

# The layers that shape professional practice in pharmacy



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# Pharmacy practice is changing...

The pharmacy professions are evolving rapidly and reshaping how care is delivered.

This brings significant opportunities for pharmacy professionals and patients but also challenges in maintaining safety, quality and public trust

Regulation provides a framework that safeguards patient care, while allowing for innovation and supporting professionals to do their best by making sound decisions



# Good professional decisions

Every time a pharmacist or a pharmacy technician makes a professional decision or takes an action as part of their practice, they do it within a **framework of requirements and influences.**

These are either explicitly legal or regulatory, or they have a sort-of-regulatory impact, in that they control, guide or otherwise influence the decisions and actions that pharmacy professionals take as part of their practice.



# The layers that shape professional pharmacy practice

- The law and legal frameworks relevant to pharmacy practice
- Statutory regulation of services, products and premises
- Team and organisation
- NHS governance, where applicable
- Professional standards and guidance
- Statutory regulation of professionals
- The individual professional



# Why this matters

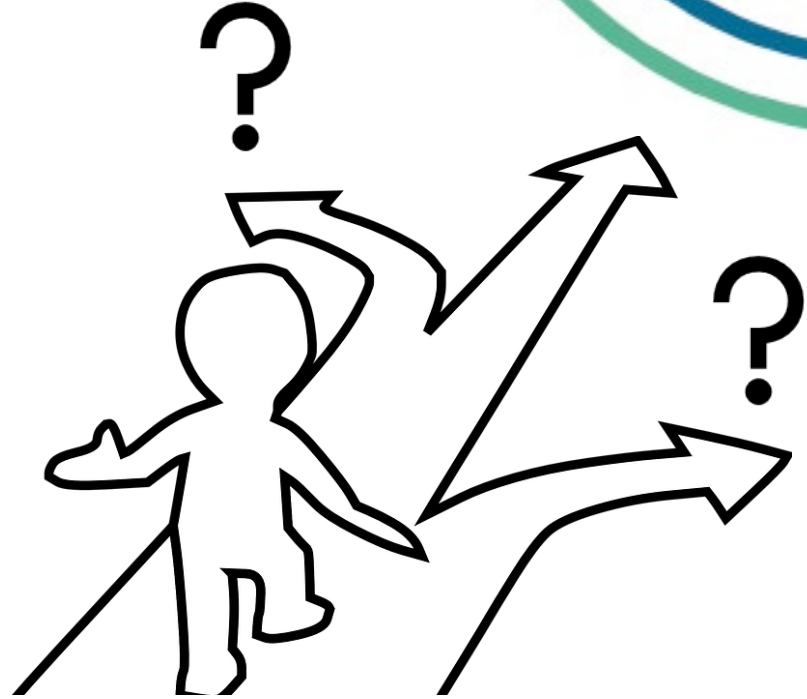


Pharmacists and pharmacy technicians must know the laws, regulations, professional standards and guidance relating to their work.

Understanding the elements of this framework and how they interact helps pharmacy professionals to **work lawfully, safely and professionally**, and to be accountable for doing that.

# Self-regulation

At the heart of this framework of protection and support sits the competence and confidence of the individual professional to **self-regulate** – to make choices about their own practice and actions that will keep the people they are serving, their colleagues and themselves safe.



# Self-regulation

Individual professional 'self-regulation' involves the application of judgement, but it is not a subjective free-for-all. Professional judgements must be shaped and informed by understanding of the other elements of the framework that are there to inform, guide and, where necessary, control professional decision-making.

Whatever the sector, scope or level of an individual's practice, this framework is there to empower professionals to practise within safe parameters.

