicion, product name, dosage, batch number and expiry date) and inform the MHRA immediately.

Tips for evaluating product sources and detecting counterfeit medicines

- Establish the integrity of the source prior to need - always purchase medicines from licensed wholesalers and suppliers – establish thorough and regular due diligence checks, and system reviews
- Where possible, establish a list of approved suppliers
- Require that any alternative source of supply provides the following as a minimum:
  - a pedigree back to the previous source
  - certification that it is not a diverted product
  - certification that any actions by the alternative source will not alter any original manufacture warranties or guarantees
  - certification that the product has been stored and handled consistent with product labelling requirements.
- Be cautious about product offered at an unusually cheap price and / or in unusually large quantities (particularly in a large quantity of the same batch number)
- Consider developing a list of key pharmaceutical products that will not be purchased from sources other than the manufacturer, or authorised distribution channel
- Look for an altered expiry date. Counterfeiters commonly purchase 'short-dated' products and then alter the labels
- Compare product physical characteristics to other units of the same medicine, particularly: colour, tablet or capsule markings, shape and thickness and weight
• Compare packaging: Particularly, paper texture, gloss or finish, size and thickness of the labels, containers and lids, font differences and print colour or texture, also on flaps
• Look for signs of tampering: removed or switched product label, tacky residue on the container, faded or discoloured label edges, breaks or tears in the sealing tape and seals
• Look for overt security features such as holograms or colour shifting inks
• Listen to patients: Counterfeit medicines are often first detected by patients.

By 2018 it is expected that the European Falsified Medicines Directive 2011 will require dispensaries across the UK to be able to scan each prescription item and where necessary manage the quarantine of products identified by the product database as potentially falsified.

More information

Changing distribution models
Preventing the risk of counterfeit medicines entering the UK supply chain has been cited as the reason for the introduction of new models of medicines distribution, particularly, the Direct to Pharmacy (DTP) model.

In the DTP model, the manufacturer sells direct to the end customer, the dispensing contractor, using an exclusive or reduced number of wholesaler/s acting as distributors or logistics service providers only. DTP tends to be chosen by the larger firms. Glaxo was first, and Pfizer the second. In 2010 Pfizer, GSK, AstraZeneca and Merck, together, were said to account for just under 30% of the total UK pharmaceutical market.

An increasing number of companies use DTP models to distribute a limited range of lines, usually those that are low volume and high cost. Their other lines are distributed using the Reduced Wholesaler Model (RWM).

RWM schemes
In Reduced Wholesaler Model Schemes (RWM or Reduced Wholesaler Agreements, RWA), a pharmaceutical company will use specific wholesaler/s partners (usually, two, although solo and three-way RWM models also exist). Apart from the restriction on the number of wholesalers used, the RWM model is based on the traditional wholesale business model, ie, the wholesaler/s owns the stock and can offer discounts in the usual way.
Since its introduction, the RWM model has been widely adopted by pharmaceutical suppliers. At the 2011 Dispensing Doctors' Association conference, it was said that only 20% of all items are supplied outside either an RWM or DTP wholesaling model.

**More information**

**Medicine shortages**
New models of medicines distribution have been cited as a cause of medicines shortages, which have affected UK dispensing contractors since 2009. Other reasons include exchange rate variations that favour medicine exports, consolidation of manufacturing sites and inappropriate quota setting.

Since 2011 the Dispensing Doctors' Association has endorsed Best Practice Guidance for Ensuring the Efficient Supply of Medicines, which calls on dispensing practices to maintain UK patient benefit as their first priority.

**The guidance also sets out:**
- The expectation that, under normal circumstances, dispensaries should receive medicines within 24 hours
- That requesting faxed prescriptions prior to supply is not acceptable routine practice and where verification is necessary, dispensers should not disclose patient or prescriber identifiable details
- The importance of regular communication between manufacturers and wholesalers so that all parties have a good understanding of the supply and demand for particular products
- The need for all in the supply chain to have contingency arrangements in place to source supply where there are supply difficulties.

**Implications for prescribers**
If wholesalers are unable to supply a particular medicine, the practice dispensary is advised to try the relevant product licence holder (manufacturing company) for emergency supplies. Otherwise, a prescribing review may be necessary, taking into account the clinical history of the patient, the therapeutic equivalence of the medicines under consideration and adherence issues relating to a packaging/presentation change. Doctors should bear in mind their primary duty to act in their patient's best interests, while making efficient use of available resources. Prescribing decisions should always be taken in consultation with the patients, and should not be influenced by the dispensing status of the patient, or any commercial or financial reasons.

Co-operation with other professionals to minimise the effects of supply problems is essential.
3.5 Disposing of medicines

Out of date or returned medicines should not be dispensed, as it is impossible to vouch for the condition of these drugs. Instead, they should be quarantined, and put aside for disposal.

Most GPs will deal with a designated firm to provide a medicine disposal service within their area. These firms provide sealable plastic containers and separate, special containers for the disposal of Controlled Drugs. If you are not aware of such a service in your area, contact your NHS England area team/health board for more information.

Under the hazardous waste regulations there is no requirement for dispensing practices to register as a hazardous waste producer.

Inhaler recycling

From April 2015, dispensing practices can take part in a national inhaler recycling and recovery scheme, Complete the Cycle. For more information on taking part, please email: ukph.complete-the-cycle-uk@gsk.com

Sending used medicines abroad

Intercare Medical Aid for Africa can accept certain donated used UK medicines for use in Africa. For more information on taking part in the Intercare scheme, please visit Intercare [online] at: http://www.intercare.org.uk/donate-medicines

More information

Chapter 4: Influences on dispensing practice

4.1 GMS Contract and Statement of Financial Entitlements (SFE)

The dispensing fee varies on a sliding scale according to dispensed item turnover (see SFE Annex G, Part 2). Dispensing doctors should ensure that the volume of items prescribed and dispensed is commensurate with the predicted norm for the practice profile unless there are good clinical reasons for significant variance.

