

Modernising pharmacy regulation: Inspection

Presented by

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History lesson...

The GPhC assumed responsibility for pharmacy regulation in September 2010.

Previously the RPSGB had been the professional body and the regulator for pharmacy. The decision was taken that those functions should be separated and so the RPS became the professional body.

The GPhC was designed to strengthen the regulation of pharmacy, not just of pharmacy professionals

Our statutory role

Pharmacy Order 2010

“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; continuing professional development (CPD); and for registered pharmacies
- **Fitness to practise:** making sure professionals on our register are fit to practise and dealing fairly and proportionately with complaints and concerns.

About the GPhC

1.2 million registered health professionals in the UK

47,300 pharmacists

over 22,000 pharmacy technicians

more than 14,000 pharmacies on our register

we are funded by those who register with us
(pharmacists, pharmacy technicians and pharmacy
owners)

Regulation

We register competent professionals to practise pharmacy...

...and set standards to regulate the system for managing and delivering pharmacy services from registered premises

What we want to achieve

“Our 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”

(From our Strategic Plan 2014 – 2017)

Professionalism – a key strategic aim

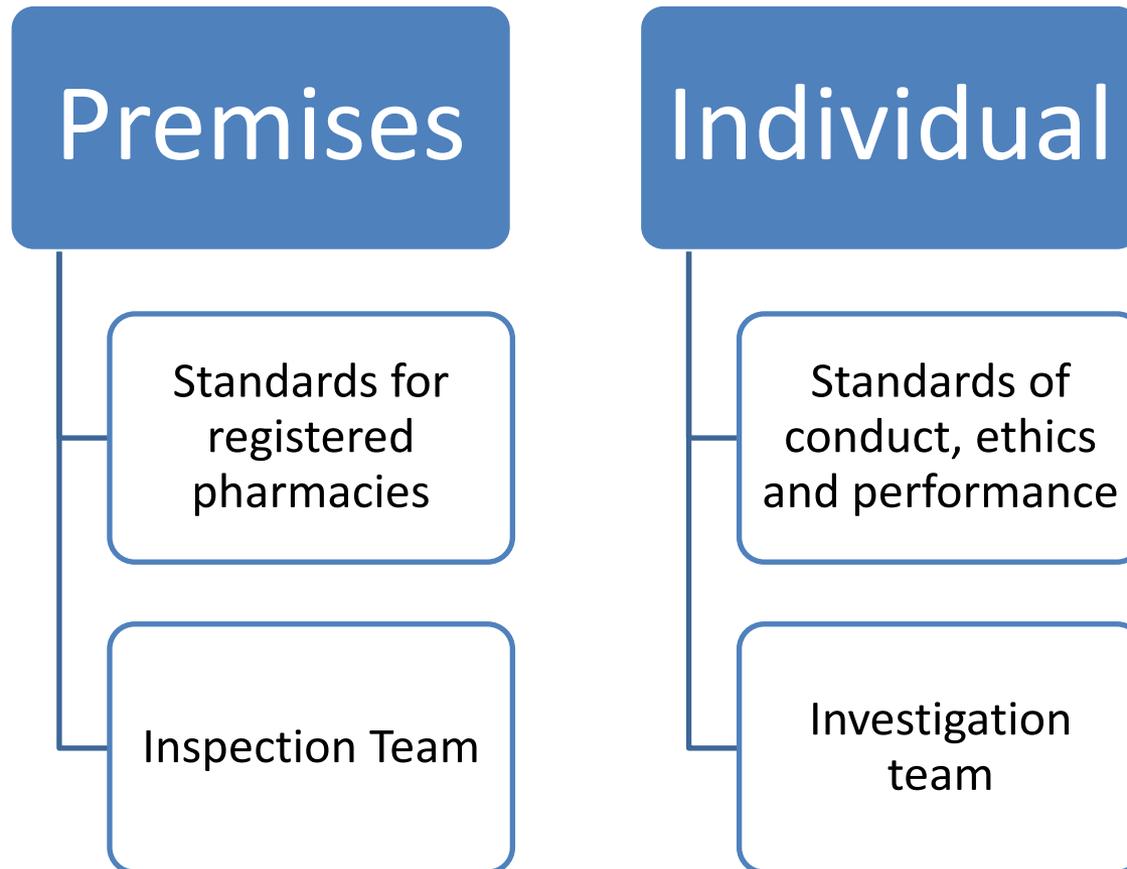
Using regulation to promote a culture of patient-centred professionalism in pharmacy

Regulating in a way which supports pharmacists and pharmacy technicians to embrace and demonstrate professionalism in their work

