

# Modernising Pharmacy Regulation

## An inspector calls: A new regulatory model in pharmacy

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# Our statutory role

“To protect, promote and maintain the health, safety and wellbeing of members of the public...by ensuring that registrants, and those persons carrying on a retail pharmacy business... Adhere to such standards as the Council considers necessary...”

# How?

- **Education:** Approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers
- **Registration:** Maintaining the register of pharmacists, pharmacy technicians and pharmacy premises
- **Setting standards:** For conduct, ethics and performance; education and training; and continuing professional development (CPD); and standards for the safe and effective practice of pharmacy at registered pharmacies
- **Fitness to practise:** Ensuring professionals on our register are fit to practise and dealing fairly and proportionately with complaints and concerns.

# About us

## Professional regulation

- Regulating pharmacy professionals through standards for conduct, ethics and performance
- Taking action where the fitness to practise of a registered pharmacy professional may be impaired
- **If the standards not met, registration of that pharmacy professional at stake**
- **Individual professional accountability**
- **Analogous to GMC/NMC**

## 'System' regulation

- Regulating pharmacies through standards for registered pharmacies
- Requiring owners and superintendents to secure compliance with those standards
- **If the standards are not met, registration of the pharmacy is at stake**
- **Organisational accountability (through owner/superintendent)**
- **Analogous to Care Quality Commission**

# Summing up our approach

*Council's vision is for pharmacy regulation to play its part in improving quality in pharmacy practice and ultimately health and well-being in England, Scotland and Wales*

# STANDARDS FOR REGISTERED PHARMACIES

General  
Pharmaceutical  
Council

## Standards for registered pharmacies

September 2012



# Our approach to standard setting

- A focus on outcomes, not prescriptive rules: set out what safe and effective pharmacy practice looks like for patients
- Leaves it to pharmacy professionals - they are the experts - to decide how to deliver that safe and effective practice
- New accountability structure: being accountable for what they are responsible for which is why pharmacy owners and superintendents are accountable for meeting the new standards

# So what do we mean by outcome ...

- An outcome is the ultimate result of something being in place or for an action being undertaken
- Example: Putting in a pedestrian crossing is an **output**
  - People are safer crossing the road is the **outcome**
  - Easier for those with mobility difficulties to get about is also the **outcome**





# What does this mean in pharmacy?

- In practice, this means pharmacies should have as their top priority, patients and keeping them safe, and should be able to show how they do that, every day
- It will be up to pharmacies to provide the evidence and examples in whatever way they choose

# Standards for registered pharmacies:

## Five principles

- Principle 1 – looks at how risk is managed
- Principle 2 – looks at how people / staff are managed
- Principle 3 – looks at how the building / premises is managed
- Principle 4 – is about how pharmacy services are delivered
- Principle 5 – is about the equipment and facilities they have and use to deliver services

# Meeting the standards

- Pharmacies should meet the standards every day – not just when an inspector calls
- Our inspections are just one way that we assure that pharmacies are keeping patients and the public safe
- For instance, owners and superintendents renewing the registration of their pharmacies need to declare that they have read the standards and undertake to meet them

# How will we know the standards are being met?

- Prototype of our approach to inspecting against the standards running from 4 November
- Testing four indicative judgements of performance – poor, satisfactory, good and excellent
  - Inspection outcome decision framework to aid inspectors in making consistent judgements
- Improvement action plans operational
- Pharmacy owner and superintendent will get a report, but no public reports during prototype phase
- Strategic relationship management has started

# Inspection labels and descriptions

## Poor pharmacy

- has failed to achieve the pharmacy standards overall. There are major concerns that require immediate improvement.

## Satisfactory pharmacy

- achieves all or the majority of standards and may require some improvement action to address minor issues.

## Good pharmacy

- achieves all standards consistently well and has systematic review arrangements that ensure continual improvement in the quality and safety of pharmacy services delivered to patients.

## Excellent pharmacy

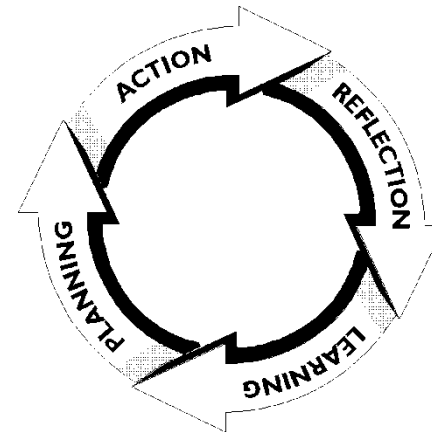
- demonstrates all the hallmarks of a good pharmacy. In addition, it is either innovative and/or provides unique services that meet the health needs of the local community and that other pharmacies might learn from.

# Action learning testing – what we've done

- On site test inspections in 3 phases
- Around 150 full test inspections completed
- 65:35 split independents to multiples
- New potential risks identified
- Quite a low level of awareness of new premises standards in general
- Language of governance and risk management is quite challenging

## Snapshot of what we found

- Most inspections identified a number of relatively minor issues
- More rigorous assessment - triangulation of evidence



# Early indicative inspection trends from testing

Most common standards not met from early testing:

- Management of medicines & medical devices (4.3)
- Risk management identification & management (1.1)
- Records management (1.6)
- Risk reviewed & monitored (1.2)
- Pharmacy services managed & delivered safely (4.2)
- Premises safe, clean & properly maintained (3.1)

Most common combinations of standards not met:

- 1.1 & 1.2
- 4.2 & 4.3
- 1.1, 1.2, 4.2 & 4.3



# What feedback was received?



- Pharmacists value the instant feedback
- Positive engagement with staff team
- ‘Show and tell’ approach welcomed
- Seen as a learning and development opportunity for all pharmacy team
- Inspector on site for longer



# Resources

- We have a new resource with more information at <http://pharmacyregulation.org/pharmacystandardsguide>