It has always been the case that the dispensing fee is regarded as a professional fee for the act of dispensing of the quantity of pharmaceutical product as ordered by the prescriber.

Therefore, if a patient is prescribed and dispensed monthly repeat medication, eg, furosemide 40mg one tab daily x 28 tabs, then one prescription form for this item should be sent to the pricing authority each month.

However, if the patient is supplied with, for example, six months’ supply of oral contraceptives on a repeat basis, then one prescription should be issued every six months and six months’ worth of items dispensed. It would be considered fraudulent to dispense a six-month quantity but to claim a monthly dispensing fee for six months.

Excessive or inappropriate prescribing

Annex 8 of the revisions of the SFE provides guidance as to what might be regarded excessive or inappropriate prescribing by health professionals involved in primary care. Guidance is given with regard to:

- Prescribing cost-effectively for the NHS and making changes to patients’ repeat prescribed medicines
- Drug purchasing
- Sponsorship/financial arrangements with pharmaceutical companies
- Prescribing incentive schemes
- Generic prescribing/endorsement of prescriptions
- Profligate prescribing.

GPs must always use their clinical judgement and prescribe what they feel appropriate for an individual patient. Statements indemnifying individual practices against possible future action by patients who believe they have been damaged by treatment restrictions have no legal force and do not provide any protection.

VAT registration

In England and Wales, the provisions for dispensing practices changed in April, 2006 and in Scotland, from July, 2011.
Following the changes, a dispensed prescription does not receive a VAT allowance unless it relates to a personally administered item as listed in paragraph 17.4 of the SFE. HMRC will, however, reimburse all input tax paid on NHS dispensed pharmaceutical products except those that are personally administered because they are regarded as a GMS-exempt supply.

**All dispensing practices should, therefore, be registered for VAT.**

It is worth noting that the definition of a personally administered item under Paragraph 17.4 is NOT the same as that defined by HMRC. For VAT return purposes, any item that is personally administered or applied to a patient by the doctor or his staff should be treated as VAT exempt.

### 4.2 The Dispensing Services Quality Scheme (England & Wales)

In summary, £2.58 will be payable for each patient on the practice dispensing list provided the practice signs up to and achieves the quality standards as specified in the SFE. The key SFE specifications are:

- There must be a nominated dispensing GP who will be accountable for dispensing service and standards
- Dispensing staff must have training appropriate to their role
- The practice must have a written record of all dispensing staff training and must ensure that they undertake continuing professional development and annual appraisal
- All dispensers should have training equivalent to pharmacy services NVQ level 2 or have signed up to such courses within three months of the practice signing up to the scheme
- For those with a limited dispensing role or where the residual term of employment is not commensurate with committing to a formal training course, such staff must have a certificate signed by the accountable GP and practice manager (if any) to confirm that a competency assessment has been made
- All dispensers who work independently must have a minimum of 1,000 hours of dispensing work experience over the preceding five years
- The practice must ensure that a minimum level of staff hours appropriate to patients’ needs is dedicated to dispensing services
- The practice must ensure that standard operating procedures (SOPs) are in place that reflect good practice in all the procedures that are actually performed in the dispensary
- The practice must commit to auditing dispensing services with significant event monitoring and reporting of untoward events to the area team/health board
- There must be a written policy for risk assessment and management
- Dispensary opening hours must be declared to the area team/health board and be on public display with information about out-of-hours services
• Practices conduct reviews of dispensing patients’ use of medicines (10 per cent of dispensing list/year).

The DSQS is a quality framework, which has patient safety at its centre. Widely adopted by dispensing practices, it will add to a practice's defence in the event of a significant dispensing error. The DDA, therefore, encourages dispensing practices to sign up to the scheme as soon as possible.

Any practice that encounters genuine difficulty with any aspect of the scheme should contact the DDA. If consensus emerges about specific logistical problems with the scheme, the DDA will take them up with the GPC and relevant health authorities, and seek appropriate amendment.

More information

4.3 Pharmaceutical Services Regulations

The NHS Regulations (Pharmaceutical Services) (England)
The 2013 (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 have been amended twice since publication – in 2014 and 2015 - and mainly to ensure a level playing field for current and potential providers of services, and prevent market distortions.

Dispensing registration
Part 8 of the 2013 regulations sets out the arrangements under which an NHS general practitioner who has, or whose practice has, a registered patient list may provide dispensing services.

Generally to do so, individual general practitioners or their medical practice face three hurdles: firstly, the patients to whom they could provide dispensing services must have applied to them for such services (regulation 48); secondly, they must have been granted premises approval for the medical practice premises from which they wish to dispense; and thirdly, they must have been granted outline consent in relation to the area to whose residents they wish to dispense (or have relevant historic rights to dispense).

New applications to dispense by doctors [Reg. 51]
This will not be permitted if there is a pharmacy within 1.6km/one mile of the premises from which the practice wishes to start dispensing. Note: This only applies to new applications. Existing dispensing practices retain their dispensing rights. However, non-dispensing practices that have patients in a rural area can apply to dispense from premises that are more than 1.6km from any pharmacy.

Small villages may expand to a point where it becomes viable for a practice to build premises given a successful application to dispense. The village would be
designated a reserved location until such time (if ever) that the population exceeds 2,750 within a 1.6km/one mile radius of any would-be pharmacy.

**Additional premises and relocation of premises [Reg. 55]**

If existing dispensing practices apply to relocate premises or open additional premises then approval will only be given if the premises are more than 1.6km/one mile from any pharmacy. Approval will not take effect until one year post-application to prevent manipulative moves by dispensing doctors by allowing time for a pharmacy to relocate in such circumstance. There is a provision for temporary premises approval during the 12 month interval, which may be extended to a maximum of 15 months in total.

