

GPhC enforcement powers – how they are used and are they adequate

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What we will cover

- Background
- Legislative powers
- Our approach to enforcement
- Numbers
- A case example
- Are the powers adequate?
- Changes to our operating context

Background

- The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016
 - Made changes to the Medicines Act and Pharmacy Order
 - Removed requirement for standards to be set in inflexible, legislative rules
 - Revised the sanctions available to us where pharmacy owners breach the standards
- Publication of Registered pharmacies enforcement policy in March 2019

Powers

➤ Improvement Notices

- Article 13 of the Pharmacy Order 2010
- Inspector - reasonable grounds for believing
- ***'there is a failure to meet the standards for registered pharmacies, or a failure to meet conditions relating to the standards'***
- Not less than 28 days to comply
- Failure to comply with an improvement notice - the Registrar **must** refer the matter to the FTPC under section 80
- Appeal to the Magistrates' Court or Sheriff

Powers

- **Conditions on premises**
 - Medicines Act 1968 - Section 74D
 - Registrar decision – test of necessity
 - ***‘of securing the safe and effective practice of pharmacy at those premises’***
 - Maybe immediate in certain situations ***‘prejudice health, safety or well-being of public’***
 - Or ‘on notice’
 - On making the entry, renewal or otherwise
 - Not appealable – but subject to judicial review

Powers

- **Disqualification**
 - Section 80 Medicines Act
 - Contains the powers to disqualify pharmacy owners
 - Powers of disqualification previously only applied to a body corporate. PSIO 2016 extended scope to retail pharmacy businesses owned by a pharmacist or a partnership
 - Fitness to practise Committee decision

