Level 3 in Pharmaceutical Science

MODULE 1 PART 1
WORKING IN A PHARMACY

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Chapter 1 – Your role in the pharmacy

By the end of this chapter you will be able to:
- State the role and qualifications required of pharmacists and support staff
- Understand the type of training you may receive on induction in a pharmacy

1.1 Roles within a Pharmacy

Your role as a pharmacy technician will involve you managing stock in the dispensary, receiving, assembling and giving out prescriptions, dealing with patient queries, filing scripts... the list is extensive. You will also need to make sure you know who can perform other roles, and who they are.

Compulsory registration as a pharmacy technician only began in July 2011 although they have been working in pharmacy for many years before then. At the same time, a formal set of standards was introduced for your conduct, ethics and performance in your work. This means that you are training to be a professional, someone who the public and patients can trust and have confidence in; someone they can talk to and know they will be treated with respect. It also means that it is always important to discuss with your pharmacist what exactly they are happy for you to do at any point in your training and when they need to be called in to help. Although your pharmacist is responsible for the overall pharmacy service, after your registration you could be held responsible for the work that you contribute to the service so make sure you know your limits and when to call for help.

Later in the course we will look at specific problems and ways of making decisions about what to do. Often there may be more than one acceptable way of dealing with a problem. As you continue your training, you will come across problems where the law does not provide an obvious answer and you will have to use your judgement and training to decide the best way to respond. Your pharmacist and this training will help you gain confidence in problem solving but you should always be prepared to ask your pharmacist for help if you are not completely confident that you are doing the right thing.

Pharmacists

In order to practise as a pharmacist in Great Britain they must be registered with the General Pharmaceutical Council. To register they must have a recognised degree in pharmacy from a United Kingdom school of pharmacy and pass an examination at the end of a year’s postgraduate practical training, termed the preregistration year. Pharmacists may practise in primary and/or secondary care, community pharmacy, pharmaceutical industry, academia and other sectors of pharmacy practice.

A pharmacist is an expert in medicines and their use. A pharmacist can be involved in any aspect of the preparation and use of medicines, from the discovery of their active
ingredients to their use by patients. Pharmacists also monitor the effects of medicines, both for patient care and for research purposes.

The majority of pharmacists work within, or are contracted to, the NHS. Their role in the healthcare team helps patients to get the maximum benefit from their medicines. So how do they do this?

- Pharmacists advise medical and nursing staff on the selection and appropriate use of medicines.
- They provide information to patients on how to manage their medicines.
- They may undertake additional training in order to allow them to prescribe medicines for specific conditions.
- They can train staff (like you) to assist in counselling patients.

**Pharmacy technicians**

After 1st July 2011 pharmacy technicians must be registered with the General Pharmaceutical Council (GPhC) in order to practise. In order to do so they require an NVQ Level 3 in Pharmacy plus an accredited programme that delivers the required knowledge such as the one you are currently studying. For an interim period until that date other technicians will be able to register having completed an alternative qualification acceptable by the GPhC (A list of these is available on their website).

Pharmacy technicians normally work in either the community or hospital sector. Their role is generally to dispense, deliver, store and order pharmaceutical products. They may also make up preparations and some may have completed a course allowing them to conduct the final check of the dispensed items known as the “accuracy check”.

Hospital technicians may also be involved in ward rounds, liaising with other healthcare professionals, education, training, IT, procurement (purchasing), clinical trials and drug information services.

Specialist technicians in hospitals can be involved in analytical control, checking of the quality of hospital medicines and in the preparation of radioactive materials.

Community technicians are principally involved with dispensing prescribed medicines and will usually have considerable patient contact. They can often be involved in services to drug misusers, care homes, domiciliary visits, collection and delivery of repeat prescriptions, and health promotion activities. They must be able to keep patient medication records, maintain sensible stock levels and provide over the counter advice to customers. They may also be involved in extemporaneous (fresh) preparation of products such as ointments, creams and simple dilutions.
Pharmacy/Dispensing assistants/Assistant Technical Officer (ATO)  

They will have completed or be undertaking a NVQ2 or Level 2 equivalent course in pharmacy, or be registered with the pharmacy regulator prior to 2005 because of their experience. Their main involvements will be dispensing prescriptions, stock management, and sale of over the counter (OTC) medicines and those in hospitals may also prepare manufactured pharmaceutical products.

Medicine Counter Assistant  

They will have completed an approved training course studying questioning techniques and the uses of over the counter medicines to enable them to advise on the sale of medicines, taking in prescriptions and handing them out. They are not able to be involved in the dispensing process or the handling of dispensary stock without further training.

For further information on training on the roles and the mandatory training of support staff in the pharmacy look at the following guidance on the GPhC website:


1.2 Induction Training  

If you are new to pharmacy or to your employment you will also receive induction training. We will briefly take a look at this to outline some of the areas of particular interest for pharmacy.

Induction training is essential to ensure that anyone starting at a company can quickly settle in so that they are safe and productive. Induction training will normally include the following:

- Company information – the history, ethos and values of the company
- Company domestics – where are the toilets, kitchen facilities or canteen? How long do I have for my breaks?
- Company policies
  - Smoking - Where are you allowed to do this?
  - Dress code - What is acceptable? (This may include restrictions on jewellery)
o Sickness - What procedure should you follow to notify any sickness?

o Holidays – What is the entitlement? What is the procedure for booking them?

o Confidentiality – Normally you will have to sign a confidentially agreement when you are working in a pharmacy, have you done this?

o Security – Do you have a locker or are you allowed to carry your valuables on you? Are you subject to security checks? Do you need a pass to access buildings?

o Grievance/disciplinary procedures - Where can you obtain a copy of these?