**Minor relocations [Reg. 55]**

A minor relocation can only be considered for a pharmacy if there has not been a relocation in the previous 12 months. A similar provision allows dispensing practices to relocate without formally reapplying for outline consent to dispense or for premises re-registration approval provided it is considered to be a minor relocation with no adverse effects on existing pharmaceutical services.

To qualify as a “minor relocation” NHS England must be satisfied that:

(a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible

(b) granting the application would not result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (including by a person on a dispensing doctor list) or of local pharmaceutical services:

   (i) in any part of its area, or

   (ii) in a controlled locality of a neighbouring Health and Wellbeing Board, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate; and

(c) the Health and Wellbeing Board is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area.

This is important for practices that outgrow their premises or where premises become condemned.

**Practice amalgamations [Reg. 59]**

This regulation has proved to be problematical. As part of the national accord with the pharmacists, it was intended that the amalgamation of a dispensing practice with a non-dispensing practice would trigger a new application for outline consent to dispense, and an application for premises approval. It was also intended that putative applications could be made before an amalgamation formally took place.
If outline consent or premises approval was not granted then the practices involved could reconsider their amalgamation plans with no detriment to patient dispensing services, provided the amalgamation did not take place. If the amalgamation were to go ahead despite a failed application to dispense for the enlarged ‘new practice’, then residual dispensing rights would apply to the existing dispensing patients and residual premises approval would be given to the existing dispensing premises only.

In the case of amalgamations where each practice is a dispensing practice and where there is no change of dispensing premises there would be no requirement to apply for outline consent or for premises approval.

Recent strategy documents for general practice in England, including NHS England’s Five Year Forward View, advocate new models of scaled-up general practice. Dispensing practices considering scaled-up models of practices are strongly advised to understand the implications of the new models for dispensing rights before acting, and they should contact the DDA for advice before any formal amalgamation takes place.

More information


Inspection [Paragraph 9 of Schedule 6, Terms of Service for dispensing doctors]

NHS England area teams maintain a list of dispensing contractors, and a list of premises from which those doctors are authorised to dispense. All premises from which dispensing by doctors takes place will be open to inspection to ensure compliance with the dispensing doctor terms of service.

Control of Entry

England

In terms of pharmacy market entry (‘control of entry’), the 2013 Regulations contain the following provisions:

- remove three of the four current exemptions to the “necessary or expedient” test: 100-hour pharmacies, large out-of-town shopping centres and large one-stop primary care centres
- introduce additional provisions for the remaining exemption, distance-selling pharmacy applications
- introduce a performance management regime, including the sanction of removal, for under-performing pharmacies
• replace the necessary or expedient “control of entry” test with determinations based on needs or improvements identified in the relevant health and wellbeing board’s local Pharmaceutical Needs Assessment (PNA)

• introduce the concept of “unforeseen benefits” to the overall provision of services allowing applicants to demonstrate innovative ways of providing services or of delivering better health outcomes not anticipated in the PNA.

Wales
The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 are the current regulations in Wales. These replace the earlier regulations published in 1992. Part 5 of the 2013 regulations cover dispensing by doctors in controlled localities

The 2014 white paper on public health, Listening to you: your health matters, opened a consultation designed to overhaul the control of entry regulations in Wales, as laid out by the 2013 regulations. A public health bill announced in June, 2015 proposes to base pharmacy control of entry in Wales on an assessment of pharmaceutical needs, so that the full range of community pharmacy services can be considered in an application.

Scotland
The current regulations for NHS pharmacies in Scotland are The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009. These regulations consolidate the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995 and all subsequent amendments.

The 2009 regulations have been amended twice since publication, most recently by The National Health Service (Pharmaceutical Services) (Scotland) (Miscellaneous Amendments) Regulations 2014, which came into effect in June 2014.

The 2014 regulations introduce significant changes designed to protect the medical services provided by dispensing GP practices in rural Scotland, namely that on receipt of a pharmacy application, NHS boards must consider whether the neighbourhood detailed in the application falls within a controlled locality (defined as a rural area served by a dispensing doctor). In a controlled locality, the board’s pharmacy practices committee (PPC) must also consider the prejudice test (to NHS pharmaceutical and medical services).

Current control of entry regulations in Scotland make no provision for a ‘one mile rule’. However, NHS boards have delegated powers that enable them to allow dispensing GP practices to continue dispensing after a local pharmacy application is accepted in a neighbourhood in certain circumstances. To determine whether practice NHS dispensing may co-exist with an NHS pharmacy, the NHS board must determine whether a person will have serious difficulty in obtaining from a pharmacist any drugs, medicines or applications, other than scheduled drugs, required for that person’s treatment due to the following reasons:
• Distance
• Inadequacy of means of communication or
• Other exceptional circumstances.

Practices in Scotland may wish to note that the DDA is unaware of any practices that have retained dispensing rights in a neighbourhood following a successful pharmacy application.

More information
Dispensing Doctors’ Association website. NHS Pharmaceutical Services Regulations available [online, subscription required] from:

4.4 Controlled Drugs (CDs): Regulations and governance

There are two classification systems of controlled drugs used in the UK: classes and schedules.

Classes
The Misuse of Drugs Act 1971 prohibits the manufacture, supply and possession of certain drugs. These are divided into classes A-C on the basis of the harmfulness attributable to a drug when it is misused. The degree of penalty, eg, for possession, is linked to the class of the drug.