# The governance framework for pharmacy professionals



[Links to relevant organisations](#)

# The Law



- **General criminal law** includes violent crimes, property crimes, sexual offences, drug offences, fraud, public order, driving, and cybercrime
- **Generally applicable legal obligations**, e.g. the Equalities Act, UK GDPR, health & safety laws and so on.
- **Specific laws affecting pharmacy practice**, with criminal or civil sanctions (e.g. Human Medicines Regulations)
- **The Pharmacy Order 2010**
- The Health and Social Care Act 2008
- **Private civil law** focuses on disputes between individuals, businesses, or the state where there's no criminal wrongdoing involved (e.g. negligence or contract law)
- **Public law** relates to the legality of actions of public bodies

# Statutory regulation – products and services



- The GPhC is the statutory regulator for pharmacy premises and has inspection and enforcement powers
- Other statutory regulators regulate other healthcare environments e.g.
  - In England – the Care Quality Commission (CQC)
  - In Scotland – Healthcare Improvement Scotland (HIS)
  - In Wales – Healthcare Inspectorate Wales (HIW)
- The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines and medical devices UK-wide
- There are other relevant regulators such as the Advertising Standards Authority (ASA) and the Competition and Markets Authority (CMA)

# Organisations and teams



Pharmacists and pharmacy technicians work in a wide variety of organisations large and small, in public bodies and private businesses and in different team structures

These employers have a big impact on the work pharmacy professionals do and how they do it, via their policies and procedures including:

- Clinical governance
- Corporate governance
- Leadership and management
- Organisation and team culture

Some elements may be regulated via GPhC premises standards and/or by another statutory regulator

# NHS governance



When pharmacy professionals work in the NHS, or in a private organisation providing NHS services, various forms of NHS governance determine the activities which must be undertaken in certain circumstances and support and guide professional practice, including:

- National, regional and local NHS policies and procedures
- Regulations, Terms of Service and service specifications
- Mandatory clinical governance requirements

# Statutory regulation - professionals



The GPhC sets standards for:

- Education and training
- Registration, annotation and revalidation
- Pharmacy professionals' practice
- Pharmacy premises

It also provides guidance which can support professionals to meet the required standards.

The GPhC has enforcement and Fitness to Practise powers which it can use where standards are not being met

# Professional standards and guidance



A number of professional leadership bodies and specialist pharmacy groups such as the Royal Pharmaceutical Society (RPS), the Association of Pharmacy Technicians UK (APTUK) and others issue guidance on specific topics

Indemnity providers also issue guidance on a range of topics and can be contacted for advice

NICE provides recommendations for healthcare professionals to improve patient outcomes

# Individual professional

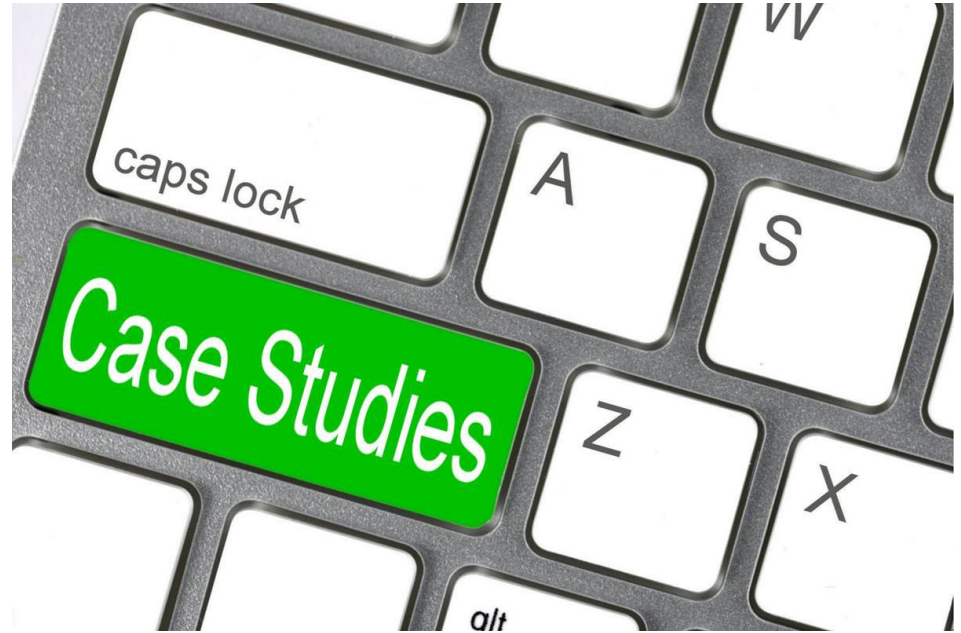


Working with all these elements is **the individual professional**.