Our approach to enforcement - principles



Proportionate - to the specific circumstances and risks



Consistent - does not mean we choose the same option each



Transparent - publish our approach and explain what is expected from owners



Targeted - prioritise regulatory efforts effectively



Accountable - clear policies and public scrutiny

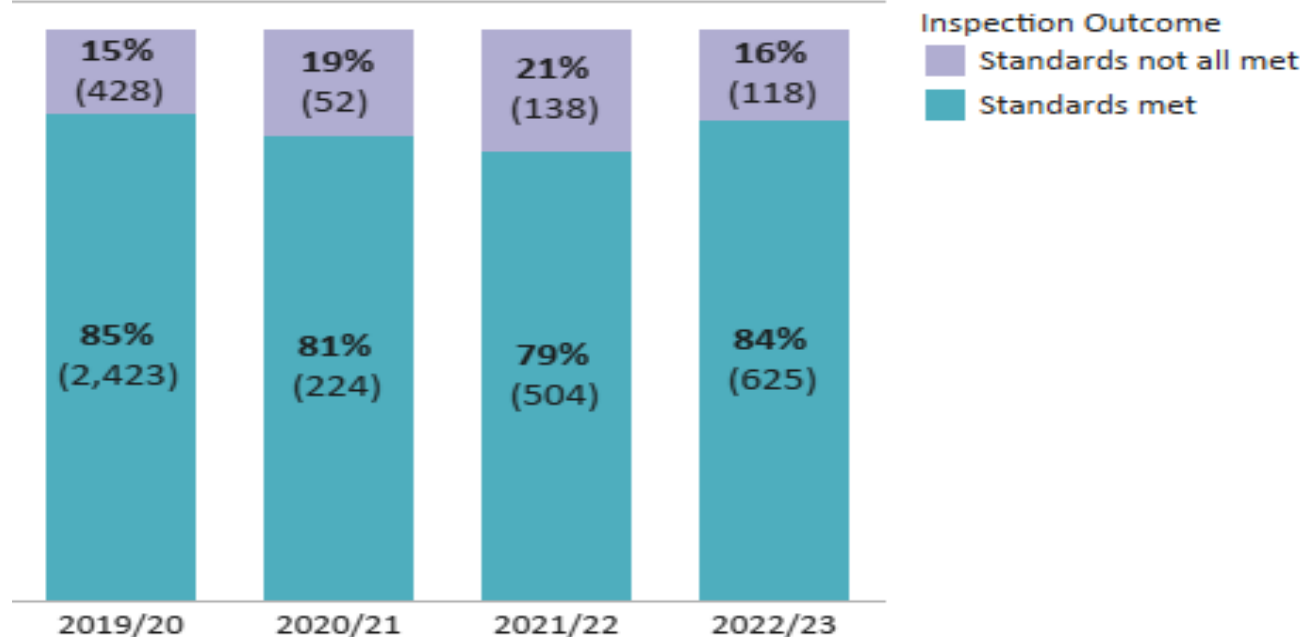
Our approach in line with the policy

- Support and encourage owners to meet the standards
- Try to secure safe and effective practice through open dialogue
 - Improvement actions plans (non-statutory)
- Take formal (statutory) enforcement action when we need to
- Act fairly, robustly and swiftly
- Make full use of our data and intelligence to support and inform decision-making
- Work with others when they are better placed to manage concerns
- Use a combination of powers – options are not sequential

Examples of factors we consider

- Seriousness of the concern
- Risk of harm to patients and the public
- The willingness and ability of the pharmacy owner to meet the standards, including steps already taken to do this
- Evidence of repeated or multiple failures to meet our standards
- The likely impact of the enforcement action on the registered pharmacy
- The likely impact of the enforcement action on the wider patient community and the public
 - For example where a condition on premises registration is imposed that restricts the provision of a certain service

% and # of standards met or not met



Enforcement numbers

Since 2019.....

- **115** Enforcement notices in total (online and non-online) since 2019
 - **96** Conditions Notices
 - **19** Improvement Notices
 - **98** Referrals of professionals to fitness to practise



Particular area of risk

- Adequacy of controls and safeguards around the provision of higher risk medicines
 - Opiates and Z drugs
 - Combinations of medicines
 - Codeine linctus and Phenergan (Purple Drank or Lean)
 - Controlled Drugs generally
- Pharmacies providing on-line services are the pharmacy types most likely to engage our enforcement powers
 - Clinical services being delivered as a transactional supply function
 - Poor risk management
 - Weak leadership and governance – including clinical governance
 - Lack of a 'whole systems' view professionals operating in
 - Breakdown of practical application of pharmacy and professional standards
 - Questionnaire only consultation approach

Enforcement numbers - online pharmacies

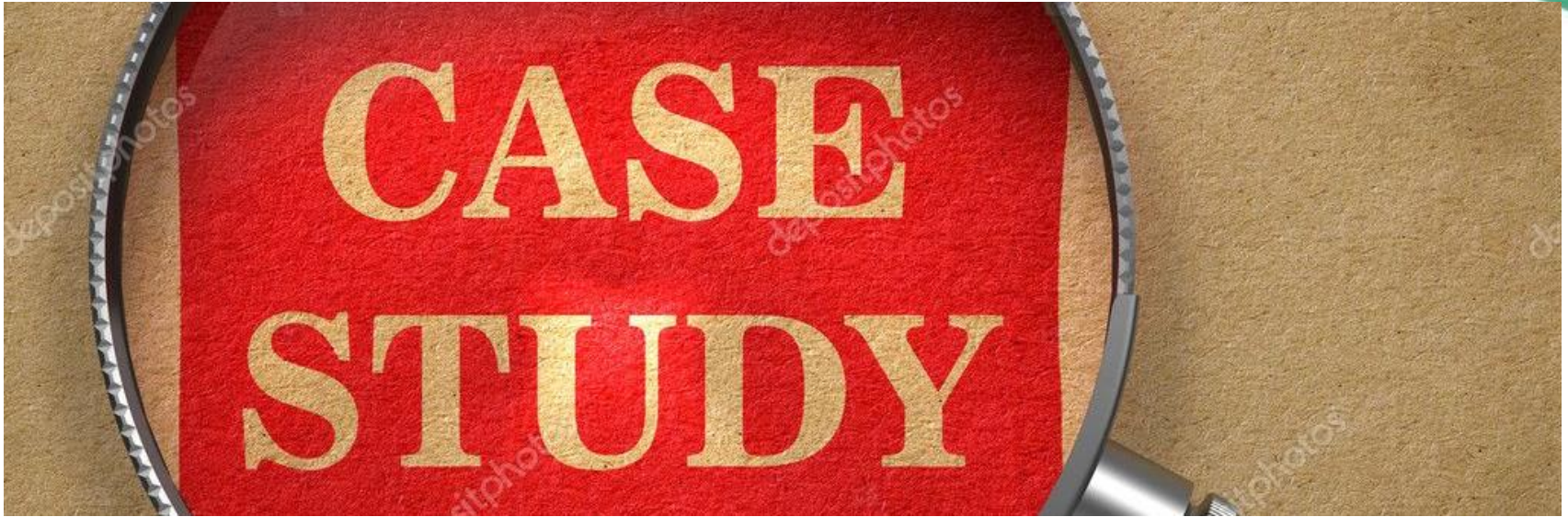
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Since 2019....