Common examples
Class A: Cocaine, morphine, diamorphine, pethidine, methadone
Class B: Amphetamines, barbiturates, cannabis, codeine, pholcodine
Class C: Buprenorphine, benzodiazepines, zolpidem, anabolic steroids

Schedules
The Misuse of Drugs Act 2001 determines who is allowed to handle these drugs for their work and divides them into five schedules. The schedule determines the regulations regarding import, export, possession, prescribing and record keeping.

Schedule 1 drugs (example: cannabis) are generally not used medically, and require Home Office authority for possession and supply.

Schedule 2 drugs (examples: diamorphine, morphine, pethidine, ketamine) are subject to the full requirements for prescriptions, safe custody and the need to keep registers (unless exempted in schedule 5).

Schedule 3 drugs (examples: barbiturates, buprenorphine, temazepam, tramadol). These are subject to prescription requirements but not safe custody nor registration. Invoices should be kept for
two years, however (the DDA recommends 11 years for product liability).

**Exemptions:**
- Buprenorphine and diethylpropion: both are subject to safe custody requirements.

**Schedule 4**
- Drugs are not subject to prescription or safe custody requirements.
  - Part I Examples include benzodiazepines (not temazepam) and zolpidem
  - Part II Examples: anabolic steroids.

**Schedule 5**
- Drugs that on the grounds of strength are exempt of all regulations, except the retention of invoices. Examples include: 10mg/10ml morphine.

**Requisitions**

Doctors or medical practices obtaining schedule 2 or 3 controlled drugs without providing the required signed order or requisition may be considered in unlawful possession of these drugs, and at risk of criminal prosecution. Supplies made to practices without the authority of a signed order or requisition are also unlawful, and may be a criminal offence.

From November 30, 2015, use of an approved NHS requisition form (see below) must be used for NHS supplies.

**England:** The standardised CD requisition form is the FP10CDF

**Wales:** The standardised CD requisition form is the WP10CDF.

**Scotland:** GP10A for NHS supplies and the CDRF for private supplies.

**Storage**

Schedule 2 and some schedule 3 CDs (eg, buprenorphine and temazepam) must be stored in a locked receptacle which can be opened only by an authorised person. For increased security, the CD cupboard should be firmly fixed to the wall with rag bolts, ideally in a location that will not be easily detection by intruders. A designated safe may offer another secure alternative.

**Prescribing**

Prescribers can issue computer-generated prescriptions for all controlled drugs including schedule 2 and 3 controlled drugs. All details can be computer-generated except for the signature.

The regulations apply several governance issues to CD prescribing:
• Prescriptions for schedule 2, 3 and 4 CDs are only valid for 28 days
• Schedule 2 and 3 CDs cannot be prescribed on repeat dispensing prescriptions
• In the case of owings, the owing balance of prescriptions for schedule 2, 3 or 4 CDs cannot be dispensed later than 28 days after the appropriate date on the prescription.

In addition: Prescriptions for schedule 2 and 3 controlled drugs must meet certain prescription requirements:

• Specific dose: As directed/when required is not acceptable
• Form (even when only one form exists)
• Strength (even if only one strength exists)
• Quantity: must be specified in words and figures
• Instalment dispensing: prescriptions must include the amount of the instalment and the instalment intervals
• Controlled drugs should always be signed before being dispensed except in an emergency.

Private prescriptions

Private prescriptions for schedule 2 and 3 CDs are subject to the same prescribing requirements as those written on the NHS, and must be written on a standardised form:

England:  FP10PCD
Scotland:  PPCD(I)
Wales:  WP10PCD

Forms must also include the prescriber’s identification number, which is issued by the local area team/health board and is different to the prescriber’s professional registration number.

Supply

Individuals should be asked to sign the back of the prescription form, when they are handed a schedule 2 or 3 CD, as confirmation of collection. Where the person collecting the CD/s does not agree to sign the back of the form, the dispensary is not obliged to supply the CDs.

Identity checks

There is a legal requirement for the dispensary to establish whether a person collecting a schedule 2 CD is the patient, the patient’s representative or a health care professional acting within their professional capacity. This only applies to schedule 2 CDs.

Where the person collecting the schedule 2 CD is the patient or the patient’s representative, the dispensary should ask for proof of identity, for example,
ask to see photo-ID or a credit or debit card. The dispensary has the discretion to decide whether to ask for proof of identity and also whether to supply the CD. Where the person collecting the schedule 2 CD is a health care professional, the dispensary must obtain the person’s name and address and must ask for proof of identity unless the health professional is known to them. The dispensary may still supply the CD even if ID is not provided.

**Transit of CDs**

Controlled drugs can be delivered as part of a home delivery service; in this scenario healthcare professionals retain a duty of care to take all reasonable steps to maintain safe custody of the CD/s. This will demand that CDs are kept out of sight and the delivery vehicle locked and otherwise secured (alarm or immobiliser activated) when left unattended.

The delivery driver should sign out CDs from the register as the patient’s representative and the patient or authorised representative should also sign the prescription to record receipt of the CD.

CDs should not be left in out-houses, or pushed through letter boxes. If nobody is in, the CD should be returned to the practice.

CDs should not generally be transported via mail, taxi services or equivalent. However, in exceptional circumstances, where urgent clinical need dictates, dispensed CDs can be sent to a patient, or stock CDs to premises, via such routes. Where the mail route is used, the CD should always be sent as a special delivery item to ensure the pathway is auditable. If transport of CDs or CD prescriptions, via mail, taxi services or equivalent, has to be used, a SOP should be developed which reflects a risk management assessment. Wherever possible a signature should be obtained indicating safe delivery of medicines.

**Remote collection**

Remote collection sites cannot be used for controlled drugs as these sites have no legal right of possession or supply.

**Doctor’s bag**

When CDs are carried in a doctor’s case, this must be lockable. The keys should be kept separate from the case unless it is fitted with a digital combination lock (a more practical option). The case should only be left unattended in exceptional circumstances and must always be locked when it is. If left unattended in a vehicle, it should be kept out of sight, in the boot for example. The vehicle should be locked and any additional security features such as an alarm or immobiliser activated.