• Health and Safety (We will look in more depth at this topic in a later module)

  o Emergency procedures – Is there routine testing of the fire alarm, where do you assemble if you have a fire drill? Where are the escape routes in case of a fire? What equipment do you have for fighting a fire in your pharmacy?

  o Health and Safety at Work Act (HASAWA) 1995 – What risk assessments have been done and what training or procedures must you follow to ensure your safety and that of the public?

  o Accident reporting - Reporting of Diseases, Injuries and Dangerous Occurrences (RIDDOR) 1995 – All accidents by both staff and customers must be reported into the accident book, do you know where this is?

  o First aid – Who is your first aider?

  o Manual handling – Have you been taught how to lift if this is part of your role?

  o Personal protective equipment – When might you need to use protective equipment and what is available?

• Pharmacy specific information

  o Standard Operating Procedures (SOPs) – Have you read all the SOPs that relate to your role? (We will discuss this more fully later on).

  o Has the use of PMR system and other pharmacy equipment been explained?
This list above is by no means comprehensive but gives you an idea of what training you might have had at induction or will have as your progress through your Technician training. It may also be a refresher to those who had their induction training some time ago!

If you feel there is anything you are unaware of, discuss this with your manager or mentor to see if it is relevant to your organisation and your role.

**Chapter 1 Summary**

- Pharmacists are experts in medicines and have had a long professional training to help them make judgements and difficult decisions
- Pharmacy technicians are trained to NVQ3 level 3 to enable them to support pharmacists in dispensing medicines and supporting patients
- Dispensing assistants must have a minimum qualification to help dispense prescriptions
- Medicine counter assistants are trained to sell over the counter medicines
- Induction training is specific to your company and workplace
Chapter 2 - Regulation of the profession

By the end of this section you will be able to:

- Describe the structure and function of the General Pharmaceutical Council to include:
  - The Council, The Chief Executive and The Registrar
  - The Inspectorate
  - Responsibilities as an independent regulator
  - Function of the statutory committees
  - Registration of pharmacists, pharmacy technicians and pharmacies
- Understand the role of the responsible pharmacist

2.1 General Pharmaceutical Council

Pharmacy in Great Britain is regulated by the General Pharmaceutical Council (GPhC). They are responsible for regulating:

- Pharmacists
- Pharmacy technicians (statutory regulation only comes into force on 1st July 2011)
- Pharmacy premises

The GPhC’s headquarters are in London and it is led by an appointed council of 14 members with a representative from each part of the country. The Council defines the organisation’s policies which then delegates activities to its staff which are led by a Chief Executive and Registrar.

They are an independent regulator with the main aim of protecting the public. Their responsibilities include:

- The control of entry into the profession
- Education/training standards
- Registration
- Setting and enforcing professional standards and a code of ethics
- Enforcing continued professional development
- Providing support for improvement
- Dealing with poor performance
- Dealing with misconduct
The Inspectorate

The GPhC employs 29 pharmacy inspectors whose role it is to visit pharmacies across Great Britain. Where a person registered with the GPhC or lawfully conducting a retail pharmacy business fails to comply with the required standards and legal obligations, it falls to the inspectorate to take action.

In addition to inspections inspectors can have two other roles:

- They will investigate complaints made to the GPhC involving registered pharmacists or technicians.
- They have an advisory role on compliance with standards.

Once the inspectorate has gathered the evidence they will then assess this against “threshold criteria” to decide if it should be referred to the three Statutory Committees which have been set up to deal with poor performance or misconduct: the Investigating committee, the Fitness to Practice committee and the Appeals committee.

Look at the flow chart on the next page to see how the whole process of a complaint is handled by the GPhC

Registered Pharmacy

A pharmacy cannot just be opened up anywhere, by anyone!

There are restrictions on who can own a pharmacy and these vary slightly in Scotland and Ireland from those in England and Wales. All pharmacy premises must be registered and must have a registered pharmacist who is responsible for the pharmacy. Large companies must have a superintendent pharmacist who is responsible for what happens in the company's branches. There is a requirement for Statutory Committees to decide whether pharmacists, companies or premises can be struck off the register for their failure or failures of staff.

To dispense NHS prescriptions the pharmacy must be on the relevant Pharmaceutical List operated by the Health Boards in Scotland, the Primary Care Trusts in England, the Area Health and Social Services Boards in Northern Ireland and the Local Health Boards in Wales. Some pharmacies do not have such a contract and must survive on the sales of medicines, private dispensing and other sales or services.

