Inspection decision making framework

Version 8.0

Principle 1 – The governance arrangements safeguard the health, safety and wellbeing of patients and the public.

(NB: the evidence for this principle will largely be drawn from that gathered under other principles – the items included below are examples only and not intended to be an exhaustive list)

Standard 1.1 – The risks associated with providing pharmacy services are identified and managed.	
A Pharmacy that is satisfactory	A Pharmacy that is good

Risks to the safety and quality of services are identified, managed and mitigated.
 	
For example:
• Procedures are in place that are appropriate to the risks for all pharmacy services provided.
• Adverse incidents such as near misses and dispensing errors are recorded and action is taken following such incidents.
• Security arrangements are reviewed and are appropriate for the pharmacy.
• Review of the arrangements for ensuring an appropriate level of hygiene for the services provided.
• Storage and management of medicines and appliances is appropriate to the risks associated with them, e.g. fridge lines are store appropriately, cytotoxic drugs are stored appropriately, Controlled Drugs (CDs) are stored in accordance with legal requirements, general stock management is adequate (through for instance date checking).
• Risks associated with providing pharmacy services to children and vulnerable adults are identified.
• Risks associated with new services are considered before they start to ensure they are managed appropriately.
• Risks of potential failure or disruption to services are planned for, such as
    o Alternative or replacement equipment and facilities are accessible/available.
    o There is sufficient capacity and skills/expertise to cope with both planned and unplanned staff absences/sickness.
    o There are alternative arrangements should the pharmacy premises not be fit for purpose.
	Continuous, proactive and systematic review of risks ensures risks are minimised.
	
	For example:
	• Proactive and regular review of adverse incidents to:
	    o identify trends;
	    o inform review of procedures;
	    o inform training/recruitment of staff;
	    o inform improvements to the design of the dispensary and/or service delivery, etc.
	• Regular review occurs to ensure that action taken has been sustained and to identify any additional actions required.
	• High risk activities/services/patients/medicines/medical devices are proactively identified and risks effectively managed.
	• More regular review of procedures taking account of trends locally and nationally.
	• All new planned services and/or changing demands are routinely assessed for risk before they are commenced, and action is taken to minimise risks.
	• Risks of potential failure or disruption to services are planned for e.g.
	    o Arrangements for business continuity planning are regularly tested
	    o Alternative or replacement equipment and facilities are accessible/available.
	    o There is sufficient capacity and skills/expertise to cope with both planned and unplanned staff absences/sickness.
	    o There are alternative arrangements should the pharmacy premises cease to be fit for purpose.

Standard 1.2 - The safety and quality of pharmacy services are regularly reviewed and monitored.	
A Pharmacy that is satisfactory	A Pharmacy that is good
Monitoring and review mechanisms ensure the safety and quality of pharmacy services. For example, mechanisms for monitoring and reviewing: • Clinical effectiveness/governance and risk management (see also Standard 1.1). • The staff profile and skills mix of the pharmacy team to ensure it is appropriate for the services provided. • Staff performance (see also Standards 2.2). • Operational procedures for services provided (including staff roles and responsibilities etc.). • Complaints and feedback (internally and externally) (see also 1.4 and 2.5). • Incidents such as near misses and dispensing and other errors. • Record keeping (also see Standard 1.6).	Systematic monitoring and review mechanisms are in place, demonstrating a culture of continuous learning, and leading to improvements in the safety and quality of services. Regular review of the staff profile and skills mix to respond to changes in services or to meet the emerging needs of patients.

Standard 1.3 - Pharmacy services are provided by staff with clearly defined roles and clear lines of accountability.	
A Pharmacy that is satisfactory	A Pharmacy that is good
Staff roles, accountabilities and responsibilities are clearly defined for all pharmacy services For example: • Staff are clear what they can and cannot do, and are fully compliant with the roles and responsibilities that have been set for them and they do not operate outside of their defined role.	Accountabilities and responsibilities are regularly and proactively reviewed and recorded. For example: • Documented job descriptions are evaluated, there are key performance indicators (KPIs) and there is an overall development plan. • The pharmacy can demonstrate how it manages risks when tasks/activities are delegated to other members of the pharmacy team.