Doctors are advised to carry the minimum quantity of CDs required to fulfil emergency treatment needs. To avoid packaging and labelling pitfalls it is better not to carry CDs in any form other than injection ampoules for emergency use and, preferably, in only one strength.
Additional guidance

- All CDs transferred to the doctor’s bag must be entered in the CD register.
- Keeping a running total stock balance in the register can ensure that any anomalies are swiftly identified.
- It is good practice (but not a legal requirement) for each doctor who carries CDs in a medical case/bag to have a personal register, segregated for different drugs and formulations, in which he or she records the drugs and dose administered, the date, and the patient’s name.
- The doctor’s bag should be regularly checked to ensure that all drugs and CDs contained are in date.
- Restocking of the bag from practice stock should be witnessed by another member of the practice staff, as should the appropriate entries into the practice’s CD register.
- Where a prescription is written by a doctor following the administration of a CD to a patient, the doctor should endorse the prescription form with the word ‘administered’ and then date it. This aims to avoid unauthorised individuals attempting to reuse such ‘prescriptions’ to obtain CDs illegally. Information should also be entered into the patient’s record as soon as practicable.

Submission

Private prescriptions

The original prescription (not a copy) for a schedule 2 or 3 CD should be submitted after dispensing to the relevant National Health Service agency (NHS Business Services Authority for England) along with a CD submission form (FP34PCD or equivalent) for data collection and audit purposes.

Disposal

Out-of-date CDs

Destruction of all out-of-date CDs must be witnessed by an authorised person such as the area team/health board accountable officer for controlled drugs. In some areas, the local water authority may have guidelines for limited disposal of CDs via the sewage system.

Returned, unused CDs

Dispensed CDs returned by a patient should be handled as follows:

- Record CD returns in a separate CD register to the main CD register.
- The CD returns register should be organised by drug formulation. Entries under the drug formulation should also show the date, the drug quantity and strength, and the name of the person who returned the CD(s). The doctor or dispenser should sign against the entry.
- Patient returned CDs must also be clearly marked to minimise the risk of errors and inadvertent supply.
It is good practice for the destruction or collection to be witnessed.

Controlled Drugs (Supervision of Management and Use) Regulations 2006 require SOPs to be in place for maintaining a record of schedule 2 drugs that have been returned by patients.

**Denaturing:** CDs must be rendered irretrievable prior to onward safe disposal. Dispensing practices require an Environment Agency T28 exemption to legally denature CDs.

The exemption can be obtained through the Environment Agency website; it is free of charge and lasts for three years. Register online at: [https://www.gov.uk/waste-exemption-t28-sort-and-denature-controlled-drugs-for-disposal](https://www.gov.uk/waste-exemption-t28-sort-and-denature-controlled-drugs-for-disposal)

**Storage prior to disposal:** All CDs awaiting disposal should be placed in a segregated, marked area in the CD cupboard to prevent them being issued in error to patients.

**Recording:** When a CD is destroyed, details of the destruction must be recorded. This should include: the name of the drug; form; strength and quantity; the date it was destroyed; and the signature of the authorised person who witnessed the destruction and the professional destroying it (ie, two signatures), eg, the accountable officer for controlled drugs.

**Governance**

**Monitoring of CDs and premises inspection**

The supply and administration of CDs in the NHS and private sectors is the responsibility of the Care Quality Commission (CQC), whose key roles are:

- To provide external assurance of arrangements including systems set up by NHS England area teams/health boards to ensure safe management of CDs by all healthcare providers
- To regulate the independent healthcare sector including the management of CDs.

Under CQC rules, all healthcare providers have to make an annual declaration as to whether they prescribe, supply or administer CDs and will be required to agree to have in place standard operating procedures (SOPs) relating to their use.

All healthcare providers will be subject to monitoring and audit of their management of CDs, using prescribing data.

GP dispensing and non-dispensing practices will be subject to inspections by dedicated area team/health board staff as part of governance procedures, and following random selection. Similar inspections will be made for community pharmacies.

Any healthcare provider that has a CD prescribing/supply profile that is considered abnormal may be targeted for a specific inspection. For the most part, inspections will be of an educational nature to ensure high standards in
the management of CDs but the inspectors will have powers to act in the event of aberrant CD management that cannot be adequately explained or justified.

**General**

**Running Balances:** As a matter of good practice the dispensary supplying the CDs should maintain a running balance of stock in their controlled drug register (CDRs). This is expected to become a mandatory requirement once electronic registers are in common use.

**Controlled drug registers:** Hard-backed, bound exercise books make acceptable CDRs, but loose-leaf ring binders, which may be tampered with, are not. It is also good practice to append each entry with the signature of the person making the entry. Information should be recorded in the CDR under the following specific headings:

**When CDs are obtained:**
- Date supply obtained
- Name and address from whom obtained (eg, wholesaler, pharmacy)
- Quantity obtained.

**When CDs are supplied:**
- Date supplied
- Name and address of person or firm supplied
- Status of person supplied (patient/representative/healthcare professional)
- Details of authority to possess: prescriber or licence holder details
- Quantity supplied
- Whether evidence of identity was requested of that person (yes/no); whether evidence of identity was provided by the person collecting the drug (yes/no).

**Electronic controlled drug registers:** Electronic CDRs are permitted, provided every computerised entry is attributable and capable of being audited. The computerised register must be accessible from the premises to which it relates and copies of the register, in its computerised or other specified form, must be available for inspection on request.

**An electronic CD register must also ensure:**
- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes
- There are access control system
- There is adequate backup.
A number of dispensing systems feature an integrated electronic CD register.