Before a new pharmacy can be opened, an application for registration must be made to the Registrar of GPhC (or the Pharmaceutical Society in Northern Ireland). The two main areas of concern are:

a) The owner(s) of the pharmacy business - if not a pharmacist, then a 'superintendent' pharmacist must be appointed to ensure compliance with the necessary laws of pharmacy. The company can only use the title ‘Chemist’ if the superintendent pharmacist is on the board of directors of the company.

b) The premises which must comply with requirements for size, layout facilities, etc.
Flow Chart to Illustrate Procedure Following Complaint to GPhC

Complaint

Inspectorate to investigate, this could include:
- Interview complainant
- Interview witnesses
- Interview alleged person complaint is regarding
- Visiting premises

Assess against threshold criteria and decide on action to take:
- No further action but a record made of complaint
- Letter of advice sent
- Refer to another regulatory body if another healthcare professional is involved
- Refer to Investigating committee

Medical reports may be required

Investigating committee for further investigation

No action

Fitness to practise committee

If fitness to practise is impaired issue:
- Warning
- Suspension
- Conditions imposed for practicing
- Removal from register

Appeals committee
The Responsible Pharmacist

Since 1st October 2009 to operate a lawful retail pharmacy you have to have a “responsible pharmacist” in charge of each registered pharmacy. They must sign in each day and display a notice to say who the responsible pharmacist is. They are however, allowed to be absent for up to two hours in any 24 hour period once they have signed in. The absence should be planned and the responsible pharmacist must still be contactable and able to return quickly if required.

During the period of absence by the responsible pharmacist, if there is no other pharmacist on the premises, then ONLY the following patient transactions are allowed:

- Selling GSL medicines
- Taking in prescriptions

Certain dispensary tasks such as labelling and assembling medicines or destroying waste medicines are also permitted if the responsible pharmacist is absent for up to 2 hours. If your responsible pharmacist makes use of the allowed two hour period to be absent, you should make sure you are clear about what you can or cannot do in their absence. You may also want to check what should happen with over the counter sales if a query arises when the pharmacist is absent. Also check how you should contact the responsible pharmacist if you need to do so – have they given you their mobile phone number?

For more information on this regulation visit

In summary the three functions of the Regulator are:

1. **Monitoring** of standards which is performed by the Inspectorate
2. **Compliance** which is achieved by the provision of written or verbal advice on the interpretation of the law and standards, and by publication of guidance documents.
3. **Enforcement** which is achieved by bringing proceedings against a person registered with the Regulator or lawfully conducting a retail pharmacy business.

**Chapter 2 Summary**

- The GPhC is the professional regulator with the aim of ensuring public protection
- The GPhC sets the standards expected within the profession
- There are 29 inspectors who visit pharmacies to enforce the standards
- There are three statutory committees to deal with infringements
- A pharmacy must be registered with the regulator and employ a responsible pharmacist when open.
Chapter 1 & 2 Quiz - Test Yourself

1. Which one of the following does not need to register with the Pharmacy Regulator?
   a) Pharmacists
   b) Pharmacy Technicians
   c) Medicine Counter Assistants

2. Which one of the following are not allowed to put dispensing stock away?
   a) Medicines Counter Assistants
   b) Pharmacy Assistants
   c) Pharmacy Technicians

3. Identify the organisation which is the professional regulatory body for pharmacy technicians in England, Scotland and Wales:
   a) RPS
   b) NPA
   c) GPhC

4. The council of the Pharmacy Regulator consists of:
   a) An elected council of 12 from all parts of the UK
   b) An appointed council of 16 from England
   c) An appointed council of 14 from England, Wales and Scotland

5. The Pharmacy Regulator is not responsible for:
   a) Registering pharmacies
   b) Lobbying the government to extend NHS Pharmacy Services
   c) Setting professional standards

6. The Pharmacy Regulator does not have the power to:
   a) Send a pharmacist to prison
   b) Impose conditions restricting the practice of a pharmacist
   c) Inspect a pharmacy premises

7. For how many hours in a 24-hour period may the responsible pharmacist be absent from the pharmacy they are responsible for?
   a) 2 hours
   b) 3 hours
   c) 4 hours
Chapter 3 - Standards within the pharmacy environment

By the end of this chapter you will be able to:

- Explain the term Clinical Governance
- Describe the use of Standard Operating Procedures in the pharmacy
- Describe common types of dispensing errors and how they can be caused
- Describe how to deal with a patient safety incident
- Explain how analysis of dispensing errors contributes to risk management
- Describe how Standard Operating Procedures and risk management can contribute to Clinical Governance

3.1 Clinical Governance

Healthcare professionals are required to have in place procedures for minimising risk and harm to patients. The umbrella term for this is “Clinical Governance”. Clinical governance is defined by the Department of Health as “a framework through which NHS organisations are accountable for continuously improving the quality of care, by creating an environment in which clinical care with excellence will flourish”.

So what does this mean to yourself and the other members of your team? More simply, I think clinical governance is about making sure that we get the right medicine to the right people at the right time. It requires us to have written procedures to make sure that everyone knows what they should be doing and what their responsibilities are.

It requires us all to:

- consider what could go wrong
- find methods of preventing errors
- document the facts when something goes wrong
- learn from our mistakes

The two main components for clinical governance are Standard Operating Procedures (SOPs) and error management. Let’s look at these in more depth.
3.2 Standard Operating Procedures (SOPs)

A Standard Operating Procedure is a written reflection of a process that you do. It is a comprehensive written guide to correctly performing a chosen task. As well as step by step instructions for undertaking the task, procedures lay down the desired objective, set standards to be achieved and ensure that the process can be consistently repeated every time. An SOP draws together all the necessary information that allows someone to undertake a process correctly and safely, ruling out guesswork and ensuring that the desired objective is achieved.

