

The GPhC's new approach to regulating pharmacies

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Cover today

1. Inspection journey and underpinning regulatory philosophy
2. Changes to our inspection approach
3. Follow on action

How we regulate registered pharmacies



A brief re-cap on our inspection journey

General
Pharmaceutical
Council

Modernising pharmacy regulation:

A consultation on the draft standards for registered pharmacies



General
Pharmaceutical
Council

Standards for registered pharmacies

September 2012



Update paper: February 2015

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, *Modernising 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Alongside the new standards we identified a need to reform the outdated inspection model.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.

General
Pharmaceutical
Council



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

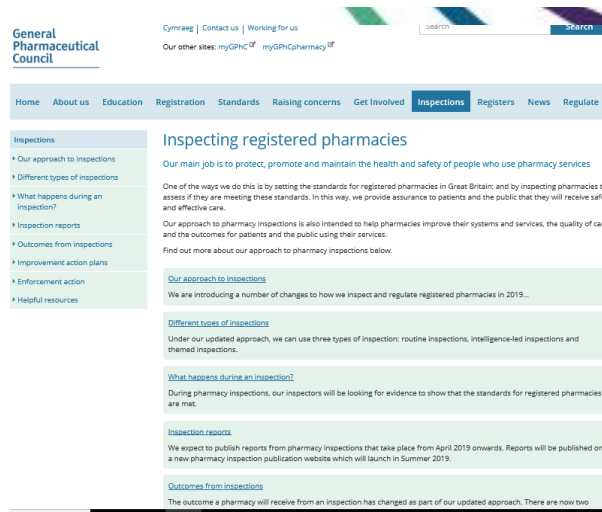
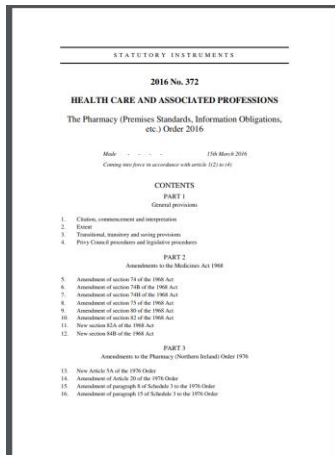
Feb 2015

Oct 2015

A brief re-cap on our inspection journey

Gov't consultation draft leg

Gov't Publishes responses



(2015)


(Feb 2016)

May 2018

2018

April 2019, changes to inspection model start to be rolled out

Our strategic approach

- 
- ▲ Continuing to provide **assurance** that pharmacies are meeting standards and driving continuous **improvement** in the quality of services and care for the public
 - ▲ Increasingly informed by intelligence, targeting our 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 principles



To be flexible, agile and responsive to the information we hold, intelligence we receive and issues we identify within pharmacy



Inspections should reflect as closely as possible how patients and the public experience pharmacy services day to day



The overall outcome of an inspection is clear and understandable



All standards for registered pharmacies need to be met every day



The outcome of an inspection is open, transparent and accessible to members of the public



Insights from inspection activities are accessible to everyone in the pharmacy sector

Key changes at a glance



Changes to the types of inspections



Moving to unannounced inspections



Changing inspection outcomes



Requiring all standards to be met to receive an overall 'standards met' outcome



Publishing inspection reports



Sharing examples of notable practice in a 'knowledge hub'