**Dispensing errors**

Significant errors and any involving CDs should be reported to the relevant accountable officer at the area team/health board. It is good practice for the doctor to check all prescriptions for controlled drugs.

To help practices with their CD management, the CQC publishes a CD governance self-assessment tool [online]. Visit: [http://www.cqc.org.uk/content/controlled-drugs#SAT](http://www.cqc.org.uk/content/controlled-drugs#SAT)

**More information**


CQC Register of Accountable Officers for Controlled Drugs in England available [online] from: [http://www.cqc.org.uk/content/controlled-drugs-accountable-officers](http://www.cqc.org.uk/content/controlled-drugs-accountable-officers)


Healthcare Improvement Scotland Register of Accountable Officers for Controlled Drugs in Scotland available [online] from: [http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/controlled_drugs.aspx](http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/controlled_drugs.aspx)


Office for Public Sector. CD Regulations available [online] from: [www.opsi.gov.uk](http://www.opsi.gov.uk)
4.5 Wholesale Dealer's Licences

The Medicines and Healthcare products Regulatory Agency has confirmed that dispensing doctors will require a wholesale dealer’s licence (WDL) to ‘trade’ medicines with other practices and pharmacies for patient benefit.

From July 2, 2012, Section 10(7) of the Medicines Act 1968 has been revoked and new provisions put in place to allow pharmacies to transact medicines without a WDL providing the transaction meets all of the following criteria:

- It takes place on an occasional basis
- The quantity of medicines supplied is small and intended to meet the needs of an individual patient
- The supply is made on a not for profit basis.

The MHRA has confirmed that the new provisions are not intended to apply to dispensing doctors.

More information

The Medicines and Healthcare products Regulatory Agency. Licences to manufacture or wholesale medicines available [online]:
https://www.gov.uk/government/collections/licences-to-manufacture-or-wholesale-in-medicines

Dispensing Doctors’ Association website. Wholesale Dealer’s Licensing Regulations [online, subscription required] from:
http://www.dispensingdoctor.org/resources/integrated-medicines-provider-forum/pharmacy-regulations/

4.6 Miscellaneous regulations

The Health and Safety at Work Act 1974

Dispensing practices must comply with the Health and Safety at Work Act 1974. This Act imposes a duty on employers to:

- Ensure a safe system of work
- Ensure safe premises for employees and visitors
- Provide safe equipment
- Ensure the safe handling of medicines
- Provide information, instruction and supervision for employees on health and safety matters.

In the dispensing practice this means that:

- Staff must be properly trained to use equipment
- Members of the public should not have unsupervised access to drug storage areas
- A first aid box must be available and accessible, and staff should be aware of what do to in the case of needlestick injuries
• Training should be provided on first aid procedures, including CPR and anaphylaxis
• Doctors, dispensers, other staff and patients should be encouraged to promote adverse drug reporting by the Yellow Card scheme. [http://yellowcard.mhra.gov.uk/](http://yellowcard.mhra.gov.uk/)

### Policy statement
Practices with more than five employees must provide a policy statement on their approach to the provisions of the Act for their staff.

### Risk assessments
If a potential working environment hazard is identified, a risk assessment should be undertaken. The outcome should be documented and appropriate action taken. A significant event register should be kept for the dispensary.

### More information

### Control of Substances Hazardous to Health Regulations 2002
Under the provisions of the Control of Substances Hazardous to Health (COSHH) Regulations 2002, all employers are required to:

- Identify hazardous substances at work
- Assess the risks
- Minimise the risks
- Inform all employees of any identified risks
- Train all employees on risks and precautions.

### In the dispensary this means:

- Compiling an accessible and up to date COSHH file containing the relevant data sheets for hazardous substances. These are available from the relevant manufacturer
- Taking particular care when handling cytotoxic agents that are not protected by original packaging. The appropriate protective garments should be worn, including gloves, masks and appropriate eye protection. Staff who are pregnant or staff of either gender who are considering conception should not handle such unprotected agents.

### More information
4.7 CQC inspections

Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) concerns safe care and treatment, and the intention of this regulation is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm.

According to the Care Quality Commission, the organisation charged with ensuring the implementation of these regulations, in a GP surgery this confers the following obligations:

- Providers must assess the risks to people’s health and safety during any care or treatment and make sure that staff have the qualifications, competence, skills and experience to keep people safe
- Providers must make sure that the premises and any equipment used is safe and where applicable, available in sufficient quantities
- Medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe
- Providers must prevent and control the spread of infection.

In terms of the dispensary, the following also apply:

- Staff responsible for the management and administration of medication must be suitably trained and competent and this should be kept under review
- Staff must follow policies and procedures about managing medicines, including those related to infection control
- Policies and procedures should be in line with current legislation and guidance and address:
  - supply and ordering
  - storage, dispensing and preparation
  - administration
  - disposal
  - recording.

Several dispensing practices have been inspected by the CQC and have received outstanding ratings. The CQC reports that three themes in particular are emerging as drivers of better quality of care:

- Care is person-centred, designed around the individual and includes their involvement
- The importance of the line-of-sight from senior leadership to the frontline staff and services
- Good care includes the provider checking on how well they are doing.