Put simply an SOP is a written procedure that details:

- What is to be done
- When it should be done
- Who should be doing it
- Where it should be done
- How it should be done

Why Do We Need Them?

There are several reasons why we should have SOPs. Some of them are merely common sense reasons for having this helpful tool such as:

- Ensure quality and consistency of service
- Ensure that good practice is achieved
- They help to ensure that the expertise of the team is fully utilised and when delegation is appropriate to the abilities/qualifications of the staff
- Providing an audit tool – a measurement if you like of what should be happening
- Assist in staff training and development.
- Use as an aide memoire when undertaking the task
- Use as part of satisfying an employer’s Health and Safety obligations.
- Ensure expensive equipment is correctly used and maintained

Perhaps more importantly, procedures are also a framework for ensuring that various legal directives or regulations are carried out. Standard Operating Procedures are a requirement of the pharmacy regulator, who oversee the standards of work within pharmacies. In the field of pharmaceutical production detailed procedures are also a requirement of Good Manufacturing Practice. They ensure that EU Directives that relate to the manufacture of medicines for human use are correctly implemented.

In either case, having a procedure in place demonstrates knowledge and understanding of the task and acknowledges the desire for the organisation to strive for high standards and maintain them and most importantly demonstrates compliance with applicable regulations.

So, SOPs are an integral part of Clinical Governance. What better way is there to describe, develop and improve practice than to have a formal process that scrutinises and evaluates a work practice, documents it and routinely reviews it with the intention of improving the outcome?
So let’s look at SOPs in practice

Find out where your SOPs are and read them.

At first glance perhaps, they may seem to you a set of rules. A set of rules made up by people who are in charge - and rules are made to be bent or broken aren’t they? Well, wrong on all counts! These are procedures that must be followed. They have been developed after consultation with the workforce. They are a means of sharing best practice. They mustn’t be deviated from. If something does go wrong as a result of deviating from the SOP any resulting court case would be unlikely to be in favour of the pharmacy. Your pharmacists will be responsible and it is unfair not to follow the procedures that they have developed to protect themselves, pharmacy staff and their patients. However, the procedures do need to be reviewed from time to time and feedback given to the management so that the procedures can be adapted and a better, more workable practice adopted.

Let’s see how it should work:
In our offices at Buttercups the first person who arrives is required to:
• open the blinds
• turn on the lights
• start up all the computers
• answer the telephone
• fill the coffee machine
• put paper and envelopes at each employee’s desk
• open the post

Then the rest of the team arrive. They sit down and have a cup of coffee. The member of the team who starts at 8.30am wasn’t very happy. So now, after consultation the other team members fill up their own stationery and start up their own computers. We’re all happy to say that the coffee machine filling is high on the list of priorities!

So, imagine that your SOP tells you that all people bringing in prescriptions should receive a docket (ticket receipt). However, your pharmacy is tiny. You know 99% of your clients. Your clients generally don’t like the dockets because they don’t see the point - you don’t look at them anyway. Your clients toss them on the floor and it makes a mess. So you decide not to give them out to people you know. A mistake occurs and the contraceptive pill is given, not to the teenage girl for whom it was prescribed, but to her elderly Aunt who has the same surname. You are in serious trouble and so is the girl. If you had discussed this with the pharmacist prior to changing the procedure perhaps a better procedure could have been developed.
3.3 Dispensing errors

Nobody is perfect; everyone makes mistakes. Thus dispensing errors are almost bound to occur. Many are picked up before the item is given to the patient and these are termed near misses. Some are picked up before the patient leaves the premises; some are dealt with when the patient is at home before the medication is taken. Sadly some are taken and cause serious consequences and others are never picked up at all.

The best thing we can do is to learn from our mistakes, we will look at how this is done shortly but first let’s look at the types of errors we make and what may cause them.

Error types
Each year around 90000 medication errors are reported to the National Patient Safety Agency and the most common errors reported are:

- 28% wrong dose
- 17.1% missing item
- 11.5% wrong item
- 6.1% quantity
- 4.9% wrong patient
- 32.4% other errors

So what can cause errors during the dispensing process?

Wrong dose:
- Not checking doses against the prescriptions, simply checking the dispensing label
- Not checking the dose is appropriate in the BNF
- Repeating the previous label on the patient’s record when the strength may have been changed
- Selection error because the drug packaging between strength is similar
- Transposition of labels - It is embarrassing if an ointment goes out labeled "one 5ml spoonful to be taken at night" and a bottle of cough linctus "to be applied to the affected area at night".