- Pharmacies providing on-line services are disproportionately overrepresented
 - Intelligence-led approach
 - Priority inspections
-
- **65/115** enforcement actions against online pharmacy premises
 - **54/96** Notices of Conditions issued
 - **11/19** Improvement Notices issued



Case study



Case study – pharmacy inspection

What we found in terms of poor practice:

- Main activity is providing opioid-based medicines
- No confirmation with regular GP that these medicines are suitable for the patients
- Prescribing service not registered with a UK regulator, when it should have been
- Insufficient risk assessments available. No procedures on counselling, business continuity, record keeping, risks or staff communications
- No controls or policies on how frequently repeat supplies could be obtained or how many repeat supplies could be given

Case study contd..

- Patient instructed to inform own GP of any prescribing
- Evidence of patients providing details of GP surgeries which they were not registered with
- Photo ID checks not routinely required
- Many instances of people trying to make multiple accounts
- No direct contact between the prescriber and the patient
- No prescribing or dispensing audits undertaken

Case study contd..

- Incomplete records of private prescriptions,
- Patients' mental capacity not assessed in any way
- Instances of supplies being made to people misusing / abusing them
- Patients under 21 being supplied with opioids without their GP being contacted prior to supply, contrary to the pharmacy's own policies

Process

- Team inspection (including clinical advisor/specialist inspector)
- Draft report prepared
- Enforcement action meeting (inspector led)
- Recommendation to Registrar
- Registrar decision
- Notice served
- Publication



Outcome

- Immediate Conditions on premises registration

‘The pharmacy must not sell or supply any controlled drugs from schedule 1 to 5’

- Referral of the prescriber to GMC
- Referral of SI to ‘fitness to practise’ for investigation
- Referral to CQC

Enforcement publication

- Publication
 - The full Notices are not published
 - Summaries are published instead
 - GPhC publication and disclosure policy

Inspections Publications website

General
Pharmaceutical
Council

Pharmacy inspections

Inspection reports and learning from inspections

➤ Main website

➤ Useful links



Inspection reports ▼

Standards

Knowledge hub

About us ▼



Search for a pharmacy inspection report

Postcode, Street, Town or City

Pharmacy name – start typing and select from the drop down list

Search

You can also search across all of our inspection reports by different criteria: [Search across all inspection reports](#)



Find out if a pharmacy is meeting standards for safe and effective care.

We set [standards for pharmacies](#) in Great Britain, which look at if the pharmacy is well-run, provides medicines and other services safely to people, protects people's privacy and confidentiality, and has staff with the right skills and training.