Individual professional decision making is impacted by:

- Knowledge and skills
- Competence and confidence (including awareness of their own limitations)
- Professional judgement and values

# The framework in action



# Mental health pharmacist

Elizabeth is an experienced mental health pharmacist employed in a major city hospital.

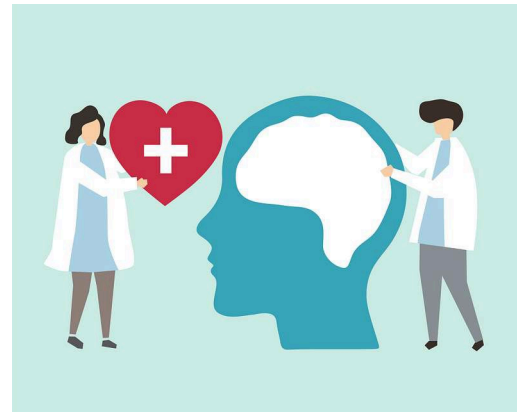
A patient diagnosed with schizophrenia has been hospitalised and is now being discharged with appropriate medication. He already has medication for two physical conditions and has a history of being non-compliant. Elizabeth is concerned about his ability to manage his medication appropriately and whether the medication is the correct one

## Possible issues:

Patient safety vs. patient autonomy

Medication risks and possible interactions

**How does the framework apply?**



# Mental Health Pharmacist

Layer	
Law	Human Medicines Regulations 2012, Misuse of Drugs Regulations 2001, The Mental Capacity Act 2005, The Mental Health Act 1983, Mental Health (Care and Treatment) (Scotland) Act 2003 & Adults with Incapacity (Scotland) Act 2000
Professionals Regulation	General Pharmaceutical Council (GPhC) Standards for pharmacy professionals
Systems Regulation / Quality Assurance	Care Quality Commission (CQC), Healthcare Improvement Scotland (HIS)/ Mental Welfare Commission Scotland / Health Inspectorate Wales (HIW)
Professional Bodies	Royal Pharmaceutical Society (RPS) and College of Mental Health Pharmacy (CMHP)
Professional Standards	RPS - Professional Standards for Hospital Pharmacy Services
Professional training	CMHP Psych 1 & Psych 2 courses, Foundation Certificate and Credentialing. RPS Consultant Pharmacist Credentialing. Framework of core mental health competencies for all pharmacy professionals, Advanced Pharmacist - Mental Health Curriculum, & Consultant Pharmacist Credentialing.
Team/Organisation	NHS, third sector or private - governance processes and <b>multi-disciplinary teamwork</b>

# GP practice pharmacy technician

Dan is a pharmacy technician working alongside a pharmacist in a GP practice with over 8000 registered patients. Part of his role is to help manage the dispensing of repeat prescriptions.

Dan notices that a repeat prescription for strong pain medication has been approved over a week before it was due. Checking the patient's records, he sees that this is becoming a pattern and a medication review has not been carried out recently. He is concerned that the patient may be abusing the medication.

## Possible issues:

Risk to patient safety and possible dependence

System issues

**How does the framework apply?**



# GP Practice Pharmacy Technician

Layer	
Law	The Medicines Act 1968, Human Medicines Regulations 2012 & Misuse of Drugs Regulations 2001
Professionals Regulation	GPhC Standards for Pharmacy Professionals
Systems Regulation / Quality Assurance	CQC, HIW or HIS
Professional Leadership Body	Association of Pharmacy Technicians UK (APTUK) & Primary Care Pharmacy Association (PCPA)
Professional Standards Framework	National Competency Framework for Primary Care Pharmacy Technicians
Team/Organisation	NHS commissioned generalist medical services policies and procedures
NHS Governance	GP practice internal governance processes, Primary Care Networks: Network Contract Directed Enhanced Service & GP NHS Core Contract.