Missing items
- Sometimes there is a long "streamer" of labels hanging out of the computer printer and it is very easy, especially if the patient has more than one medicine, to lose one.
- Multiple prescriptions which get separated in the dispensing process
- Fridge items or CD which are specifically left out for storage but not reunited when the patient collects their medicine

Wrong item
- Selection error because drugs have similar names
- Knowledge error because the person dispensing did not realise there was more than one formulation of the same drug.
Quantity
- Multiple packs of the same medicine
- Different generics manufacturers having different pack sizes

Date expired
- Poor stock rotation
- No date checking procedure for stock in the dispensary

Wrong patient
- Leaving the patient's name on the computer screen for the next prescription
- Patients with same name and address or DOB not checked

Other factors that can lead to an error

Let us consider the many other factors that can contribute to the cause of an error

- Poor handwriting
  Fortunately handwritten prescriptions in community are in the minority but in hospitals this can still be a major issue. The result could be fatal if the wrong drug or dose is given due to interpretation of the handwriting...if in any doubt contact the prescriber to clarify what it says

- A mental block
  It is so easy to confuse a pair of drugs on the shelf or read something as you expect it to be not as it really is. Have a look at the example below:

  Aoccdrnig to rscheearch at Cmabrigde Uinervtisy, it deosn't mttarer in waht ordr the ltteers in a wrod are, the olny iprmoatnt thng is taht the frist and lsat ltteer be at the rghit pclae. Tihs is bcuseae the huamn mnid deos not raed ervey ltteer by istlef, but the wrod as a wlohe.

Pairs of drugs most commonly confused are amiloride 5mg and amlodipine 5mg, atenolol 50mg and atenolol 100mg, and co-codamol 30/500 with co-codamol 8/500.¹

¹Pharm.J 1/9/01 Learning from medication errors
• Calculations
Particularly those involving the decimal point or a mixture of dosage units e.g. micrograms and milligrams.

Example
In a Durogesic 75 Patch there are 7.5 mg of Fentanyl at a dose of 75 micrograms per hour. **Micrograms should always be written in full to avoid confusion with mg which could result in a 1000 fold error.**

• Dose forms
In hospital, injections can cause added problems as IM and IV injections may be different and not interchangeable. IV doses may be different to those given orally especially for drugs which are metabolised by the liver. Certain injections are only appropriate for particular routes of administration and it is therefore prudent to label accordingly e.g. "For intra muscular use only”.

Example:
Since 1985 accidental intrathecal administration of vincristine has left at least 13 patients dead or paralysed. The Department of Health responded by launching compulsory guidelines intended to eliminate these errors completely.

• Foreign bodies
Although not a dispensing error as such, medicines containing foreign bodies or dirt which cause harm to the patient could cause the supplier to be prosecuted under the Medicines Act. Always store containers either capped or inverted and check before use. Be especially careful if you notice a broken container in a shrink wrap, that none of the bits from this has gone into another container.

• Poor procedure
Too little space and too much clutter and untidiness are recipes for disaster. Interruptions can create distractions and lead to errors. If someone is in the middle of dispensing or checking a prescription wait until they have finished the task before interrupting them.

• Unreasonable workloads
This can be considered as a cause of error for some however for others it can concentrate the mind. The important factor is sufficient time to perform dispensing checks. Note also that staff who work in the dispensary less frequently have higher error rates.

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2 PJ 1/9/01 Dave Roberts, Cardiff and Vale NHS Trust
• Self checking
The more people involved in the dispensing process at different stages the more chance you have of spotting an error. Don't be surprised if your pharmacist or colleague asks you to check his/her work; it is always good practice.

• No patient counselling
If the patient is expecting something for their asthma and you have dispensed a nasal spray rather than an inhaler counselling the patient might uncover that. Similarly if the patient is receiving diabetic medication check they are a diabetic patient, or if they take warfarin ask them for their anticoagulation record book to double check their dose.

• No patient confirmation check
It is imperative to check a person's address as well as their name and any particulars on a docket (ticket). Patients assume because you took their prescription into the dispensary that any medication you bring out is for them. There have been cases of people accepting and taking medicine labelled for a totally different patient.

Example
A colleague of mine had an unfortunate error. A patient had brought in a prescription for head lice treatments. He accepted and confirmed the details of another prescription for digoxin tablets which he then took home and swallowed. After hospitalisation he was asked if he had not been surprised that his head lice infection was treated with tablets. He had assumed that the pharmacist knew what he was doing.

3.4 Patient Safety Incidents
If an error occurs and it reaches the patient the term used by the National Patient Safety Agency for this is a Patient Safety Incident, this is regardless of whether there was any harm to the patient.

How do we deal with them?
Honesty is the best policy and prompt action can save lives. Prompt action can make good the situation and leave the patient impressed by the professionalism with which the incident was dealt.

If an error has occurred make sure that you know the procedure laid down by your employer for dealing with these. Under no circumstances should the matter be kept quiet i.e. always inform the pharmacist (as the insured legally responsible professional). All NHS pharmacies must have a standard operating procedure in place for dealing with complaints.

The following is a suggested procedure for pharmacists to follow. Think about where you come in? How much are you expected to do/say? Do locum pharmacists know your procedure - might they ask you for help?
Suggested procedure for dealing with a patient safety incident

- Listen and find out the facts
  - Stay calm when the patient is present
  - Take all complaints seriously - Work on the basis that the error is genuine, even if you believe that there are grounds for doubt. Nobody should jump to conclusions without checking the facts very carefully.

- Outcome
  - If it transpires that an error has occurred then the pharmacist will need to assess the harm that has been caused and report it. The errors are rated in 5 categories according to the NPSA: no harm, low harm, moderate harm, severe harm and death. Look at Appendix B of the following article to see the differences between these outcomes:
    http://www.nrls.npsa.nhs.uk/resources/all-settings-specialties/?entryid45=83726

- Rectify the situation if possible
  - Replace the incorrect item, change the label etc. Deliver the correct product and visit to reassure if necessary.
  - It must be followed up by an acceptance of the error and an assurance that steps are going to be taken to ensure that it never happens again. The patient has a right to an apology and a frank explanation of what has occurred. The welfare of the patient must be your prime concern, not whether your neck is on the block, and it should show by your genuine concern.