Types of inspections

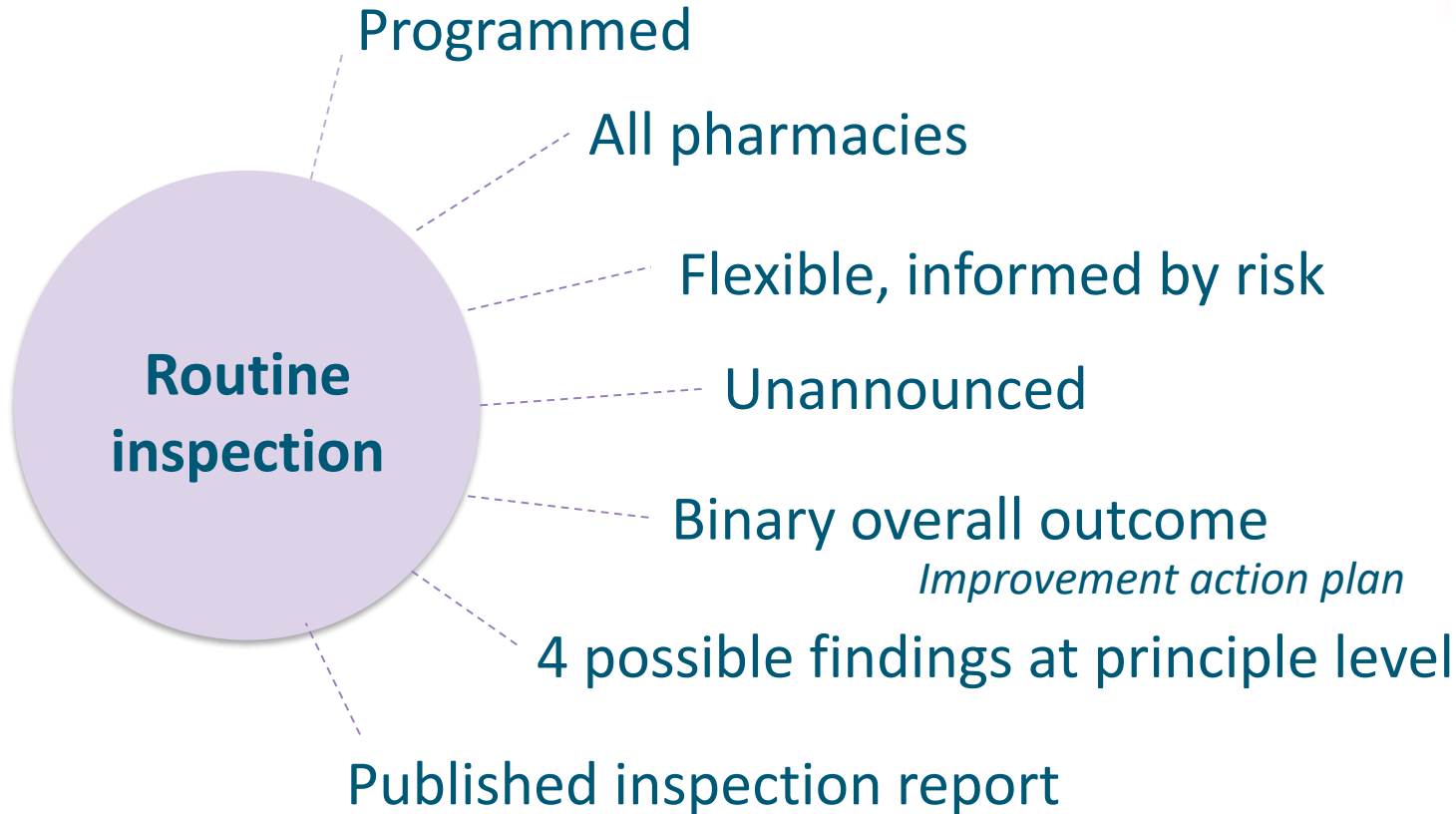


**Routine
inspection**

**Intelligence-
led inspection**

**Themed
inspection**

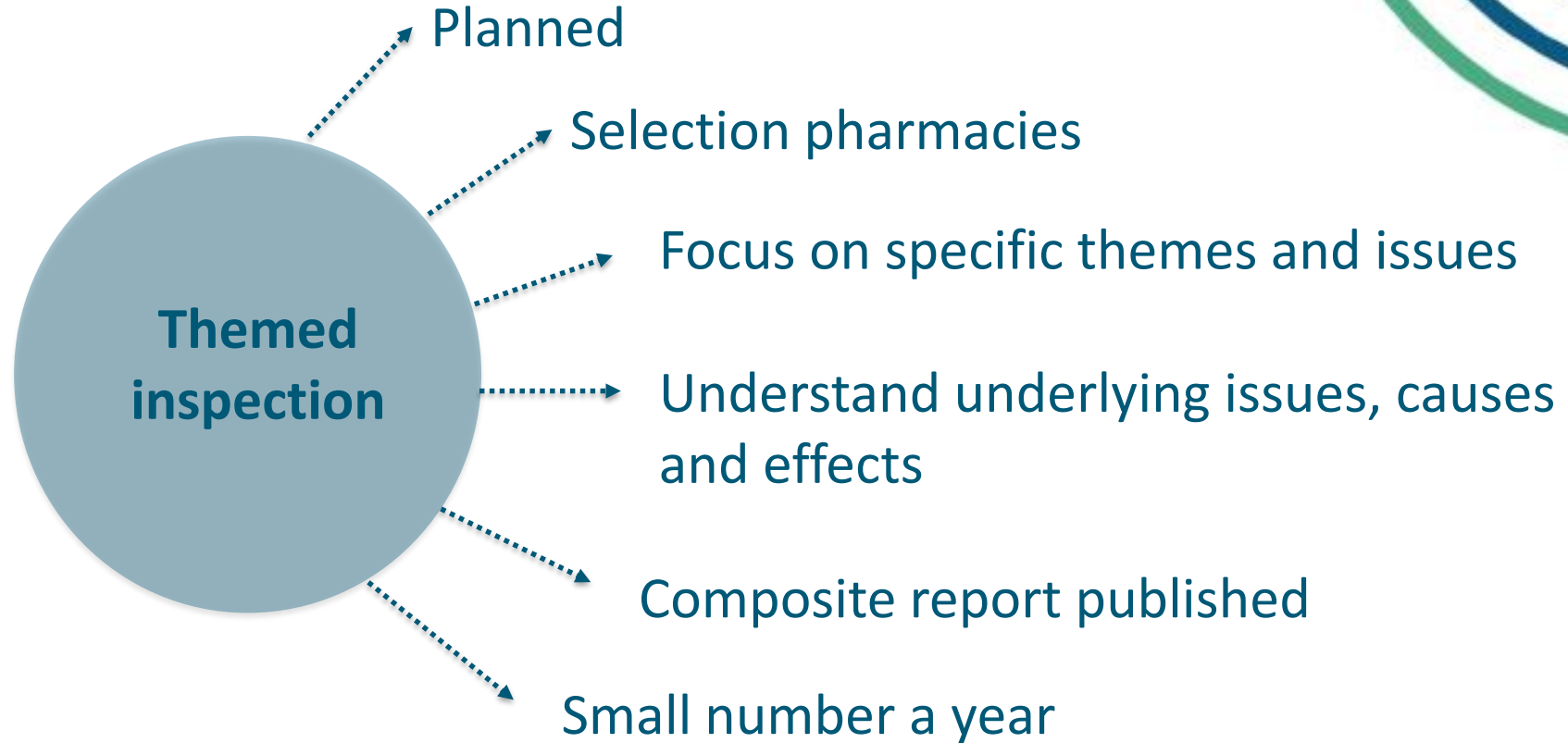
Types of inspections



Types of inspections



Types of inspections



Changes to inspection outcomes

Outcome of an inspection

STANDARDS NOT ALL MET

or

STANDARDS MET

Findings at Principle Level

Standards
not all met

or

Standards
met

or

Good
practice

or

Excellent
practice

Publication



Inspections publication website launches in Summer 2019



Linked to main GPhC website and register

Importantly



We will also publish short examples of notable practice, to help drive continuous learning and improvement

— Knowledge hub for sector

Our aim



New website will make it easy to search for and analyse inspection outcomes and the examples of notable practice

Follow on action

Our enforcement policy

- Sets out the approach and principles we follow when using our enforcement options
 - Summarises the range of enforcement options available to us
 - Outlines the criteria we take into account when making decisions about which enforcement option, or combination of options, to use
 - Supports consistent decision-making about when to use our enforcement options
 - Aligns with our wider strategic approach to regulation

Key principles for enforcement

- ☐ Proportionality
- ☐ Consistency
- ☐ Transparency
- ☐ Targeting
- ☐ Accountability



Minimum regulatory intervention required to achieve the desired result

Factors we will consider

- Seriousness of the concerns
 - Risk of harm to patients or the public, and the wider public interest
- Willingness and ability of the pharmacy owner to meet the standards, including any steps already taken to do this
 - Evidence of repeated or multiple failures to meet our standards
 - Compliance with other regulatory or enforcement requirements
- Impact or potential impact of
 - Non compliance
 - Enforcement action on the wider patient community and public and registered pharmacy
- Potential for wider learning points for pharmacy owners
- Any other relevant considerations

The range of follow on actions



- Improvement action plans
- Conditions on registered pharmacy premises
- Improvement notice
- Disqualify a pharmacy owner for failing to meet the standards
 - Remove all premises entries from the register
 - Remove one or more premises entries from the register
 - Suspend one or more premise entries

Other relevant powers

RIPA

- We now have legal powers to carry out covert (directed) surveillance activity surveillance
 - But not to use covert human intelligence sources
- We will only use powers in very limited cases
- Use of these powers must be proportionate, lawful, properly authorised and necessary
- We will always consider relevant and practicable alternatives first

Any questions





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