The following learning points have been raised by dispensing practices that have received an outstanding rating from the CQC:
• Inspectors see a clear system where dispensary staff manage the ordering and supply of repeat prescriptions overseen by GPs who signed all prescriptions before they are supplied to patients

• The practice has written procedures in place for the production of prescriptions and dispensing of medicines

• The practice is signed up to the Dispensing Services Quality Scheme (DSQS) to help ensure processes were suitable and the quality of the service was maintained

• Dispensing staff have all completed appropriate training and have their competency annually reviewed

• Focused team meetings are held regularly, including for nurses, reception staff and dispensary staff. This helps to ensure that information is shared at the appropriate levels and in a timely manner

• Processes are in place to check medicines were within their expiry date and suitable for use in the dispensary. Expired and unwanted medicines are disposed of in line with waste regulations

• Dispensing staff at the practice are aware that prescriptions should be signed before being dispensed. If prescriptions are not signed before they were dispensed, staff are able to demonstrate that these are risk assessed and a process that worked in practice is followed to minimise risk

• Where the practice has an established service for people to pick up their dispensed prescriptions at a different location, these are supported by robust systems to monitor how these medicines are collected

• The practice has systems in place to assess the quality of the dispensing process, and to report, learn and check the effectiveness of improvements made to the management of medication by the dispensary

• Dispensing errors are clearly recorded and investigated, with investigation outcomes and learning points noted. Policies and procedures are in place to ensure the effective management of medicines, including records of dispensed batch numbers and expiry dates, and to support clinical audit.

Practical tips for practices

The standards and good practice detailed in this guide are considered essential attributes for achieving quality in dispensing practice both in everyday practice and when a CQC inspection is due. Practices sharing their experience of a CQC inspection with the DDA also reveal the following inspection tips:

MHRA alerts

• Have a robust SOP and audit in place, covering action undertaken and the outcome.

CDs

• Ensure there are actively followed SOPs in place covering the security of the controlled drugs cabinet: ensuring it is locked at all times when not in
use, and specifying the holder/s and location of the CD key when the dispensary is closed

- Ensure there is a robust audit record for destruction of CDs, eg patient returns.

**Patients**

- Auditable comprehensive response to complaints and suggestions from patients.

**Security**

- Dispensary and other medicines storage containers (fridge) are secured from unauthorised access
- The practice manages and secures blank prescription forms and paper.

**Temperature**

- Install a room thermometer
- Ensure all dispensary fridges have maximum and minimum temperature monitors and that there is an actively followed SOP in place covering breaches of the acceptable fridge temperature range.

**Vaccines**

- Robust SOPs in place and followed for vaccines ordered from ImmForm – see also section 1.10.

**More information**


### 4.8 Working with pharmacists

The DDA believes that joint working between pharmacists and doctors has the potential to benefit patients, and make better use of doctors’ and pharmacists’ skills.

**Models of joint working may include:**

- Increased contact within existing business models
• Co-location of practice and pharmacy as separate entities
• Practice-based pharmacists.
Whatever model of interdisciplinary working is adopted, practices are advised to ensure that prescriptions are not ‘directed’ to a particular pharmacy. The following list illustrates activities to avoid in order to maintain good practice:
• Providing a practice endorsement for a pharmacy
• Allowing a practice database to be used to facilitate the promotion of a pharmacy, or any other promotional activity
• Suggesting that the practice, GP or member of staff would like a patient to use a particular pharmacy
• Allowing a patient to believe that the level of care they receive from their medical practice could be influenced by their choice of pharmacy
• Recommending that the patient collects a prescription from a certain pharmacy which is not the pharmacy that the patient had chosen
• Manipulating the prescription management process in favour of a particular pharmacy, including, but not limited to, offering a pharmacy privileged access to prescriptions generated by the practice
• Failing to be equitable when liaising with pharmacies, by offering differing levels of cooperation such as for repeat prescriptions
• Ignoring a patient’s freely stated choice of pharmacy
• Misrepresenting a practice’s relationship with a pharmacy
• Showing a lack of candour when providing information about dispensing and pharmacies (including, for example, making unsubstantiated or misleading claims about a particular pharmacy)
• Failing to be transparent about a financial relationship between a practice and a pharmacy
• Any other practice, which is designed to unduly influence a patient’s choice of pharmacy.

More information

4.9 The Electronic Prescription Service (England)

The Electronic Prescription Service (EPS) is an NHS service that will enable GP practices in England to send prescriptions electronically for dispensing by an EPS-compliant dispensary.

As this guide went to press (September, 2015) dispensing list patients are unable to use the EPS for medicines dispensed by the practice dispensary, although the DDA is aware that an integrated EPS solution for GP dispensaries is in test-stage development.

The DDA is currently lobbying NHS England for system and connectivity (broadband) improvements and funding to support the implementation of the EPS in dispensing practice, in order to release the full benefits of the system for the NHS and patients.

The DDA is aware of aggressive marketing of the EPS by online pharmacies in order to secure the patient’s EPS pharmacy nomination. Dispensing practices in EPS ‘live’ areas are advised to protect dispensing patients’ rights to use the GP dispensary by using the EPS patient communication resources produced by the DDA and available from the library of member resources.

In England pharmacy level dispensing data is available online. The data identifies the medical practice where prescriptions originate, allowing analysis of potential direction of prescriptions or inappropriate setting of nomination (e.g. setting in bulk, without patient consent). The data can provide compelling evidence and may be of use to dispensing practices whose dispensing lists or affiliated pharmacies are affected by prescription direction.

Where local analysis points to direction of prescriptions, contractors are asked to raise this with NHS regions and to copy this to the DDA. The EPS does not apply to Scotland and Wales, which are developing their own electronic prescribing systems.

More information

Health and Social Care Information Centre website. EPS Statistics and progress available [online] from: http://systems.hscic.gov.uk/eps/stats


Dispensing Doctors’ Association website. EPS resource pack available [online, subscription required] from: http://www.dispensingdoctor.org/resources/dispensary-management-zone/dda-members-resources/
4.10 Generic prescribing: reducing NHS costs

The following guidance is designed to help dispensing practices to achieve high dispensed generic rates yet maintain or improve practice income:

1) It is advisable that the practice nominates a lead GP with an interest in dispensing/prescribing. The lead GP will be responsible for formulating policy and ensuring consensus within the practice. The lead GP should be given protected time to fulfil this important role.