3.5 Risk management

Once you have dealt with the immediate complaint the next steps to take are part of the risk management process. This is all about learning from mistakes to provide a safer practice for your patients.

- Reporting
  The pharmacist should record the error, how it happened, who was involved and any actions taken. The technician should also sign it. Many pharmacies have a designated form to do this which has a duplicate copy to be sent to the person responsible for clinical governance within your organisation, often this is the Pharmacy Superintendent.

  This record is also helpful should a patient later decide to make a complaint.

- Investigating
  You need to find out why this incident occurred. Ideally this should be done by someone who was not involved in the incident and they should talk to those involved and look at the systems in place. This should identify the contributing factors so that they can be dealt with.
Planning
An action plan will then be developed with the purpose of preventing this incident reoccurring. It may involve anything from changing procedures or providing staff training to increasing the staffing levels or changing the layout. Whatever the plan it needs to detail when this should be completed by.

Sharing
It might be tempting to think that it is kinder not to tell the individuals involved but it is vital that they are told exactly what has happened. Even if no further action is required it at least serves to sharpen up their concentration and attention to procedures.

Incident reports can be used to analyse trends of errors within your pharmacy and within your organisation. Errors can also be reported to the NPSA to help monitor national problems and provide national guidance to prevent medication errors across the whole of the country. From 1st October 2011 there is a requirement to report any patient safety incidents to the NPSA as part of the NHS community pharmacy contract in England.

What has been observed is those organisations/pharmacies that make reporting an integral part of their procedures actually have fewer incidents!

Familiarise yourself with the dispensing error reports procedure for your pharmacy now.

Near Misses
What should we do if an error occurs within the pharmacy but does not reach the patient, what we term a near miss?

You can still go through the whole risk management process but often in this case they will be analysed as a batch during an audit (survey) rather than after each individual incident. It is recommended that pharmacies complete a near miss audit on a regular basis to identify any trends and see if procedures can be changed or if training is required to reduce the incidents of near misses and potentially prevent an error in the future.

Chapter 3 Summary
- Clinical governance is ensuring patient safety
- Standard operating procedures (SOP) are required in pharmacies to ensure that all processes are consistent, safe and accountable
- SOPs must be reviewed periodically
- Dispensing errors can have a variety of causes, knowledge of these can help to reduce errors
- Errors and near misses should be analysed as part of a risk management process.
**Now take a break!**

Time for a break. Make a cuppa then test your knowledge with some quick quiz questions.

**Chapter 3 Quiz - Test Yourself**

1. Identify the **false** statement about Standard Operating Procedures (SOPs):
   a) SOPs should be reviewed
   b) SOPs must be followed at all times
   c) SOPs only need to be read once as they never change

2. Products with similar names cause dispensing errors as a result of:
   a) Poor handwriting
   b) A mental block
   c) Either of the above

3. What sort of pharmacies need a protocol for dealing with complaints?
   a) NHS pharmacies must have a protocol in place for dealing with complaints
   b) Multiples require only a centrally held protocol
   c) Independent pharmacies only

4. Identify the **correct** statement about clinical governance:
   a) Clinical governance is only considered when a dispensing error has happened
   b) Clinical governance is about managing risk and continually improving the quality of services provided
   c) Clinical governance is only relevant to hospitals providing NHS services

5. Identify the false statement relating to the management of errors:
   a) The patient should only be referred to the pharmacist if they have been harmed
   b) The incident should be promptly investigated
   c) The members of staff involved should be notified

6. Identify the correct statement about records of errors:
   a) Records need only be kept if the patient plans to take legal action
   b) Records should include as much information as possible to allow an accurate analysis of the error
   c) Records need only be kept if the patient took the medication
Chapter 4 – Licensing of Medicines

Now we will look at the law concerning the licensing of medicines. These laws were introduced in order to protect the public from remedies that are dangerous or have no medicinal value. (You will learn in a later module about laws relating to health and safety, pharmacy practice, employment and the sale of goods).

By the end of this chapter you will be able to:

- Appreciate the range of the Medicines Act
- State how GSL, P medicines and POM medicines differ
- Describe the licensing of medicines, including herbal, homeopathic and veterinary medicines
- Explain the role of MHRA in licensing of medicines

4.1 The Medicines Act 1968

Three Acts legislate for all retail and wholesale dealings of medicines and poisons. The three Acts are:

- Medicines Act 1968
- Poisons Act 1972

The Medicines Act came about after thalidomide caused deformities when given in pregnancy and after an accident where non sterile intravenous fluids killed several patients in Devonport hospital. The aim of this Act is to protect the public from the supply of harmful and/or ineffective remedies and ensure quality, safety and efficacy.

So the Medicines Act deals with substances used as medicinal products covering pharmacy services, prescribing arrangements, legal classification of medicines, labelling requirements, advertising and promotion, clinical trials and much more. (Note: when a product is not used as a medicine it is not subject to the Act).