Standard 1.4 – Feedback and concerns about the pharmacy, services and staff can be raised by individuals and organisations, and these are taken into account and action taken where appropriate.

A Pharmacy that is satisfactory	A Pharmacy that is good
Feedback, concerns and complaints are recorded, listened to, responded to in a timely manner, and acted upon if appropriate to prevent a recurrence. For example: • The pharmacy has a complaints procedure which is openly available, easily understood by patients and the public and has evidence of it being used. • Pharmacy staff can explain how a patient can make a complaint about the pharmacy. • The pharmacy can show that it has made improvements to pharmacy services following individual feedback received.	Opportunities to give feedback or raise concerns about pharmacy services are highly visible, proactively publicised and encouraged, and improvements made as a result are made public. For example: • Patients are routinely involved in shaping and improving pharmacy facilities and services. The pharmacy can show that it has made improvement to pharmacy services following feedback leading to positive outcomes for patients. • There is a flexible approach to obtaining feedback that takes into account the equality and diversity of different patient groups. • Learning from feedback is shared within and outside the pharmacy. For example, a Patient and Public Advisory Group has been set up for the pharmacy. Complaints are analysed for trends and emerging issues and proactively acted upon to improve the safety and quality of services provided.

Standard 1.5 - Appropriate indemnity or insurance arrangements are in place for the pharmacy services provided.

A Pharmacy that is satisfactory	A Pharmacy that is good
Appropriate insurance arrangements are in place. Insurance services are reviewed in light of new services.	This is intentionally blank

Standard 1.6 – All necessary records for the safe provision of pharmacy services are kept and maintained.

A Pharmacy that is satisfactory	A Pharmacy that is good
The pharmacy maintains legally compliant records required to support the delivery of pharmacy services. For example, legally compliant records for: • The Controlled Drugs (CD) register • Private prescriptions • Emergency supplies	This is intentionally blank

- Extemporaneously prepared medicines
- Specials
- The Responsible Pharmacist (RP) record

Other records, such as staffing training, patient identifiable records, and calibration of equipment are also appropriately maintained.

Records are clear, legible, accurate, up to date and available at the registered pharmacy.

Records are kept for the necessary amount of time, for example, in accordance with relevant legal requirements.

Records are organised, held securely and easily retrievable.

All Patient Medication Records (PMRs) are backed up securely.

Standard 1.7 - Information is managed to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.	
A Pharmacy that is satisfactory	A Pharmacy that is good
Information governance arrangements ensure necessary safeguards for, and appropriate use of, corporate (where appropriate), patient and personal information. Data is secure and only available to suitable individuals. Confidentiality is maintained via appropriate systems and processes. In normal circumstances patient identifiable information is not shared, either intentionally or unintentionally, without consent, unless there are compelling ethical considerations supporting the need for disclosure. Records are disposed of securely.	Information governance practices are regularly reviewed and audited to ensure compliance and drive improvement (for example the latest version of Information Governance Toolkit has been submitted) The pharmacy publicises how it protects/monitors compliance with data protection principles. Passwords to computerised records are used and changed frequently and there are different levels of access for support staff and pharmacists. Security measures and controls are monitored and updated.

There is a culture of protecting patients' and customers' privacy at all times.	
Standard 1.8 - Children and vulnerable adults are safeguarded.	
A Pharmacy that is satisfactory	A Pharmacy that is good
Staff are aware of and apply policies when necessary to safeguard the safety and wellbeing of children and vulnerable adults. Staff are aware of, and use when necessary, the mechanisms for reporting concerns about the safety of children, young people and vulnerable adults. Information and advice given is provided in a way that is easily understood by children and vulnerable adults, or their carers/advocates. All service users, in particular children and vulnerable adults are treated with respect and dignity at all times, and children and vulnerable adults feel safe.	Potentially vulnerable patients are proactively identified and the pharmacy liaises with or notifies relevant agencies. There is a clear culture of safeguarding the safety and wellbeing of children and vulnerable adults, including support for staff where they raise concerns. Children and vulnerable adults are listened to, consulted and involved in the development of services.

