

Consultation on developing approach to regulating registered pharmacies



2018

Pharmacy inspections: a brief recap

General Pharmaceutical Council

General Pharmaceutical Council

Modernising pharmacy regulation:

A consultation on the draft standards for registered pharmacists



Standards for registered pharmacies

September 2012



Update paper: February 2015

General Pharmaceutical Council

Modernising pharmacy regulation: from prototype to full implementation

Update paper

In 2012 we set out a new vision for the regulation of pharmacies. In our consultation on new standards for pharmacies, [Guidance Pharmacy Regulation](#), we made clear our ambition for pharmacy regulation to move beyond a focus on legal compliance, check lists and standard operating procedures.

Our aim was to develop new standards which all pharmacies registered with the GPhC would have to meet. These standards would put patients first, describing the things that pharmacies need to deliver – or ‘outcomes’ – rather than publish a long list of proscribed rules from the regulator. The feedback we have received about these new standards has been very positive.

Alongside the new standards we identified a need to reform the outdated inspection model. The feedback we received through our engagement and consultation was that the previous inspection model lacked transparency, was inconsistent, narrow in focus towards issues such as controlled drugs monitoring, and too focused on monitoring compliance with checklists and standard operating procedures.

Over the previous twelve to eighteen months we have completely overhauled our inspection model. We implemented a new prototype inspection system which makes assessment against a single set of standards. This assessment is supported by a clear decision-making framework developed in partnership with the profession. It is focused not just on safety, but on quality improvement. We are pleased that this model has received such high levels of support from stakeholders, particularly through the feedback we capture from the pharmacies we inspect.

However, in part due to the need for [further legislative change](#), our inspection model remains in a prototype phase. This has enabled us to learn and refine our new inspection model and to provide feedback to pharmacies on a confidential basis. Although we have a range of legal powers to protect patients, we do not yet have full enforcement powers or the power to publish inspection reports. It is our intention to do so, when we have the necessary legal powers, and only after a public consultation exercise on our regulatory model including the process of publication.



ICF

Evaluating the GPhC's approach to regulating community pharmacies

Final Report to the General Pharmaceutical Council
ICF Consulting Services

20 August 2015

Apr 2012

Sept 2012

November 2013,
introduction of new
inspection model

Feb 2015

Oct 2015

To now - 2018

- Almost completed a full cycle of inspections
 - Most pharmacies meet the standards
- Evaluation indicates approach is working well
 - Overall support, with areas for further consideration
- Now want to further develop regulatory approach
 - To take the next step to provide further assurance and drive improvement
- Significant changes
 - The GPhC will shortly have powers to publish inspection reports

The GPhC strategic approach



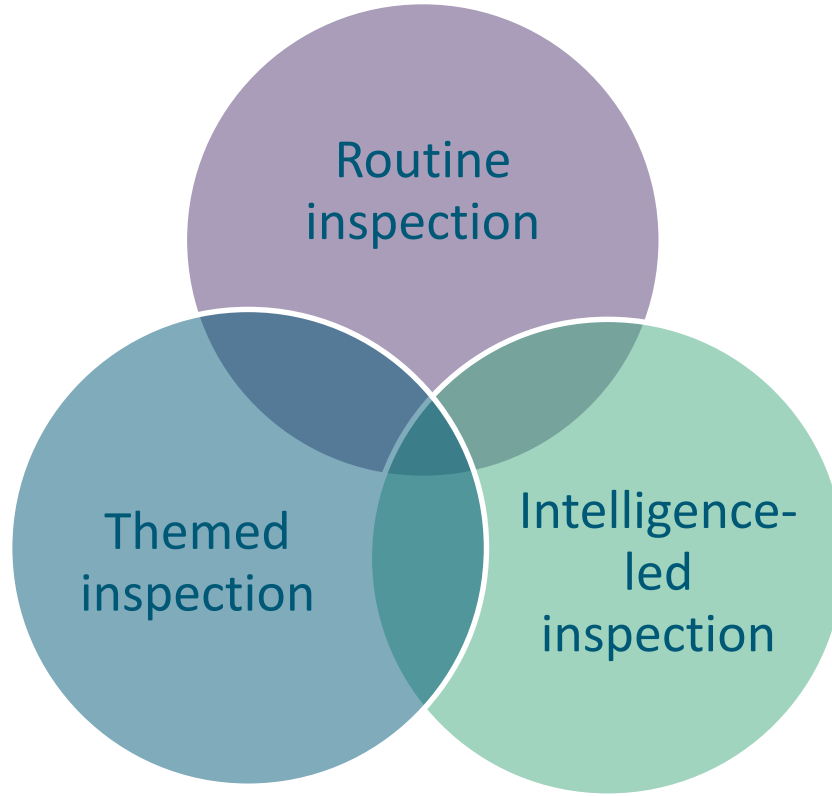
- Providing **assurance** that pharmacies are meeting standards and driving continuous **improvement** in the quality of services and care for the public
- Moving to a flexible and agile approach, responding effectively to the changing needs of patients and the public and to changes in pharmacy
- Increasingly informed by information and intelligence, targeting resources where they can have the greatest impact
- Publishing reports to strengthen assurance for patients and to enable the sector to learn and continuously improve

Key proposals at a glance



1. Changes to the types of inspections
2. Moving to unannounced inspections
3. Changing inspection outcomes
4. Requiring all standards to be met to receive an overall 'standards met' outcome
5. Publishing inspection reports
6. Sharing examples of notable practice in a 'knowledge hub'

Introducing new types of inspections



Changes to inspection outcomes



- Overall outcome for an inspection would be either ‘standards met’ or ‘standards not all met’
 - providing clear and simple assurance for the public
- Findings at principle level: ‘standards not all met’, ‘standards met’, ‘good practice’ or ‘excellent practice’
- Designed to focus the pharmacy owner and the team on the content of the report, specific positive outcomes, areas for improvement or failed standards in the report
- Enables the GPhC to identify notable practice, which can be shared to help others learn and support continuous improvement

Publication

- Plan to publish all inspection reports in the future, as well as improvement action plans where appropriate
- Plan to publish short examples of notable practice, to help drive continuous learning and improvement
- New website will make it easy to search for and analyse inspection outcomes and the examples of notable practice

Future work

1. Reviewing standards for registered pharmacies
2. Developing an enforcement policy
3. Seeking views on the information collected about pharmacies
4. Seeking views on the information published and disclosed in relation to registered pharmacies
5. Publishing a report of what has been learnt from inspections
6. Considering whether other options for identifying which pharmacies to inspect- including sampling- would provide assurance

Take part in the consultation:

**[www.pharmacyregulation.org/
registered-pharmacies](http://www.pharmacyregulation.org/registered-pharmacies)**



**Closes
9 August
2018**

Find our more

- Visit the GPhC website –
www.pharmacyregulation.org
- Join the discussion on social media
 - @TheGPhC on twitter, hashtag #RegPharm
 - Facebook.com/TheGPhC