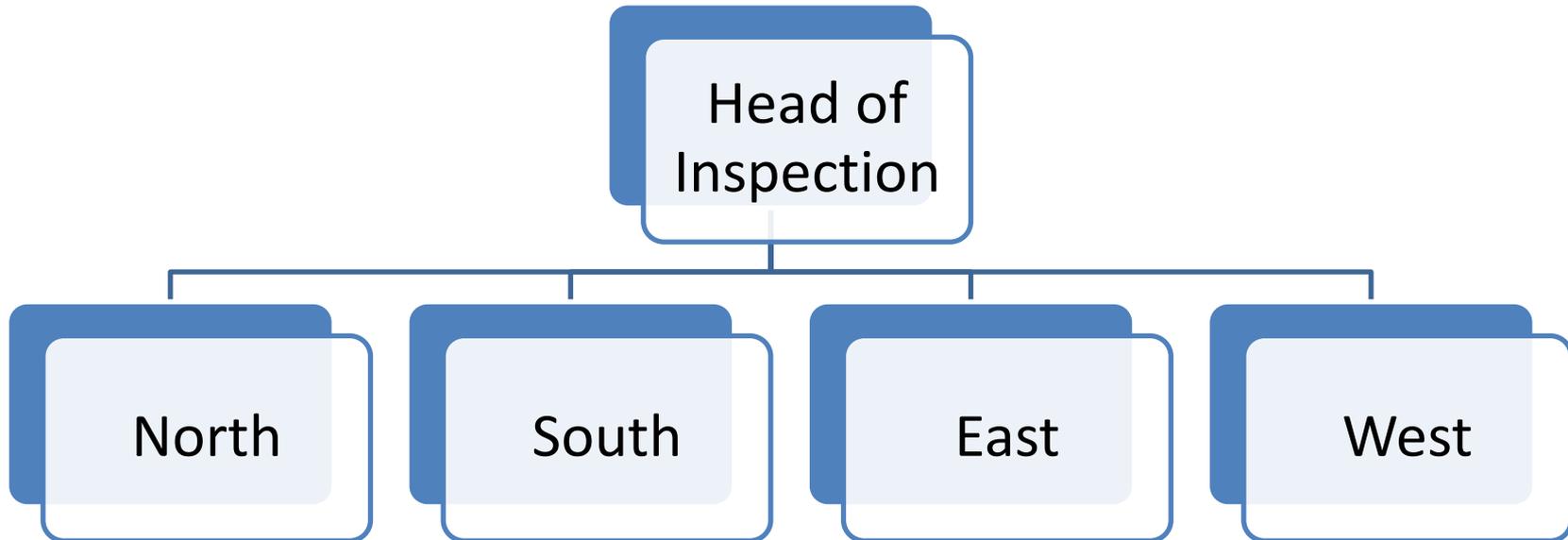
Professionalism, not rules and regulations, provides most effective protection for patients

Prescriptive rules let us all off the hook...

Inspection & Fitness to practise



Inspection team



Inspection Team

Head of Inspection and four regional teams

Each consisting of a Regional Manager and seven Inspectors

Each Inspector has an area with approximately 500 registered pharmacies (200 for RMs)

What Inspectors do

- Inspect pharmacies
- Pre-opening approvals
- Deal with 'stream 1' complaints
- Work collaboratively with the investigation team for stream 2 complaints
- Attend LINs, deal with queries, write reports, etc., etc...

Standards for registered pharmacies

General
Pharmaceutical
Council

Standards for registered pharmacies

September 2012



Standards for registered pharmacies

Focus on outcomes for patients - what safe and effective pharmacy practice looks like for patients

Allow pharmacy professionals to decide how to deliver that safe and effective practice. They are the experts

Make pharmacy owners and superintendents accountable for meeting the standards

What do we mean by outcome

an outcome is the ultimate result of something being in place or for an action being undertaken

e.g. putting in a pedestrian crossing is an **output**

People are safer crossing the road is the **outcome**



Five principles

Principle 1 – how risk is managed

Principle 2 – how staff are managed

Principle 3 – how the building / premises is managed

Principle 4 – how pharmacy services are delivered

Principle 5 – equipment and facilities

Under each principle is a list of standards that must be met.

Some overlap between standards, risk, confidentiality etc.

Owners and superintendents renewing registration of their pharmacies need to declare they have read the standards and undertake to meet them

Key elements of our approach to inspection

Prototype of inspection approach running since 4 November

Testing four indicative judgements of performance – poor, satisfactory, good and excellent

- Inspection outcome decision framework to aid inspectors in making consistent judgements

Pharmacy owner and superintendent will get a report, but no public reports during prototype phase

Improvement action plans are operational

Meeting the standards

‘Show and tell’ approach – pharmacies decide how to demonstrate they are caring for patients and practising pharmacy safely and effectively

But what do I need to show you and tell you?

GPhC inspection decision making framework available on website

Inspection procedure

Look at documentation

Inspectors talk to the pharmacy team and ask questions to test systems

Pose scenarios and ask for examples

Observe what is going on and how staff interact with each other and with patients

SOPs

Compliance with Responsible Pharmacist Regulations

Are they a true reflection of how the pharmacy operates?

Is there evidence that staff are aware of the SOPs

Are they just 'pieces of paper'?