# Prison pharmacist

Yousaf is a pharmacist in a large prison. The facilities and medicines stock available are limited and security protocols require that a guard is present when a patient is in the pharmacy, all of which can present Yousaf with a number of issues

## Possible issues:

- Limited range and availability of medicines
- Prisoners may have complex health needs but complex treatment regimes can be difficult to implement and monitor
- Safety vs. confidentiality

**How does the framework apply?**



# Prison Pharmacist

Layer	
Law	The Medicines Act 1968, Human Medicines Regulations 2012, Misuse of Drugs Regulations 2001 & Misuse of Drugs (Safe Custody) Regulations 1973
Professionals Regulation	GPhC – Standards for Pharmacy Professionals
Systems Regulation / Quality Assurance	GPhC, CQC, HIS or HIW
Professional Leadership Body	Royal Pharmaceutical Society (RPS), Secure Environments Pharmacist Group and Health and Justice Pharmacy Network
Professional Standards	RPS Professional Standards for optimising medicines for people in secure environments
Team/Organisation	National Health Service / Prisons Service – policies and procedures
NHS/Private Provider Governance	NHS, third sector or private healthcare provider governance processes

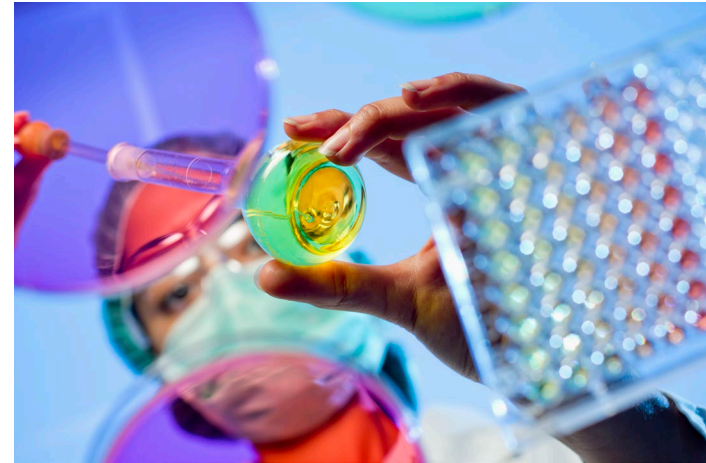
# Industry pharmacist

Maryam holds a senior position at a pharmaceutical company carrying out research and development in new medicines. Increasing commercial pressures and the pace of technological change are causing a number of issues in Maryam's workplace

## Possible issues:

- Navigating the complex regulatory landscape around new medicines
- Ethical concerns related to the pricing of and access to new medicines
- Balancing these with commercial considerations
- Keeping up with new developments

**How does the framework apply?**



# Industry Pharmacist

Layer	
Law	Medicines Act 1968, Human Medicines Regulations 2012 & Medicines and Medical Devices Act 2021
Professionals Regulation	GPhC Standards for Pharmacy Professionals
Systems Regulation / Quality Assurance	Medicines and Healthcare products Regulatory Agency (MHRA) - Good Manufacturing Practice & Good Distribution Practice
Professional Leadership Body/ Associations	RPS - Industrial Pharmacy Expert Advisory Group (IPEAG) The Association of the British Pharmaceutical Industry (ABPI)
Professional Standards	Code of Practice for the Pharmaceutical Industry 2021 & The Prescription Medicines Code of Practice Authority (PMCPA)
Team /Organisation	Pharmaceutical company policies and procedures
Governance	Internal corporate governance processes
Arm's Length Bodies	National Institute for Health & Care Excellence, Scottish Medicines Consortium, & All Wales Medicines Strategy Group

# Community Pharmacy-Pharmacy Technician

Layer	
Law	The Medicines Act 1968, Human Medicines Regulations 2012 & Misuse of Drugs Regulations 2001
Professionals Regulation	GPhC Standards for Pharmacy Professionals
Systems Regulation	GPhC Standards for Registered Pharmacies
Professional Body	Association of Pharmacy Technicians UK (APTUK)
Professional Training Programmes	Two-year training programme - NHSE Workforce, training & education, NHS Education for Scotland (NES) & Health Education and Improvement Wales (HEIW). Independent and employer-based training
Team/Organisation	Community pharmacy - policies and procedures
NHS Governance	Community Pharmacy Contractual Framework & internal corporate governance processes