The Poisons Act controls the supply of poisons when not being used for a medicinal purpose. The Misuse of Drugs Act controls the supply of dangerous drugs or those with a potential for misuse, and effectively outlines that their possession is illegal resulting in the criminal classifications of these drugs. However, another piece of legislation then permits the supply of these “controlled drugs” in medicine, this is the Misuse of Drugs Regulations 2001. You will learn much more about this legislation in module 2.
Classifications of medicines

Under the Medicines Act there are two classifications of medicines:

- General Sales List (GSL) medicines
- Prescription only medicines (POM)

Pharmacy medicines which may only be sold from pharmacies (P) are not specifically listed. **NB. The Act rules that no medicine may be sold anywhere other than from a pharmacy unless it is listed as a GSL medicine.**

To find out the classification of a medicine you can check the Summary of Product Characteristics at the following website:

http://www.medicines.org.uk/emc/

- Pharmacy and GSL medicines
Pharmacy medicines termed P medicines can usually only be supplied under a pharmacist's supervision, while GSL medicines can be sold in any retail outlet as long as certain conditions are met.

*You can read a summary of medicine prescribing, sale and supply regulations at the MHRA website. [http://www.mhra.gov.uk/index.htm](http://www.mhra.gov.uk/index.htm)*

- Prescription Only Medicines
POMs can usually only be supplied by a pharmacist against a prescription written by an appropriate prescriber. We will look at this in more detail in the next part of this module.

*You can find a list of all the legislation that applies to POMs in the UK at the MHRA website.*

- Herbal medicines
A herbal medicine is a medicine that is made from a plant material. Over the years scientists have been using plants as sources for conventional medicines e.g. aspirin derived from willow bark, but what manufacturers do now is isolate the single active ingredient for mass production as a medicine. However, with herbal medicines it is often a range of active ingredients obtained from the plant source that are made into medicines. So, herbal medicines can still have potent effects and, because they contain active ingredients, they can also have side-effects and interactions just like any other type of medicine.

Some herbal products will have the usual Marketing Authorisation (see later in this chapter) that you would expect with any other drug to indicate their quality and efficacy, but, many
are sold as unlicensed herbal products. The unlicensed products are produced by manufacturers under the Section 12 exemption to the Medicines Act but they are not allowed to be branded or carry any therapeutic claims. It is also possible to have a Section 12 exemption which allows the supply of an unlicensed herbal product for a specific patient after a consultation with a practitioner.

This situation is in the process of changing with a new licensing system compulsory from 30th April 2011. After April all herbal medicines, except those for a specific patient after a consultation, will need to be licensed. There will be two ways this can be done:
- As a medicinal product with a normal product licence as seen on all UK medicines (licence starts with “PL” then has 9 numbers after).
- The product is registered under the Traditional Herbal Registration Scheme and they are given a licence number starting with “THR” then 9 numbers after. This scheme doesn’t require evidence of efficacy to the products but does regulate the quality of the product.

Find out more about herbal medicines at the MHRA website.

- Homeopathic Medicines

Homeopathy is a type of complementary medicine which is not based on the same theory as conventional medicines. The principle used is “like cures like” so if a patient presents with symptoms of a runny nose and watery eyes a homeopath may recommend a homeopathic remedy derived from onion (when you cut an onion think what happens...your eyes water).

However the problem that many conventional healthcare providers have with homeopathy is that the remedies are considered more potent when they are diluted and they are diluted to such a degree that technically there is no molecule of the active ingredient left in the product. The other issue is the lack of randomised clinical trials on homeopathic medicines. Many critics say that the effect with homeopathy is purely placebo.

Supporters of homeopathy argue that this is not the case, that the successive dilutions alter the water molecules and they retain an “imprint” of the original molecule.

The NHS recommends that homeopathy should not be used to treat severe acute illness or potential chronic life-threatening conditions. It sees homeopathy as an additional treatment to conventional medicines for minor illness.

Currently there are two ways in which new homeopathic products may be registered in the UK. They may be:
- Registered under the Simplified Scheme, in order to qualify for registration the products must:
  o be for oral or external use
  o be sufficiently dilute to guarantee their safety
make no therapeutic claims.

- Registered under the National Rules Scheme. This scheme enables homeopathic medicinal products to be registered with indications for the relief or treatment of minor symptoms and conditions (any that would normally be treated without the intervention of a doctor). Any application must be supported by data on quality, safety and efficacy, together with appropriate product labelling and product literature.

*Find out more about homeopathic products at the MHRA website.*

**Veterinary Medicines**

Veterinary medicines used to come under the Medicines Act but since 2005 this has no longer been the case. However a vet is still classed as an appropriate practitioner to be able to prescribe under the Medicines Act but any medicine dispensed comes under the Veterinary Medicines Regulations 2011 for labelling and records.

The MHRA is not responsible for veterinary medicines - that role falls to the Veterinary Medicines Directorate whose website address is [www.vmd.gov.uk](http://www.vmd.gov.uk). They are covered in the Veterinary Medicines Regulations 2011 which covers animals including birds and bees, reptiles, fish, crustaceans, fish and molluscs. Who gives medicines to molluscs?!

**Administering medicines**

Medicines legislation only specifically covers the administration of medicine when this is done by injection. Injections can only be given by:

- doctors, dentists and, in some cases, independent nurse prescribers and supplementary prescribers
- patients themselves
- anyone else who is following patient-specific directions given by a doctor or other authorised prescriber

The MHRA issues guidelines for clinics that administer cosmetic treatments such as Botox injections.