We are now publishing reports from inspections of pharmacies that have taken place since April 2019. In each report, you can see if the pharmacy has met or not met all of our standards. Search for a pharmacy and find out more.

Reports published in the last 28 days

We published 178 inspection reports in the last 28 days. You can see the outcomes of those inspections below:

Standards met

144

Learning from inspections

Read our new report about what we have learnt from inspecting pharmacies over the last five years, including key themes, patterns and trends which impact on performance:

Knowledge hub for the pharmacy team

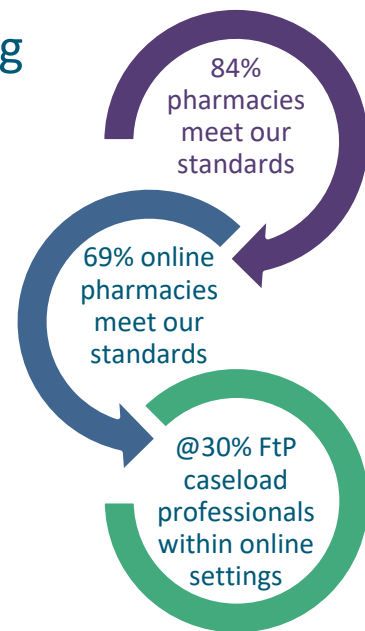
Learn from short examples of excellent, good and poor practice in meeting our standards that we have identified during pharmacy inspections:

Are the current powers adequate?

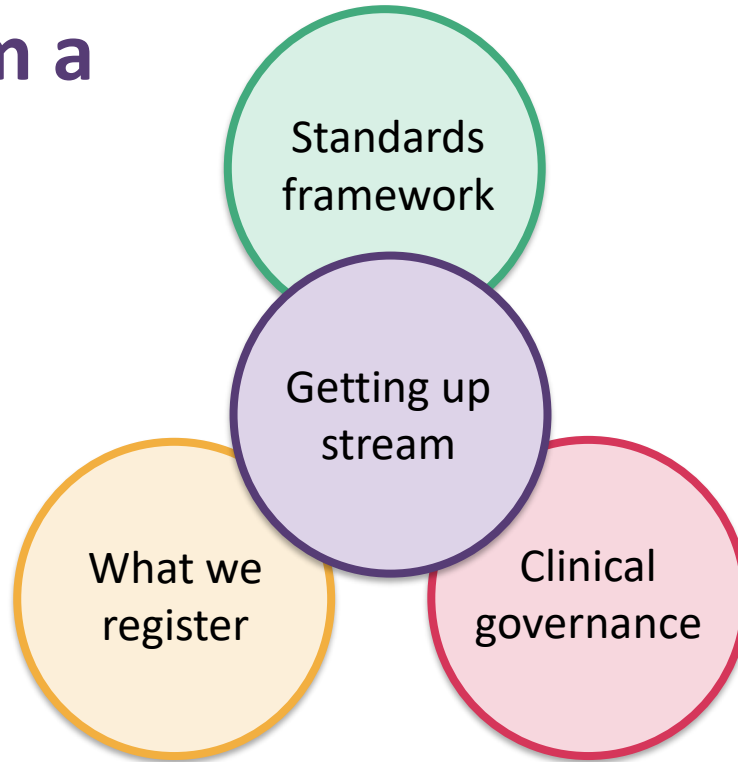
- Adequate for who?
- Speed
- Flexibility
- Fairness
- Range

What we're seeing on the ground

- Fast growth in a much broader range of clinical services being delivered in community pharmacy
- Much greater use of technology enabled models of service delivery
- More varied and complex business models
 - leadership, governance and culture
- Rapidly increasing utilisation of PIPs
- Professionals working across a broader range of settings



Challenges from a regulatory perspective



What is happening

The regulator is part of a much wider system to keep people safe....

- Modernising education and training
- Strengthening pharmacy governance
- What we register
- Clinical governance
- Engagement with DHSC and others over premises powers



Questions