Principle 2 – Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.

Standard 2.1 – There are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided.	
A Pharmacy that is satisfactory	A Pharmacy that is good
There is the appropriate skill mix of staff for the services provided and volume of work For example: • Staffing levels and roles are appropriate for the workload and services provided.	Staff numbers and the skills mix are continually and systematically reviewed in line with changing workloads and services provided and appropriate plans put in place. Any necessary changes are made in a timely manner.

Standard 2.2 – Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training.	
A Pharmacy that is satisfactory	A Pharmacy that is good
Staff are suitably qualified/appropriately registered, trained, or are in training, to the appropriate level for their role. All staff are appropriately supervised including those in training. Staff receive the training they need to fulfil their duties effectively. Staff are trained in accordance with the published GPhC policy. The competence and performance of staff is appropriately reviewed. Staff understand the procedures in place in the pharmacy, and the pharmacy professionals ultimately responsible for the staff are able to satisfy themselves of this.	Regular reviews of staff qualifications and/or registration status ensure the pharmacy has an appropriate skills mix for individuals' roles and the services provided by the pharmacy. For example: • The skills mix of the pharmacy team is proactively reviewed and reassessed when there are any planned changes to the services the pharmacy provides. • Staff are actively encouraged to reflect on their performance and identify learning and development needs and they are supported to address them. • Staff/team development plans are in place to address skills gaps. The pharmacy encourages, supports and provides appropriate access to Continuing Professional Development/Continuing Education (CPD/CE), for example, providing protected time to undertake training

Standard 2.3 – Staff can comply with their own professional and legal obligations and are empowered to exercise their professional judgement in the interests of patients and the public.

A Pharmacy that is satisfactory	A Pharmacy that is good
Pharmacy professionals are able to meet the GPhC's *Standards of conduct, ethics and performance* For example: - Pharmacy professionals are able to make professional decisions in the interest of their patients/the public and other staff members. - Staff with management and control responsibilities have the genuine authority they need to live up to their legal and/or professional duties. All staff understand that healthcare professionals who provide services for the pharmacy have their own legal and professional obligations.	Pharmacy professionals and staff are able and supported and empowered to make decisions and act proactively for the benefits of their patients/the public and other staff members.

Standard 2.4 –There is a culture of openness, honesty and learning.

(NB: the evidence for this standard will largely be drawn from that gathered under other standards in this principle)

A Pharmacy that is satisfactory	A Pharmacy that is good
The performance of staff is reviewed (2.2). All staff accept responsibility for their mistakes. Staff are encouraged to report and record incidents and to learn from them. For example: - The pharmacy maintains near miss and error logs and ensures learning points are identified to avoid a recurrence. - If an incident occurs, systems and procedures are reviewed to reduce the likelihood of it reoccurring. Staff act with openness, honesty, and integrity.	There is a culture of learning and continuous improvement. For example: Staff are fully involved in improving the delivery of pharmacy services. Regular reporting and review of errors, near misses and incidents has led to improved service delivery and/or sustained reduction in risks. All staff are able to accept responsibility for their mistakes and share learning. The culture of openness, honesty and learning is embedded throughout the organisation.

Standard 2.5 –Staff are empowered to provide feedback and raise concerns about meeting these standards and other aspects of pharmacy services.