2) The lead GP should liaise closely with dispensers so that they can share ownership in the prescribing/dispensing policy decisions.

3) Seek agreement within the practice to use as many generics as possible and create a formulary for each MIMS or BNF section. Some PCOs run incentive schemes whereby the practice derives income for achieving specified dispensed generic targets or addressing specific prescribing quality issues.

4) Review current generic manufacturer/wholesaler supply. Some practices may use a variety of suppliers and manufacturers, switching around in order to get best deals of the moment. It is well worth considering using a main generic manufacturer who can work with and supply you through your mainstream wholesaler. Choose a manufacturer with an extensive range of generic lines.

5) Negotiate to see which company will offer the best discount rate in exchange for becoming the practice’s mainstream generic supplier. Companies will be keen to secure a high-volume customer and should be prepared to give a good discount. Ask about product line supply failure rates.

6) Dispensed generic status is only attributed to those items where the prescription is written in generic format for products that are listed in Part III of the Drug Tariff.

7) There are a few exceptions where it is good practice to prescribe by brand name. This relates to drugs where consistent bio-availability is particularly important, ie, anticonvulsant drugs and sustained-released calcium antagonists.

8) It is desirable that dispensing practices maintain a good rapport with their prescribing colleagues within their PCO. Dispensing policy should, where possible, conform to PCO prescribing policy.

Practices should take note of the GMS guidance on excessive or inappropriate prescribing (also see Section 4.1)

Guidance from the General Medical Council

GMC guidance should also inform prescribing decisions. Information is available [online] at: [http://www.gmc-uk.org/guidance/index.asp](http://www.gmc-uk.org/guidance/index.asp)
4.11 Understanding Category M

Category M was introduced into the Drug Tariff in April 2005 when the new community pharmacy contract was launched. Category M is used to adjust the reimbursement prices of more than 500 generic medicines in England, Wales and Scotland. It uses information gathered from manufacturers on volumes and prices of products sold plus information from the NHSBSA Prescription Services on dispensing volumes to calculate margins in the supply chain. Its purpose is to ensure that the total contract funding available to pharmacies contains the agreed amount of retained purchase profits (in 2014-15 this amount was set at £800 million in England, and proportionate amounts in Wales and Scotland).

The mechanism takes no account of dispensing doctors’ remuneration, nor the volumes dispensed or prices paid by dispensing doctors.

Key points about Category M

- Prices have to be set in advance each quarter, and estimated volumes used may differ from actual volumes
- Quarterly adjustments are made to account for any over or under recovery of pharmacists’ retained purchase profits
- Products may not be available to purchase at the Category M reimbursement price. The Department of Health sets Category M prices at levels substantially above the prices notified by manufacturers. But when the Category M reimbursement price for a particular product falls, it may take time for wholesale prices to respond. During this period, it is essential that contractors exert maximum pressure on wholesalers. There have been a number of examples where manufacturers prices were below the Drug Tariff price but a product could not be obtained at the Drug Tariff price from a number of wholesalers
- The prices paid for the new generic equivalent drugs will be determined by Category M. Any under-recovery of RPP (retained purchase profit) as a result of the time-lag in Category M price-setting will be recovered in subsequent quarters. Practices are recommended to consider the impact of the subsequent profit recovery by the Department of Health on cash-flow.

More information
Dispensing Doctors’ Association website information. Category M in dispensing practice available [online] from:
http://www.dispensingdoctor.org/dispensing-practice/challenges-dispensing-practice/category-m/

Definitions
Dispensing doctor: A doctor who has been granted consent under the relevant regulations to provide pharmaceutical services to his patients.
In Scotland, services provided by dispensing doctors are not considered pharmaceutical services. A dispensing doctor is defined as a contractor who is required by the NHS Board to provide dispensing services where no pharmaceutical services exist.

**Controlled (rural) locality:** A geographical area judged to be rural in nature by the primary care organisation. In England and Wales, the area team/health board or a local pharmaceutical committee may ask for such a review, providing no determination has been made in the previous five years (unless there has been a significant change in the population or housing provision).

**One mile rule:** Patients in England and Wales may only request dispensing services from their doctor:
- if the patient lives in an area which is rural in character, known as a controlled locality, at a distance of more than one mile (1.6km) from a pharmacy’s premises (but excluding any distance-selling chemist premises). The pharmacy’s premises do not have to be in a controlled locality
- If a patient satisfies the PCO that they would have serious difficulty in obtaining any necessary drugs or appliances from a chemist by reason of distance or inadequacy of means of communication (colloquially known as the serious difficulty test which can apply anywhere in England or Wales).

**Reserved location:** (England and Wales) In a controlled area, if the registered patient population on all GP lists within 1.6 km of a pharmacy is less than 2,750, the area team may designate such an area as a reserved location. The effect of such a designation is that the 1.6 km rule does not apply to patients within it and they continue to have free choice to use either a pharmacy or their doctor’s dispensary.

**Reserved locations**
1. If the total population living within a radius of 1.6km (one mile) of a new pharmacy in a controlled area is less than 2,750, then although the pharmacy may open, dispensing patients will be able to continue to receive dispensing services from their doctor (ie the 1.6km/one mile patient rule does not apply).
2. The reserved location provision applies whether or not the pharmacy application is subject to the control of entry regulations (Regs.13-16). Once the population reaches 2,750 a pharmacy, if already open, can request a redetermination re reserved location status and, if removed, then subject to the prejudice test, the dispensing pharmacy would gain the 1.6km/one mile protection (i.e. the doctors lose dispensing rights within a mile of the pharmacy). If an applicant thinks that the population level has reached 2,750, any new pharmacy application would trigger a redetermination of the reserved location status. If successful, reserved location status would be removed and the applicant would be subject to the prejudice test.
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