S4 CDs

Principle 1 – managing risk

How do you identify and manage risk?

Are staff clear what they can and cannot do?

Do you encourage patients to provide feedback?

Can you demonstrate how you respond to feedback?

Are records in order?

How do you protect confidential information?

How do you safeguard vulnerable patients?

Principle 2

Are there enough staff?

Are staff able to meet their obligations and put patients first?

Are they encouraged to express their views and report their mistakes?

Do staff know how to raise concerns?
Are there targets and incentives?

Principle 3

Is it clean?

Can you hold a private conversation with a patient or make a private phone call?

Is the environment suitable?

Is it secure?

Principle 4

Are services accessible?

Signposting

Stock management arrangements

Audit trails

Medicine sales

Principle 5

Is the necessary equipment available?

Is it appropriate and properly maintained?

Is the consultation room used?

How are paper records stored?

Are PMRs password protected?

General thoughts...

Examples are good.

How do you know?

What happens on your day off?

Don't be scared, it's a chance to show off!

After the inspection

RP asked to read and sign evidence

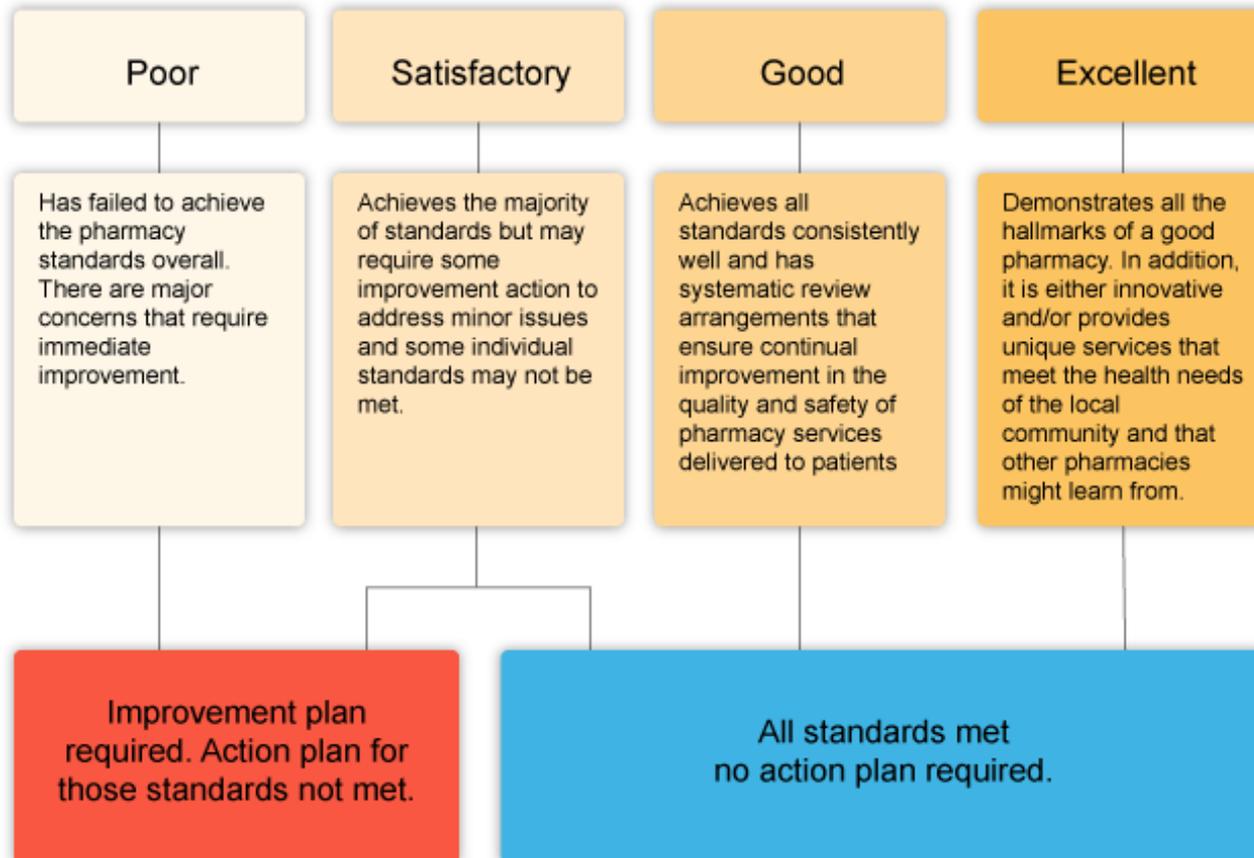
Judgements made

Report finalised and sent to QA

Report sent to owner or superintendent

Asked to confirm factually correct

Action plan/follow up visit



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.

Resources

Our online resource includes links to useful documents e.g. our evidence bank and the inspection decision making framework.

<http://pharmacyregulation.org/pharmacystandardsguide>

Questions?



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