A Pharmacy that is satisfactory	A Pharmacy that is good
Staff know how to report concerns they have about how the pharmacy is operating. Staff feel able to raise concerns about poor practice or if the standards are not being met. For example: • Where actions of others are putting patients or the public at risk. • Where the systems or procedures in place represent a risk to the patients, staff or the public. The feedback or views of staff on how pharmacy services are provided are considered and acted upon. The pharmacy has a whistleblowing policy in place.	There is a culture within the pharmacy that means staff are confident to raise concerns about how the pharmacy is operating, or inappropriate practice of other staff and are actively supported to do so. The feedback or views of staff on how pharmacy services are provided are actively encouraged, regularly sought and acted upon to improve pharmacy services and/or reduce risks, with clear outcomes for patients and/or the public as a result. The outcomes are fed back to staff.

Standard 2.6 – Incentives or targets do not compromise the health, safety or wellbeing of patients and the public, or the professional judgement of staff.

A Pharmacy that is satisfactory	A Pharmacy that is good
Targets and financial incentives for staff have no adverse effect on the safety and quality of services. Targets and financial incentives are set taking into account patient needs and the context of the pharmacy.	This is intentionally blank

Principle 3 – The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.

3.1 - Premises are safe, clean, properly maintained and suitable for the pharmacy services provided.	
A Pharmacy that is satisfactory	A Pharmacy that is good
The building within which pharmacy services are provided is well maintained and safe. For example: • Any repair or maintenance work is carried out safely and in a timely manner. • The pharmacy premises are clean, tidy and well organised. • Floor spaces are kept clear from obstructions. The size, design and layout of the pharmacy premises is appropriate for the range of services provided, and the volume of work, enabling a safe workflow. For example: • There is sufficient and appropriate storage space in the pharmacy premises for medicinal stock, assembled medicines awaiting delivery or collection, and medical devices.	Patients are given advance notice of planned maintenance work and provided with appropriate information. For example: • The pharmacy services that may be affected. • Sign-posting or alternate arrangements during this time. • How long services will be affected. Patient and public feedback informs the design and layout of the public area of the pharmacy. There is evidence of pre-planned maintenance. For example: • Call out arrangements. • Service contracts. • Regular inspections/surveys.
3.2 - Premises protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.	
A Pharmacy that is satisfactory	A Pharmacy that is good
Patient confidentiality and privacy is protected through the design and layout of the premises. For example: • Patients are able to have confidential conversations with pharmacy staff.	The suitable dedicated area for confidential conversations is actively signposted and promoted. Confidential discussions and consultations take place in a separate consultation room/area which is suitably screened and conversations cannot be overheard.

3.3 - Premises are maintained to a level of hygiene appropriate to the pharmacy services provided.

A Pharmacy that is satisfactory	A Pharmacy that is good
The pharmacy premises is clean and hygienic. Hygiene facilities are provided and maintained to an appropriate clinical level for the services provided. For example: Adequate sink/wash hand basins with hot and cold water supplies are provided in appropriate areas to allow for the hygienic preparation of medicines, cleaning/sanitation and hand washing.	This is intentionally blank

3.4 - Premises are secure and safeguarded from unauthorised access.

A Pharmacy that is satisfactory	A Pharmacy that is good
The pharmacy premises is protected from unauthorised access. For example: The security measures prevent unauthorised access and safeguard staff, patients and the public.	Security measures are regularly reviewed, for example, in light of local incidents, for the protection of staff, the pharmacy premises, and patients.

3.5 - Pharmacy services are provided in an environment that is appropriate for the provision of healthcare.

A Pharmacy that is satisfactory	A Pharmacy that is good
The pharmacy provides an appropriately controlled working environment for staff to deliver healthcare services. For example: - There is suitable and sufficient lighting and ventilation. - Ambient room temperature is maintained at a level to ensure medicines remain fit for purpose and services can be provided comfortably. There is a clearly defined professional area. Materials for sale in the professional area are healthcare related. For example: - alcohol and tobacco are not sold. The external appearance of the premises is maintained and presents a	This is intentionally blank

professional image appropriate for the provision of pharmacy services. The positioning, volume levels, and content of any audio and/or video equipment on the pharmacy premises are appropriate for a professional healthcare environment.	