# Online Pharmacy- Prescribing Pharmacist

Layer	
Law	The Medicines Act 1968, Human Medicines Regulations 2012 & Misuse of Drugs Regulations 2001
Professionals Regulation	GPhC – Standards for pharmacy professionals Guidance for pharmacist prescribers
Systems Regulation / Quality Assurance	GPhC - Guidance for registered pharmacies providing pharmacy services at a distance, including on the Internet. Care Quality Commission (CQC), Healthcare Improvement Scotland (HIS), & Health Inspectorate Wales (HIW)
Professional Leadership Body	Royal Pharmaceutical Society (RPS) and others depending on scope of practice
Professional Standards	Royal Pharmaceutical Society - A Competency Framework for all Prescribers
Organisation/Team	Organisational policies and procedures
Governance	Organisational internal governance processes

# Homecare Pharmacist

Layer	
Law	The Medicines Act 1968, Human Medicines Regulations 2012 & Misuse of Drugs Regulations 2001
Professionals Regulation	General Pharmaceutical Council (GPhC)
Systems Regulation / Quality Assurance	General Pharmaceutical Council (GPhC), Care Quality Commission (CQC), Healthcare Improvement Scotland (HIS), & Health Inspectorate Wales (HIW)
Professional Leadership Body	Royal Pharmaceutical Council (RPS)
Professional Standards/Guidance	Homecare Services Professional Standards (RPS) Homecare: a good practice guide for pharmaceutical manufacturers (ABPI)
Team/Organisation	Internal corporate governance processes
NHS Governance	Key Performance Indicators and/or Service Level Agreements agreed between NHS Trusts and Homecare Medicines Services providers

# Layers template...

Layer	
Law	
Professionals Regulation	
Systems Regulation / Quality Assurance	
Professional Leadership Body	
Professional Standards/Guidance	
Team/Organisation	
NHS Governance	

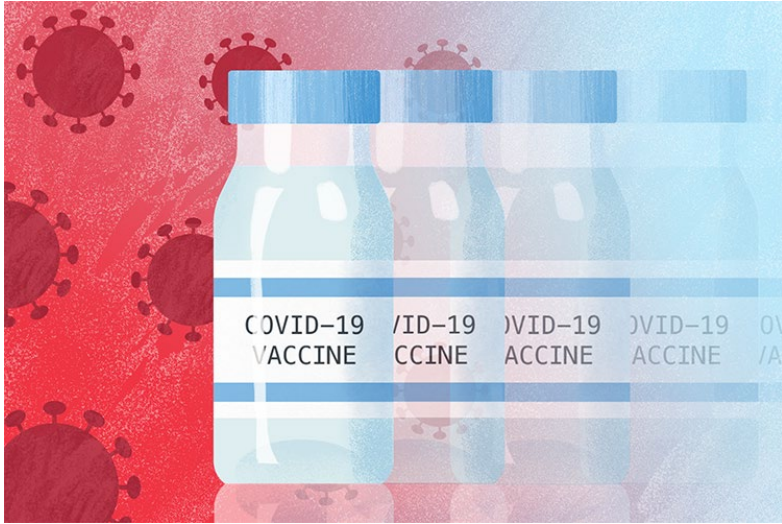
# Other important factors...

Beyond the layers of governance, there are other important issues that affect decision-making in practice. Understanding these will help improve your confidence and competence in practice

- Context
- Risk
- Indemnity
- CPD and Revalidation
- Peer group (?)



# Context



The same question  
may have different  
answers, depending  
on the situation

# Risk



The possible  
consequence of doing  
- or not doing – a  
particular thing

# Indemnity

A requirement to practise,  
protection for you and for  
patients – but do you know  
how far it goes?





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