

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?