Principle 4 – The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.

4.1 – The pharmacy services provided are accessible to patients and the public.	
A Pharmacy that is satisfactory	A Pharmacy that is good

All patients and members of the public can access pharmacy services.
 	
Reasonable adjustments or alternative arrangements for service provision are made to enable this.
 	
Pharmacy services which are available are clearly displayed.
 	
Patients and the public can identify the healthcare staff.
For example:
• Staff wear badges showing job role/title.
 	
Patients are referred/signposted or directed to other appropriate health and social care providers or support organisations, when the pharmacy cannot meet their needs.
	There is current, relevant, and up-to-date display of services available within the pharmacy which are actively promoted.
	
	Services provided are aligned with patient needs and reflect the health needs of the local community.
	For example:
	• There is a pro-active and evidence-based approach to identifying services that would be beneficial to patients including review of the local Joint Strategic Needs Assessment, Health and Wellbeing Strategy and Pharmaceutical Needs Assessment.
	• Alternative methods of communication are available, as required:
	  o Use of a telephone translation service.
	  o Bilingual leaflets/labels.
	• Labelling information is available in different languages to meet the needs of the local community.
	• Facilities to enable patients with a disability, such as hearing or sight impairment, etc, to access pharmacy services.
	• Provision of seating for patients and/or the public waiting for services and/or who find it too difficult to stand.
	
	The Pharmacy Team can articulate to patients the details and benefits of the services offered and are actively promoting the use of these services where appropriate.
	For example:
	• Flu vaccinations.
	• Discharge Medicines Review (DMR).
	• Weight loss.
	• Smoking cessation.
	• Repeat prescription collection etc.

4.2 - Pharmacy services are managed and delivered safely and effectively.

A Pharmacy that is satisfactory	A Pharmacy that is good
Staff practice within the pharmacy follows documented operating procedures. For example: - Local Patient Group Direction protocol is followed - There is an audit trail on the pharmacy label to identify staff involved in dispensing the medicine and the pharmacist responsible for supply - Labelling of Monitored Dosage System (MDS) trays includes a description of individual medicines so that they can be identified. Adequate stock management procedures are in place. For example: - Date checking. - Stock rotation. Medicines and medical devices are supplied accurately and in a timely manner. Reasonable steps are taken to ensure that patients' care is not compromised when their medicines are not available. Patients are encouraged to take actions which will improve their health through promotion of key healthy lifestyle and public health messages.	Pharmacy services are managed proactively to ensure effective care. For example: - Patients receiving high risk medicines (such as methotrexate, controlled drugs, cytotoxics, insulin) are proactively targeted and suitably counselled. - High risk patients (such as those receiving prescriptions who appear to: have diabetes; be at risk of coronary heart disease/have high blood pressure; smoke; or are overweight) are proactively targeted for health promotion and healthy lifestyle advice.

4.3 - Medicines and medical devices are:
- **obtained from a reputable source**
- **safe and fit for purpose**
- **stored securely**
- **safeguarded from unauthorised access**
- **supplied to the patient safely**
- **disposed of safely and securely**

A Pharmacy that is satisfactory	A Pharmacy that is good
All medicines and medical devices are sourced from licensed wholesalers, or direct from the manufacturer.	Once received in the pharmacy, the quantity of waste medicines is minimised by arranging additional waste collections where necessary.

For example:
- homeopathic, herbal and unlicensed specials comply with current Medicines and Healthcare Products Regulatory Agency (MHRA) guidance.

Medicines and medical devices which are safe and appropriate to sell or supply are clearly segregated from those which are not.
For example:
- out of date stock
- patient returned medicines.

Medicines are sold or supplied in containers that are appropriate for the medicine.

