

## 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...”

# 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 are 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*

# Professionalism – a key strategic aim

- Using regulation to promote a culture of patient-centred professionalism in pharmacy
- We are committed to regulating in a way which supports pharmacists and pharmacy technicians to embrace and demonstrate professionalism in their work
- Professionalism, not rules and regulations, provides most effective protection for patients
- Prescriptive rules let us all off the hook

# 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.

# What feedback was received from testing?



- 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

## Responsible Pharmacist Feedback since 4

### November

RPs strongly agreed/agreed:

- 'Feedback from inspector was helpful and well presented'
- 'Feedback from inspector was accurate'
- 'Inspector explained clearly what would happen after the inspection'
- 'Inspector identified where the pharmacy was performing well'  
'Inspector helped me to think about how I can improve the quality of services provided to patients and the public'
- A clearer understanding of the standards after the inspection

## Responsible Pharmacist feedback (continued)

- 'Very professional & clear'
- 'Relaxed approach and constructive'
- 'Issues were raised we may have not thought of i.e. vulnerable people'
- 'Explained what she was looking for and summarised feedback'
- 'Very informative and conveyed ideas clearly and explained where we needed improvement and why'
- 'Inspector was informative, helpful and friendly'
- **Improvement areas:** mainly around making appointments, but many understood need for unannounced visit.

## Owners/Superintendents strongly agreed/agreed:

- ‘The inspector has explained clearly what action I am required to take following the inspection’
- ‘The judgements in the report are supported by the evidence and are in line with the Inspection decision making framework’
- ‘The report broadly reflects my knowledge of the pharmacy and its likely performance against the registered pharmacy standards’
- ‘The report has helped me to think about how we can improve the quality of services we provide to patients and the public’

## Owner/Superintendent feedback (continued)

- ‘Very comprehensive ... very fair and accurate report’
- ‘I find the reports informative and they represent a paradigm step forward’
- ‘Well structured way of inspecting a pharmacy’
- ‘Focussed on patient safety, clear standards’
- ‘Non confrontational meant that the learning process for us was better’
- ‘Positive, helpful and friendly style of the inspector; involvement of staff in the process’
- ‘I felt that it made us think about what we are doing and look at ways to improve the service we offer’



## Areas for improvement from feedback

- ‘Would appreciate more time to reflect on our inspection report and comment’
- ‘There are still areas which are 'grey' and we were told to think about how we do something. I still like to be told what is acceptable and what is not’
- ‘I have concerns about publishing the report with certain sensitive figures, such as prescription numbers’

# Resources

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

# Questions?