*You can read guidelines on administering Botox on the MHRA website.*
The Licensing System

No one can make, sell or supply medicine without a licence, although there are some exceptions for pharmacists, doctors and nurses for a particular patient in response to a prescription which we will discuss shortly.

The Medicines and Healthcare Products Regulatory Agency (MHRA) was established to control all aspects of the sale, supply, and administration of medicines. They operate a system of licensing for manufacture and handling of medicines under the Medicines Act.

The main licences are:

- Marketing Authorisation (formerly called a Product Licence)
- Manufacturer’s Licence
- Wholesale Dealer’s Licence.

- Marketing Authorisation (formerly Product Licence)
  All medical products (except those made extemporaneously by you and some biopharmaceuticals) must have a Marketing Authorisation before manufacturers can supply them.

  Before the licensing authority (MHRA) grants a Marketing Authorisation they look very carefully at the product, considering its safety, efficacy and quality. When a medicinal product is launched onto the market it has already gone through years of development and testing, all of which is considered by the authority. There can literally be a lorry load of documents about a product gathered over the years, all of which need to be looked at.

  The Marketing Authorisation controls the manufacture, quality control, packaging, storage and usage of the product. They are issued for 5 years or shorter periods. The Commission on Human Medicines may review, suspend or withdraw Marketing Authorisation if additional information comes to light after it has been granted.

  Before a product can be promoted, it must have a Summary of Product Characteristics (SPC) that details the licensed uses of the medicine. Companies may not advertise outside the terms of the Marketing Authorisation and the SPC must accompany promotional literature. Occasionally a product may be prescribed outside its Market Authorisation for another purpose or for a child that is not covered by the use of the licence. In this sense the drug use is unlicensed and you may hear it referred to as “off-label” use; the prescriber is responsible if things go wrong rather than the drug company.

- Manufacturer’s Licence
  Once a drug has been granted a Marketing Authorisation it can be manufactured for supply. The manufacturer must be in possession of a manufacturers licence in order to manufacture or assemble a drug product, (assembly means to package and label). To obtain one of these
licences the company is required to provide evidence of all their procedures: types of equipment, premises, qualifications of staff, storage and records.

Pharmacies do not require a manufacturer’s licence for small amounts of products made under the supervision of a pharmacist; this is known as a section 10 exemption. The products made in a pharmacy do not need a marketing authorisation either if they are made in response to a prescriber’s instructions for a specific patient. Any product made in this way would be classed as “unlicensed” and cannot be advertised for sale or be sold from other outlets.

Sometimes a pharmacy cannot make up an unlicensed product because it is needed in large quantity or has unusual ingredients or must be sterile. They have to order this from a manufacturer licensed to make such products. These products are known as “specials” as they do not have a marketing authorisation. A number of hospitals and larger companies have their own licensed specials manufacturing facility which supplies products to wards, practitioners, community pharmacies etc. These products are often very expensive to make and may not be reimbursed on a GP prescription. Another important point is that the person who prescribes the “special” is responsible for the product quality if there is a subsequent problem.

Until August 2010 a manufacturer was not able to advertise any specials they made, however since then have been allowed to publish prices of specials to healthcare professionals.

Another exception is Chemists’ Nostrums. These are products that are prepared in a registered pharmacy for retail sale from that pharmacy and are not advertised. No licence is required but the product must be labelled with the usual information and a P in a box. See Chemists’ Nostrums in the Medicines Ethics and Practice Guide for further details.

- Wholesale Dealer’s Licence
  This is required by wholesalers to ensure that transport and storage of products is appropriate. Practitioners, such as doctors, dentists and veterinary surgeons do not need these licences. A pharmacy also does not need this license unless more than 5% of their turnover is wholesale trading.

**Chapter 4 Summary**

- The Medicine Act, The Misuse of Drugs Act and the Poisons Act regulate medicines and non-medicinal poisons in the UK.
- There are three main categories of medicines available: POM, P and GSL
- There are three main types of licence issued by the MHRA for the manufacturing or handling of medicines.
- Herbal and homeopathic medicines are also licensed by the MHRA
- The Veterinary Medicine Directorate oversee the licensing of veterinary medicines
Chapter 4 Quiz - Test Yourself

1. Which one of the following statements is true?
   a) A company needs a manufacturer’s licence and wholesaler’s licence to manufacture and sell a product
   b) A company needs a manufacturer’s licence and marketing authorisation to manufacture and sell a product
   c) A company needs a wholesaler’s licence and marketing authorisation to manufacture and sell a product

2. Which one of the following types of medicine is not licensed by the MHRA?
   a) POMs
   b) Herbal Medicines
   c) Veterinary Medicines

3. Which one of the following types of medicines can be sold from a supermarket?
   a) P medicines
   b) GSL medicines
   c) POM medicines

4. Which of the following medicines can only be sold to a customer under the supervision of a pharmacist?
   a) P medicines
   b) GSL medicines
   c) POM medicines

5. The Medicines Act does not legislate for which one of the following?
   a) The labelling of human medicines
   b) The advertising of cosmetics
   c) The administration of injections

Chapter 4 Quiz - Test Yourself

Chapter 4 Quiz answers
1.b; 2.c; 3.b; 4.a; 5.b