Medicines and medical devices are stored correctly and securely, according to their legal category, specific requirements, and the level of risk associated with them.
For example:
- Storage space is sufficient - e.g. the fridge is large enough to accommodate stock in an orderly fashion.
- Fridge lines are stored between 2-8°C.
- Controlled drugs (CDs) are stored in accordance with the CD regulations.
- The environment for medicines and medical devices in associated premises, delivery and collection sites, is appropriate.

Access to the dispensary and medicines is restricted to authorised staff.
Medicines and medical devices are disposed of in a timely, safe and secure manner, and in a way that safeguards the confidentiality of patients and the public
For example:
- Patient returned needles are disposed of safely and in accordance with current guidelines.
- Disposal is in line with product and environmental guidance and legal requirements.

Patients are actively counselled to promote the return of unwanted/unused medicines/medical devices.

Medicines are supplied safely and accurately and appropriate to patients' individual needs.
For example:
- Pharmacy medicines sold are appropriate for the patient.

Patients receive medicines with sufficient shelf life to cover the period of treatment.

Patients or their carers/advocates are given the right information and advice to enable them to:
- Choose the most appropriate treatment when buying medicines or seeking advice; and
- make effective and safe use of medicines, medical devices and pharmacy services.

4.4 - Concerns are raised when it is suspected that medicines or medical devices are not fit for purpose.

A Pharmacy that is satisfactory	A Pharmacy that is good
Pharmacy staff respond to, and report concerns that medicines/medical devices are counterfeit or not fit for purpose. For example: • Suspected stock is quarantined. • The relevant authority is notified. The pharmacy takes all reasonable steps to contact patients who have received a medicine/medical device which is not fit for purpose.	The pharmacy raises concerns/problems about medicines/medical devices with other pharmacies, prescribers and manufacturers. The pharmacy proactively follows up with patients who have received a medicine/medical device which is not fit for purpose.

Principle 5 – The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

5.1 - Equipment and facilities needed to provide pharmacy services are readily available.	
A Pharmacy that is satisfactory	A Pharmacy that is good
The appropriate equipment and facilities for services offered/provided within the pharmacy are readily available. For example: • IT including internet access, blood measuring /glucose/cholesterol measuring kits, etc. Appropriate up to date reference sources are used effectively to deliver improved outcomes for patients.	The pharmacy proactively reviews its equipment and facilities used for the delivery of pharmacy services to improve patient care. For example: • Equipment to produce large print labels, etc.

5.2 - Equipment and facilities are: • **obtained from a reputable source** • **safe to use and fit for purpose** • **stored securely** • **safeguarded from unauthorised access** • **appropriately maintained**	
A Pharmacy that is satisfactory	A Pharmacy that is good
All equipment is fit for purpose and properly validated for its intended use. For example: • British Standard/CE stamped measures, refrigerator, weighing scales. • Use of recognised suppliers. Equipment and facilities are appropriately installed, maintained/ calibrated, cleaned and in working order. For example: • Installed and serviced by recognised manufacturers/technicians/companies. Equipment is stored securely, safely and appropriately.	Equipment is regularly monitored to identify deficiencies and corrective action taken. The pharmacy shares its concerns with other pharmacies/organisations to raise awareness of equipment deficiencies. For example: • Chief pharmacist's network in hospital/LPC, a communication log, locum network. • NHS England Local Area Teams/Local Health Boards in Wales/the Royal Pharmaceutical Society/General Pharmaceutical Council.

For example:	
• Computers containing confidential patient information. • Sharps are stored safely in patient-accessible areas. Equipment and facilities are clean and hygienic.	

5.3 - Equipment and facilities are used in a way that protects the privacy and dignity of the patients and the public who receive pharmacy services.

A Pharmacy that is satisfactory	A Pharmacy that is good
Equipment and facilities are appropriately placed/ installed and/or used to maintain confidentiality and protect the privacy and dignity of patients. For example: • Appropriate positioning of PMR screens/prescription retrieval systems to prevent disclosure of confidential information. • Records are safeguarded against unauthorised access.	This is intentionally blank